Exhibit JAK-9

NORTH DAKOTA DEPARTMENT OF HEALTH

INTRADEPARTMENTAL MEMORANDUM

REF FILE: Sure-Way Systems, Inc. (TS-036)
Big Dipper Enterprises (SW-257)

TO: L. David Glatt, Director
Division of Waste Management

THROUGH: Steven J. Tillotson, Asst. Director
Division of Waste Management

FROM: James C. Loken, Env. Scientist
Division of Waste Management

SUBJECT: Recent Operations

DATE: January 11, 2001

July 10, 2000 - Load of medical waste from Sure-Way Systems, Inc. (SWS) arrives at the Big Dipper Enterprises (BDE) landfill near Gwinner, N.D. Waste contained a large amount of medical sharps. An employee at BDE had a needle stick into his boot. The Department was not notified of this incident when it occurred.

July 13, 2000 - Scott Hopfauf, Environmental Engineer with the Division, learns of the July 10 load, received at BDE, containing what appeared to be a large amount of unground sharps.

July 20, 2000 - Scott Hopfauf and James Loken conduct an inspection of SWS in Valley City. The inspection was prompted by the July 10 incident at BDE. The sharps grinder is operational after being inoperable for several months. When the grinder was repaired, a set of new teeth were installed which were coarser than the original ones. The processed material from the grinder looks considerably different (much larger) than the material which was processed at the time the facility began operations. To remedy the situation, SWS ordered a sizing screen which will aid in the reduction of materials which are processed through the grinder. SWS has one full roll-off container (approximately 20 cubic yards) in storage which may contain compacted materials of this type. A label has been placed on the container stating "Do not take this container." This container will remain on-site until the Department makes a decision on how the materials will be handled.

July 21, 2000 - Meeting in Bismarck with Dudley Chilcott ,SWS; Lyle Witham, Asst. Attorney General; Dave Glatt; Steve Tillotson; and James Loken. Meeting discussion centered on the incident which took place at BDE on July 10, 2000. Mr. Chilcott brought a sample of the material from BDE as well as a ground sample from SWS. The sample from BDE contained several whole needles, some were bent while others were fully intact. The sample from SWS contained ribbons of plastic approximately one inches wide and up to six inches long, bent needles and whole needles (needle content of the SWS sample is estimated at around 25%). The material is very different than what the plant was producing at the start of operations in 1999. The materials documented in the May 11, 1999 photographs had a maximum size of approximately one and one-half inches square. Mr. Chilcott stated that when new teeth were installed in the grinder, a coarser tooth was used and the end result was larger-sized material. According to Mr. Chilcott, a sizing screen has been ordered and will be installed as soon as it arrives. It is hoped that the screen will help produce a smaller-sized material suitable for disposal. North Dakota's requirement of rendering sharps nonsharp prior to disposal was discussed. Mr. Chilcott stated North Dakota is the only state which has this requirement.

July 31, 2000 - Brad Torgerson, Environmental Scientist with the Division, and James Loken conduct a site visit at SWS. The purpose of the visit was to check on the status of the installation of the sizing screen on the sharps grinder. The screen was already installed upon our arrival. The materials which had been processed using the new sizing screen were considerably finer with no recognizable sharps present.

August 4, 2000 - Steve Tillotson performs a site inspection at SWS. Observations were made of the facility, the ground sharps, and the stored roll-off container.

August 9, 2000 - Due to the impracticability of reprocessing the single load of compacted medical waste, the Department gave a letter approving a one-time variance for the disposal of the contents of the roll-off container stored at the SWS facility. The disposal location was approved contingent on the approval of BDE. The letter also outlined conditions and guidance for the disposal to ensure public and employee safety from exposure to unshredded sharps.

August 22, 2000 - Steve Tillotson; James Loken; and Justin Griffin, Environmental Engineer with the Division of Air Quality, conduct a multimedia inspection of SWS to investigate allegations made by former employees of SWS. Each of the employees were interviewed separately. During the inspection, the Department was unable to fully substantiate the allegations; however, several operational deficiencies were noted and discussed with SWS staff members. During the inspection, SWS allowed one of the former employees to tour the facility with us and point out his concerns. This former employee also pointed out how a container, which has been run through an autoclave, looks (warped sides and top with a distorted label). This description was confirmed while interviewing the current SWS employees.

One of the major allegations of the former employees was the storing of untreated infectious medical waste and pathological waste in a 32-foot trailer around January or February 2000. The containers observed during our visit showed signs of being autoclaved; however, we were unable to determine if the ones in the front of the trailer were autoclaved. A future date will be setup to observe the unloading of the trailer. Other areas of concern to the Department include a backlog of treated unground sharps in the building and in other trailers in the yard, monitoring equipment such as the process chart recorder and the radiation detector not being used as specified, a large number of flies in the facility, the lack of accurate records on the amount and date that the pathological waste is shipped off-site for incineration, and the lack of accurate records on the number of roll-off containers shipped to BDE on a weekly/monthly basis.

August 23, 2000 - Phone conversation #1 with Dudley Chilcott. Estimated they would need approximately one week per trailer to process the contents and should be completely caught up with the backlog of accumulated sharps no later than the end of October. Long-term plans are to install a second sharps grinder within the next few months.

Phone conversation #2 with Dudley Chilcott. Mr. Chilcott stated he wants NDDH staff on hand to witness the unloading of the 32-foot trailer which holds suspected waste. He also stated he suspected one of his former employees of trying to sabotage the boiler system for the autoclaves. An antioxidizing chemical feed system had been turned off which could have damaged the boiler over an extended period of time. The efficiency of the boiler to produce the specified water temperature for operations was not affected.

August 25, 2000 - Brad Torgerson conducts a site visit at SWS. The purpose of the visit was to photograph the facility. At that time the pathological waste freezer was about three-fourths full and the 32-foot trailer was about one-half full.

August 28, 2000 - James Loken conducts a site visit to SWS. The purpose of the visit was to inspect and document any changes to the 32-foot trailer which has been at the loading dock since August 18, 2000. It has been alleged that the trailer contains unsterilized infectious medical waste. No changes were noted.

September 5, 2000 - James Loken conducts a site visit at SWS. The purpose of the visit was to inspect and document any changes to the 32-foot trailer which has been at the loading dock since August 18, 2000. A few of the white containers, which were present in the back of the trailer, appear to have been unloaded. When the staff was questioned, they stated they were told to grind containers from this trailer if they catch up on sharps grinding. I informed them the contents are not to be unloaded until arrangements can be made for NDDH staff to observe the unloading.

September 7, 2000 - James Loken was at BDE as the on-site inspector and observed the unloading of two roll-off containers from SWS at BDE. Large quantities of ground sharps were present in both roll-offs verifying there has been an increase in sharps grinding activity at SWS.

James Loken conducts a site visit to SWS. The purpose of the visit was to inspect and document any changes to the 32-foot trailer which has been at the loading dock since August 18, 2000. No changes were noted to the contents. One of the 48-foot trailers storing sharps has now been emptied, all that remains in the trailer are empty appliance boxes.

September 11, 2000 - James Loken conducts a site visit to SWS to witness and document the unloading of a 32-foot trailer which allegedly contained untreated medical waste and pathological waste. A visual examination was performed on each of the containers as they were unloaded. Each displayed the general characteristics of autoclaving (warped sides or top and distorted labels). Dates found on the containers were between November 1999 through January 2000. These dates concur with the general time period the trailer was reportedly loaded, January or February 2000. Photographs were taken to document the activity.

September 20, 2000 - James Loken conducts a site visit to SWS. The purpose of this visit was to check on the progress SWS has made in the grinding of the sharps. Some headway has been made on the grinding of the sharps; however, the grinder was down for repairs on the day I visited. The radiation detector was also in the wrong position, this was quickly remedied when pointed out to an employee.

September 21, 2000 - James Loken was at BDE landfill as the on-site inspector. A load containing miscellaneous sharps containers (approximately ten) was received at BDE. Because of the low number of containers, BDE was allowed to bury the material. Contacted Steve Tillotson about the situation. While on the phone with Mr. Tillotson, Mr. Chilcott called the BDE office. I informed him of the concerns the Department had with the load containing unground sharps, especially if it contained waste from Minnesota which may be using different sorting procedures. He informed me that one of his employees was not screening properly. He also stated that this employee has now been properly trained in screening procedures. He also has concerns that a few sharps containers may be present in the next load to be delivered to the landfill.

October 5, 2000 - James Loken conducts an inspection of SWS. The process chart recorder appears to be used as intended, continuous during the hours of operation. The pathological waste freezer has had a minor increase in the amount of waste stored for incineration, it is now about three-fourths full. There has been an increase in the amount of waste processed at SWS due to a short-term contract with Steri-Cycle. It has been stated that the additional waste is from a Minnesota facility. The sharps grinder is down once again. With the breakdown, there has been an accumulation of treated sharps in both the loft and shop areas. One of the previously unloaded 48-foot trailers has been reloaded with treated unground sharps for short-term storage.

October 16, 2000 - James Loken conducts a site visit to SWS. Sharps grinder currently down for repairs, an increased accumulation of treated sharps in the loft area and in the shop since my October 5, 2000 visit. Pathological waste freezer now has a biohazard label on it.

October 18, 2000 - James Loken conducts a site visit to SWS. Sharps grinder is still down for repairs, although the part needed for repair just arrived back from the machine shop. A number of appliance boxes filled with treated unground sharps containers have been loaded into a trailer for temporary storage until the grinder is repaired. Radiation detector is in wrong position, Mr. Chilcott corrected this while I was on-site.

November 15, 2000 - Kent Belland, BDE on-site inspector, calls and states a load of medical waste from SWS contained a large amount of unground medical sharps, both loose and in containers. Dudley Chilcott was called on-site to collect the rejected portion of the load. Two red 20+ gallon tubs of unground sharps were retrieved by Mr. Chilcott. Sorting problems were stated as the cause of the incident. The second roll-off container was rejected by BDE.

November 16, 2000 - Dudley Chilcott calls seeking permission to dump the rejected roll-off container in his shop yard and have his employees sort the load. I informed him I would need to visit with Steve Tillotson and Dave Glatt on this issue and get back to him. Mr. Chilcott stated a new policy where an employee is assigned a roll-off container and is responsible for the contents. If future loads are found to have this problem, it could be grounds for the employee's termination.

A decision was made to allow SWS to transport the roll-off container back to BDE where it would be unloaded and SWS representatives would retrieve the unacceptable portion of the load without endangering employee safety. A letter was sent on November 16, 2000 regarding this matter.

November 20, 2000 - SWS roll-off containers arrive at BDE. A large hole was dug in Friday's working face (November 16, 2000) and the contents of the roll-offs were dumped on the level area above the hole. SWS employees retrieved four red containers, approximately twenty gallons plus, full of sharps from the loads. The remainder of the load was buried. Kent Belland was on hand to document the activity.

November 21, 2000 - Dudley Chilcott was in Bismarck for a meeting with Dave Glatt, Steve Tillotson, and James Loken. Concerns were raised by Mr. Chilcott about rumors circulating that the Department was issuing a NOV to SWS (the Department had not issued a NOV). He stated these rumors have caused SWS to lose one of the larger contracts they had in the state. Mr. Chilcott was told that the Department had not informed his customers or anyone that the NDDH had issued a NOV.

We discussed the concerns the Department has with the waste from Minnesota. State law requires that the storage or disposal of waste from outside of the state is not allowed unless the governing authority or generator of the waste has an effective program for waste quality control and for waste characterization. Mr. Chilcott stated that they are having problems with that waste because of the sorting practices at the source; however, he was quick to point out that waste collected in North Dakota was sorted properly. He also stated that this contract would be finished in March 2001. Mr. Chilcott was reminded that the waste processed at his plant must meet North Dakota standards and that all sharps processed in North Dakota must be rendered nonsharp prior to disposal. He indicated the sharps grinder is up and running; however, it has been blowing fuses.

December 8, 2000 - Scott Hopfauf and Kent Belland conduct a site visit to SWS. The purpose of the visit was to orient Kent with the type of waste he will typically see at BDE for disposal.

December 29, 2000 - A roll-off container full of sharps containers arrives at BDE. Kent Belland estimated the number of sharps containers in the load to be around 20-30. Mr. Chilcott was contacted in Montana and informed him of the problem about unground sharps in the load. Mr. Chilcott stated he would get back to me after he visited with his staff at the Valley City plant.

Kent Belland calls back and stated he has counted 51+ larger sharps containers in the load. Mr. Chilcott had contacted the landfill and said there was a mixup in roll-off containers. He was sending a crew down to retrieve the rejected portion of the load. BDE allowed the second roll-off to be unloaded. The contents of this container were fine.

Kent Belland calls back and stated SWS employees retrieved 104+ sharps containers. One of the SWS employees was stuck by a needle during the retrieval. The remainder of the waste was buried.

Mr. Chilcott calls and states the roll-off which contained the sharps containers was originally to be hauled to a landfill in South Dakota for disposal. This waste is apparently from hospitals in South Dakota and the waste was to be disposed of in South Dakota. Mr. Glatt pointed out that the sharps still need to be rendered nonsharp prior to disposal when they are treated in North Dakota no matter where they are disposed of. Mr. Chilcott stated they have had this contract since November 2000.

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Exhibit JAK-10

Exhibit JAK-10

U.S. Department of Labor
Occupational Safety and Health Administration
1640 East Capitol Avenue
Bismarck, ND 58501
Phone: (701)250-4521 FAX: (701)250-4520

Citation and Notification of Penalty

To:
Sure-Way Systems
and its successors
P.O. Box 239
Valley City, ND 58072

Inspection Site:
1019 Fourth Avenue SW
Valley City, ND 58072

Inspection Number: 300243482
Inspection Date(s): 10/03/2000-10/04/2000
Issuance Date: 01/08/2001

The violation(s) described in this Citation and Notification of Penalty is (are) alleged to have occurred on or about the day(s) the inspection was made unless otherwise indicated within the description given below.

This Citation and Notification of Penalty (this Citation) describes violations of the Occupational Safety and Health Act of 1970. The penalty(ies) listed herein is (are) based on these violations. You must abate the violations referred to in this Citation by the dates listed and pay the penalties proposed, unless within 15 working days (excluding weekends and Federal holidays) from your receipt of this Citation and Notification of Penalty you mail a notice of contest to the U.S. Department of Labor Area Office at the address shown above. Please refer to the enclosed booklet (OSHA 3000) which outlines your rights and responsibilities and which should be read in conjunction with this form. Issuance of this Citation does not constitute a finding that a violation of the Act has occurred unless there is a failure to contest as provided for in the Act or, if contested, unless this Citation is affirmed by the Review Commission or a court.

Posting - The law requires that a copy of this Citation and Notification of Penalty be posted immediately in a prominent place at or near the location of the violation(s) cited herein, or, if it is not practicable because of the nature of the employer's operations, where it will be readily observable by all affected employees. This Citation must remain posted until the violation(s) cited herein has (have) been abated, or for 3 working days (excluding weekends and Federal holidays), whichever is longer. **The penalty dollar amounts need not be posted and may be marked out or covered up prior to posting.**

Informal Conference - An informal conference is not required. However, if you wish to have such a conference you may request one with the Area Director during the 15 working day contest period. During such an informal conference you may present any evidence or views which you believe would support an adjustment to the citation(s) and/or penalty(ies).

If you are considering a request for an informal conference to discuss any issues related to this Citation and Notification of Penalty, you must take care to schedule it early enough to allow time to contest after the informal conference, should you decide to do so. Please keep in mind that a written letter of intent to contest must be

submitted to the Area Director within 15 working days of your receipt of this Citation. The running of this contest period is not interrupted by an informal conference.

If you decide to request an informal conference, please complete, remove and post the page 5 Notice to Employees next to this Citation and Notification of Penalty as soon as the time, date, and place of the informal conference have been determined. Be sure to bring to the conference any and all supporting documentation of existing conditions as well as any abatement steps taken thus far. If conditions warrant, we can enter into an informal settlement agreement which amicably resolves this matter without litigation or contest.

Right to Contest - You have the right to contest this Citation and Notification of Penalty. You may contest all citation items or only individual items. You may also contest proposed penalties and/or abatement dates without contesting the underlying violations. **Unless you inform the Area Director in writing that you intend to contest the citation(s) and/or proposed penalty(ies) within 15 working days after receipt, the citation(s) and the proposed penalty(ies) will become a final order of the Occupational Safety and Health Review Commission and may not be reviewed by any court or agency.**

Penalty Payment - Penalties are due within 15 working days of receipt of this notification unless contested. (See the enclosed booklet and the additional information provided related to the Debt Collection Act of 1982.) Make your check or money order payable to "DOL-OSHA". Please indicate the Inspection Number on the remittance.

OSHA does not agree to any restrictions or conditions or endorsements put on any check or money order for less than the full amount due, and will cash the check or money order as if these restrictions, conditions, or endorsements do not exist.

Notification of Corrective Action - For each violation which you do not contest, you must notify the Area Director of the Bismarck OSHA Area Office, by letter, within 10 calendar days after each abatement date, that you have taken appropriate corrective action within the time frame set forth on this Citation. Where the citation indicates that ***abatement certification*** is necessary, only the abatement method and date when abatement occurred are required. Where the citation indicates that ***abatement documentation*** is necessary, evidence of the purchase or repair of equipment, photographs or video, receipts, etc., verifying that abatement has occurred is required. The abatement letter must be posted at the location where the violation appeared and the corrective action took place or employees must otherwise be effectively informed about abatement activities. A sample abatement certification letter is enclosed with this Citation.

Employer Discrimination Unlawful - The law prohibits discrimination by an employer against an employee for filing a complaint or for exercising any rights under this Act. An employee who believes that he/she has been discriminated against may file a complaint no later than 30 days after the discrimination occurred with the U.S. Department of Labor Area Office at the address shown above.

Employer Rights and Responsibilities - The enclosed booklet (OSHA 3000) outlines additional employer rights and responsibilities and should be read in conjunction with this notification.

Notice to Employees - The law gives an employee or his/her representative the opportunity to object to any abatement date set for a violation if he/she believes the date to be unreasonable. The contest must be mailed to the U.S. Department of Labor Area Office at the address shown above and postmarked within 15 working days excluding weekends and Federal holidays) of the receipt by the employer of this Citation and Notification of Penalty.

Inspection Activity Data - You should be aware that OSHA publishes information on its inspection and citation activity on the Internet under the provisions of the Electronic Freedom of Information Act. The information related to your inspection will be available 30 calendar days after the Citation Issuance Date. You are encouraged to review the information concerning your establishment at **www.osha.gov**. If you have any dispute with the accuracy of the information displayed, please contact this office.

ABATEMENT CERTIFICATION

Bruce C. Beelman, Area Director
U.S. Department of Labor - OSHA
1640 East Capitol Avenue
Bismarck, ND 58501
Phone: (701)250-4521

Sure-Way Systems
P.O. Box 239
Valley City, ND 58072

The hazard referenced in Inspection Number _____ for the violation identified as Citation _____ and Item _____ was corrected on _____ by doing the following: _____.

The hazard referenced in Inspection Number _____ for the violation identified as Citation _____ and Item _____ was corrected on _____ by doing the following: _____.

The hazard referenced in Inspection Number _____ for the violation identified as Citation _____ and Item _____ was corrected on _____ by doing the following: _____.

The hazard referenced in Inspection Number _____ for the violation identified as Citation _____ and Item _____ was corrected on _____ by doing the following: _____.

The hazard referenced in Inspection Number _____ for the violation identified as Citation _____ and Item _____ was corrected on _____ by doing the following: _____.

I attest that the information contained in this document is accurate and that the affected employees and their representatives have been informed of the abatement activities described in this certification.

_____
Signature

_____
Typed or Printed Name

NOTICE TO EMPLOYEES OF INFORMAL CONFERENCE

An informal conference has been scheduled with OSHA to discuss the citation(s) issued on 01/08/2001. The conference will be held at the OSHA office located at 1640 East Capitol Avenue, Bismarck, ND, 58501 on _____ at _____. Employees and/or representatives of employees have a right to attend an informal conference.

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

The alleged violations below have been grouped because they involve similar or related hazards that may increase the potential for illness.

Citation 1 Item 1A Type of Violation: Serious

29 CFR 1910.134(c)(1): The employer did not establish and implement a written respiratory protection program with worksite-specific procedures including provisions (i)-(ix) , as applicable:

(a) No written respiratory protection program had been established for respirator use.

Abatement Note:

A minimally acceptable respiratory protection program shall include all of the following requirements:

1. Written standard operating procedures governing the selection and use of respirators shall be established.

2. Only approved respirators shall be used. Respirators shall be selected on the basis of hazards to which the worker is exposed.

3. Respirators must be provided free-of-charge where respirators are needed to protect the health of the employees.

4. Employers must provide (free-of-charge) a medical evaluation to determine each employee's fitness to wear a respirator before initial use.

5. Before initial respirator use, fit testing is required for all employees using negative or positive pressure tight-fitting respirators where such respirators are required by OSHA or where the employer requires the use of such a respirator.

6. The user shall be instructed and trained in the proper use of respirators and their limitations.

7. Surveillance of work area conditions and degree of employee exposure or stress shall be conducted.

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

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8. Employer must ensure the use of respirators where respirators are needed to protect the health of the employees.

9. Respirators shall be regularly cleaned and disinfected to keep them in a sanitary condition.

10. Respirators shall be stored in a clean and sanitary location to prevent damage and contamination.

11. Respirators shall be inspected during cleaning and repaired when necessary.

12. There shall be regular inspection and evaluation to determine the continued effectiveness of the program.

13. Compressed breathing air must meet at least the requirements for Grade D breathing air.

14. The employer must establish and retain medical evaluations and fit-testing records.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 01/25/2001
Proposed Penalty: $ 450.00

Citation 1 Item 1B Type of Violation: Serious

29 CFR 1910.134(e)(1): The employer did not provide a medical evaluation to determine the employee's ability to use a respirator, before the employee was fit tested or required to use the respirator in the workplace:

(a) For employees using Cabot Safety 1/2-mask respirator TC-23C-585.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 02/12/2001

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

Citation 1 Item 1C Type of Violation: Serious

29 CFR 1910.134(f)(1): The employer did not ensure that employees using a tight-fitting facepiece respirator pass an appropriate qualitative fit test (QLFT) or quantitative fit test (QNFT):

(a) No fit testing had been conducted for employees using Cabot Safety 1/2-mask respirator.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 02/12/2001

Citation 1 Item 1D Type of Violation: Serious

29 CFR 1910.134(h)(2)(i): All respirators were not stored to protect them from damage, contamination, dust, unlight, extreme temperatures, excessive moisture, and damaging chemicals:

(a) Cabot Safety 1/2-mask respirator was stored on light bracket on forklift.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 01/11/2001

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

Citation 1 Item 2 Type of Violation: Serious

29 CFR 1910.146(c)(1): The employer did not evaluate the workplace to determine if any spaces were permit-required confined spaces:

(a) Autoclave, Shredder, and Compactor were not evaluated to determine if they were confined spaces.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated:	02/12/2001
Proposed Penalty:	$ 600.00

Citation 1 Item 3A Type of Violation: Serious

29 CFR 1910.147(c)(4)(ii): The energy control procedures did not clearly and specifically outline the scope, purpose, authorization, rules, and techniques to be utilized for the control of hazardous energy, including, but not limited to, Items A-D of this section:

(a) The energy control program was not machine specific.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated:	02/12/2001
Proposed Penalty:	$ 450.00

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e pages 1 through 5 of this Citation and Notification of Penalty for information on employer and employee rights and responsibilities.

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

Citation 1 Item 3B Type of Violation: Serious

29 CFR 1910.147(c)(5)(ii)(D): Lockout devices and tagout devices did not indicate the identity of the employee applying the device(s):

(a) Process Area, lockout device utilized when performing maintenance work on shredder on 10/3/00 did not contain the identity of the individual performing the maintenance work.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 01/16/2001

Citation 1 Item 4 Type of Violation: Serious

29 CFR 1910.151(c): Where employees were exposed to injurious corrosive materials, suitable facilities for quick drenching or flushing of the eyes and body were not provided within the work area for immediate emergency use:

(a) No emergency eyewash/body flush station was available for employees using Auto-Chlor Sanitizing Solution in the clean room.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 02/12/2001
Proposed Penalty: $ 450.00

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

Citation 1 Item 5 Type of Violation: Serious

29 CFR 1910.178(l)(1)(i): The employer did not ensure that each powered industrial truck operator is competent to operate a powered industrial truck safely, as demonstrated by the successful completion of the training and the evaluation specified:

(a) Truck drivers who intermittently use forklift on weekends had not received training.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated:	01/25/2001
Proposed Penalty:	$ 450.00

Citation 1 Item 6 Type of Violation: Serious

29 CFR 1910.212(a)(1): Machine guarding was not provided to protect operator(s) and other employees from hazard(s) created by rotating shaft and/or scalding hot steam pipes:

(a) Process area, rotating shaft on compactor was not protected by service panel.

(b) Process area, scalding hot steam pipes were not protected.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated:	01/22/2001
Proposed Penalty:	$ 450.00

See pages 1 through 5 of this Citation and Notification of Penalty for information on employer and employee rights and responsibilities.

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

Citation 1 Item 7 Type of Violation: Serious

29 CFR 1910.303(b)(1): Electrical equipment was not free from recognized hazards that were likely to cause death or serious physical harm to employees:

(a) 220-volt circuit breakers inside control panel were not protected against inadvertent contact.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated:	01/25/2001
Proposed Penalty:	$ 600.00

Citation 1 Item 8A Type of Violation: Serious

29 CFR 1910.1030(f)(2)(i): Hepatitis B vaccination was not made available after the employee had received the training required in 29 CFR 1910.1030(g)(2)(vii)(I) or within 10 working days of initial assignment to employees who had occupational exposure to blood or other potentially infectious materials:

(a) Process area, laborer was not offered the Hepatitis B vaccination within 10 working days of initial assignment.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated:	01/22/2001
Proposed Penalty:	$ 1050.00

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

Citation 1 Item 8B Type of Violation: Serious

29 CFR 1910.1030(f)(2)(iv): The employer did not ensure that employees who declined to accept the hepatitis B vaccination offered by the employer signed the statement in appendix A:

(a) Employees who had chosen not to accept the hepatitis B vaccination had not completed a declination form.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 01/12/2001

Citation 1 Item 8C Type of Violation: Serious

29 CFR 1910.1030(f)(3)(iv): The post-exposure evaluation and follow-up of an exposure incident did not include post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service:

(a) Post-exposure follow-up of an exposure incident did not include post-exposure prophylaxis as recommended by the U.S. Public Health Service.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 01/22/2001

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

Citation 1 Item 8D Type of Violation: Serious

29 CFR 1910.1030(h)(1)(iii)(A): The employer did not ensure that employee medical records required by 29 CFR 1910.1030 (h)(1) were kept confidential:

(a) Medical records were accessible to unauthorized personnel.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 01/22/2001

Citation 1 Item 9A Type of Violation: Serious

29 CFR 1910.1030(g)(1)(i)(A): Warning labels were not affixed to containers of regulated waste, refrigerators, or freezers containing blood or other potentially infectious material:

(a) Freezer containing human feet was not labeled biohazard.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 01/12/2001
Proposed Penalty: $ 1050.00

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

Citation 1 Item 9B Type of Violation: Serious

29 CFR 1910.1030(g)(2)(i): The employer did not ensure that employees with occupational exposure participated in a training program:

(a) Truck drivers had not received training on bloodborne pathogens.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 01/25/2001

Citation 1 Item 9C Type of Violation: Serious

29 CFR 1910.1030(g)(2)(vii)(N): The bloodborne pathogens training program did not contain an opportunity for interactive questions or answers with the person conducting the training session:

(a) Bloodborne pathogen training did not include an opportunity for questions and answers from a qualified medical professional.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 01/22/2001

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

Citation 1 Item 10 Type of Violation: Serious

29 CFR 1910.1048(d)(1)(i): Employees of a workplace covered by this standard were not monitored to determine their exposure to formaldehyde:

(a) Employees were not monitored for formaldehyde when autoclaving medical waste from funeral homes and hospital facilities.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated:	02/12/2001
Proposed Penalty:	$ 1050.00

Citation 1 Item 11A Type of Violation: Serious

29 CFR 1910.1096(d)(1): The employer did not make such surveys as necessary to evaluate the radiation hazards incident to the production, use, release, disposal or presence of radioactive materials or other sources of radiation under a specific set of conditions, as were necessary for him/her to comply with the provisions of this section:

(a) No radiation survey had been conducted to determine exposure in process and storage areas.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated:	02/12/2001
Proposed Penalty:	$ 600.00

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e pages 1 through 5 of this Citation and Notification of Penalty for information on employer and employee rights and responsibilities.

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

Citation 1 Item 11B Type of Violation: Serious

29 CFR 1910.1096(d)(2): Appropriate personnel monitoring or equipment such as film badges, pocket chambers, pocket dosimeters of film rings were not supplied to or used by employee(s) described in subparagraph (i), (ii) and (iii):

(a) Personnel monitoring was not conducted for employees handling radiation contaminated materials when loading, unloading, transferring, and working in close proximity to such materials.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 02/12/2001

Citation 1 Item 12A Type of Violation: Serious

29 CFR 1910.1200(e)(1): The employer did not develop, implement, and/or maintain at the workplace a written hazard communication program which describes how the criteria specified in 29 CFR 1910.1200(f), (g), and (h) will be met:

(a) No written hazard communication program had been developed for workplace chemicals such as but not limited to: Auto-Chlor Super Red Detergent.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 01/16/2001
Proposed Penalty: $ 450.00

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

Citation 1 Item 12B Type of Violation: Serious

29 CFR 1910.1200(h): Employees were not provided information and training as specified in 29 CFR 1910.1200(h)(1) and (2) on hazardous chemicals in their work area at the time of their initial assignment and whenever a new hazard was introduced into their work area:

(a) Employees had not received training on workplace chemical hazards.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated: 01/25/2001

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

Citation 2 Item 1 Type of Violation: Other

29 CFR 1910.24(h): Standard railing(s) were not provided on the open side(s) of all fixed industrial stairway(s) and stair platform(s):

(a) Stairway to office area was not equipped with standard railings.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated:	01/16/2001
Proposed Penalty:	$ 0.00

Citation and Notification of Penalty

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072

Citation 2 Item 2 Type of Violation: Other

29 CFR 1910.132(d)(1): The employer did not assess the workplace to determine if hazards were present, or were likely to be present, which would necessitate the use of personal protective equipment (PPE):

(a) No personal protective equipment hazard assessment had been conducted for all aspects and situations of the workplace.

Abatement Note: Abatement certification is required for this item (see enclosed "Sample Abatement Certification Letter").

Date By Which Violation Must be Abated:	01/22/2001
Proposed Penalty:	$ 0.00

Bruce Beelman

Bruce C. Beelman
Area Director

U.S. Department of Labor
Occupational Safety and Health Administration
1640 East Capitol Avenue
Bismarck, ND 58501
Phone: (701)250-4521 FAX: (701)250-4520

INVOICE/
DEBT COLLECTION NOTICE

Company Name: Sure-Way Systems
Inspection Site: 1019 Fourth Avenue SW, Valley City, ND 58072
Issuance Date: 01/08/2001

Summary of Penalties for Inspection Number 300243482

Citation 1, Serious	= $	**7650.00**
Citation 2, Other	= $	**0.00**
TOTAL PROPOSED PENALTIES	= $	**7650.00**

To avoid additional charges, please remit payment promptly to this Area Office for the total amount of the uncontested penalties summarized above. Make your check or money order payable to: "DOL-OSHA". Please indicate OSHA's Inspection Number (indicated above) on the remittance.

OSHA does not agree to any restrictions or conditions or endorsements put on any check or money order for less than full amount due, and will cash the check or money order as if these restrictions, conditions, or endorsements do not exist.

Pursuant to the Debt Collection Act of 1982 (Public Law 97-365) and regulations of the U.S. Department of Labor (29 CFR Part 20), the Occupational Safety and Health Administration is required to assess interest, delinquent charges, and administrative costs for the collection of delinquent penalty debts for violations of the Occupational Safety and Health Act.

Interest. Interest charges will be assessed at an annual rate determined by the Secretary of the Treasury on all penalty debt amounts not paid within one month (30 calendar days) of the date on which the debt amount becomes due and payable (penalty due date). The current interest rate is 5%. Interest will accrue from the date on which the penalty amounts (as proposed or adjusted) become a final order of the Occupational Safety and Health Review Commission (that is, 15 working days from your receipt of the Citation and Notification of Penalty), unless you file a notice of contest. Interest charges will be waived if the full amount owed is paid within 30 calendar days of the final order.

Delinquent Charges. A debt is considered delinquent if it has not been paid within one month (30 calendar days) of the penalty due date or if a satisfactory payment arrangement has not been made. If the debt remains delinquent for more than 90 calendar days, a delinquent charge of six percent (6%) per annum will be assessed accruing from the date that the debt became delinquent.

Administrative Costs. Agencies of the Department of Labor are required to assess additional charges for the recovery of delinquent debts. These additional charges are administrative costs incurred by the Agency in its attempt to collect an unpaid debt. Administrative costs will be assessed for demand letters sent in an attempt to collect the unpaid debt.

Bruce Beelman
Bruce C. Beelman
Area Director

1-9-01
Date

Exhibit JAK-11

COPY

Sure-Way Systems
1019 4th Ave. SW P.O. Box 239
Valley City, North Dakota 58072
(701) 845-0672

January 22, 2001

U.S. Department of Labor
OSHA
1640 East Capital Ave.
Bismarck, ND 58501

Attn: Bruce C. Beelman

Dear Mr. Beelman:

I would like to contest the following Citations and/request a reduction of penalty. General justification: SWS history in Valley City is **limited to 1 ½ years** as of the date of the initial inspection. The use of an autoclave system is new to our company and every effort had been made to learn how to effectively and safely operate this system. We in fact gone down to Florida (manufacturer) and observed the proper operations on site. Additionally we had the manufacturer come up to Valley City and show us how to safely operate this system. In addition we implemented more stringent safety practices in those areas deemed necessary such as separation between clean and dirty side.
Additionally SWS has **never before received a violation** of any kind in the 11 year history of this company. We understand and accept that it is your responsibility to enforce all codes as outlined in OSHA standards. However we regret the fact that you and your office was used as a tool to cause SWS problems not because of concern for the workers but rather as a weapon by our competition. I believe that you will agree that we have made every attempt to be a safe and responsible employer providing training, supplies and practices. We are a small company and unable to have the specialized personnel for every possible facet in our industry such as a OSHA compliance specialist. In an effort to offset this understandable shortcoming I had (prior to your surprise inspection) arranged for a **courtesy visit** by the state OSHA officer. This should show you that we do take our responsibilities serious and have been working aggressively to make further improvements. I believe that should we have had the opportunity to utilize this service many if not all of the simple safety improvements necessary could and would have been made with little or no cost to SWS and without penalty. In fact he would have had the courtesy inspection in time if it had not been postponed due to a death in my family. The focus areas we were going to work on included general review of physical, mechanical and procedural plant safety items. Additionally I emphasized that I needed help with records and training programs. Our company has taken great pride in our safety record and will comply with every reasonable effort to ensure our employees safety.

Citation 1 Item 1A, B, C, D - Respiratory program.

SWS has not had a respiratory program nor had the need for one been identified during any previous safety inspection. The reason we have respirators here was due to the fact that when Fleet Farm pulled out of Valley City they had a big close-out sale and I bought everything in their safety area as a package. This included many items we could use and many we did not have a designated use for. The respirators were among them. This is why we did not have a respiratory program, fit test, specific cartridges and some of the related items needed for a full and comprehensive program.

1. To our knowledge no medical waste facility of our type have a respiratory program.
2. To our knowledge no such program has been deemed necessary.
3. The reason for employee access to such safety equipment was due to a sale rather than recognized requirement.

This Citation should be reclassified to 'Other' Penalty $0.00 as it is not reasonable to penalize a company for providing extra safety equipment that is beyond the industrial norm and could only be intended as an added safety item.

1. SWS will complete a full evaluation as planned through the 'courtesy visit' and if deemed necessary provide such safety measures as needed. It may be mechanical ventilation at the source or respiratory equipment and related respiratory program.
2. If it is not deemed necessary I would still like to have respirators on hand since we have them. However if this requires a full program we can and likely will remove them.

Citation 1 Item 2 Confined Space

This should be **combined with written safety programs**. Item 2, 3 &12

I would like to reserve the right and extend the opportunity to challenge this citation following the 'courtesy inspection'.

1. We had already planned to complete a review of such hazards during the courtesy visit.

Citation 1 Item 3A, B Lock Out Tag Out

I believe that this Citation should be changed to 'Other'

This should be **combined with written safety programs**. Item 2, 3 &12

1. we have a lock out tag out program
2. we have a lock out tag out station and informational packet.
3. Employees have had safety training including a video on Lock out Tag out.
4. The device in question was locked out and key was in the possession of the repairman.
5. We did not have the tag labeled however we all know who has the key in such a small company but concede it should have been there.
6. The specifications where generic in writing but on site training is specific for the few items we have.
7. Such specifications would have been identified during the courtesy visit.

Citation 1 Item 4, Eyewash

I believe that this Citation should be changed to 'Other'

- The eye wash station we had was broken off before the OSHA visit and had not yet been replaced. It was fortunate as it turns out the station type we had was not adequate for our situation.
- A new water supply eye and face wash station was installed within a week of the visit.

Citation 1 Item 5 'Fork Lift Operations'

I believe that this Citation and Proposed Penalty should be significantly reduced.
I was not aware that this individual was operating the forklift and was not given permission to do so. Our practice/policy prior to forklift operation is that;

1. Each operator watches the safety video supplied by the manufacturer.
2. The floor supervisor personally reviews the proper operation, care and maintenance of the forklift.
3. Provides the potential operator with some supervised operating time and than has limited use of the forklift only under supervision and until they have proven to be a qualified operator.
4. I was not aware that had operated the forklift however as employer I accept that was not adequately supervised and should not have been operating the forklift.

Citation 1 Item 6, missing protective covers.

I believe that this Citation should be changed to 'Other'

1. The cover on the end of the compactor had been recently pulled off due to repair maintenance. The cover and locking clips were directly adjacent as they are generally left in place.
   - There is no rotating shaft or device in this area, the winch located in there is not used nor does it have a power source.
2. The scalding steam pipes in question were left uncovered because;
   - The model plant we visited did not.
   - The pipes are not scalding hot rather hot and used as vents only so they are only hot for short periods of time. Do not require a cover base not mechanical code.
   - The warning sign again was there for additionally cautionary reasons not because of a recognized hazard.
   - This area is not in the work floor and therefore generally considered isolated.

Corrective actions taken, the cover was replaced the same day. The pipes were insulated the following week after materials had been found.

Citation 1 Item 7, Possible Electrical hazard.

I believe that the proposed penalty should be reduced.
This should be combined with Item 3, lock out tag out.

1. The Control panel in question was designed, demonstrated and utilized as shown by the manufacturer. The design requires us to open the cover and view the LCD Modicon display.

The corrective action taken will have a 3" whole cut into the cover and that covered with a Plexiglas piece. This will allow us to keep the cover closed and observe the Modicon through the window.

Citation 1 Item 8A,B, C, D, Hepatitis

I believe that this Citation proposed penalty should be reduced.

8A. All employees are offered Hep. B upon hire however in this case the employee slipped through and went past the 10 days.

- We now have the ability to get shots on the day of hire and have made that our practice.

8B. Declination

1. We have a declination and have had a declination letter attached to the hire package. I believe in the case of had taken the series in the military and did not understand that the form needed to be signed anyway and was missed at the office.
2. All such declinations are now signed.

8C. Post-exposure

1. As discussed during the initial inspection we have a doctor who provides the post exposure service and it was professional decision as to how to handle the incidents on a case by case basis.
2. We have discussed this with as you have and will continue to provide the post exposure service. This is to include prophylaxis as prescribed by doctor.

8D. Locked Personnel Files

1. A locked file cabinet was installed the week following the on-site inspection, all personnel files are located in this file cabinet.

Citation 1 Item 9A, B, C, Bloodborne; Warning Label, Training,

I believe this Citation should be changed to 'Other'

9A. Warning label on freezer.

1. The need for such a label was unknown to me and I would not have guessed it was necessary as the freezer is in a restricted area of the plant and not in a common area. Obviously all plant operators and employees knew where the freezer was and its use.
2. This oversight would have been picked up during the courtesy inspection and easily corrected.
3. We had the signs on site and put on the freezer a few days after you brought it to our attention.

9B. Truck Driver Training.

1. I do not know which truck driver this is related to but we have a bloodborne pathogen employee information sheet in their hire package and signed after review upon hire.
2. Each employee watches a training video developed and sponsored by Department of Labor/OSHA on Bloodborne Pathogen.

3. I review bloodborne pathogen safety procedures with each employee during the initial training period.

9C. Question and answer period.

1. We have weekly safety lunches sponsored by the employer. We review safety issues, current plant safety and condition of equipment, and review a training video. At the end of this video there is a discussion period as I discus specific applications of related safety issues addressed in the video as it relates to Sure-Way.
2. I was in education for a number of years and in small adult training groups there is a hesitancy to offer a question and so in many cases I will address pertinent issues and bring them up as discussionary type items. While this does not necessarily mimic the traditional 1940s K-12 style of education used today it does provide a question of answer period. The individual may well not have realized it as it could have taken place during the wrap up of the video or in the field.

Citation 1 Item 10 Air Monitoring

I believe that this should have been **included in the Respiratory** 'Item 1A' as it directly relates for the need at all.

I believe this Citation should be changed to 'Other'

1. Again this may have been identified as a need during the courtesy inspection.
2. This is not an industrial norm since respiratory equipment is not found in the industry, using vacuum autoclave systems. To penalize us for what could be considered an opinion or 'what if' is not fair, I cannot reasonably be expected to see all possible contingencies.
3. We are willing and plan to conduct such testing based on your recommendation and with the assistance of the state.

Citation 1 Item 11A, B, Radiation

I believe this Citation should be changed to 'Other' and/or dropped completely.

11A. No Radiation monitoring of plant.

1. Radiation Monitoring testing has been conducted with redundant monitoring equipment. We have identified background radiation levels to the point that we can tell when it is raining outside or a solar flare is taking place. The chart recorder has a constant print out of radiation levels including background.
2. Such monitoring was also done, on-site, by the state as well.

11B. Personal monitoring.

1. This is not an industrial norm since radiation equipment is set up to keep such contaminants out of the plant. Such an issue is not found in the industry. To penalize us for what could be considered an opinion or 'what if' is not fair.
2. The equipment in place is very sensitive. We are assured by the radiation experts we have worked closely with that there is no risk to our employees, given the very short potential exposure time.

3. We have had numerous state visits and reviews of our radiation equipment and practices, we asked directly of potential risk and given no indication of any risk given our system. Again this has not been recognized as a need.
4. We have had a radiation instructor come in from the university and provide training.
5. We are willing and plan to conduct such testing based on your recommendation and with the assistance of the state. However since this has been closely reviewed by experts I do not believe it truly is warranted.

Citation 1 Item 12A,B HAZCOM program.
I believe this Citation should be changed to 'Other'.
This should be **combined with written safety programs**. Item 2, 3 &12

12A.Written program
1. Again this is one of the specific items I had asked for help on during the courtesy visit. It was a recognized area of need as we addressed most of the parts but it had not yet been pulled together into a comprehensive program.
2. Specific to chemicals, we have a MSD program that includes MSD sheets for all chemicals including Auto-Chlor chemicals.
3. The employees were given training on MSD and site specific hazards.
4. The MSD station is on the plant floor and complete with all warnings and generic information. Each employee was shown the station.

12B Employee Training
1. Employees have been given training and have access to the MSD center on the plant floor.
2. While this training may lack some, it was another part of the courtesy visit we had planned.

Citation 2 Item 1, Stair railing.
Completed the week following the inspection.

Citation 2 Item 2, PPE assessment.
1. We currently are following the industrial norm for PPE and will complete the special case assessment during the courtesy visit.

Sincerely,

Dudley Chilcott
VP Operations

Exhibit JAK-12

Exhibit JAK-12

Establishment Registration Database

Establishment:
SURE-WAY SYSTEMS, INC.
107 South Parkmont
Butte, MT 59701
Operations: Specification Developer
Status: Active; Awaiting Assignment Of Registration Number

Owner/Operator:
SURE-WAY SYSTEMS, INC.
404 Main St.
Deer Lodge, MT 59722
Owner/Operator Number:
9073720

Official Correspondent:
Mr. Gary Chilcott
SURE-WAY SYSTEMS, INC.
404 Main St.
Deer Lodge, MT 59722
Phone: 406-846-2033

Database Updated 7/05/2005

Establishment Registration Database

Establishment:
SURE-WAY SYSTEMS, INC.
1019 4th Ave., S.W.
Valley City, ND 58072
Operations: Specification Developer
Status: Active; Awaiting Assignment Of Registration Number

Owner/Operator:
SURE-WAY SYSTEMS, INC.
404 Main St.
Deer Lodge, MT 59722
Owner/Operator Number:
9073720

Official Correspondent:
Mr. Gary Chilcott
SURE-WAY SYSTEMS, INC.
404 Main St.
Deer Lodge, MT 59722
Phone: 406-846-2033

Database Updated 7/05/2005

Establishment Registration Database

Establishment:
SURE-WAY SYSTEMS, INC.
807 Market St.
Decatur, AL 35601
Operations: Specification Developer
Status: Active; Awaiting Assignment Of Registration Number

Owner/Operator:
SURE-WAY SYSTEMS, INC.
404 Main St.
Deer Lodge, MT 59722
Owner/Operator Number:
9073720

Official Correspondent:
Mr. Gary Chilcott
SURE-WAY SYSTEMS, INC.
404 Main St.
Deer Lodge, MT 59722
Phone: 406-846-2033

Database Updated 7/05/2005

Establishment Registration Database

Establishment:
SURE-WAY SYSTEMS, INC.
13200 58th North #2
Clearwater, FL 33760
Registration Number: 3005189677
Operations: Specification Developer

Status: Active
Date Of Registration Status: 2005

Owner/Operator:
SURE-WAY SYSTEMS, INC.
404 Main St.
Deer Lodge, MT 59722
Owner/Operator Number:
9073720

Official Correspondent:
Mr. Gary Chilcott
SURE-WAY SYSTEMS, INC.
404 Main St.
Deer Lodge, MT 59722
Phone: 406-846-2033

Database Updated 7/05/2005

Exhibit JAK-13

Exhibit JAK-13

Device Listing Database

Proprietary Device Name:	SURE-WAY SYSTEMS REUSABLE SHARPS CONTAINER
Common/Generic Device Name:	SHARPS CONTAINER
Classification Name:	NEEDLE, HYPODERMIC, SINGLE LUMEN
Device Class:	2
Product Code:	FMI
Regulation Number:	880.5570
Medical Specialty:	General Hospital
Owner/Operator:	SURE-WAY SYSTEMS, INC.
Owner/Operator Number:	9073720
Registered Establishment Name:	SURE-WAY SYSTEMS, INC.
Date of Listing:	05/24/05
Listing Status:	Active
Establishment Operations:	Specification Developer

Database Updated 7/05/2005

Device Listing Database

Proprietary Device Name:	SURE-WAY SYSTEMS REUSABLE SHARPS CONTAINER
Common/Generic Device Name:	SHARPS CONTAINER
Classification Name:	NEEDLE, HYPODERMIC, SINGLE LUMEN
Device Class:	2
Product Code:	FMI
Regulation Number:	880.5570
Medical Specialty:	General Hospital
Owner/Operator:	SURE-WAY SYSTEMS, INC.
Owner/Operator Number:	9073720
Registered Establishment Name:	SURE-WAY SYSTEMS, INC.
Date of Listing:	05/24/05
Listing Status:	Active
Establishment Operations:	Specification Developer

Database Updated 7/05/2005

Device Listing Database

Proprietary Device Name:	SURE-WAY SYSTEMS REUSABLE SHARPS CONTAINER
Common/Generic Device Name:	SHARPS CONTAINER
Classification Name:	NEEDLE, HYPODERMIC, SINGLE LUMEN
Device Class:	2
Product Code:	FMI
Regulation Number:	880.5570
Medical Specialty:	General Hospital
Owner/Operator:	SURE-WAY SYSTEMS, INC.
Owner/Operator Number:	9073720
Registered Establishment Name:	SURE-WAY SYSTEMS, INC.
Date of Listing:	05/24/05
Listing Status:	Active
Establishment Operations:	Specification Developer

Database Updated 7/05/2005

FDA U.S. Food and Drug Administration — Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Device Listing Database

Proprietary Device Name:	SURE-WAY SYSTEMS REUSABLE SHARPS CONTAINER
Common/Generic Device Name:	SHARPS CONTAINER
Classification Name:	NEEDLE, HYPODERMIC, SINGLE LUMEN
Device Class:	2
Product Code:	FMI
Regulation Number:	880.5570
Medical Specialty:	General Hospital
Owner/Operator:	SURE-WAY SYSTEMS, INC.
Owner/Operator Number:	9073720
Registered Establishment Name:	SURE-WAY SYSTEMS, INC.
Establishment Registration Number:	3005189677
Date of Listing:	05/24/05
Listing Status:	Active
Establishment Operations:	Specification Developer

Database Updated 7/05/2005

Exhibit JAK-14

Exhibit JAK-14

510(k) Premarket Notification Database

Device Classification Name	Needle, Hypodermic, Single Lumen
510(K) Number	K992626
Regulation Number	880.5570
Device Name	SURE-WAY REUSABLE SHARPS CONTAINER
Applicant	SURE-WAY SYSTEMS, INC. 310 Harry Bridges Blvd. Wilmington, CA 90744
Contact	Gary Chilcott
Classification Product Code	FMI
Date Received	08/05/1999
Decision Date	12/16/1999
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General Hospital
Statement/Summary/Purged Status	Statement Only
Statement	Statement
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 7/05/2005

Center for Devices and Radiological Health / CDRH

Exhibit JAK-15

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

m3412n

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-29

February 10, 2000

Carlos M. Campos, President & CEO
Safety Disposal System, Inc.
1100 25th Street, Suite 7B
West Palm Beach, Florida 33407

Dear Mr. Campos:

We are writing to you because on January 10 through 18, 2000 FDA Investigator Bill Tackett, Jr. inspected your facility and collected information that revealed serious regulatory problems involving your firm's reprocessing of medical devices (reusable sharps containers).

Under the Federal Food, Drug, and Cosmetic Act (the Act), the products that your firm reprocesses are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers conform to the Quality System (QS) regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that devices that you sort and clean for further reprocessing 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 their manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

QS Regulation/GMPs

1. Failure to establish a quality policy as required by 21 CFR 820.20. For example, there is no written policy establishing the objectives for and commitment to quality (FDA 483, Item #1).

2. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system pursuant to a defined schedule to ensure the quality system meets the requirements of the established quality policy and objectives as required by 21 CFR 820.20(c). For example, no reviews have been conducted to determine the effectiveness or suitability of the quality system (FDA 483, Item #2).

3. Failure to establish procedures for quality audits and conduct of audits to assure the quality system is in compliance with the established quality system requirements and the effectiveness of the quality system as required by 21 CFR 820.22. For example, no internal quality audits have been conducted (FDA 483, Item #3).

4. Failure to validate the processes for cleaning and sanitizing reusable sharps containers as required by 21 CFR 820.75. For example, no validation has been conducted (FDA 483, Item #7).

5. Failure to establish a complaint handling system as required by 21 CFR 820.198. For example, no procedures have been established or are maintained for receiving, reviewing and evaluating complaints by a formally designated unit (FDA 483, Item #4).

6. Failure to establish and maintain procedures for acceptance of incoming new product and product being returned for reuse as required by 21 CFR 820.80. For example, no acceptance activities are conducted including inspection, tests or other verification of activities involving condition, cleaning and sanitation (FDA 483, Item #6).

7. Failure to establish and maintain procedures for the calibration, adjustment or maintenance of process equipment as required by 820.70(g). For example, no inspections were conducted pursuant to your own procedures, which require a daily inspection of the Reusable Container Wash and Disinfection System (FDA 483, Item #8).

8. Failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications as required by 21 CFR 820.70(a). For example, there are no procedures available describing the current washing system in use (FDA 483, Item #11).

The specific QS/GMP violations noted in this letter and in the List of Observations (FDA 483) issued to Peter A. Light, Chief of Operations 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 violations 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 awards of contracts.

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, injunction, and/or civil penalties.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Reva J. Melton
Acting Director
Florida District

· DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M 5251 n

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

HAND-DELIVERED

WARNING LETTER

FLA-00-34

March 7, 2001

Carlos M. Campos, President
Safety Disposal System, Inc.
6175 N.E. 153rd Street, suite 324
Miami Lakes, Florida 33014

Dear Mr. Campos:

During an inspection of your establishment located in West Palm Beach, Florida on January 10-12 & 16, 2001, FDA Investigator Michelle S. Dunaway determined that your establishment is a specification developer, reprocessor and distributor of reusable sharps containers, a medical device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Under the Federal Food, Drug, and Cosmetic Act (the Act), the product(s) that your firm manufactures/reprocesses are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers conform to the Quality System (QS) regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The above-stated inspection revealed that this device is 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/reprocessing, packing, storage, or installation are not in conformance with the Quality System regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

QS Regulation/GMPs

1. Your firm failed to establish a policy and objectives for, and commitment to, quality that management with executive responsibility shall ensure is understood, implemented, and maintained at all levels of the organization as required by 21 CFR 820.20. For example, the plant manager responsible for the supervision of the sharps container quality system, and individuals performing sharps container reprocessing have not been trained and are unfamiliar with the Quality System requirements. Your quality policy has not been implemented. Corrections to these observations were promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item # 1) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #s 1-3).

2. Your firm failed to conduct management reviews covering the overall suitability of your quality system as required by 21 CFR 820.20(c). For example, the only area of the reprocessing operation that has been reviewed is the container washing area on May 4, and June 28, 2000. Corrections to this observation were promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item # 2) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item # 4).

3. Your firm failed to conduct quality audits that address all quality system requirements as required by 21 CFR 820.22. For example, the only areas of the reprocessing system that have been audited were the container washing area including the number of containers washed and rejected. Corrections to these observations were promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item # 3) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #5).

4. Your firm failed to establish and maintain procedures for implementing corrective and preventive action as required by 21 CFR 820.100. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item #s5 & 9) and Warning Letter #FLA-00-29 issued on February 10, 2000. The same observations were again made and issued to your firm on January 18, 2000, which was listed on the Inspectional Observations (FDA 483, Item # 15).

5. Your firm failed to validate the cleaning and disinfection processes of the reprocessing operation as required by 21 CFR 820.75(a) & (c). For example, the current process was implemented only three months ago, which replaced germicidal soap with an unspecified level of chlorine/bleach and changed the temperature of the wash from 180°F to an uncontrolled temperature range. It was also determined during the inspection that the water heater coil had been broken for three months and had not been replaced. The temperature of "hot" water was observed to be 65°F. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item # 7) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item # 6).

6. Your firm failed to establish complaint handling procedures and there is no record that a failure investigation was conducted of a confirmed complaint required by 21 CFR 820.198. For example, a rack of sharps containers were released without being cleaned and no documented investigation was made. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item #s 4 & 11) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #s 7 & 10).

7. Your firm failed to establish and maintain written acceptance criteria for reprocessed sharps containers to ensure that each production run, lot, or batch of reprocessed devices meets acceptance criteria as required by 21 CFR 820.80(d). For example, leakage, physical condition, lid closeability and labeling are not included in the criteria for release. There is no specified sampling plan and acceptance activities are not documented unless one or more containers are rejected. A field examination of released sharps containers revealed one container that had rust colored stains on the lid opening, one container had an approximate quarter sized hole just below the lid, and at a minimum, five containers were missing the removable sliding door. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item #6) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #s 9 & 12).

8. Your firm failed to establish and maintain procedures for the current cleaning and disinfection processes as required by 21 CFR 820.70(a), (b). For example, chlorine and water temperature levels are not specified, controlled or monitored. Chlorine levels on January 11 and 12, 2000 were observed to below 0.5ppm and the washer temperature to be 100°F and 70°F later and 200 ppm and 70°F, respectively. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item #11) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #10).

9. Your firm failed to establish and maintain procedures to prevent contamination of equipment or product substances that could reasonably be expected to have an adverse effect on product quality as required by 21 CFR 820.70(e). For example, an individual responsible for handling disinfected sharps containers was observed to be using gloves that had been used during the lid cleaning process that had a visible rust colored substance. Cloth towels are reused by laying them or tying them to a large fan. These towels are used for an unspecified or unknown number of day's production. The restrooms for workers do not have hot running water and there was nothing available for drying hands except for toilet paper (FDA 483, Item #11).

10. Your firm failed to maintain device history records (DHR's) to ensure that each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with specifications listed in the device master record (DMR) as required by 21 CFR 184. For example, employees marked the "Daily Protocol Parameter Log" for approximately three months, while the water heater coil was broken, "Yes" reporting the water temperature was 180°F even though the temperature was observed to be 100°F or below. These logs were reviewed and maintained by the Plant manager (FDA 483, Item #13.

11. Your firm failed to ensure that each DMR is prepared and approved as required by 21 CFR 820.181. For example, the DMR fails to include device and labeling specifications that address the useful life of sharps containers and the level required to effect disinfection (FDA 483, Item #16).

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to Jorge Barroso, Plant Manager, 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 violations 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 Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contract, and to resume marketing clearance, and export clearance for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that they have conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device QS regulation/GMPs (21 CFR Part 820). You should also submit a copy of the consultant's report, and your certification that you have reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

- Date and certification of initial audit by consultant and firm (to be conducted within four (4) months of the receipt of this letter).

- Monthly reports and timeline of progress to achieve compliance to be submitted by the last day of each month until all corrective actions have been corrected not to exceed 4 months.

- Final certification of accomplished corrective and preventive actions related to this Warning Letter to be submitted no later than June 30, 2001.

- An annual certification and a report of an annual audit by an outside consultant for each of the next two years covering your firm's current status with regard to the Quality Systems regulation.

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, injunction, and/or civil penalties. Any further distribution of this product is made on your own responsibility.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) 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.

You should also advise your intention to continue or cease distribution of the product in writing, until your firm's level of compliance with the Quality System regulation can be verified by the FDA .

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Emma Singleton
Director, Florida District

Exhibit JAK-16

K992626

Sure-Way Sharps Disposal Services

Division of Sure-Way Systems, Inc.

Exhibit JAK-16

AUG 5 1 25PM '99

Office of Device Evaluation - 510 (k)
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

ATTN: Infection Control Devices Branch

RE: 501 (k) Premarket Notification for Reusable Sharps Container

Dear Sir or Madam:

Pursuant to section 510(K) of the Federal Food, Drug and Cosmetic Act (FDC Act) and the requirements of 21 C.F.R. § 807.87, Sure-Way Systems, Inc. is submitting this premarket notification to market its Reusable Sharps Container, which are waste receptacles intended to hold discarded needles.

The information contained in Attachments 3, 4, 5 and 6 herein constitutes proprietary, trade secret and/or confidential business information, and has therefore been marked "Confidential." Sure-Way Systems, Inc. hereby requests that this information be afforded confidential treatment within the meaning of the Freedom of Information Act, 5 U.S.C. § 20.61, and that such information not be divulged to unauthorized persons. We also ask that you consult with Sure-Way Systems, Inc. as provided in 21 C.F.R. § 20.45, before making any part of this submission publicly available.

We trust that the information provided in this notification will be sufficient to enable FDA to find the Reusable Sharps Container substantially equivalent to its predicate device.

Please direct any questions or requests for additional information to the undersigned.

Sincerely,

Sure-Way Systems, Inc.

By: Gary Chilcott

Gary Chilcott
CEO/President

310 Harry Bridges Blvd. Wilmington, CA 90744 310-522-0150 FAX 310-522-0431

5K25

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HD II

510(k) PREMARKET NOTIFICATION CHECKLIST

ITEM	COMMENT
1. Device trade or proprietary name section I	See 510(k) notice
2. Device common or unusual name or classification name	See 510(k) notice section I
3. Manufacturer/distributor information	See 510(k) notice section II
4. Class into which the device is classified	See 510(k) notice section III
5. Classification Panel	See 510(k) notice section III
6. Action taken to comply with section 514 of the Act	Not applicable- no performance standards or special controls apply.
7. Proposed labels, labeling and advertisements (if applicable) that describe the device, its intended use, and directions for use	See Attachment 1
8. A 510(k) Summary or a 510(k) Statement	See Attachment 7
9. For class III devices only, a class III certification and a class III summary	Not applicable, this is a class I device
10. Photographs of the device	See Attachment 3 (engineering drawings)
11. Engineering drawings for the device with dimensions and tolerances	See Attachment 3
12. The marketed device(s) to which equivalence is claimed including labeling and description of the device	See 510(k) notice section VI and Attachment V
13. Statement of similarities and/or differences with marketed device(s)	See 510(k) section IX
14. Data to show consequences and effects of a modified device	Not applicable
15. Submitter's name and address	See 510(k) notice section XIII
16. Contact person, telephone/fax number	See 510(k) notice section XIV
17. Representative/Consultant, if applicable	Not applicable
18. Table of Contents with pagination	See 510(k) notice page i
19. Comparison table of the new device to the marketed device(s)	See Attachment 6

20. Action taken to comply with voluntary standards	No voluntary standards apply
21. Performance data	
a. marketed device	
1. bench testing	Not applicable
2. animal testing	Not applicable
3. clinical data	Not applicable
b. new device	
1. bench testing	See Attachment 5
2. animal testing	Not applicable
3. clinical testing	Not applicable
22. Sterilization information	Not applicable
23. Software information	Not applicable
24. Hardware information	Not applicable
25. Is this device subject to issues that have been addressed in specific guidance documents(s)?	Yes
26. Truthful and Accurate Statement	See Attachment 8
27. Indications for Use Sheet	See Attachment 9

SURE-WAY SYSTEMS, INC.

510(K) PREMARKET NOTIFICATION

FOR

REUSABLE SHARPS CONTAINERS

Sure-Way Systems, Inc.
310 Harry Bridges Boulevard
Wilmington, CA 90744
(310)522-0150

Table of Contents

Table of Contents
Continued

Attachments

The following information is provided as required by 21 C.F.R. § 807.87 and FDA's "Draft 510(k) Guidance on Sharps Containers" (October 1993):

I. Name of Device

A. Classification Name: Accessory to hypodermic needle
B. Common Name: Sharps Container
C. Proprietary Name: Sure-Way Reusable Sharps Container

II. Manufacturer/Distributor

The manufacturer of the Reusable Container is:

L & H Molds and Engineering
2240 East Cedar Street
Ontario, CA 91761
(909) 930-1550

The establishment registration number of the manufacturer is pending

The distributor and entity submitting this 510(k) notification is:

Sure-Way Systems, Inc.
310 Harry Bridges Boulevard
Wilmington, CA 90744
(310) 522-0150

The establishment registration number of the distributor is pending

III. Product Code/Classification: 80 FMI; Class II

IV. Performance Standards

No FDA - established performance standards or special controls apply.

V. Labeling/Advertising

The proposed labels which will appear on the devices are enclosed as Attachment 1. Promotional Literature is enclosed as Attachment 2.

The sharps containers are delivered by Sure-Way Systems, Inc. to the facility for installation. Placement of the container at the facility is done by facility staff at their desired location. Trained Sure-Way representatives check all container sites on a regular schedule and exchange all containers once they have reached the fill point. Another option is for the health care facility employees to exchange the containers and bring them to a secured central location for collection by Sure-Way staff. The exchanged containers are brought back to the Sure-Way facility for processing, i.e., automated container dumping, cleaning and waste disposal.

VI. General Description

A. The Sure-Way Reusable Container is a reusable plastic container into which used needles and other medical waste sharps are discarded. It is a nonsterile device for nonsterile applications. Engineering drawings for the container are provided in Attachment 3.

B. The volume of this device is 14.5 liters.

C. The containers are injection molded from high density polyethylene plastic resin at an average wall thickness of 1/8" (0.125"). Attachment 4 sets forth the specifications for this material, which is semi-opaque.

D. The intended locations for use are any areas in a medical, dental, veterinarian, or other health care facility where there is a need for used sharps disposal.

E. The projected life expectancy of the device is at least five (5) years. Polyethylene is a non-degrading material. Other sharps containers using the same material for the same purpose have remained in use over five (5) years without showing failure.

F. Upon their return to the Sure-Way facility, the containers are removed from a security cart one at a time. The container locking pin is removed by the operator. The container is then placed into a mechanical dumper-washer. A mechanical gripper removes the top from the container base. The gripper lifts off the cover and carries it onto a conveyer and on through the washing equipment. The container base is then inverted, the sharps and other material are then dumped into a cart and mechanically dumped into an autoclave bin or incinerator for decontamination and disposal. The entire process will use one or two employees. The sharps container base, like the top, is washed and sanitized with chemicals and 180 degree water and steam.

VII. Design Features of Container

A. Each container is <u>lockable.</u> Each container has a bayonet style lid closure that horizontally slides into place and is removed mechanically for emptying and cleaning. The lid features nylon locking push pin fastener to further help hold the lid in place.

The container lid features a horizontal drop entry hole that is approximately 9" X 2.25". The container has a paddle wheel security system which prevents unauthorized access to the contents, thus minimizing exposure. The container lid also features an attached top that closes the entire entry port and locks into place with a security locking pin.

B. The device is <u>puncture resistant.</u>

C. The device is <u>leakproof</u> on the sides and bottom.

D. The device is labeled in accordance with OSHA requirements and ANSI standards. A biohazard label (Attachment 1) is permanently affixed to the front and back of the container by adhesive backing.

E. The container features four raised legs for stability when used in a free standing mode. The device is capable of maintaining a stable, upright position during use in a free standing mode. The container system also features a locking mounting bracket for additional stability and security.

F. The device does not incorporate any features to break, bend, or shear needles.

G. The device does not feature a needle unwinder.

VIII. Test Methods for Design Features

A. The impact resistance of the Reusable Sharps Container was determined in accordance with the U.S. Department of Transportation "Drop Test" (49 C.F.R. § 178.603). The laboratory test report is enclosed as Attachment 5. The following is a summary of the test and results.

Method: The Reusable Sharps Containers were filled with medical waste to a density of 3.76 pounds per cubic foot. After stabilizing for 4 hours, the test units were dropped on a concrete floor from a height of 39".

Results: The Reusable Containers met with the requirements set forth in 49 C.F.R. § 178.603 when using nylon locking push pin fasteners for the lids. The units did not exhibit any signs of damage from the test.

B. The puncture resistance of the Reusable Containers were determined in accordance with proposed ASTM Task Force F04.65.01, draft #12, dated 6/11/92. The test report is enclosed as Attachment 5. The following is a summary of the test and the results.

Method: A sample of the thinnest area on the container was cut for testing. The container was subjected to 3 penetrations by a hypodermic needle attached to a force gauge, which was mounted to a press.

NB

Results: All samples met the requirements of ASTM F04.65.01. Draft #12, which an average puncture resistance greater than 3.4 pounds.

C. There are no standard or test methods for the overfill detection design feature. A "fill line" is clearly marked on each label to identify the capacity of the container. A legend "DO NOT FILL ABOVE THIS LINE" is prominently displayed along the line. In addition, as explained above, the containers are serviced on a regularly scheduled basis, thus reducing the possibility of an overfilled container.

D. Leak Resistance was determined in accordance with the ECRI test method (health Devices, Aug.- Sept. 1993, ECRI Vol. 22, Nos. 8-9, P. 384). The laboratory test is enclosed as Attachment 5. The following is a summary of the tests and results:

Method: The containers were placed on a level surface and filled with water to the top of the container. After 24 hours the containers were checked for loss of liquid.

Results: All containers retained the water for the 24 hour time period, therefore passing the test.

E. Sharps Access and Closure. There are no standards or test methods for this design feature. The container has a horizontal access port in the lid for depositing sharps. The entry port is approximately 9" X 2.25".

F. Stability was determined in accordance with the ECRI test Method(id.)

Method: The container mounting bracket was fastened to a plywood board. With the sharps container attached to the bracket, the board was rotated and/or tilted but the containers did not topple because of the bracket construction. The containers were positioned on a flat floor without the bracket.

Results: All containers remained stable without tipping in accordance with OSHA specifications 29 C.F.R.1910.1030.

G. Mounting Accessories/Locking Mechanism. The mounting bracket for the reusable container has a locking mechanism that prevents unauthorized removal of the container. The mounting accessories allow for easy container replacement.

H. Handling (safe transportation features). See tests described in paragraphs A, B, C and D above.

I. Capacity was determined using the ECRI test method (id., at p. 387) (see attachment 5), as follows.

Method: The container was filled with water to capacity, and the volume of water was measured.

Results: The total capacity of the container was within 10% of the specified volume, thus passing the test.

IX. Comparison to a Predicate Device

The Sure-Way Reusable Sharps Container is substantially equivalent to MedX and BioMed Sharps Containers. The medX predicated device was cleared for marketing by the FDA under 510(k). Notification #K943771. A side by side comparison of the design features and specifications of the MedX reusable sharps container and the Sure-Way Reusable Sharps Container is enclosed as Attachment 6.

There are no significant functional differences between the predicate device and this new device. The basic differences relate to the construction and added features.

- The MedX reusable container was blow molded, resulting in the average wall thickness of 0.070". The Sure-Way Reusable Sharps Container was injection molded, resulting in an average wall thickness of 0.125".

- The lid and container base assembly of the Sure-Way Reusable Container is designed to be compatible with the mechanical dumping and washing equipment.

- The Sure-Way Reusable Container offers a tortuous path entry to minimize exposure of the contents to humans.

Since the Sure-Way Reusable Container has the same intended use, principles of operation and technological characteristics, as it's predicate device, the MedX reusable sharps container, no new issues of safety or effectiveness are raised.

X. Sterilization Information

Not applicable.

XI. Statements

Attachment 7 of this submission contains the company's 510(k) statement. Attachment 8 contains the company's Truthful and Accurate Statement.

XII. Indications for Use Sheet

Attachment 9 contains the completed "Indications for Use Sheet.

XIII. Confidentiality

Some of the material in this submission may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. These item have been marked "CONFIDENTIAL." We ask that you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

XIV. Submitter's Name and address

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

Telephone: 310-522-0150
Fax: 310-522-0431

XV. Contact Person and Telephone/Fax Numbers

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

Telephone: 310-522-0150
Fax: 310-522-0431

CURRAN MENDOZA

ATTORNEYS

Curran Mendoza P.S.
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Facsimile (253) 852-2030 • (253) 859-8037
www.curranmendoza.com

June 1, 2005

Mr. Stephen B. Johnson
Garvey Schubert Barer
1191 Second Ave.
Seattle, WA 98101-2939

VIA MESSENGER

Re: Sure-Way Systems, Inc.

Dear Steve,

Enclosed are copies of documents in response to your Protestant's data request numbers 8, 9, 10 and 12.

Sincerely,

CURRAN MENDOZA, P.S.

Greg W. Haffner

Enclosures

cc: Gary Chilcott (w/o enclosures)

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