

# **Exhibit JAK-17**

**SURE-WAY SYSTEMS, INC.**  
**Sharps Disposal Service Program**  
Ensuring safe disposal in the medical community

**SHARPS  
DISPOSAL SERVICE  
CONTRACT**

OFFICE USE ONLY

PICK-UP SCHEDULE _____
AREA _____
DATE _____
EST. WASTE OUTPUT _____

Sure-Way Systems, Inc. (hereafter referred to as **SWS**) proposes to provide the following services to \_\_\_\_\_ (hereafter referred to as **Generator**) and understands that there is a mutual agreement to the following terms and conditions:

**1. SHARPS CONTAINER REPLACEMENT AND REGULATED MEDICAL WASTE REMOVAL**

**1.1** SWS will supply **Generator** with reusable sharps containers to service the existing \_\_\_\_\_ sharps container locations in the hospital with 510K FDA and DOT approved reusable sharps containers. This quote is for the Sure-Way Systems Smart-Sharps Service in which the **Generator** will handle all container exchanges.

**1.2** The annual cost for this service is (Yr. 1)\$\_\_\_\_\_ for \_\_\_\_\_ sharps container locations and \_\_\_\_\_ sharps containers annually.

**1.3** There is no additional monthly charge for the 1 transport cart stationed at the facility. Any additional carts above the 1 issued are charged at \$50 per cart per month.

**2. TERM**

**2.1** The terms of this Agreement will commence on the date set forth in Section 11 and shall continue in effect for the period set forth in Section 2. This agreement will be automatically renewed for an additional one year term unless cancelled on or before the thirty (30) day anniversary date or each subsequent annual anniversary date.

### 3. TRAINING AND INSERVICES

3.1 **SWS** will provide in-service training for waste reduction and/or blood borne pathogen procedures as related to Sharps containers upon request 6 times on an annual basis. Additional seminars may be requested and performed at a set price of \$100.00 per inservice.

### 4. FEES AND BILLING

4.1 For the services provided to **Generator** under this Agreement, **Generator** shall pay to **SWS** fees as set forth above. In the event any governmental regulation, tax, tariff, fee or surcharge is to be assessed or imposed on the transportation, storage, treatment, or disposal of the Infectious Waste Material, the fees charged by **SWS** will be increased by the amount of such tax, tariff, fee, implementation of regulations, or surcharge. Any such increase in fees shall be set forth as a separate item on the invoices submitted to **Generator**. Should additional locations be requested by the facility they will be billed at the same rate per month as the rest of the locations in the facility.

4.2 Fees set forth are firm for the term of this Agreement, with the exception of new governmental regulations that will require changes in the program that are unforeseen at this time. The increase will be only the amount needed to cover the documented increase.

4.3 Invoices will be submitted monthly by **SWS** to **Generator** and shall be paid no later than thirty (30) days from the date of invoice. Payments not paid within thirty (30) days will accrue interest at 1.5% monthly.

4.4 **SWS** shall retain records of all invoices, record of disposal, and delivery receipts for at least five (5) years.

### 5. TRANSFER OF WASTES AND TITLE

5.1 Transfer of waste will be considered complete when **SWS** or its designee signs a standard form of manifest indicating an acceptance of delivery of the Infectious Waste Material. At that time, title, risk of loss and all other incidents of ownership with respect to those Infectious Waste Materials shall be transferred from the **Generator** to **SWS**.

5.2 If, following signature of a manifest pertaining to **Generator's** Infectious Waste Material, such waste material is discovered to be "non-conforming" in whole or in part, **SWS** may revoke its acceptance of all such Infectious Waste Material. A revocation of acceptance shall operate to revert title, risk or loss, and all other incidents of ownership to **Generator** at the time revocation is communicated, either orally or in writing, to **Generator** and **Generator** shall

hold **SWS** harmless thereof. Infectious Waste Material shall be considered "non-conforming" for the purposes of this Agreement:

- a. If it is not in accordance with the descriptions, limitations, or specifications stated in the Sure-Way Systems Infectious Waste Profile Sheet attached hereto as Exhibit A; or
- b. If it contains constituents or components, not specifically identified in Sure-Way's Infectious Waste Material Profile Sheet with (1) increases the nature or extent of the hazard and risk undertaken by **SWS** in agreeing to handle, load, transport, store, treat or dispose of the Infectious Waste Material; or (2) cannot, for reasons relating to the designing or permitting of the facility, be stored, treated, or disposed of at the relevant waste management facility.

## 6. SURE-WAY WARRANTIES

- 6.1 **SWS**, or its designee, understands the currently known hazards which are presented to persons, property and the environment in the transportation, storage and disposal of the Infectious Waste Material;
- 6.2 **SWS**, or its designee, will transport, store and dispose of the Infectious Waste Material in full compliance with all State and Federal EPA regulations and other state and local laws and regulations.
- 6.3 The waste management facilities utilized are now licensed and permitted to store and dispose of waste materials within the description of the Infectious Waste Material
- 6.4 In the event such waste management facilities lose permitted status during the term of this Agreement, **SWS** will promptly notify **Generator** of such loss and take its waste to a secondary, properly licensed facility for disposal so as to not disrupt service to the **Generator**.

## 7. GENERATOR'S WARRANTIES

The **Generator** shall warrant conformance and compliance with the following conditions:

- 7.1 All material packed Sure-Way's containers conform to the descriptions of its Infectious Waste Material made in Section 1, and that the Sure-Way Infectious Waste Material Profile Sheet attached hereto as Exhibit A, is true and correct;
- 7.2 Infectious Waste Material transferred by **Generator** hereunder will be packaged in Sure-Way's patented sharps containers and suitably protected from damage until time of pick-up.
- 7.3 Hazards and risks known to or learned by **Generator** to be of incident to the handling, transportation, storage, treatment, and disposal of the Infectious

Waste Material are to be communicated to **SWS** in a timely fashion. They have been communicated, and will continue to be communicated during the term hereof.

- 7.4 If the Infectious Waste Material is, or contains, hazardous substances as defined pursuant to Section 101 of the Federal Comprehensive Environmental Response, Compensation and Liability Act of 1980 or any other Federal, State or local law or regulation, **Generator** will advise **SWS** or their designee of the load or Infectious Waste Material containing a reportable quantity of any hazardous substance or substance pursuant to Section 102 of said Act or other applicable law or regulation, specifying those hazardous substances present in a reportable quantity. If such hazardous materials cannot be stored, treated, or disposed of by **SWS**, **SWS** shall decline to accept and shall return said shipment.
- 7.5 If the Infectious Waste Material is covered by requirements of any state or local laws or regulations relating to hazardous wastes or hazardous materials, it will comply with all applicable requirements of such laws or regulations.
- 7.6 The **Generator** is responsible for any loss or damage to sharps container brackets, cabinets, or transport carts furnished and installed by Sure-Way in the **Generators** facility in the course of providing these services.
- 7.7 The **Generator** warrants and understands that the container usage given to Sure-Way for determining the volume of sharps waste produced at the facility is accurate and that if it is determined that faulty numbers were provided the contract **price will be adjusted to reflect the accurate volumes** and rest of the contract will remain in force as stated.

## 8. TERMINATION

### 8.1 This agreement may be cancelled by **SWS**:

- A. If the **Generator** fails to pay its bill in a timely manner.
- B. If the **Generator** ships or tenders material in violation of the Agreement;  
or;
- C. If **SWS** loses permitted status.

### 8.2 This Agreement may be cancelled by the **Generator**:

- A. If notice is given thirty (30) days prior to the termination date set forth in this agreement.
- B. With or without cause with a 90 day notice.
- C. For failure to perform by **SWS**.

8.3 Damage for improper termination shall not be more than the amount due under the remaining term of the Agreement or part thereof up to the next anniversary date of this agreement.

**9. CONFIDENTIALITY**

Each party shall treat this Agreement as confidential and not disclose to others during or subsequent to the term of this Agreement, except as is required by law or is necessary to properly perform this Agreement (and then only on a confidential basis satisfactory to the other party) any information regarding the Infectious Waste Material. Neither party shall make any news release, advertisement, or public announcement regarding the subject matter of this Agreement without the prior approval of the other party.

This validity, interpretation and performance of this Agreement shall be governed and constructed in accordance with the laws of the State of Montana and applicable federal laws and regulations.

**10. AGREEMENT**

This Agreement incorporates the entire understanding and agreement regarding the transportation, storage, and disposal of the Infectious Waste Material and supersedes any and all terms and conditions which may be contained in any purchase orders issued by **Generator** prior to or subsequent to this Agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

**11. SERVICE COMMENCEMENT**

Start up date for service will be for entire facility the billing start date is \_\_\_\_\_ Please sign below where indicated and return the original to Sure-Way Systems. This is a 3 year contract.

**THIS PROPOSAL IS AGREED TO AND ACCEPTED BY:**

**Sure-Way Systems, Inc.**

\_\_\_\_\_ **Facility**

\_\_\_\_\_  
Authorized Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Authorized Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Title

\_\_\_\_\_  
Title

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Sure-Way Systems, Inc.  
Business Office Information

Frequency of Pick-Up: \_\_\_\_\_

**Generator Information:**

Mailing Address: \_\_\_\_\_

Billing Address: \_\_\_\_\_

Service Contact Person: \_\_\_\_\_ Title: \_\_\_\_\_

Phone: \_\_\_\_\_

Billing Contact Person: \_\_\_\_\_ Title: \_\_\_\_\_

Phone: \_\_\_\_\_

Price Per Location: \_\_\_\_\_

Number of Locations: \_\_\_\_\_

# **Exhibit JAK-18**



**Steve Johnson**

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**From:** Greg W. Haffner [GWH@CurranMendoza.com]  
**Sent:** Wednesday, June 15, 2005 3:06 PM  
**To:** Steve Johnson  
**Cc:** Gary Chilcott  
**Subject:** Sure-Way



tax.pdf (25 KB)

Steve,

Attached is a letter from Sure-Way's accountant stating that the 2003 tax return will be completed subsequent to the issuance of audit reports, which should be issued by the end of July 2005. Below is an explanation from Sure-Way of the financial issue that caused the 2003 return to be delayed.

Greg Haffner

We wanted to have a 2003 audit done as soon after the end of 2003 as possible but we owed the auditors money. Every month we had the intention of getting them paid off so they could get started. It was thought that since we were going to do it soon (which turned out not to be the case) that we would file the 2003 tax return after the 2003 audit was done to avoid having to do an amended 2003 tax return after the audit. When we did get them paid off, 2004 was almost done and so in an effort to save some money, we wanted to combine the audit effort into a single effort, thus extending the time again.

Let me know if you need further explanation, but it wasn't intentional, it just kept getting postponed in hopes that we would have the 2003 audit started and completed.

Let me know if you need more explanation, thanks, Christie <<tax.pdf>>

**Steve Johnson**

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**From:** Steve Johnson  
**Sent:** Monday, June 13, 2005 3:11 PM  
**To:** 'Greg W. Haffner'  
**Subject:** Sure-Way Responses to Stericycle Data Requests

Greg,

(1) Sure-Way has entirely failed to respond to our requests for information concerning the registration of Sure-Way's processing facilities and the listing of its reusable sharps containers with the Food & Drug Administration ("FDA"), including our requests for copies of applications, registrations, notifications, listings or other written communications submitted by Sure-Way to the FDA and all written communications received from the FDA concerning Sure-Way's processing facilities and reusable sharps containers. See Data Requests No. 8, 9 and 10.

For each Sure-Way processing facility, please provide a copy of Sure-Way's application to the FDA for registration of the facility, if any, and any other written communications to or from the FDA concerning the registration and/or any of Sure-Way's processing facilities.

For each Sure-Way reusable sharps container, please provide a copy of Sure-Way's application to the FDA for listing of the sharps container as a medical device, if any, and any communications to or from the FDA concerning the listing and/or Sure-Way's reusable sharps containers.

Sure-Way should have filed annual reports with the FDA for each of its processing facilities, if they were properly registered with the FDA. These annual reports fall within the scope of our requests for written communications to the FDA concerning Sure-Way's processing facilities. Please provide copies of all such annual reports and any communications to or from the FDA concerning such annual report(s).

The materials provided to us under cover of your letter dated June 1, 2005 deal only with Sure-Way's 510(k) premarket notification filings with the FDA and thus are not responsive at all to our Data Requests No. 8 and 9, which requested information and documents related to Sure-Way's registration of its processing facilities and listing of its sharps containers with the FDA. Similarly, the materials previously provided with your June 1 letter are only partially responsive to Data Request No. 10.

(2) Sure-Way has failed to respond to our requests that Sure-Way identify each inspection, examination or review of any of Applicant's facilities, vehicles or operations conducted by the FDA or any other governmental agency since 1990 and provide copies of inspection reports, citations, notices of violation or other actions, notices or reports issued by the agency and any correspondence between Applicant and the agency with respect thereto. See Data Request No. 13.

(3) I am still waiting for an explanation as to why Sure-Way's 2003 tax return is "unavailable" and again request that you pursue this issue with your client. In the absence of an adequate explanation for Sure-Way's failure to file a 2003 tax return, we must continue to insist that Sure-Way provide us a copy of its 2003 tax return.

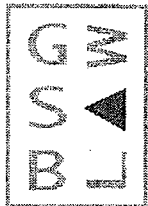
Please advise me when we can expect to receive the information and materials identified above. If by tomorrow I do not receive your assurance that these materials will be promptly made available to us, I will ask Judge Caille to schedule a discovery conference to consider the matter.

Thank you for your assistance.

Steve

STEPHEN B. JOHNSON  
[sjohnson@gsblaw.com](mailto:sjohnson@gsblaw.com)

7/18/2005



GARVEY SCHUBERT BARER  
GSBLAW.COM  
*eighteenth floor*  
*1191 second avenue*  
*seattle, washington 98101-2939*  
TEL 206 464 3939 FAX 206 464 0125  
DIRECT 206 816 1309

# **Exhibit JAK-19**

**Steve Johnson**

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**From:** Greg W. Haffner [GWH@CurranMendoza.com]  
**Sent:** Friday, July 15, 2005 8:47 AM  
**To:** Steve Johnson  
**Subject:** Sure-Way

Steve,

The following are provided to you in response to your letter to me dated July 8, 2005:

<<prior QSR manuals.pdf>> <<contract with Small Business Exchange.pdf>> <<tri fold and post card.pdf>>  
<<Container Spec Sheets.pdf>> <<Certificate of Liability Insurance.pdf>> <<Safety Manual.pdf>> <<OSHA North  
Dakota.pdf>> <<Health Department Violation - ND.pdf>>

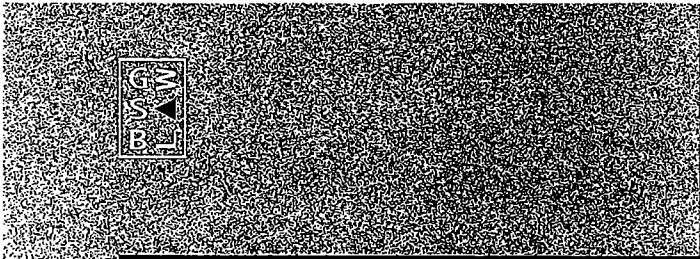
Additional documents related to container testing were provided earlier with the 510k file

I still don't have the audited financial statements and tax returns for 03 and 04.

There are no records of distribution of the 1/5/05 QSR manual, or of compliance with the QSR manuals.

Greg W. Haffner  
Curran Mendoza P.S.  
555 West Smith Street  
P. O. Box 140  
Kent, WA 98035-0140  
(253) 852-2345 Phone  
(253) 852-2030 Fax  
[www.curranmendoza.com](http://www.curranmendoza.com)

7/15/2005



SEATTLE OFFICE  
eighteenth floor  
second & seneca building  
1191 second avenue  
seattle, washington 98101-2939  
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OTHER OFFICES  
beijing, china  
new york, new york  
portland, oregon  
washington, d.c.  
GSBLAW.COM

G A R V E Y S C H U B E R T B A R E R

A PARTNERSHIP OF PROFESSIONAL CORPORATIONS

Please reply to STEPHEN B. JOHNSON  
sjohnson@gsblaw.com TEL EXT 1309  
DIRECT: (206) 816-1309

July 8, 2005

Mr. Greg Haffner  
Curran Mendoza  
555 W. Smith Street  
Kent, WA 98035

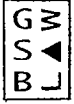
Re: In re the Application of Sure-Way Systems, Inc./WUTC Docket No. 042089

Dear Greg:

During the deposition on June 24, 2005, we requested and Gary Chilcott agreed to provide us the following additional documents and records:

- Copies of prior versions (prior to 1/5/05) of Sure-Way's QSR Manual, if they can be located;
- Copies of transmittal letters or other records documenting when Sure-Way's most recent QSR Manual (dated 1/5/05) was distributed to Sure-Way's processing plants;
- A copy of Sure-Way's contract with "Small Business Exchange," the company that employs the personnel who work in Sure-Way's operations;
- A copy of Sure-Way's marketing "trifold;"
- Copies of the container test reports generated by Container-Qwinn or other testing company;
- Copies of Sure-Way's audited financial statements and federal income tax returns for 2003 and 2004;
- Evidence that Sure-Way has auto liability insurance;
- Sure-Way's "safety manual," if it exists.

In addition, I advised you at Mr. Chilcott's deposition of our additional requests for:



Greg Haffner  
July 8, 2005  
Page 2

(a) copies of records and documents evidencing Sure-Way's compliance with the requirements of its QSR Manual, including any predecessor version of the QSR Manual (an itemized list of the records and documents we seek is enclosed); and

(b) clarification concerning certain discrepancies noted by our accounting expert in reviewing the Sure-Way financial statements previously provided to us in response to our data requests.

With respect to financial statement issues, we have agreed that our accounting expert will speak directly to Sure-Way's accountant(s) to clarify the apparent discrepancies.

We understand from our prior discussions of this subject that Sure-Way's audited financial statements and federal income tax returns for 2003 and 2004 will not be available until the end of July and that you will provide copies of these materials to us as soon as they are available. In the absence of those materials, we ask that you provide us with a complete copy of Sure-Way's 2002 federal income tax return, since it is apparently the most recent available.

Because the requested materials will be important in preparing Stericycle's prefiled testimony, I request that you provide us the materials and information referenced above as soon as possible and by no later than the end of next week. If that schedule proves to be a problem, please let me know as soon as possible.

Thank you for your cooperation and assistance.

Sincerely,

GARVEY SCHUBERT BARER

By

Stephen B. Johnson

Cc: Greg Trautman  
Mike Philpott

Stericycle requests complete copies of the following records and documents evidencing Sure-Way's compliance with the requirements of its QSR Manual ("QSR"). If the records requested are numerous, and are regularly completed many times each month, please provide one sample of the record for each month within the specified time period.

- All completed "Audit Completion Records" for Quality System reviews evidencing compliance with Management Review requirements for the last three years (QSR 820.20(c))
- All completed "Audit Completion Records" evidencing Quality Audits for the last three years (QSR 820.22) – see QSR Appendix III
- All completed "Audit Worksheets" for the last three years – see QSR Appendix II
- All completed "Quality Manual Training Worksheets" evidencing compliance with Quality Training requirements for the last three years (QSR 820.25) – see QSR Appendix IV
- All completed "Manual Change Record Forms" evidencing changes and modifications to the Design Master Record in the last three years (QSR 820.3(j)) – see QSR Appendix V
- Copies of the "Quality System Record" evidencing changes to the Quality System Manual and the Facility Operating Manual during the last three years (QSR 820.40)
- All documents or other evidence demonstrating that each container manufacturer from whom Sure-Way purchases containers has a Quality System in place (QSR 820.50)
- All documents or other evidence demonstrating that each container has been subjected to a validation test prior to initial use and a challenge test on a quarterly basis thereafter (QSR 820.70(a))
- All completed "Defect Notification Worksheets" for the last three years (QSR 820.80(b)) – see QSR Appendix VI(c)
- All completed "batch worksheets" indicating authorization for containers to be returned to service for the last three years (QSR 820.80(d,e))
- All completed "Customer Complaint Worksheets" for the last three years (QSR 820.100) – see QSR Appendix VII
- All completed "Acceptance Reports" for "reuse" containers for the last three years (QSR p.32)
- All completed "Acceptance Reports" for new containers for the last three years (QSR p.32) – see QSR Appendix VI(a)
- All completed "New Product Defect Notification Acceptance Reports" for the last three years – see QSR Appendix VI(b)

Items identified in Sure-Way Systems, Inc.'s Facility Operations Manual, which is part of the QSR Manual:

- All documents or records demonstrating that any modification of the design of the tipper and washer or the containers is signed off by the CEO and the COO (QSR p.39)



- The complete file history related to the manufacturing of the reusable containers (QSR p.39)
- All completed “container logs” for the last three years (QSR pp.39-40)
- All completed “processing logs” for the last three years (QSR p.40) – see QSR Exhibit 2
- All documents or records evidencing the checking and testing of the tipper, washer, and water as described in Section 6, Equipment and Calibration (QSR p.43)
- The “Design Master Record” (QSR p.44)
- All documents or records demonstrating that all changes to the Quality System Regulations Manual are approved in writing by the Compliance Officer and the CEO (QSR p.45)
- All completed “monthly reports” prepared by the Operations Manager related to discarded and/or defective containers as described in Section 10 (p.49)
- All completed “New Sharps Container Acceptance Checklists” for the last three years – see QSR Exhibit 1
- All completed “Daily Container & Rack Checklists” for the last three years – see QSR Exhibit 3(a)
- All completed “Daily 10 & 17 Gallon Checklists” for the last three years – see QSR Exhibit 3(b)
- All completed “Damaged Container Reports” for the last three years (QSR p.83)

Items identified in Sure-Way Systems, Inc.’s Bloodborne Pathogens Exposure Control Plan, which is part of the QSR Manual:

- All completed “Infectious Exposure Forms” for the last three years – see QSR Appendix B
- All completed “Training recognition/confirmation forms” for the last three years (QSR p.76)

# **Exhibit JAK-20**

**Steve Johnson**

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**From:** Greg W. Haffner [GWH@CurranMendoza.com]  
**Sent:** Tuesday, June 14, 2005 4:43 PM  
**To:** Steve Johnson  
**Subject:** RE: Sure-Way Responses to Stericycle Data Requests

Steve,

Gary Chilcott is on the road this week, but he was able to provide me with some information to respond to your continued inquiries. He will try to provide some limited additional information tomorrow. I will respond to each of your questions below in ***bold blue italics***.

Greg

-----Original Message-----

**From:** Steve Johnson [mailto:SJohnson@gsblaw.com]  
**Sent:** Monday, June 13, 2005 3:11 PM  
**To:** Greg W. Haffner  
**Subject:** Sure-Way Responses to Stericycle Data Requests

Greg,

(1) Sure-Way has entirely failed to respond to our requests for information concerning the registration of Sure-Way's processing facilities and the listing of its reusable sharps containers with the Food & Drug Administration ("FDA"), including our requests for copies of applications, registrations, notifications, listings or other written communications submitted by Sure-Way to the FDA and all written communications received from the FDA concerning Sure-Way's processing facilities and reusable sharps containers. See Data Requests No. 8, 9 and 10.

For each Sure-Way processing facility, please provide a copy of Sure-Way's application to the FDA for registration of the facility, if any, and any other written communications to or from the FDA concerning the registration and/or any of Sure-Way's processing facilities. ***Sure-Way is not required to register its facilities with the FDA. See attached email. We will provide copies of the FDA authorizations for the manufacturers of the containers (L&H and Rotonics) those requests will be made tomorrow. I understand Stericycle uses Rotonics so I assume Stericycle doesn't have a problem with them.***

For each Sure-Way reusable sharps container, please provide a copy of Sure-Way's application to the FDA for listing of the sharps container as a medical device, if any, and any communications to or from the FDA concerning the listing and/or Sure-Way's reusable sharps containers. ***We already provided you with our 510(k) file which has all the information we have. If you are looking for information based on the different sizes of the containers, it does not exist, since Sure-Way was only required to register its family of containers based on its largest container. The Rotonics containers are handled the same.***

Sure-Way should have filed annual reports with the FDA for each of its processing facilities, if they were properly registered with the FDA. These annual reports fall within the scope of our requests for written

7/18/2005

communications to the FDA concerning Sure-Way's processing facilities. Please provide copies of all such annual reports and any communications to or from the FDA concerning such annual report(s). ***Sure-Way is not required to register its facilities with the FDA. See attached email.***

The materials provided to us under cover of your letter dated June 1, 2005 deal only with Sure-Way's 510(k) premarket notification filings with the FDA and thus are not responsive at all to our Data Requests No. 8 and 9, which requested information and documents related to Sure-Way's registration of its processing facilities and listing of its sharps containers with the FDA. Similarly, the materials previously provided with your June 1 letter are only partially responsive to Data Request No. 10. ***The 510(k) file is what Sure-Way has. We note that Stericycle only produced copies of its letters of authorization to market in response to our similar data request.***

(2) Sure-Way has failed to respond to our requests that Sure-Way identify each inspection, examination or review of any of Applicant's facilities, vehicles or operations conducted by the FDA or any other governmental agency since 1990 and provide copies of inspection reports, citations, notices of violation or other actions, notices or reports issued by the agency and any correspondence between Applicant and the agency with respect thereto. See Data Request No. 13. ***We may have older versions of the Montana state inspections which we believe say the same as the 2004 version we already provided. We will produce them if we find any and will look for them this week. Sure-Way's California plant was inspected by the FDA in 2000, but no records of the inspection can be found and the plant was sold in 2000. The only vehicle inspections we are aware of are road-side inspections by DOT. Sure-way has no records of those inspections because of the frequency of their occurrence.***

(3) I am still waiting for an explanation as to why Sure-Way's 2003 tax return is "unavailable" and again request that you pursue this issue with your client. In the absence of an adequate explanation for Sure-Way's failure to file a 2003 tax return, we must continue to insist that Sure-Way provide us a copy of its 2003 tax return. ***Sure-Way does not have a 2003 tax return to provide you and will not until approximately late July 2005, when the accountant has told them it will be ready. I will try to get for you an explanation from the accountant.***

Please advise me when we can expect to receive the information and materials identified above. If by tomorrow I do not receive your assurance that these materials will be promptly made available to us, I will ask Judge Caille to schedule a discovery conference to consider the matter.

Thank you for your assistance.

Steve



STEPHEN B. JOHNSON

[sjohnson@gsblaw.com](mailto:sjohnson@gsblaw.com)

GARVEY SCHUBERT BARER

[GSBLAW.COM](http://GSBLAW.COM)

*eighteenth floor*

*1191 second avenue*

*seattle, washington 98101-2939*

TEL 206 464 3939 FAX 206 464 0125

DIRECT 206 816 1309

# **Exhibit JAK-21**



OFFICE OF ATTORNEY GENERAL  
STATE OF NORTH DAKOTA

November 14, 2001

Wayne Stenehjem  
ATTORNEY GENERAL

**CAPITOL TOWER**  
State Capitol  
600 E. Boulevard Ave.  
Dept. 125  
Bismarck, ND 58505-0040  
701-328-2210  
800-366-6888 (TTY)  
FAX 701-328-2226

**Consumer Protection  
and Antitrust Division**  
701-328-3404  
800-472-2600  
Toll Free in North Dakota  
FAX 701-328-3535

**Gaming Division**  
701-328-4848  
FAX 701-328-3535

**Licensing Section**  
701-328-2329  
FAX 701-328-3535

**SOUTH OFFICE BUILDING**  
500 N. 9th St.  
58501-4509  
FAX 701-328-4300

**Civil Litigation**  
701-328-3640

**Natural Resources**  
701-328-3640

**Racing Commission**  
701-328-4290

**Bureau of Criminal  
Investigation**  
P.O. Box 1054  
Bismarck, ND 58502-1054  
701-328-5500  
800-472-2185  
Toll Free in North Dakota  
FAX 701-328-5510

**Fire Marshal**  
P.O. Box 1054  
Bismarck, ND 58502-1054  
701-328-5555  
FAX 701-328-5510

**Information Technology**  
P.O. Box 1054  
Bismarck, ND 58502-1054  
701-328-5500  
FAX 701-328-5510

Dudley Chilcott  
Sure-Way Systems Inc.  
1019 4<sup>TH</sup> Ave SW  
Valley City, ND 58072

**RE: Consent Agreement and Complaint**

Dear Mr. Chilcott:

Enclosed is a Consent Agreement, Complaint, Order for Judgment, and Judgment for your review. The Consent Agreement has been drafted to resolve the Notice of Violation that was issued to you on May 18, 2001 regarding solid waste management and radiological issues at your facility and incorporate the suspended penalty discussed during our meeting of July 24, 2001. After the Consent Agreement is executed by both parties, it will be filed in District Court together with the Complaint, Order for Judgment and Judgment.

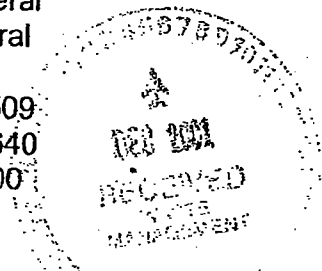
If the Consent Agreement is acceptable to you, please execute and return it to me at the North Dakota Office of Attorney General, 500 North 9<sup>th</sup> Street, Bismarck, North Dakota 58501-4509. If you would like to schedule a meeting to discuss this matter further, please contact Dave Glatt at (701) 328-5166.

If you have any questions or concerns, call me at (701) 328-3640.

Sincerely,

Carmen Miller  
Assistant Attorney General  
Office of Attorney General  
500 North 9<sup>th</sup> Street  
Bismarck, ND 58501-4509  
Telephone (701) 328-3640  
Facsimile (701) 328-4300

jjt  
Enclosures



STATE OF NORTH DAKOTA

IN DISTRICT COURT

COUNTY OF BARNES

SOUTHEAST JUDICIAL DISTRICT

State of North Dakota, )  
 State Department of Health, )  
 )  
 Plaintiff, )  
 )  
 vs. )  
 )  
 Sure-Way Systems, Inc., )  
 )  
 Defendant. )

**COMPLAINT**

**Civil No.**

Plaintiff, for its Complaint against the Defendant, states:

I.

This is a civil action for the imposition of a civil penalty against the Defendant for violations of N.D.C.C. chs. 23-29 and 23-20.1 and North Dakota Administrative Code (N.D. Admin. Code) arts. 33-20, Solid Waste Management and 33-10, Radiological Health Rules. Authority to bring this action is vested in the North Dakota Department of Health (Department) pursuant to N.D.C.C. §§ 23-29-12 and 23-20.1-10. The Attorney General for the State of North Dakota brings this action on behalf of the Department.

II.

That Defendant constitutes a "person" as defined in N.D.C.C. §§ 23-29-03(11) and 23-20.1-01(6), as follows:

11. "Person" means any individual, corporation, limited liability company, partnership, firm, association, trust, estate, public or private institution, group, federal agency, political subdivision of this state or any other state or political subdivision thereof, and any legal successor, representative agent, or agency of the foregoing."

6. "Person" means any individual, corporation, limited liability company, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state

or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, other than the commission, and other than federal government agencies licensed by the commission.

III.

Sure-Way Systems, Inc. (SWS) having its principal place of business at 1019 4<sup>th</sup> Avenue Southwest, Valley City, North Dakota, operates a medical waste transfer station, including a medical waste autoclave. SWS is authorized to conduct waste operations in accordance with the Department's Permit Number TS-036 issued on August 11, 1998 and effective until August 11, 2008. SWS is subject to the requirements of N.D.C.C. chs. 23-29 and 23-20.1 and rules promulgated thereunder.

IV.

N.D. Admin. Code §§ 33-20-12-01 and 33-20-12-02 provide in part:

**33-20-12-01. Definitions.**

1. As used in this article, "regulated infectious waste" means an infectious waste which is listed in subdivisions a through g of this subsection. . . .
4. Sharps. Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.
  - g. Unused sharps. Unused, discarded sharps, hypodermic needles, suture needles, and scalpel blades.

**33-20-12-02. Management standards.** In addition to sections 33-20-01.1-04, 33-20-01.1-05, 33-20-02.1-01, and 33-20-04.1-08, every person who collects, store, transports, treats, or disposes of regulated infectious waste will comply with these standards of performance.

5. All regulated infectious waste must be incinerated or disinfected and sharps that are not incinerated must be rendered nonsharp before disposal. Incineration and disinfection equipment and facilities will meet the requirements of article 33-15 and this article.



V.

N.D. Admin. Code §§ 33-20-01.1-04, 33-20-04.1-02, 33-20-04.1-03, 33-20-04.1-04 provide in part:

**33-20-01.1-04. Care and disposal of solid waste.**

...

3. Solid waste must be stored, collected, and transported in a manner that provides for public safety, prevents uncontrolled introduction into the environment, and minimizes harborage for insects, rats, or other vermin.

...

**33-20-04.1-02. General facility standards.** An owner or operator of a solid waste management facility shall comply with these general facility standards:

1. All personnel involved in solid waste handling and in the facility operation or monitoring must be instructed in specific procedures to ensure compliance with the permit, the facility plans, and this article as necessary to prevent accidents and environmental impacts. Documentation of training, such as names, dates, description of instruction methods, and copies of certificates awarded, must be placed in the facility's operating record.

...

**33-20-04.1-03. Plan of operation.** All solid waste management facilities, except those permitted by rule, shall meet the requirements of this section.

1. The owner or operator of a solid waste management unit or facility shall prepare and implement a plan of operation approved by the department as part of the permit. The plan must describe the facility's operation to operating personnel and the facility must be operated in accordance with the plan. ....

**33-20-04.1-04. Recordkeeping and reporting.** The owner or operator of a solid waste management facility, except those permitted by rule, shall comply with these recordkeeping and reporting requirements:

...

2. An owner or operator shall keep an operating record consisting of a copy of each application, plan, report, notice, drawing, inspection log, test result or other document required by this article, including those enumerated in the subdivisions of this subsection, or a permit. The operating record must include any deviations from this article, the permit, and facility plans where department approval is required. The owner or operator shall provide a copy of any document in the operating record upon receiving a

request from the department. The operating record must be kept at the facility, or at a location near the facility within North Dakota and approved by the department.

...  
h. Facility inspection logs, section 33-20-04.1-03.

...  
i. Records of the weight or volume of waste, section 33-20-04.1-09.

## VI

Conditions E.5., E.8., and E.10. of Permit Number TS-036 provide in part:

### E. Conditions:

E.5. The Permittee or his representatives shall construct and operate this facility in the manner outlined in the permit application. . . .

E.8. Within three (3) months of the permit issuance date and prior to the onset facility operation, the owner/operator shall develop and receive Departmental approval of amendments to the plan of operation to meet the full requirements of Section 33-20-04.1-03 NDAC. Such amendments shall include, but not be limited to, industrial waste and special waste procedures to inform waste generators, the generator's employees, and waste haulers on the waste screening requirements. At minimum, the industrial waste procedures must address training on an ongoing basis for: (1) sharps segregation and handling, (2) the prohibition for commingling toxic material including, but not limited to, mercury-containing devices, batteries, etc., (3) the prohibition on disposal of radioactive materials, and (4) any other related issues deemed necessary to control material potentially commingled with regulated infectious waste. . . .

E.10. Except as modified by the conditions of this permit, this facility and related waste management units and structures shall be designed, constructed, operated, and closed in accordance with previous correspondence and documents contained in Departmental files pertaining to this facility and as described in the documents listed below, which are hereby incorporated by reference in this permit:

1. Application for a Solid Waste Management Facility Permit SFN 19269 (03/98), received June 5, 1998.
2. Future submittals approved by the Department may supersede or supplement items listed above.

VII.

SWS's Application for a Solid Waste Management Facility Permit SFN 19269 (03/98), received June 5, 1998, included an Operational Plan, which has been periodically amended. The Operational Plan currently states, "all sharps are processed through the shredder before being transported to the solid waste compactor."

VIII.

On July 13, 2000, the Department was notified that on July 10, 2000 a load of medical waste from SWS arrived at the Big Dipper Enterprises (BDE) landfill near Gwinner, N.D. The waste contained a large number of medical sharps. A BDE employee had a needle stick into his boot. This disposal of sharps that have not been incinerated or otherwise rendered non-sharp is a violation of N.D. Admin Code § 33-20-12-02(5) and Permit TS-036 Conditions E.5 and E.10.

IX.

On July 20, 2000, the Department conducted an inspection of SWS. The sharps grinder had been repaired resulting in the replacement of new teeth that were coarser than the original ones causing the processed material to be considerably larger. SWS had one full roll-off container (about 20 cubic yards) in storage containing compacted materials of this type with a label stating, "Do not take this container." SWS was instructed to retain container on-site until further notice.

X.

On August 22, 2000, the Department conducted a multimedia inspection of SWS to investigate allegations made by former employees of SWS. Areas of concern to the Department and discussed with SWS staff members included: the backlog of treated underground 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.

XI.

On September 20, October 5, October 16, and October 18, 2000, the Department conducted a series of site visits and inspections at SWS. The sharps grinder was inoperable during all of these inspections and visits, resulting in an accumulation of unground sharps.

XII.

On November 15, 2000, the Department received a call from the Department's BDE onsite inspector indicating a load of medical waste from SWS contained a large amount of unground medical sharps, both loose and in containers. Dudley Chilcott was called onsite to collect the rejected portion of the load. Two red 20 plus gallon tubs of unground sharps were retrieved by Mr. Chilcott. SWS informed the Department that sorting problems were the cause of the incident. The second roll-off container was also rejected by BDE due to concerns that it may have also contained unground medical sharps.

XIII.

On November 16, 2000, the Department received a call from Dudley Chilcott seeking permission to dump the rejected roll-off container in his shop yard and he would have his employees sort the load. After Department staff discussed the issue, they informed SWS that they would allow them 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. The Department sent SWS a letter allowing a one-time variance for disposal of unground medical sharps.

XIV.

On November 20, 2000, the SWS roll-off containers arrive at BDE. A large hole was dug in the November 16, 2000 working face 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.

XV.

On December 4, 2000, the Department conducted a site visit at SWS. The sharps grinder was still inoperable. Based on the series of five site visits from September 20 thru December 8, 2000, a pattern of unreliability of the grinder used for rendering the sharps nonsharp became apparent. During each of the visits, the grinder was found to be inoperable, contributing to a backlog of processed but unground sharps being stored at the facility. During this time period, there was also an increase in the amount of unground sharps containers arriving at the disposal facility.

XVI.

On December 29, 2000, SWS off loaded material at the BDE landfill for disposal. The material included what appeared to be autoclaved medical waste, including a large quantity of one to 15-gallon red plastic containers of hypodermic needles and other sharps. The Department's inspector stopped counting the containers at 104. The disposal of sharps that have not been incinerated or rendered nonsharp is a violation of N.D. Admin. Code §§ 33-20-12-01 and 33-20-12-02 and Permit TS-036 Conditions E.5 and E.10.

XVII.

Paragraphs VIII, IX, X, XI, XII, XIII, XIV, XV and XVI establish a pattern of management and operation that violates N.D. Admin. Code §§ 33-20-01.1-04, 33-20-04.1-02, 33-20-04.1-03, 33-20-04.1-04 and Permit TS-036 Conditions E.5 and E.10.

XVIII.

N.D. Admin. Code § 33-10-04.1-14, Waste Disposal, establishes requirements for disposal of radioactive waste in North Dakota.

XIX.

N.D. Admin. Code § 33-20-01.1-09 provides that every person who handles and disposes of radioactive waste shall comply with article 33-10.

XX.

Conditions E.5., E.8., and E.10. of Permit Number TS-036 provide in part:

E. Conditions:

E.5. The Permittee or his representatives shall construct and operate this facility in the manner outlined in the permit application. . . .

...

E.8. Within three (3) months of the permit issuance date and prior to the onset of facility operation, the owner/operator shall develop and receive Departmental approval of amendments to the plan of operation to meet the full requirements of Section 33-20-04.1-03 NDAC. Such amendments shall include, but not be limited to, industrial waste and special waste procedures to inform waste generators, the generator's employees, and waste haulers on the waste screening requirements. At minimum, the industrial waste procedures must address training on an ongoing basis for: (1) sharps segregation and handling; (2) the prohibition for commingling toxic material including, but not limited to, mercury-containing devices, batteries, etc., (3) the prohibition on disposal of radioactive materials, and (4) any other related issues deemed necessary to control material potentially commingled with regulated infectious waste. . . .

E.10. Except as modified by the conditions of this permit, this facility and related waste management units and structures shall be designed, constructed, operated, and closed in accordance with previous correspondence and documents contained in Departmental files pertaining to this facility and as described in the documents listed below, which are hereby incorporated by reference in this permit:

Application for a Solid Waste Management Facility Permit SFN 19269 (03/98), received June 5, 1998.

Future submittals approved by the Department may supersede or supplement items listed above.

## XXI.

In its Operational Plan, supplemental Emergency Equipment Locations and Descriptions dated November 30, 1999, Radiation Alarm Procedures and Radiation Checklist for Permit TS-036, SWS indicated that: (a) The Eberline RMS3 portal radiation detection system would be mounted to the west wall in the medical waste processing room near the facility's waste entrance, with the SPA-3 two inch by two-inch NaI (TI) portal scintillation detector at the facility waste entrance conveyor system; (b) The two handheld ASP-2/SPA-8 portable radiation micro-R meters would be located in the safety cabinet and be used to monitor and survey waste during radiation alarm incidents; and (c) The RMS-3 portal radiation detection equipment would be tested each day the facility accepts or processes waste. The rolling conveyor system was to carry each waste container individually past the portal radiation detector at a fixed distance from the detector and at a predictable speed. This configuration was supported by a map drawing included with the permit application. During the Department's May 11, 1999 inspection, the portal radiation detection system was observed in this configuration.

## XXII.

SWS began processing waste in April 1999. SWS responded to two radiation alarm incidents, one each in April 1999 and May 1999. The next radiation alarm incident reported by SWS was February 13, 2001. On the Department's inspection of the SWS radiation monitoring equipment on April 27, 2000, the portal monitor was not operational since it had just returned from calibration and was not reassembled. The two handheld survey meters were not available. This is a violation of Permit TS-036 Conditions E.5. and E.10.

## XXIII.

During the April 27, 2000 inspection, the rolling conveyor with the detector in fixed proximity to the waste stream had been disassembled. Instead, the detector was

mounted 27 inches above the floor on a moveable floor stand, and was being moved back and forth between the two unloading doors as needed. The waste containers were stacked three high and passed by the detector on a two-wheel dolly. There was little or no control on the lateral distance from the detector nor the speed at which the containers passed by the detector. Unloading waste in this configuration was again observed during an inspection on February 7, 2001. Based on these observations, the facility was no longer configured as indicated in the Operational Plan and Emergency Equipment Locations and Descriptions. This is a violation of Permit TS-036 Conditions E.5 and E.10.

#### XXIV.

During site visits on September 20 and October 18, 2000, the portal radiation detector was not located in the position indicated in the Operational Plan and the Emergency Equipment Locations and Descriptions. During both site visits, employees of SWS repositioned the detectors. This is a violation of Permit TS-036 Conditions E.5 and E.10.

#### XXV.

During the April 27, 2000 inspection, the portal detector was reported to be extremely unreliable and causing sporadic spikes due to what appeared to be a faulty cable connection at the back of the connector. SWS hoped the manufacturer had repaired this problem during the calibration. During the Department's February 7, 2001 inspection, the poor cable connection at the back of the detector was still bad and appeared to have gone unrepaired for approximately 10 to 12 months. This caused the detector to be unreliable and to experience false alarms. This is a violation of Permit TS-036 Conditions E.5. and E.10.

#### XXVI.

In the SWS Radiation Alarm Procedures, item No. IV indicates the facility will fill out a radiation alarm incident report each time a radiation alarm occurs. On previous



inspections as well as the inspection on February 7, 2001, numerous radiation spikes on past circular charts had gone unmarked and without radiation alarm incident reports. This is a violation of Permit TS-036 Conditions E.5. and E.10.

XXVII.

The SWS Operational Plan lists radioactive waste as non-conforming waste that will not be accepted by SWS. The Operational plan further states that if non-conforming waste is received by SWS, it will be rejected, and the generator will be liable for any unacceptable waste.

XXVIII.

On March 9, 2001, a shipment of medical waste triggered the radiation alarm at SWS. In an attempt to locate the cause of the radiation alarms, the lids identifying the name and location of the waste generators were removed from the containers, resulting in the inability to determine the generator of the contaminated waste. On Saturday, March 10, 2001, a Department inspector visited the SWS facility. A total of eighteen (18) individual bags from the March 9 shipment were found to emit noticeable amounts of radiation. Because of its mishandling of the waste containers, SWS was unable to determine where the contaminated items originated, and the radioactive material had to be stored at the SWS facility until an alternate disposal option was discovered, or until the radioactive material decayed to background. The failure to properly handle and reject radioactive waste is an apparent violation of Permit TS-036 Conditions E.5. and E.10.

XXIX.

SWS does not possess a radioactive material license for storage of radioactive material. Its storage of radioactive waste is a violation of N.D. Admin. Code ch. 33-10-03 of the North Dakota Radiological Health Rules, and N.D.C.C. § 23-20.1-08.

XXX.

The SWS Contingency Plan requires that waste which sets off the alarm of the portal monitor is to be surveyed with handheld meters. SWS possess two Eberline handheld Model ASP-2 meters with external 1" x 1" sodium-iodide crystal probes (Eberline Model SPA-8). During the March 10, 2001 inspection, one of these survey meters had a broken knob and was nonfunctional. The second survey meter also did not provide accurate readings when compared to the Department's survey meter. Normal background readings should be between 8 and 12 micro-rem per hour. SWS's second meter fluctuated wildly and had erroneous background readings as high as 200 micro rem per hour. Failure to have at least one functional survey meter on site for surveying waste that may contain radioactive material is a violation of Permit TS-036 Conditions E.5 and E.10.

XXXI.

Based on paragraphs XXII, XXIII, XXIV, XXV, XXVI, XXVIII, XXIX and XXX, SWS's failure to operate and manage the facility in the manner indicated in the permit and as required by North Dakota law are violations of N.D.C.C. § 23-20.1-08, N.D. Admin. Code ch. 33-10-03, N.D. Admin. Code § 33-20-04.1-03, and the Department's Permit Number TS-036 and N.D. Admin. Code arts. 33-20 and 33-10.

XXXII.

On May 18, 2001, Defendant was served with a Notice of Violation issued by the Department regarding the above-referenced alleged violations which is attached hereto as Exhibit A.

XXXIII.

N.D.C.C. § 23-29-12 authorizes the Department to seek a civil penalty not to exceed One Thousand Dollars (\$1,000) per day of such violation for any violation of N.D.C.C. ch. 23-29 or any limitation implemented thereunder.

XXXIV.

N.D.C.C. § 23-20.1-10 authorizes the Department to seek a civil penalty not to exceed Ten Thousand Dollars (\$10,000) per day of such violation for any violation of N.D.C.C. ch. 23-20.1 or any limitation implemented thereunder.

WHEREFORE, Plaintiff prays:

- A. That a civil penalty not to exceed One Thousand Dollars (\$1,000) per day of violation be imposed against the Defendant, pursuant to N.D.C.C. § 23-29-12.
- B. That a civil penalty not to exceed Ten Thousand Dollars (\$10,000) per day of violation be imposed against the Defendant, pursuant to N.D.C.C. § 23-20.1-10.
- C. That the Court grant Plaintiff such other and further relief as it may deem just and necessary.

Dated this \_\_\_\_ day of November, 2001.

State of North Dakota  
Wayne Stenehjem  
Attorney General

By:

\_\_\_\_\_  
Carmen Miller  
Assistant Attorney General  
State Bar ID No. 05131  
Office of Attorney General  
500 North 9<sup>th</sup> Street  
Bismarck, ND 58501-4509  
Telephone (701) 328-3640  
Facsimile (701) 328-4300

Attorneys for Plaintiff.

STATE OF NORTH DAKOTA

IN DISTRICT COURT

COUNTY OF BARNES

SOUTHEAST JUDICIAL DISTRICT

State of North Dakota, )  
State Department of Health, )

Plaintiff, )

vs. )

Sure-Way Systems, Inc., )

Defendant. )

**CONSENT AGREEMENT**

Civil No.

**PRELIMINARY STATEMENT**

WHEREAS, the Plaintiff, State of North Dakota, State Department of Health, (Department), notified the Defendant, Sure-Way Systems, Inc. (SWS) of Plaintiff's intention to institute an action in District Court against the Defendant for violations of North Dakota Century Code (N.D.C.C.) Chapters 23-29, Solid Waste Management and Land Protection and 23-20.1, Ionizing Radiation Development; and North Dakota Administrative Code (N.D. Admin. Code) Articles 33-20, Solid Waste Management Rules and 33-10, Radioiological Health Rules; and

WHEREAS, the Plaintiff and the Defendant desire to settle this matter through the contemporaneous filing of a Complaint along with this fully-executed Consent Agreement;

THEREFORE, the Plaintiff and the Defendant agree to be bound by the terms and conditions of this Consent Agreement.

**STIPULATION**

It is stipulated and agreed to between the parties as follows:

I.

Defendant accepts service of the Complaint filed with the Court along with this Consent Agreement in this action.

II.

That Defendant admits to all jurisdictional allegations contained in the Complaint.

III.

Sure-Way Systems, Inc. (SWS) having its principal place of business at 1019 4<sup>th</sup> Avenue Southwest, Valley City, North Dakota, operates a medical waste transfer station, including a medical waste autoclave. SWS is authorized to conduct waste operations in accordance with the Department's Permit Number TS-036 issued on August 11, 1998 and effective until August 11, 2008. SWS is subject to the requirements of N.D.C.C. chs. 23-29 and 23-20.1 and rules promulgated thereunder.

IV.

N.D. Admin. Code §§ 33-20-12-01 and 33-20-12-02 provide in part:

**33-20-12-01. Definitions.**

1. As used in this article, "regulated infectious waste" means an infectious waste which is listed in subdivisions a through g of this subsection. . . .
  - d. Sharps. Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.
  - g. Unused sharps. Unused, discarded sharps, hypodermic needles, suture needles, and scalpel blades.

**33-20-12-02. Management standards.** In addition to sections 33-20-01.1-04, 33-20-01.1-05, 33-20-02.1-01, and 33-20-04.1-08, every person who collects, store, transports, treats, or disposes of regulated infectious waste will comply with these standards of performance.

5. All regulated infectious waste must be incinerated or disinfected and sharps that are not incinerated must be rendered nonsharp before disposal. Incineration and disinfection equipment and facilities will meet the requirements of article 33-15 and this article.

V.

N.D. Admin. Code §§ 33-20-01.1-04, 33-20-04.1-02, 33-20-04.1-03, 33-20-04.1-04 provide in part:

**33-20-01.1-04. Care and disposal of solid waste.**

...

3. Solid waste must be stored, collected, and transported in a manner that provides for public safety, prevents uncontrolled introduction into the environment, and minimizes harborage for insects, rats, or other vermin.

...

**33-20-04.1-02. General facility standards.** An owner or operator of a solid waste management facility shall comply with these general facility standards:

1. All personnel involved in solid waste handling and in the facility operation or monitoring must be instructed in specific procedures to ensure compliance with the permit, the facility plans, and this article as necessary to prevent accidents and environmental impacts. Documentation of training, such as names, dates, description of instruction methods, and copies of certificates awarded, must be placed in the facility's operating record.

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...  
h. Facility inspection logs, section 33-20-04.1-03.

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Conditions E.5., E.8., and E.10. of Permit Number TS-036 provide in part:

E. Conditions:

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...  
E.8. Within three (3) months of the permit issuance date and prior to the onset of facility operation, the owner/operator shall develop and receive Departmental approval of amendments to the plan of operation to meet the full requirements of Section 33-20-04.1-03 NDAC. Such amendments shall include, but not be limited to, industrial waste and special waste procedures to inform waste generators, the generator's employees, and waste haulers on the waste screening requirements. At minimum, the industrial waste procedures must address training on an ongoing basis for: (1) sharps segregation and handling, (2) the prohibition for commingling toxic material including, but not limited to, mercury-containing devices, batteries, etc., (3) the prohibition on disposal of radioactive materials, and (4) any other related issues deemed necessary to control material potentially commingled with regulated infectious waste. . . .

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- b. Future submittals approved by the Department may supersede or supplement items listed above.

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lack of accurate records on the number of roll-off containers shipped to BDE on a weekly/monthly basis.

XI.

On September 20, October 5, October 16, and October 18, 2000, the Department conducted a series of site visits and inspections at SWS. The sharps grinder was inoperable during all of these inspections and visits, resulting in an accumulation of unground sharps.

XII.

On November 15, 2000, the Department received a call from the Department's BDE onsite inspector indicating a load of medical waste from SWS contained a large amount of unground medical sharps, both loose and in containers. Dudley Chilcott was called onsite to collect the rejected portion of the load. Two red 20 plus gallon tubs of unground sharps were retrieved by Mr. Chilcott. SWS informed the Department that sorting problems were the cause of the incident. The second roll-off container was also rejected by BDE due to concerns that it may have also contained unground medical sharps.

XIII.

On November 16, 2000, the Department received a call from Dudley Chilcott seeking permission to dump the rejected roll-off container in his shop yard and he would have his employees sort the load. After Department staff discussed the issue, they informed SWS that they would allow them 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. The Department sent SWS a letter allowing a one-time variance for disposal of unground medical sharps.

XIV.

On November 20, 2000, the SWS roll-off containers arrive at BDE. A large hole was dug in the November 16, 2000, working face 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.

XV.

On December 4, 2000, the Department conducted a site visit at SWS. The sharps grinder was still inoperable. Based on the series of five site visits from September 20 thru December 8, 2000, a pattern of unreliability of the grinder used for rendering the sharps nonsharp became apparent. During each of the visits, the grinder was found to be inoperable, contributing to a backlog of autoclaved but unground sharps being stored at the facility. During this time period, there was also an increase in the amount of unground sharps containers arriving at the disposal facility.

XVI.

On December 29, 2000, SWS off loaded material at the BDE landfill for disposal. The material included what appeared to be autoclaved medical waste, including a large quantity of one-to 15-gallon red plastic containers of hypodermic needles and other sharps. The Department's inspector stopped counting the containers at 104. The disposal of sharps that have not been incinerated or rendered nonsharp is a violation of N.D. Admin. Code §§ 33-20-12-01 and 33-20-12-02 and Permit TS-036 Conditions E.5 and E.10.

XVII.

Paragraphs VIII, IX, X, XI, XII, XIII, XIV, XV and XVI establish a pattern of management and operation that violates N.D. Admin. Code §§ 33-20-01.1-04, 33-20-04.1-02, 33-20-04.1-03, 33-20-04.1-04 and Permit TS-036 Conditions E.5 and E.10.

XVIII.

N.D. Admin. Code § 33-10-04.1-14, Waste Disposal, establishes requirements for disposal of radioactive waste in North Dakota.

XIX.

N.D. Admin. Code § 33-20-01.1-09 provides that every person who handles and disposes of radioactive waste shall comply with article 33-10.

XX.

Conditions E.5., E.8., and E.10. of Permit Number TS-036 provide in part:

E. Conditions:

E.5. The Permittee or his representatives shall construct and operate this facility in the manner outlined in the permit application. . . .

E.8. Within three (3) months of the permit issuance date and prior to the onset of facility operation, the owner/operator shall develop and receive Departmental approval of amendments to the plan of operation to meet the full requirements of Section 33-20-04.1-03 NDAC. Such amendments shall include, but not be limited to, industrial waste and special waste procedures to inform waste generators, the generator's employees, and waste haulers on the waste screening requirements. At minimum, the industrial waste procedures must address training on an ongoing basis for: (1) sharps segregation and handling, (2) the prohibition for commingling toxic material including, but not limited to, mercury-containing devices, batteries, etc., (3) the prohibition on disposal of radioactive materials, and (4) any other related issues deemed necessary to control material potentially commingled with regulated infectious waste. . . .

E.10. Except as modified by the conditions of this permit, this facility and related waste management units and structures shall be designed, constructed, operated, and closed in accordance with previous correspondence and documents contained in Departmental files pertaining to this facility and as described in the documents listed below, which are hereby incorporated by reference in this permit:

- a. Application for a Solid Waste Management Facility Permit SFN 19269 (03/98), received June 5, 1998.
- b. Future submittals approved by the Department may supersede or supplement items listed above.

XXI.

In its Operational Plan, supplemental Emergency Equipment Locations and Descriptions dated November 30, 1999, Radiation Alarm Procedures and Radiation Checklist for Permit TS-036, SWS indicated that: (a) The Eberline RMS3 portal radiation detection system would be mounted to the west wall in the medical waste processing room near the facility's waste entrance, with the SPA-3 two inch by two-inch NaI (TI) portal scintillation detector at the facility waste entrance conveyor system; (b) The two handheld ASP-2/SPA-8 portable radiation micro-R meters would be located in the safety cabinet and be used to monitor and survey waste during radiation alarm incidents; and (c) The RMS-3 portal radiation detection equipment would be tested each day the facility accepts or processes waste. The rolling conveyor system was to carry each waste container individually past the portal radiation detector at a fixed distance from the detector and at a predictable speed. This configuration was supported by a map drawing included with the permit application. During the Department's May 11, 1999 inspection, the portal radiation detection system was observed in this configuration.

XXII.

SWS began processing waste in April 1999. SWS responded to two radiation alarm incidents, one each in April 1999 and May 1999. The next radiation alarm incident reported by SWS was February 13, 2001. On the Department's inspection of the SWS radiation monitoring equipment on April 27, 2000, the portal monitor was not operational since it had just returned from calibration and was not reassembled. The two handheld survey meters were not available. This is a violation of Permit TS-036 Conditions E.5. and E.10.

XXIII.

Also, during the April 27, 2000 inspection, the rolling conveyor with the detector in fixed proximity to the waste stream had been disassembled. Instead, the detector

was mounted 27 inches above the floor on a moveable floor stand, and was being moved back and forth between the two unloading doors as needed. The waste containers were stacked three high and passed by the detector on a two-wheel dolly. There was little or no control on the lateral distance from the detector nor the speed at which the containers passed by the detector. Unloading waste in this configuration was again observed during an inspection on February 7, 2001. Based on these observations, the facility was no longer configured as indicated in the Operational Plan and Emergency Equipment Locations and Descriptions. This is a violation of Permit TS-036 Conditions E.5 and E.10.

#### XXIV

During site visits on September 20 and October 18, 2000, the portal radiation detector was not located in the position indicated in the Operational Plan and the Emergency Equipment Locations and Descriptions. During both site visits, employees of SWS repositioned the detectors. This is a violation of Permit TS-036 Conditions E.5 and E.10.

#### XXV.

During the April 27, 2000 inspection, the portal detector was reported to be extremely unreliable and causing sporadic spikes due to what appeared to be a faulty cable connection at the back of the connector. SWS hoped the manufacturer had repaired this problem during the calibration. During the Department's February 7, 2001 inspection, the poor cable connection at the back of the detector was still bad and appeared to have gone unrepaired for approximately 10 to 12 months. This caused the detector to be unreliable and to experience false alarms. This is a violation of Permit TS-036 Conditions E.5. and E.10.

#### XXVI.

In the SWS Radiation Alarm Procedures, Item No. IV indicates the facility will fill out a radiation alarm incident report each time a radiation alarm occurs. On previous

inspections as well as the inspection on February 7, 2001, numerous radiation spikes on past circular charts had gone unmarked and without radiation alarm incident reports. This is a violation of Permit TS-036 Conditions E.5. and E.10.

XXVII.

The SWS Operational Plan lists radioactive waste as non-conforming waste that will not be accepted by SWS. The Operational plan further states that if non-conforming waste is received by SWS, it will be rejected, and the generator will be liable for any unacceptable waste.

XXVIII.

On March 9, 2001, a shipment of medical waste triggered the radiation alarm at SWS. In an attempt to locate the cause of the radiation alarms, the lids identifying the name and location of the waste generators were removed from the containers, resulting in the inability to determine the generator of the contaminated waste. On Saturday, March 10, 2001, a Department inspector visited the SWS facility. A total of eighteen (18) individual bags from the March 9 shipment were found to emit noticeable amounts of radiation. Because of its mishandling of the waste containers, SWS was unable to determine where the contaminated items originated, and the radioactive material had to be stored at the SWS facility until an alternate disposal option was discovered, or until the radioactive material decayed to background. The failure to properly handle and reject radioactive waste is a violation of Permit TS-036 Conditions E.5. and E.10.

XXIX.

SWS does not possess a radioactive material license for storage of radioactive material. Its storage of radioactive waste is a violation of N.D. Admin. Code ch. 33-10-03 of the North Dakota Radiological Health Rules, and N.D.C.C. § 23-20.1-08.

XXX.

The SWS Contingency Plan requires that waste which sets off the alarm of the portal monitor is to be surveyed with handheld meters. SWS possess two Eberline

handheld Model ASP-2 meters with external 1" x 1" sodium-iodide crystal probes (Eberline Model SPA-8). At the March 10, 2001 inspection, one of these survey meters had a broken knob and was nonfunctional. The second survey meter also did not provide accurate readings when compared to the Department's survey meter. Normal background readings should be between 8 and 12 micro-rem per hour. SWS's second meter fluctuated wildly and had erroneous background readings as high as 200 micro rem per hour. Failure to have at least one functional survey meter on site for surveying waste that may contain radioactive material is a violation of Permit TS-036 Conditions E.5 and E.10.

XXXI.

Based on paragraphs XXII, XXIII, XXIV, XXV, XXVI, XXVIII, XXIX and XXX, SWS's failure to operate and manage the facility in the manner indicated in the permit and as required by North Dakota law are violations of N.D.C.C. § 23-20.1-08, N.D. Admin. Code ch. 33-10-03, N.D. Admin. Code § 33-20-04.1-03, and the Department's Permit Number TS-036 and N.D. Admin. Code arts. 33-20 and 33-10.

XXXII.

On May 18, 2001, Defendant was served with a Notice of Violation issued by the Department regarding the above-referenced alleged violations.

XXXIII.

A. That the Plaintiff and Defendant desire to settle this matter on the following terms:

1. Defendant will be levied a civil penalty in the amount of Four Thousand Dollars (\$4,000) for violations listed in the Complaint and admitted to herein. Such penalty shall be suspended and ultimately dismissed upon the following conditions:

(a) That Two Thousand Dollars (\$2,000) of said penalty shall be suspended and ultimately dismissed based upon Defendant's

compliance with all North Dakota Solid Waste Management laws, rules and permit conditions, for a period of two years from the effective date of this Consent Agreement.

- (b) That Two Thousand Dollars (\$2,000) shall be suspended and ultimately dismissed based upon Defendant's compliance with all North Dakota Radiological Health laws, rules, and permit conditions for a period of two years from the effective date of this Consent Agreement.
2. That Defendant agrees to the entry of judgment in accordance with the terms contained herein.
3. That each party shall bear its own costs, disbursements and attorneys' fees.

IN WITNESS WHEREOF, the parties have set their hands.

PLAINTIFF:

For the Department:

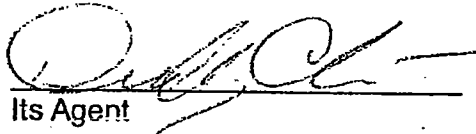


Francis J. Schwindt, Chief  
Environmental Health Section

Date: 1/3/02

DEFENDANT:

Sure-Way Systems, Inc.



Its Agent

Date: 12/3/01



STATE OF NORTH DAKOTA  
COUNTY OF BARNES

IN DISTRICT COURT  
SOUTHEAST JUDICIAL DISTRICT

State of North Dakota,  
State Department of Health,

Plaintiff,

vs.

Sure-Way Systems, Inc.,

Defendant. )

**ORDER FOR JUDGMENT**

Civil No.

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WHEREAS, Plaintiff and Defendant have entered into a Consent Agreement wherein Defendant admits liability for violations of N.D.C.C. chs. 23-29 and 23-20.1, and N.D. Admin. Code arts. 33-20 and 33-10.

IT IS HEREBY ORDERED, that there be levied a civil penalty against the Defendant in the amount of Four Thousand Dollars (\$4,000) by the State of North Dakota for violations cited in the Complaint filed herein, and that the penalty shall be suspended and ultimately dismissed upon the following conditions:

1. Two Thousand Dollars (\$2,000) of said penalty shall be suspended and ultimately dismissed based upon Defendant's compliance with all North Dakota Solid Waste Management laws, rules and permit conditions for a period of two years from the effective date of the Consent Agreement.
2. Two Thousand Dollars (\$2,000) shall be suspended and ultimately dismissed based upon Defendant's compliance with all North Dakota Radiological Health laws, rules and permit conditions for a period of two years from the effective date of the Consent Agreement.