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8 BEFORE THE WASHINGTON UTILITIES AND TRANSPORTATION COMMISSION

9
10 In Re Application of
11 SURE-WAY SYSTEMS, INC.
12 P.O. Box 899
Deer Lodge, MT 59722

No. GA-079331
TG-042089

**SUBPOENA DUCES TECUM TO GARY
CHILCOTT**

13
14 TO: GARY CHILCOTT, an individual and CEO of Sure-Way Systems, Inc.
15 AND TO: GREG HAFFNER, counsel for Sure-Way Systems, Inc.

16 YOU ARE HEREBY COMMANDED to be and appear before the Washington Utilities
17 and Transportation Commission, in the Kent City Hall Chambers East Room, 220 Fourth
18 Avenue South, Kent, Washington, on **Tuesday, August 30, 2005, at 8:00 a.m.** to testify at the
19 request of Protestant Stericycle of Washington, Inc., in the above entitled proceeding now
20 pending before the WUTC, and to remain in attendance until discharged; and, pursuant to the
21 WUTC procedural rules, WAC 480-07-400(2)(a), you are to bring with you any and all
22 documents, described in the attached Exhibit "A", that you have in your possession or control,
23 either as an individual or as CEO of Sure-Way Systems, Inc.
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26 **HEREIN FAIL NOT AT YOUR PERIL**

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DATED this 15th day of August, 2005.

GARVEY SCHUBERT BARER

By: Stephen B. Johnson
Stephen B. Johnson, WSBA #6196
Attorneys for Protestant Stericycle of
Washington, Inc.

1 **EXHIBIT A**

2 **Definitions**

3 Documents and Records shall be defined as including but not limited to, any written,
4 recorded or graphic or other material, however produced and whatever the medium in which it
5 was produced or reproduced, such as microfilm, papers, books, records, memoranda, contracts,
6 pictures, photographs, printouts, e-mails, electronic data compilations, computer discs,
7 computer programs, computer software, tapes, and other tangible things on which any
handwriting, typing, printing, drawing, representation, photostatic or other copy, magnetic or
electrical impulse, or other form of data or information is recorded or reproduced, now in your
possession, custody, or control or to which you have access.

8 FDA shall be defined as the federal Food and Drug Administration, and any of its
9 subdivisions, including the Center for Devices and Radiological Health.

10 2005 QSR Manual shall be defined as the document entitled "Sure-Way Systems QSR
11 Manual" that Sure-Way provided in response to Stericycle's Data Requests, which states "Last
12 Modified December 2004" on the first page, and which states "Revised – 1/05/05" on the top
left corner of each page. This document was attached to Dudley Chilcott's previously
submitted Prefiled Testimony as Exhibit DC 5.

13 2003 QSR Manual shall be defined as the document entitled "Sure-Way Systems QSR
14 Manual" that Sure-Way provided in response to Stericycle's supplemental request, which states
15 "Last Modified September 2003" on its first page. This document was attached to Jennifer A.
Krebs' previously submitted Prefiled Testimony as Exhibit JAK-22.

16 Employee Handbook shall be defined as the document entitled "Sure-Way Systems,
17 Inc. Employee Handbook," with an effective date of August 2, 2004. Sure-Way provided this
document as an attachment to its Response to Stericycle's Data Request #50.

18 North Dakota Medical Waste Processing Permit is defined as the document providing
19 information regarding Sure-Way's Butte, Montana facility that has the word "**GENERAL**" at
20 the top. Sure-Way provided this document as an attachment to its Response to Stericycle's
Data Request #50.

21 Safety Manual is defined as the document entitled "Safety Manual for All Employees
22 Working at Sure Way Systems, Inc." Sure-Way provided this document through its counsel
Greg Haffner on July 15, 2005 as a supplemental response to Stericycle's Data Requests.

23 Sure-Way shall be defined as the corporate entity Sure-Way Systems, Inc., as well as
24 any of its facilities, plants, subsidiaries, and any related or associated entities.

25 **Document Requests**

1 1. Produce all Documents and Records which evidence the appointment of any
2 person or persons to the following positions identified in the 2005 QSR Manual:

3 a. The "Management Representative," per 2005 QSR Manual §820.20(b)B,
4 for each Sure-Way facility.

5 b. The "Internal Auditor," per 2005 QSR Manual §820.20(b)F, for each
6 Sure-Way facility.

7 c. The "External Auditor," per 2005 QSR Manual §820.20(b)G, for each
8 Sure-Way facility.

9 2. Produce any and all QSR Manuals that are currently in effect and being
10 followed at Sure-Way's facilities, i.e., ones that have facility-specific information instead of,
11 e.g., "LOCATION" and "NAME".

12 3. Produce any and all Documents and Records that Sure-Way was required to
13 keep or maintain by the terms of the 2005 QSR Manual or any predecessor QSR Manual,
14 including, without limitation, the following:

15 a. All completed "Audit Completion Records," evidencing compliance with
16 the requirement for Management Reviews of Sure-Way's quality system, per 2005 QSR
17 Manual §820.20(c), and/or compliance with the requirement for Quality Audits, per
18 2005 QSR Manual §820.22, a blank example of which is attached to the 2005 QSR
19 Manual as Appendix III.

20 b. All completed "Audit Worksheets," which are used by Sure-Way's
21 Internal Auditor to conduct Quality Audits, per 2005 QSR Manual §820.22, a blank
22 example of which is attached to the 2005 QSR Manual as Appendix II.

23 c. All completed "Quality Manual Training Worksheets" evidencing
24 compliance with the Quality Training requirements of 2005 QSR Manual §820.25,
25 which Quality Training Sure-Way personnel are required to receive as a component of
26 their production training, a blank example of which is attached to the 2005 QSR Manual
as Appendix IV.

 d. All completed "Manual Change Record Forms" evidencing changes and
modifications to the procedures, plans, and specifications that constitute the Design
Master Record, per 2005 QSR Manual §820.3(j), a blank example of which is attached
to the 2005 QSR Manual as Appendix V.

 e. Copies of the "Quality System Record" evidencing changes to the 2005
QSR Manual and the Facility Operations Manual attached thereto, per 2005 QSR
Manual §820.40.

 f. All documents or other records evidencing that each manufacturer from
whom Sure-Way purchases reusable sharps containers¹ has a Quality System in place,
per 2005 QSR Manual §820.50.

¹ For brevity, Sure-Way's reusable sharps containers are hereinafter referred to simply as

1 g. All documents or other records evidencing that Sure-Way's production
2 system for disinfection, inspection and reassembly of containers was subjected to a
3 validation test prior to initial use and a challenge test on a quarterly basis thereafter, per
4 2005 QSR Manual §820.70(a).

5 h. All completed "Defect Notification Worksheets," describing any
6 defective new components discovered through inspection, per 2005 QSR Manual
7 §820.80(b), a blank example of which is attached to the 2005 QSR Manual as Appendix
8 VI(c).

9 i. All completed "new container acceptance forms" evidencing that new
10 containers have been inspected, per 2005 QSR Manual §820.80(b), a blank example of
11 which is attached to the 2005 QSR Manual as Appendix VI(a) and (b).

12 j. All completed "batch worksheets" indicating authorization for containers
13 to be returned to service after use, per 2005 QSR Manual §820.80(d,e).

14 k. All completed "Customer Complaint Worksheets" per 2005 QSR
15 Manual §820.100, a blank example of which is attached to the 2005 QSR Manual as
16 Appendix VII.

17 4. Produce any and all Documents and Records that Sure-Way was required to
18 keep or maintain by the terms of the Sure-Way Systems Facility Operations Manual or the
19 2003 QSR Manual,² including any predecessor manuals, and including without limitation the
20 following:

21 a. All completed "processing logs" evidencing that Sure-Way's tipping and
22 washing equipment is operated within the designated parameters (as required by Section
23 3 at p.40 of the 2005 QSR Manual; and at p.10 of the 2003 QSR Manual), a blank
24 example of which is attached to the 2003 QSR Manual as Exhibit 2 (pp.29-32).

25 b. All completed "container logs" evidencing that each group of containers
26 has been inspected as required by Section 3 at p.40 of the 2005 QSR Manual; and at
p.10 of the 2003 QSR Manual.

a. All documents or records evidencing the checking and testing of the
tipper, washer, and water as described in Section 6 of the 2005 QSR Manual at p.43;
and at p.15 of the 2003 QSR Manual.

d. All documents or records comprising what is alternatively described as
the "Device Master Record" and the "Design Master Record," per Section 7 of the 2005
QSR Manual at p.44; and at pp.17-18 of the 2003 QSR Manual.

e. All documents or records evidencing that all changes to the Quality
System Regulations Manual have been approved in writing by the Compliance Officer

"containers."

² The Sure-Way Systems Facility Operations Manual is part of the 2005 QSR Manual, beginning at
p.34. This document is substantially identical to Sure-Way's 2003 QSR Manual. Accordingly, the
following document requests cite to both the 2005 QSR Manual and the 2003 QSR Manual.

1 and the CEO, per Section 7 of the 2005 QSR Manual at p.45; and at p.18 of the 2003
2 QSR Manual.

3 f. All completed "acceptance logs" indicating that processed containers
4 have been accepted, per Section 8 of the 2005 QSR Manual at p.47; and at p.21 of the
5 2003 QSR Manual.

6 g. All completed "monthly reports" prepared by the Operations Manager
7 providing specific information regarding discarded and/or defective containers, per
8 Section 10 of the 2005 QSR Manual at p.49; and at p.23 of the 2003 QSR Manual.

9 h. All completed "Infectious Exposure Forms," required by Sure-Way's
10 Bloodborne Pathogens Exposure Control Plan (at p.70 of the 2005 QSR Manual and at
11 p.47 of the 2003 QSR Manual), a blank example of which is attached to the Bloodborne
12 Pathogens Exposure Control Plan as Exhibit B (2005 QSR Manual at p.75).

13 i. All completed "Training recognition/confirmation" forms, required by
14 Sure-Way's Bloodborne Pathogens Exposure Control Plan, p.73 of the 2005 QSR
15 Manual and p.50 of the 2003 QSR Manual, a blank example of which is attached to the
16 2005 QSR Manual at p.76.

17 5. Produce any and all Documents and Records that 21 C.F.R. Part 820, the FDA
18 Quality System Regulation, required Sure-Way to keep or maintain, including without
19 limitation the following:

20 a. Sure-Way's Design History File, evidencing that the design of the
21 containers was developed in accordance with the approved design plan and FDA
22 regulations. (21 C.F.R. §820.30(j)).

23 b. Any and all documents evidencing Sure-Way's purchasing controls, to
24 ensure that Sure-Way's suppliers conform to the specified requirements. (21 C.F.R.
25 §820.50).

26 c. Any and all documents evidencing Sure-Way's production and process
controls, which ensure that the containers conform to specifications. (21 C.F.R.
§820.70(g)(1) and (2)).

d. Sure-Way's Device History Record, evidencing that the containers are
manufactured in accordance with the FDA's Quality System Regulation. (21 C.F.R.
§820.184).

e. Any and all documents showing the dates and results of quality system
reviews performed by or on behalf of Sure-Way. (21 C.F.R. §820.20(c)).

f. Any and all documents showing the dates and results of quality audits
performed by or on behalf of Sure-Way. (21 C.F.R. §820.22).

6. Produce any and all Documents and Records that Sure-Way was required to
keep or maintain by the terms of the current Employee Handbook or any predecessor Employee
Handbook, including, without limitation, the following:

1 a. A copy of the "Supervisor's Manual" referred to in the "Accident or
2 Injury Reporting" section of the Employee Handbook.

3 b. Any and all documents evidencing that the procedures described in the
4 "Problem Resolution Procedure" section of the Employee Handbook are being
5 followed.

6 c. A copy of Sure-Way's "Work Force Drug & Alcohol Testing Act" as
7 described in the Drug and Alcohol Policy of the Employee Handbook.

8 d. Any and all documents evidencing that all persons that operate a
9 commercial motor vehicle on behalf of Sure-Way have been screened with a pre-
10 employment drug/alcohol test as mandated by the Drug and Alcohol Policy of the
11 Employee Handbook.

12 7. Produce any and all Documents and Records that Sure-Way was required to
13 keep or maintain by the terms of the document designated as the North Dakota Medical Waste
14 Processing Permit ("Permit"), including, without limitation, the following:

15 a. Any and all documents evidencing compliance with the waste
16 sterilization and autoclave operation procedures described in the "Treatment" section of
17 the Permit.

18 b. Any and all documentation substantiating the claim that "OSHA has
19 completed a full review of operations insuring employee safety," asserted in the
20 "Cleaning and Decontamination of Reusable Containers" section of the Permit.

21 c. Any and all documents evidencing Sure-Way's compliance with the
22 "Training Plan" section of the Permit by administering its "Training Program" to
23 include the following:

24 (1) Biohazardous waste training, documentation of which is to be
25 retained for three years,

26 (2) Radiation detection and prevention training, documentation of
which is to be retained for three years,

(3) Continuing education, including annual "formal documented
training," and

(4) Confirmation of employee training attendance through attendance
sheets, copies of which are retained for three years.

8. Produce any and all Documents and Records that Sure-Way was required to
keep or maintain by the terms of its Safety Manual, including, without limitation, the
following:

a. Any and all signed receipts indicating that all Sure-Way employees
received and read the Safety Manual (p.6).

b. Any and all documentation evidencing compliance with safety training
requirements, including completed Safety Meeting Attendance Sheets, showing the date

1 and subject of the training, a blank example of which is attached to the Safety Manual
2 as "F".

3 c. Any and all documentation evidencing compliance with the
4 Documentation and Record Keeping section of the Safety Manual, which requires
5 documentation of the following to be kept for at least three years:

6 (1) Initial safety orientation training and all subsequent safety
7 training and meetings.

8 (2) Safety inspections, hazard assessments and corrective actions
9 taken.

10 (3) Issuance of safety rules and regulations to employees.

11 (4) Accident, injury and illness reports and investigations.

12 (5) Employee disciplinary action for safety violations.

13 (6) First aid and CPR training.

14 (7) Worker's compensation claim reports.

15 (8) Any other formal activities relating to safety within the company.

16 d. A copy of the written "Respiratory Protection Program" referred to on
17 p.8 of the Safety Manual.

18 e. Any and all copies of specific "Lock Out/Tag Out" procedures for
19 specific machines, referred to on p.32 of the Safety Manual.

20 f. Any and all copies of completed "Lock Out/Tag Out Checklists," a blank
21 example of which is on p.33 of the Safety Manual.

22 g. Any and all Material Safety Data Sheets and MSDS logs, listing any
23 known hazardous chemicals at Sure-Way facilities, required to be kept by the Hazard
24 Communication Program at p.36 of the Safety Manual.

25 h. Any and all completed copies of the "Supervisor's Report of Accident/
26 Injury," a blank example of which is attached to the Safety Manual as "Page B."

i. Any and all completed copies of the "Near Miss Incident or Safety
Concern Report Form," a blank example of which is attached to the Safety Manual as
"D."

j. Any and all completed copies of "Safety Meeting Attendance Sheets," a
blank example of which is attached to the Safety Manual as "F."

k. Any and all completed copies of the "Forklift Training and Evaluation
Certification" forms, a blank example of which is attached to the Safety Manual as "G."

9. Produce Sure-Way's 2003 and 2004 federal income tax returns and any
applications submitted to the IRS by Sure-Way for extension of the time to file such returns.

10. Produce Sure-Way's audited financial statements for 2003 and 2004.

1 11. Produce any and all documents, records, communications or correspondence to
2 or from any representative, employee, principal or agent of Sure-Way that reflect, refer, or
3 pertain to the dispute regarding audit fees between Sure-Way and the CPA firm referenced in
4 paragraph 28 of David Sullivan's Prefiled Reply Testimony with which Sure-Way had a
5 dispute regarding payment of its audit bill.

6 12. Also produce the following:

7 a. All correspondence, e-mail communications, notes or other records or
8 documents documenting, evidencing or otherwise related or pertaining to
9 communications between Sure-Way and the FDA (i) in connection with Sure-Way's
10 May 2005 applications for establishment registration and device listing; and (ii) in
11 connection with Sure-Way's communications with Walter Snesko of the FDA.

12 b. An unredacted copy of the FDA Establishment Inspection Report from
13 the FDA's inspection of Sure-Way's Wilmington, CA sharps container processing
14 facility conducted in January 2000. A redacted form of this document was attached to
15 Jennifer A. Krebs' previously submitted Prefiled Testimony as Exhibit JAK-2.

16 c. An unredacted copy of Sure-Way's "Response to FDA 483 Inspection
17 Memorandum," dated February 28, 2000. A redacted form of this document was
18 attached to Jennifer A. Krebs' previously submitted Prefiled Testimony as Exhibit JAK-
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1 **CERTIFICATE OF SERVICE**

2 I, Rondi Susort, certify under penalty of perjury under the laws of the State of
3 Washington that, on August 15, 2005, I caused to be served on the person listed below in the
4 manner shown:


5 **SUBPOENA DUCES TECUM TO GARY CHILCOTT**

6 Greg W. Haffner
7 Curran Mendoza
8 P.O. Box 140
9 555 W. Smith Street
10 Kent, WA 90835

Greg Trautman, Asst. Attorney general
1400 S. Evergreen Park Drive S.W.
P.O. Box 40128\
Olympia, WA 98504-0128

- 11 United States Mail, First Class, Postage Prepaid
12 By Legal Messenger
13 By Facsimile

14 Dated at Seattle, Washington this 15th day of August, 2005.

15 
16 _____
17 Rondi Susort