

DEPARTMENT OF PUBLIC SERVICE REGULATION  
PUBLIC SERVICE COMMISSION  
OF THE STATE OF MONTANA  
TRANSPORTATION DIVISION

INTRASTATE  
CERTIFICATE OF PUBLIC CONVENIENCE AND NECESSITY

P.S.C. NO. 9342

Pursuant to the provisions of Title 69, Chapter 12, Montana Code Annotated, and the finding heretofore made by the Commission that public convenience and necessity require such operations,

Sure-Way Transportation, Inc.  
(Deer Lodge, Montana)

is hereby authorized to transport:

**Biohazardous waste**

as a **CLASS D**, common carrier in intrastate service, by motor vehicles for hire over and on the public highways of the State of Montana,

originating from health care facilities in Montana (including, but not limited to, hospitals; nursing homes; medical, dental, and veterinary offices, surgical centers, and laboratories; outpatient treatment facilities; mortuaries; and drug stores) to a Butte-Silver Bow, Montana facility designed, constructed, and intended for the treatment of biohazardous waste,

subject to the limitations hereinafter set forth and to the rules and regulations of the Commission duly adopted and promulgated under the authority of said Title 69, Chapter 12, Montana Code Annotated.

**LIMITATIONS: Transportation is limited to the account of Sure-Way Systems of Montana**

Dated at Helena, Montana,  
July 11, 1994

By order of the PUBLIC SERVICE COMMISSION

(SEAL)

*Bob Anderson*  
Bob Anderson, Chairman

*Bob Rowe*  
Bob Rowe, Vice Chairman

*Dave Fisher*  
Dave Fisher, Commissioner

*Nancy McCaffrey*  
Nancy McCaffrey, Commissioner

*Danny Oberg*  
Danny Oberg, Commissioner

*[Signature]*  
Secretary

**DEPARTMENT OF ENVIRONMENTAL QUALITY  
PERMITTING AND COMPLIANCE DIVISION  
SOLID WASTE LICENSING PROGRAM**

**SOLID WASTE MANAGEMENT SYSTEM  
ANNUAL RENEWAL CERTIFICATE**

This certifies that

**Sure Way Systems Inc**

has been approved for renewal and is licensed from

**July 1, 2004 through June 30, 2005**

by the Montana Department of Environmental Quality as a

**Minor Class II Infectious Waste Treatment Facility**

**LICENSE NUMBER 358**

This annual renewal certificate is only valid if the licensee or the owner/operator has paid annual fees and is in compliance with all provisions of Title 75, Chapter 10, Parts 1 and 2, Montana Code Annotated, and solid waste management rules adopted in accordance with that law.



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**Edward A. Thamke, Bureau Chief**  
Waste and Underground Tank Management Bureau

**THIS CERTIFICATE IS NON-TRANSFERABLE**

EXHIBIT \_\_\_\_\_ (GC14)



**PERMIT FOR SOLID WASTE MANAGEMENT FACILITY**  
**NORTH DAKOTA DEPARTMENT OF HEALTH — DIVISION OF WASTE MANAGEMENT**  
**REV. 01/97**

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Pursuant to Chapter 23-29 of the North Dakota Century Code (NDCC), (Solid Waste Management and Land Protection Act) and Article 33-20 of the North Dakota Administrative Code (NDAC), (Solid Waste Management Rules), and in reliance on statements and representations heretofore made by the owner or owner's representative designated below, a Permit to Operate is hereby issued authorizing such owner to operate a solid waste management facility at the location designated below.

**A. Owner/Operator:**

1. **Name:** Sure-Way Systems, Inc.
2. **Physical Address:** 1019 4th Avenue SW, Valley City, ND 58072  
**Mailing Address:** 401 Main Street, Deer Lodge, MT 59722

**B. Permit Number:** TS-036

**C. Type of Facility:** Medical Waste Treatment and Transfer Station

**D. Operation Location:**

1. Lot 5, Block 2, Fairhill Addition, of the E1/2 of Sec 28 TWP 140N R 58W
2. **County:** Barnes

The owner/operator of the facility is subject to the Solid Waste Management and Land Protection Act and Solid Waste Management Rules and orders now or hereafter effected by the North Dakota Department of Health (hereinafter the Department), and to any and all conditions listed below.

**E. Conditions:**

- E.1. This permit may be modified during its term through mutual agreement or Department Order for the purpose of preventing or abating adverse impact to the environment.
- E.2. This permit addresses only the environmental aspects and operational procedures of the facility. It does not supersede local zoning authority, or any other requirements of any political subdivision of the State. The Permittee must obtain any and all local zoning, conditional use permits, or meet any other county, township, or municipal requirements prior to commencing construction and/or operation.

**Solid Waste Management Permit**  
**Permit No. TS-036**  
**Page 2 of 3**

- E.3.** All reasonable precautions shall be taken to prevent and/or minimize fugitive dust emissions from the construction and operation of the facility.
- E.4.** The discharge of any objectionable odorous air contaminant shall not exceed two concentration units outside of the property boundary.
- E.5.** The Permittee or his representatives shall construct and operate this facility in the manner outlined in the permit application, unless modifications are specified through permit conditions, or through Departmental directive.
- E.6.** The medical waste treatment, transfer station, and the waste handling areas shall be maintained in a clean and nuisance-free condition at all times. The handling of wastes shall be strictly controlled to eliminate odors, harboring of insects and rodents, scattering of materials by the wind, or interference with the operation of the facility.
- E.7.** Any entity that controls the permit holder (Permittee) agrees to accept responsibility for any remedial measures, closure and post-closure care, or penalties incurred by the permit holder (Permittee).
- 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. Educational materials could include, but not be limited to, letters, training materials, notices on containers, notices posted in the work areas, etc. All generators must be notified of the approved procedures within five (5) months of the permit issuance date or at the time of the initial contract, and must be re-trained on an annual basis. Upon Departmental approval, the amended operation plan shall be utilized in the facility's operation.

**Solid Waste Management Permit  
Permit No. TS-036  
Page 3 of 3**

- E.9. Within thirty (30) days of the permit issuance date, the Permittee shall obtain approval from the Department's Division of Environmental Engineering, Radiation Control Program, for monitoring equipment plans for detecting and screening the waste stream for radioactive materials. This equipment must be installed and properly functioning prior to initial operation.
  
- 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.

In consideration of information provided regarding the facility and its operation and in consideration of the conditions above, the North Dakota Department of Health hereby issues a permit to Sure-Way Systems, Inc.

This permit is effective as of August 11, 1998 and shall remain in effect until August 11, 2008, unless modified, superseded, or revoked under Section 33-20-02.1-06, NDAC or continued in accordance with Section 33-20-02.1-07, NDAC.

  
Neil M. Knatterud, Director  
Division of Waste Management

8/11/98  
Date

EXHIBIT \_\_\_\_\_ (GC15)

# SURE-WAY SYSTEMS, INC.

## Request for Proposal

March 30, 2000

### 1. INTRODUCTION

Sure-Way Systems, Inc. (SWS) is hereby requesting proposals to provide long-term services for the disposal of treated medical waste generated at its processing facility located in Butte, Montana. The processing of this medical waste conforms with Sure-Way's operating permit issued through the Montana Solid Waste permits which includes the use of autoclave steam technology for the sterilization of the waste. Documentation of the sterilization of this material can be provided for each load.

### 2. GENERAL CONDITIONS

- 2.1 SWS will process medical waste by sterilization methods in compliance with both State of Montana and Federal regulations.
- 2.2 The processed waste is acceptable under state solid waste rules as regular garbage category once sterilized. Some of the waste may be shredded and some not shredded.
- 2.3 SWS has secured long-term contracts for its waste steam and desires to secure a long-term contract for hauling and final disposal of this waste steam to a state approved landfill selected by the contractor.
- 2.4 SWS desire to contract for the hauling and disposal of this waste steam to a state approved landfill selected by the contractor.
- 2.5 The quality of material to be hauled and landfilled is in excess of 150 tons per month.

### 3. SPECIFICATIONS OF PERFORMANCE

- 3.1 The contractor shall provide transport and disposal of compacted, treated medical wastes on the basis of full capacity loading on a 24-hour notice.
- 3.2 Contractor shall furnish SWS with a minimum of 4 enclosed compactor rolloff containers, with not less than 2 cans available to be used on-site at all times.
- 3.3 Furnished compactor cans shall be compatible with the existing SWS Kilcom compactor located on-site.
- 3.4 The contractor will have same rails as SWS' own container.

### 4. CONDITIONS OF PERFORMANCE

- 4.1 Contractor shall provide \$1,000,000 of general liability insurance coverage on the truck to be leased to SWS, naming SWS as an additional insured.
- 4.2 Contractor shall commit the availability of a back-up truck as required to service SWS.
- 4.3 Contractor shall be obligated for 5 years under the terms of this agreement to meet the price offered.

### 5. PROPOSAL

Bid Item	Description	Estimated Quantity	Unit Price
1	Waste hauled Mileage	20+ tons per haul 459 miles round-trip	\$40.32 per ton \$ 1.00 per running mile
2	Waste hauled Mileage	Below 20 tons per haul 459 miles round-trip	\$294.25 per container \$ 1.00 per running mile

  
 Gary Chilcott, CEO/Pres.  
 Sure-Way Systems, Inc.

  
 Roger Bridgford, General Manager  
 Montana Waste Systems

**DEPARTMENT OF ENVIRONMENTAL QUALITY  
PERMITTING AND COMPLIANCE DIVISION  
SOLID WASTE LICENSING PROGRAM**

**SOLID WASTE MANAGEMENT SYSTEM  
ANNUAL RENEWAL CERTIFICATE**

This certifies that

**High Plains Sanitary Landfill**

has been approved for renewal and is licensed from

**July 1, 2004 through June 30, 2005**

by the Montana Department of Environmental Quality as a

**Major Class II Landfill & Burn Site**

**LICENSE NUMBER 225**

This annual renewal certificate is only valid if the licensee or the owner/operator has paid annual fees and is in compliance with all provisions of Title 75, Chapter 10, Parts 1 and 2, Montana Code Annotated, and solid waste management rules adopted in accordance with that law.



Edward A. Thamke, Bureau Chief  
Waste and Underground Tank Management Bureau

**THIS CERTIFICATE IS NON-TRANSFERABLE**



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 16 1999

EXHIBIT \_\_\_\_\_

(GC16)

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

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

Dear Mr. Chilcott:

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

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



Page 2 - Mr. Chilcott

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

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

Sincerely yours,



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

Enclosure

6-1

Indications for Use Statement  
Revised 11/10/99

Ver/ 3 - 4/24/96

Applicant: Sure-Way Systems, Inc.

S10(k) Number (if known): K992626

Device Name: Sharps Container

Indications For Use:

The Sure-Way Reusable Container is intended to be used for the disposal of contaminated medical sharps in health care facilities.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

Chin S. Lin

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

Number K 992626

3

ROTONICS 510(k) APPROVAL REFERENCE LETTER

ATTACHMENT A



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 27 1995

Food and Drug Administration  
8200 Corporate Boulevard  
Rockville MD 20856

Ed Krausse  
Rotonics Manufacturing Inc. - Chicago Div.,  
736 Birginal Drive  
Bensenville, Illinois 60106

Re: K944121  
Single Deposit Container 18  
Regulatory Class: II  
Product code: FMI  
Dated: October 26, 1994  
Received: October 31, 1994

Dear Mr. Krausse:

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

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Device: General GMP Regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not

SEP-02-99 02:29 PM

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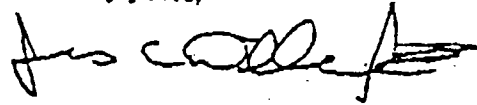
Report No.: 10408.3  
Re: 17-Gallon RNC

ESTABLISHED 1923

Date of Report: 31 August 1999

promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff, (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Philip J. Phillips  
Deputy Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

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Tariff No. 1	Original Page 9																				
Company Name: Stericycle of Washington, Inc. (G-244) (A) All rates on this page are new rates																					
(A) Item 95	<p><u>Rates for Collection and Transportation of Biomedical Waste in, and Processing of, Re-Usable Sharps Containers – Prices per rack (240 gallon maximum)</u></p> <table style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;"><u>Quantity</u></th> <th style="text-align: right; border-bottom: 1px solid black;"><u>Collection and Disposal</u></th> <th style="text-align: right; border-bottom: 1px solid black;"><u>Container Processing</u></th> <th style="text-align: right; border-bottom: 1px solid black;"><u>Total Charge Per Rack</u></th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td style="text-align: right;">\$190.40</td> <td style="text-align: right;">\$90.00</td> <td style="text-align: right;">\$280.40</td> </tr> <tr> <td style="text-align: center;">2</td> <td style="text-align: right;">142.20</td> <td style="text-align: right;">90.00</td> <td style="text-align: right;">232.20</td> </tr> <tr> <td style="text-align: center;">3</td> <td style="text-align: right;">110.85</td> <td style="text-align: right;">90.00</td> <td style="text-align: right;">200.85</td> </tr> <tr> <td style="text-align: center;">4 or more</td> <td style="text-align: right;">79.55</td> <td style="text-align: right;">90.00</td> <td style="text-align: right;">169.55</td> </tr> </tbody> </table> <p style="text-align: center; margin-top: 20px;"><i>[This space intentionally left blank]</i></p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Note 1: Stericycle will provide wheeled racks, with a maximum capacity of 240 gallons per rack, for the collection, transportation and disposal of sharps waste in Stericycle's standard re-usable sharps containers. The rates specified in this Item 95 apply only to a combined service including the collection, transportation and disposal of sharps waste using Stericycle racks and sharps containers and the processing of such containers for re-use by the customer.</p> <p>Note 2: Sharps containers are classified by the United States Food and Drug Administration ("FDA") as Class II medical devices. The "container processing" charge specified in this Item 95 includes processing of Stericycle's re-usable sharps containers for re-use in accordance with FDA requirements.</p> </div>	<u>Quantity</u>	<u>Collection and Disposal</u>	<u>Container Processing</u>	<u>Total Charge Per Rack</u>	1	\$190.40	\$90.00	\$280.40	2	142.20	90.00	232.20	3	110.85	90.00	200.85	4 or more	79.55	90.00	169.55
<u>Quantity</u>	<u>Collection and Disposal</u>	<u>Container Processing</u>	<u>Total Charge Per Rack</u>																		
1	\$190.40	\$90.00	\$280.40																		
2	142.20	90.00	232.20																		
3	110.85	90.00	200.85																		
4 or more	79.55	90.00	169.55																		
Issued By: Michael S. Philpott, District Manager																					
Issue Date: June 25, 2004 <span style="float: right;">Effective Date: June 29, 2004</span>																					
(This box for official use only)																					
Effective: _____ Docket No. _____																					
LSN: _____ Hearing _____ By _____																					

Tariff No. 1

6<sup>th</sup> Revised Page No. 1

Company Name: Stericycle of Washington, Inc. (G-244)

Cancels

5th Revised Page No. 1

**CHECK SHEET**

All of the pages contained in this tariff are listed consecutively by number. The pages to the tariff and/or any supplements to the tariff listed on this page have issue dates which are the same as, or are prior to, the issue date of this page. "0" in the revision column indicates an original page.

<u>Page Number</u>	<u>Current Revision</u>	<u>Page Number</u>	<u>Current Revision</u>
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5B	1		
5C	0		
6	3		
7	0		
8	1		
9	0		

SUPPLEMENTS IN EFFECT, including tax supplements:

- Supplement No. 6
- Supplement No. 7
- Supplement No. 8
- Supplement No. 9
- Supplement No. 10
- Supplement No. 11

Issued By: Michael S. Philpott, District Manager

Issue Date: June 25, 2004

Effective Date: June 29, 2004

(This box for official use only)

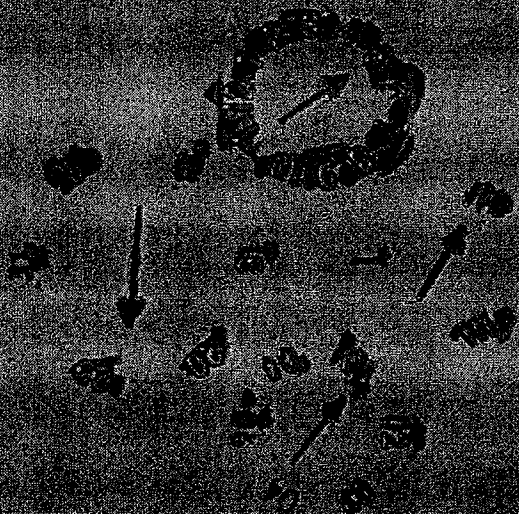
Effective: \_\_\_\_\_ Docket No. \_\_\_\_\_ By: \_\_\_\_\_

# NIOSH Standard Compliance Issues and Hospital Container and Lid Options

## NIOSH, JACO & FDA Compliance Issues

	Sure-Way Systems	BioSystems (Stericycle)	Danials Sharps Smart	Solutions
Small (1-gallon wall/counter mounted)	X			
Medium (1.5- to 2-gallon wall/counter mounted)	X		X	X
Large (3- to 4-gallon wall/counter mounted)	X	X	X	X
Small Lab (6- to 10-gallon floor mounted)	X	X	X	X
Supply Chemo Containers in all sizes to participating hospitals	X		X	
Large Lab (17-gallon floor mounted)	X	X	X	
<b>Lid Choices</b>				
Straight Drop (1-,2- & 4-gallon sharps containers)	X	X		X
Horizontal Drop (1-,2- & 4-gallon sharps containers)	X			
Balance lid for 1, 2, and 4 gallon sharps containers)			X	
Lab Lid w/Open Top (1-, 2-, & 4-gallon sharps containers)	X		X	
Balance Drop w/Complete Hand Restriction (1-,2- & 4-gallon sharps containers)	X			
Lockable Lid for Small and Large Lab Containers w/Final Closure	X		X	
Electronic Lid for Small and Large Lab Containers	X			
<b>Bracketry and Cabinet Options</b>				
Lockable Cabinets (1-, 2-, & 4-gallon sharps containers)	X	X		X
Lockable Brackets for Wall or Cart Mounting	X	X	X	
Container Counter Stabilizers (1-, 2-, & 4-gallon sharps containers)	X			
Floor Stabilizer Dolly	X	X	X	
<b>NIOSH Compliance Issues</b>				
FDA Compliant Container Warning Labels on All Containers	X	X	X	
DOT Accepted for Transportation without Additional Packaging	X		X	
Design Resists Opening After Sealing for Final Disposal (Tool Needed to Reopen)	X		X	
Lids Pass FDA Accepted Puncture Tests	X		X	
Translucent Container Allows for Visual Observation of Container Fullness	X	X	X	
Provides Third Party Testing of Containers to Quantify Sanitation of Containers	X		X	X
<b>Quality of Customer Service</b>				
Offers a Variety of Service Levels (Full Service or Dockside Service)	X	X		
Demonstrates a Commitment to Always Provide a Totally NIOSH Compliant Program	X		X	
Long Term Level Service Contracts	X	X	X	X
Accounting Available for Sharps Volume by Hospital Department (Full Service Only)	X	X	X	
<b>TOTAL ISSUES IN COMPLIANCE</b>	<b>27</b>	<b>12</b>	<b>18</b>	<b>7</b>

**This comparison is based on the best available information on each Sharps Disposal System**







EXHIBIT

(C.C. 22)

