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       BEFORE THE WASHINGTON UTILITIES AND TRANSPORTATION
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                           COMMISSION
     In re Application No. GA-079331 )
     of SURE-WAY SYSTEMS, INC.,
                                     ) DOCKET NO. TG-042089
 4
                                     ) Volume III
     For a Certificate of Public
                                    ) Pages 37 - 70
 5
     Convenience and Necessity to
     Operate Motor Vehicles in
 6
     Furnishing Solid Waste
                                     )
 7
    Collection Service.
                                     )
 8
 9
               A prehearing conference in the above matter
10
     was held on August 23, 2005, at 9:53 a.m., at 1300
11
     South Evergreen Park Drive Southwest, Olympia,
12
     Washington, before Administrative Law Judge KAREN
13
     CAILLE.
14
15
               The parties were present as follows:
16
               SURE-WAY SYSTEMS, INC., by GREG W. HAFFNER,
     Attorney at Law, Curran Mendoza, 555 West Smith Street,
     Post Office Box 140, Kent, Washington 98035-0140;
17
     telephone, (253) 852-2345.
18
               STERICYCLE OF WASHINGTON, INC., by STEPHEN B.
19
     JOHNSON, Attorney at Law, Garvey, Schubert, Barer, 1191
     Second Avenue, 18th Floor, Seattle, Washington
20
     98101-2939; telephone, (206) 464-3939.
21
               WASHINGTON UTILITIES AND TRANSPORTATION
     COMMISSION, by GREGORY J. TRAUTMAN, Assistant Attorney
22
     General, 1400 South Evergreen Park Drive Southwest,
     Post Office Box 40128, Olympia, Washington 98504-0128;
23
     telephone, (360) 664-1187.
24
    Kathryn T. Wilson, CCR
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    Court Reporter
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- JUDGE CAILLE: We are here for a prehearing
- 3 conference in Docket No. TG-042089. This is an
- 4 application by Sure-Way Systems, Inc., for a
- 5 certificate of public convenience and necessity to
- 6 operate motor vehicles in furnishing solid waste
- 7 collection service, specifically medical refuse.
- 8 Today is August 23rd and we are convened in a
- 9 hearing room in Olympia, Washington, and I will take
- 10 the appearances for the record, please, beginning with
- 11 the Applicant.
- MR. HAFFNER: Would you like us to state
- 13 addresses and phone numbers?
- 14 JUDGE CAILLE: That is unnecessary.
- MR. HAFFNER: Greg Haffner appearing for
- 16 Sure-Way Systems, Inc.
- 17 MR. JOHNSON: Stephen Johnson appearing for
- 18 Stericycle of Washington, Inc.
- 19 MR. TRAUTMAN: Greg Trautman, assistant
- 20 attorney general, for Commission staff.
- 21 JUDGE CAILLE: Let the record reflect there
- 22 are no other appearances. The purpose of this
- 23 prehearing conference is to exchange cross-exhibits,
- 24 and I see the parties have brought in their
- 25 cross-exhibits; also to go over the order of witnesses

- 1 and the times for cross-examination; to attend to any
- 2 dispositive motions, and hopefully to stipulate to the
- 3 admission of as many of these exhibits, the prefiled
- 4 exhibits, as possible.
- 5 I recognize that you have just received the
- 6 cross-exhibits today and have not had an opportunity to
- 7 look at those, so what we will do is reserve some time
- 8 either at the beginning of the hearing next Tuesday or
- 9 when the witness takes the stand and those exhibits are
- 10 offered. We will deal with the admission of those
- 11 exhibits that way.
- 12 Having talked to the parties before going on
- 13 the record this morning, I understand that there is no
- 14 objection to any of the exhibits that have been
- 15 prefiled; is that correct?
- MR. HAFFNER: Correct from Applicant's
- 17 standpoint, Your Honor.
- 18 MR. JOHNSON: Your Honor, I have questions
- 19 about a couple of the prefiled exhibits from the
- 20 Applicant, but I believe they are questions that can be
- 21 raised as to the weight of these materials, so I'm
- 22 going to stipulate to them as well.
- JUDGE CAILLE: All the prefiled exhibits are
- 24 stipulated to with your caveat, Mr. Johnson.
- 25 I also distributed before going on the record

- 1 this morning an exhibit list, and the parties have
- 2 agreed to -- I'm going to send it to you
- 3 electronically, and I understand that you will be
- 4 filling in the portion with the cross-exhibits.
- Now, I have done a description of the
- 6 prefiled exhibit. I would appreciate you look at
- 7 those. I also have some questions about some of them
- 8 because I did not know how to describe them. I really
- 9 pretty much got through the Applicant's exhibits. I
- 10 have not looked at Stericycle's exhibits closely to
- 11 know whether I can describe them or not.
- 12 So I will do a description of those and then
- 13 e-mail that to you, and if you will read through those,
- 14 or if I have questions on those, Mr. Johnson, I will
- 15 put those question marks in the description area.
- 16 MR. JOHNSON: That would be fine. The other
- 17 alternative that might save you some time is for us to
- 18 go ahead and put descriptors in.
- 19 JUDGE CAILLE: I will accept that help.
- 20 Otherwise, I'm doing it because we don't have enough
- 21 support staff right now to do it.
- 22 So the order of witnesses, as we discussed
- 23 before going on the record this morning, will be Gary
- 24 Chilcott, Jeffrey Gibbs, David Sullivan, and Dudley
- 25 Chilcott. Mr. Johnson, could you just tell me how much

- 1 time you expect for cross-examination on each of those?
- 2 MR. JOHNSON: Your Honor, my basic thought is
- 3 that Gary Chilcott and Dudley Chilcott would take about
- 4 a day, and Jeffrey Gibbs and David Sullivan would
- 5 probably take one day, one in the morning, and one in
- 6 the afternoon.
- 7 JUDGE CAILLE: And we were talking about
- 8 beginning at nine o'clock and going until five, unless
- 9 we finish early, of course. Commission staff, do you
- 10 have an estimate on your cross-examination time?
- 11 MR. TRAUTMAN: Yes. I believe we sent in a
- 12 letter yesterday, and we've asked for essentially a
- 13 placeholder of about 15 minutes on each witness.
- 14 Sometimes we use 15 or 20. Sometimes we don't have any
- 15 questions.
- 16 MR. JOHNSON: Mr. Trautman, I don't believe
- 17 we got a copy of your letter. Do you have one today?
- 18 MR. TRAUTMAN: You should have gotten it
- 19 electronically.
- 20 MR. HAFFNER: I don't recall receiving one
- 21 either.
- 22 MR. JOHNSON: You can certainly provide it to
- 23 us later today.
- JUDGE CAILLE: As I recall, I think mine is
- 25 in my office. It was a letter just reserving the 15.

- 1 MR. TRAUTMAN: I think it said 10 to 15
- 2 minutes.
- 3 JUDGE CAILLE: But you will see that the
- 4 parties get that letter eventually?
- 5 MR. TRAUTMAN: Yes.
- JUDGE CAILLE: So then we have Robert
- 7 Sheridan, Michael Philpott, Christopher Stromerson, and
- 8 Nanette Walker. Mr. Haffner, how much time do you need
- 9 for each of these witnesses?
- 10 MR. HAFFNER: I don't anticipate taking more
- 11 than an hour to two hours at the most with each of
- 12 those witnesses, and it's probably closer to an hour or
- less.
- 14 JUDGE CAILLE: My understanding is these
- 15 witnesses are going to be available for
- 16 cross-examination the week of September 20th.
- 17 MR. JOHNSON: That is correct, Your Honor.
- 18 JUDGE CAILLE: Mr. Trautman, same thing for
- 19 these witnesses?
- MR. TRAUTMAN: Yes.
- 21 JUDGE CAILLE: 15 minutes then. I have just
- 22 a couple of quick questions, and then unless the
- 23 parties have anything further, I can get you out of
- 24 here quickly.
- MR. HAFFNER: I have two things.

- 1 JUDGE CAILLE: Let me just finish up with the
- 2 exhibits. I have a question for Mr. Johnson about
- 3 Jennifer Krebs. Will she been taking the stand?
- 4 MR. JOHNSON: It would be my hope that since
- 5 she's an attorney in my office that we just stipulate
- 6 to the admissibility of these. They reflect production
- 7 of documents from Mr. Haffner and some e-mails and
- 8 other communications from state agencies. If
- 9 Mr. Haffner is agreeable, she does not need to appear.
- MR. HAFFNER: I'm agreeable.
- JUDGE CAILLE: So these are prefiled
- 12 exhibits?
- MR. HAFFNER: Yes. They are responses to
- 14 discovery and should be admitted as prefiled exhibits.
- 15 Likewise, I have submitted one prefiled testimony that
- 16 has an exhibit attached to it that is in a similar
- 17 vein.
- 18 MR. JOHNSON: We have no objection to that
- 19 either, Your Honor. We have a couple of other exhibit
- 20 issues that I would like to raise with you at an
- 21 appropriate time.
- JUDGE CAILLE: Do you have all your exhibits
- 23 with you? I'm looking at --
- MR. HAFFNER: I believe I do.
- 25 JUDGE CAILLE: I'm looking at what would be

- 1 Gary Chilcott's Exhibit 15, and I just want to make
- 2 sure that -- are there two pages to this exhibit? The
- 3 first page says "Request for Proposal." The second
- 4 page says "Department of Environmental Quality,
- 5 Permitting and Compliance Admission Solid Waste
- 6 Licensing Program." Are those both part of the same
- 7 exhibit?
- 8 MR. HAFFNER: Yes.
- 9 JUDGE CAILLE: And on Mr. Gary Chilcott's
- 10 Exhibit 20, this is a photograph?
- 11 MR. HAFFNER: Yes. That is a photograph of a
- 12 stamp or embossing that goes on the Sharps containers.
- 13 MR. JOHNSON: Your Honor, we have received
- 14 from Mr. Haffner's client actual Sharps containers from
- 15 his client that would show this kind of thing on them.
- 16 I would propose to bring to the hearing both the
- 17 Sure-Way containers that have been provided to us by
- 18 Sure-Way and the Stericycle container so that when we
- 19 are referring to these different containers, we know
- 20 exactly what we are looking at, and to the extent this
- 21 is difficult to read, Exhibit No. 20, we will have the
- 22 actual container that could be looked at.
- MR. HAFFNER: Are you proposing to bring the
- 24 containers that we delivered to you?
- MR. JOHNSON: Absolutely.

- JUDGE CAILLE: Are they large?
- 2 MR. JOHNSON: They are large and somewhat
- 3 bulky, but I can bring them along.
- 4 JUDGE CAILLE: I think that would be helpful
- 5 to actually see those for my perspective.
- 6 MR. HAFFNER: I assume they will be used for
- 7 illustrative purposes only and not admitted as
- 8 exhibits?
- 9 MR. JOHNSON: My assumption is we would use
- 10 them that way. By the way, I think you would want
- 11 those same containers for the shipper testimony. If
- 12 that's the case, would you let us know if you are going
- 13 to have them in the Tri-Cities, because I don't plan to
- 14 box those things and take them on the road with me.
- 15 MR. HAFFNER: We will work with that when we
- 16 get there.
- JUDGE CAILLE: On the rest of these, I think
- 18 what I will do is -- I'm just not sure what the
- 19 description should be, so when I e-mail the exhibit
- 20 list form, I will just ask for description on that, and
- 21 I think I can take care of the rest of these too.
- 22 I have one other question about -- this is
- DS, so this is David Sullivan's Exhibit 3, and it's the
- 24 fourth page of that exhibit. I just wanted to make
- 25 sure that is also part of DS-3.

- 1 MR. HAFFNER: The fourth page?
- 2 JUDGE CAILLE: The fourth page has the data
- 3 request number of 51 labor services?
- 4 MR. HAFFNER: Yes. The rest of these, I
- 5 think, I will just need descriptions, so there is no
- 6 problem with that.
- 7 Mr. Johnson, you have volunteered to put your
- 8 descriptions in, and I thank you very much for doing
- 9 that. Mr. Haffner, please just check my description of
- 10 what your exhibit is for accuracy, and please feel free
- 11 to edit it.
- 12 MR. HAFFNER: Yes.
- 13 JUDGE CAILLE: Since we are still on the
- 14 subject of exhibits, did you have an issue about
- 15 exhibits, Mr. Haffner, or is it something else?
- MR. HAFFNER: Not about the exhibits that
- 17 have been presented, but I wanted to go on the record
- 18 that yesterday in preparing for this hearing, I found a
- 19 stack of documents that were responsive to
- 20 Mr. Johnson's discovery requests to me earlier, and I
- 21 just brought them to him this morning.
- 22 So I would recognize that he should be given
- 23 permission to go through those documents and add them
- 24 as cross-examination exhibits because it's my fault
- 25 they didn't get to him in time.

- JUDGE CAILLE: Is that correct?
- 2 MR. JOHNSON: Yes.
- 3 MR. HAFFNER: That's different than the
- 4 cross-examination exhibits I gave you.
- 5 JUDGE CAILLE: This is discovery.
- 6 MR. HAFFNER: This is discovery responses
- 7 that I anticipate Mr. Johnson will find some documents
- 8 in there that he will want to use on cross-examination,
- 9 so he should be given the opportunity to submit them.
- 10 JUDGE CAILLE: Mr. Johnson, can you just add
- 11 those into your list?
- 12 MR. JOHNSON: I will add them to the extent
- 13 they need to be. Your Honor, just so you are aware of
- 14 what this material is, it seems to be documents, and
- 15 correct me if I'm wrong, Greg, but it seems to be
- 16 documents that are responsive to our request for
- 17 documents that demonstrate compliance with the
- 18 requirements of the QSR Manual. We will need to look
- 19 at them, of course.
- MR. HAFFNER: That's a correct
- 21 characterization.
- 22 JUDGE CAILLE: All right. So we are still on
- 23 the exhibit list.
- MR. HAFFNER: The other item I had was not
- 25 having to do with the exhibit list. It was having to

- 1 do with the hearing schedule.
- 2 MR. JOHNSON: I have a couple of exhibit
- 3 issues.
- 4 JUDGE CAILLE: Let's do the rest of the
- 5 exhibit issues.
- 6 MR. JOHNSON: Thank you. We had attached to
- 7 our prefile testimony some redacted copies of materials
- 8 we had received from the FDA in response to our FYA
- 9 requests to them. Mr. Haffner has since been able to
- 10 receive unredacted copies of those same documents from
- 11 the FDA and has provided the unredacted versions to us.
- 12 Those should be at some point either added as
- 13 a supplement or added as additional exhibits. I think
- 14 they should just be substituted for the redacted
- 15 copies.
- JUDGE CAILLE: Are these going to be treated
- 17 as confidential exhibits?
- MR. HAFFNER: No.
- 19 JUDGE CAILLE: I think then that perhaps just
- 20 substituting them.
- 21 MR. HAFFNER: My only comment to Mr. Johnson
- 22 was that some of the redacted exhibits were reviewed by
- 23 a witness that he is using as an expert witness, and I
- 24 felt that since this person is giving his opinion on
- 25 that particular document -- I hate to increase the

- 1 record with more exhibits, but it seems to me it would
- 2 be maybe more appropriate to supplement the record and
- 3 identify this as an admitted exhibit that is the
- 4 unredacted version of the version that his expert
- 5 referred to.
- 6 JUDGE CAILLE: I think your point is well
- 7 taken, and I think that is a good idea. We will call
- 8 this the unredacted version of the same exhibit, so it
- 9 will have an exhibit number.
- 10 Here's what I propose to do: I am going to
- 11 number the exhibits, and so in my numbering -- let me
- 12 see.
- MR. HAFFNER: I would propose that the
- 14 easiest way would be to use it as a cross-examination
- 15 exhibit and confirm with my witness who you are cross-
- 16 examining that it is, in fact, the document that we
- 17 believe it to be, or we can just stipulate to that,
- 18 because that is what it is.
- 19 JUDGE CAILLE: I would prefer to do it this
- 20 way: This is the way we handle confidential exhibits
- 21 is to put in the exhibit list that there is both a
- 22 redacted version and an unredacted version, and
- 23 actually, what I would probably do is give it a
- 24 separate number.
- MR. HAFFNER: Actually, Your Honor,

- 1 confidentiality is not the issue here. The reason it
- 2 was redacted in its original form that Mr. Johnson used
- 3 was because I believe it was a request from the FDA
- 4 that Mr. Johnson had made that they submitted that to
- 5 you, and you asked us to get the unredacted copy, and
- 6 so he had used the redacted version because the FDA has
- 7 its rules for confidentiality.
- 8 We reviewed the document and don't find any
- 9 concerns about confidentiality and so submitted that to
- 10 Mr. Johnson as the unredacted original version. So
- 11 there is not an issue of confidentiality. The only
- 12 issue is his expert relied on the redacted version, and
- 13 it just seems to me that since his opinion was based on
- 14 that version, we should clear it up with him
- 15 substituting.
- 16 MR. JOHNSON: I don't have any problem with
- 17 that, Your Honor. I will probably give the unredacted
- 18 copy to the expert anyway for him to review prior to
- 19 his testimony, but I think where these redacted
- 20 exhibits appear primarily is in the prefiled testimony
- 21 of Jennifer Krebs where we are just basically providing
- 22 copies of documents from public agencies to the
- 23 Commission, and perhaps what we can do is either just
- 24 substitute them there, which strikes me as just trying
- 25 to avoid having to have twice as much -- we've got

- 1 plenty of paper here, I realize, but in this case, it
- 2 doesn't seem to have much value to have two sets of
- 3 them, and then we can leave Mr. Sheridan's prefiled
- 4 testimony the way it is.
- 5 MR. HAFFNER: That would be fine.
- 6 JUDGE CAILLE: So now my understanding is
- 7 that we would substitute --
- 8 MR. HAFFNER: Substituting the version
- 9 that --
- 10 MR. JOHNSON: Substituting the clean version
- in the prefiled testimony of Jennifer Krebs.
- 12 MR. HAFFNER: That would be acceptable. So
- 13 the version attached to Mr. Sheridan's testimony would
- 14 remain --
- 15 MR. JOHNSON: Sure. Would stay the same. So
- 16 for example, Exhibit JAK-2 is the redacted copy of an
- 17 inspection report for which we now have the unredacted
- 18 copy and so on.
- 19 JUDGE CAILLE: But we don't have Exhibit
- 20 numbers on those.
- MR. JOHNSON: I haven't put them on at
- 22 present. I can put them on and provide them to the
- 23 parties and yourself.
- JUDGE CAILLE: Yes.
- MR. JOHNSON: It would be Exhibits JAK-2,

- 1 JAK-4, and JAK-5.
- JUDGE CAILLE: I will prefer that you mark
- 3 those so that I don't by any chance mix those up, since
- 4 they are your exhibits.
- 5 MR. JOHNSON: Sure.
- 6 JUDGE CAILLE: So 2, 4, and 5 substituted
- 7 with the unredacted. What is the name of the gentleman
- 8 who is your expert?
- 9 MR. JOHNSON: His name is Robert Sheridan.
- 10 JUDGE CAILLE: Is there another exhibit
- 11 issue, Mr. Johnson?
- MR. JOHNSON: Yes, Your Honor, a couple of
- 13 additional issues, and I don't know what the best way
- 14 to handle this is, so I will tell you and you can tell
- 15 me whether that will work.
- In response to the analysis presented by
- 17 Nanette Walker in her prefiled testimony, Mr. Haffner's
- 18 witnesses in their reply testimony questions certain
- 19 assumptions related to mileage that a truck driver
- 20 would need to drive to serve Eastern Washington 12
- 21 counties that are part of the Application.
- 22 In response to that, Ms. Walker and
- 23 Mr. Philpott, looking at the transportation side of the
- 24 issue, Ms. Walker looking at the implications for her
- 25 financial analysis, went back and looked at the mileage

- 1 again. Mr. Philpott and his staff have generated an
- 2 additional sort of route analysis that shows the
- 3 mileage that their trucks travel in a sample, and we
- 4 have generated a document that I would like to see
- 5 added as an exhibit to Mr. Philpott's testimony and add
- 6 it at the end of his testimony.
- 7 He will speak to it, if I may be permitted,
- 8 during his direct examination, and it shows in more
- 9 detail the routes that Stericycle's Eastern Washington
- 10 drivers travel with some supporting information, and
- 11 then based on that new route analysis, Nanette Walker
- 12 has factored the revised mileage numbers in her
- 13 economic analysis or her analysis of Sure-Way's pro
- 14 forma projections and has developed a revised exhibit,
- 15 Exhibit 3 to her testimony.
- So what we would like to do is offer new
- 17 route analysis as Exhibit 20 to Mike Philpott's
- 18 testimony and this revised 12-month pro forma analysis
- 19 of Ms. Walkers as an exhibit. Either we call it 3-A,
- 20 because it's a modification of her Exhibit 3, or we can
- 21 put it at the end of her testimony.
- JUDGE CAILLE: Do you have any response to
- that, Mr. Haffner?
- MR. HAFFNER: Well, I get worried about
- 25 allowing too many new exhibits brought into the record,

- 1 but I know that this process will happen throughout
- 2 this hearing. I guess my concern is Mr. Philpott did
- 3 address miles driven for their operations in Eastern
- 4 Washington in his prefiled testimony, and it seems that
- 5 this is now granting the Protestant an opportunity to
- 6 submit reply testimony that wasn't considered in our
- 7 prehearing order.
- 8 So I guess I would object to it on the
- 9 grounds that it's not contemplated within our original
- 10 scheduling, and it's different information -- well, I
- 11 don't know how different it is, but it's additional
- 12 information to what they could have submitted with
- 13 their original prefiled testimony, because they did
- 14 address mileage in that prefile testimony.
- 15 As to the revision to the pro forma, it
- 16 sounds like those are based on mileage, and again, they
- 17 had mileage information that they were using in
- 18 Mr. Philpott's prefiled testimony, and as I recall in
- 19 Ms. Walker's initial pro forma and prefiled testimony,
- 20 she replied on that mileage and that Mr. Philpott
- 21 included it in his prefiled testimony, so now they are
- 22 going back and giving reply testimony, which is what we
- 23 had an opportunity to do but the prehearing scheduling
- 24 didn't provide for them to do.
- JUDGE CAILLE: Anything further?

- 1 MR. JOHNSON: Well, Your Honor, I do think
- 2 that it's appropriate when during the course of
- 3 proceedings a critique of presented testimony that the
- 4 witness be allowed to modify that testimony to reflect
- 5 the facts as they understand them, and I guess what we
- 6 are suggesting is I would like to provide this
- 7 additional information now so that Mr. Haffner and his
- 8 client have full opportunity to see it and address it
- 9 rather than having it arise as an adjustment to an
- 10 opinion in the context of the hearing itself.
- 11 JUDGE CAILLE: Mr. Johnson, tell me again,
- 12 why is this change now? Are you saying there is new
- 13 information that came to light?
- 14 MR. JOHNSON: It's more detailed, and a
- 15 different type of analysis was done of the mileage that
- 16 the truck drivers drive with more detail as to exactly
- 17 where they go, and the original analysis was done on
- 18 the basis of how much mileage would be included within
- 19 the 12-county area based on the number of stops in that
- 20 12-county area compared to the mileage in the entire
- 21 Eastern Washington. What they have done now is a
- 22 route-by-route analysis to produce a different number.
- JUDGE CAILLE: Tell me why this wasn't
- 24 provided earlier.
- 25 MR. JOHNSON: I think it wasn't provided

- 1 because the folks doing the analysis thought the
- 2 analysis was sufficient. When they were critiqued by
- 3 Mr. Haffner, they looked at it again and decided they
- 4 had over-estimated mileage in certain respects. They
- 5 went back and redid the analysis in a different way and
- 6 came up with a different number.
- 7 JUDGE CAILLE: Here's the problem. Each
- 8 party can go on and on and revise their testimony to
- 9 try to reach perfection. This isn't an exact science
- 10 here, and I really want to try not to get into this
- 11 mode.
- 12 I really think that we need to keep control
- over this type of adding to the record, so I'm going to
- 14 deny your request to do those additional exhibits and
- 15 bring them in because it is now putting into the record
- 16 a new analysis, and I do not think it's fair. The
- 17 Applicant would need to look at that and then reply, so
- 18 your motion is denied.
- 19 MR. JOHNSON: Your Honor, may I ask that we
- 20 be allowed to make a written motion and submit the
- 21 materials so you have an opportunity to look at it? In
- 22 that way, I would preserve the record of our request to
- 23 have these things admitted and your specific denial of
- 24 these particular exhibits, so we can have the exhibits
- 25 on the record in that fashion as a means for review, if

- 1 we choose to proceed that way.
- 2 JUDGE CAILLE: You may do that. Have we
- 3 covered all your exhibit issues?
- 4 MR. JOHNSON: There is one additional item,
- 5 Your Honor, and that is I've had an exchange of e-mail
- 6 communications with the FDA with respect to one of the
- 7 issues that Mr. Haffner's folks have been arguing with
- 8 respect to their FDA compliance, and I received an
- 9 e-mail back yesterday from the FDA's medical device
- 10 quality systems expert, Kimberly A. Trautman, and I
- 11 would like to offer this as an additional exhibit with
- 12 respect to the issue of how the FDA regulations apply
- 13 to a company such as Sure-Way, and I earlier provided a
- 14 copy to Mr. Haffner.
- JUDGE CAILLE: Mr. Haffner, response?
- 16 MR. HAFFNER: Yes, Your Honor. I would
- 17 oppose the admission of this exhibit also because the
- 18 person from the FDA who is responding admits in her
- 19 exhibit that she's not an expert in registration and
- 20 listing questions or issues, and I think those go to
- 21 the heart of matter as to whether QSR regulations are
- 22 even relevant in this proceeding, because there is a
- 23 dispute between the opposing parties as to whether the
- 24 Applicant is required to register with the FDA as a
- 25 manufacturer or not, and this person from the FDA that

- 1 apparently is the author of this e-mail, confirming her
- 2 conversations with Mr. Johnson, admits that she's not
- 3 an expert in the area of registration and listing but
- 4 that her expertise is in quality system regulation.
- 5 MR. JOHNSON: Your Honor, may I respond
- 6 briefly?
- 7 JUDGE CAILLE: Yes, just a moment. Did you
- 8 say that she admits that she's not an expert in
- 9 regulation; that she is an expert in the QSR?
- 10 MR. HAFFNER: In her own words, "I defer any
- 11 comment on the registration and listing questions and
- 12 issues that you state below as I am not the
- 13 registration and listing expert. I am the expert in
- 14 quality system regulation, 21-CFR-820, and therefore
- 15 can only make statements to that particular
- 16 regulation."
- JUDGE CAILLE: Mr. Johnson?
- 18 MR. JOHNSON: If you would like to review the
- 19 e-mail, I have a copy here. To the extent that the
- 20 exact text is relevant, you may want to review it. The
- 21 issue that Mr. Haffner raises goes to the weight that
- 22 should be given to the e-mail correspondence.
- 23 This woman's title is medical device quality
- 24 systems expert, so that is her title. She says she is
- 25 not the registration and listing expert, so she's not

- 1 going to comment on these issues, but she does respond
- 2 and comment on the issue of whether the quality system
- 3 regulation applies to a company in the position of
- 4 Sure-Way, and for that matter, bio systems and
- 5 Stericycle.
- 6 So the issue of exactly how it cuts and on
- 7 exactly which issue I think is an issue that Your Honor
- 8 is quite capable of determining and taking into
- 9 account, but the issue is one of weight and
- 10 responsiveness rather than whether it should be
- 11 permitted or not, I believe. And, Your Honor, your
- 12 concern about not having materials, people sort of
- 13 amend their testimony, doesn't apply to this particular
- 14 case because a response came yesterday.
- 15 JUDGE CAILLE: I understand. That would not
- 16 be the reason I would exclude it. Is Ms. Trautman
- 17 available for cross-examination?
- 18 MR. JOHNSON: Your Honor, I don't think she's
- 19 available for cross-examination, but neither are --
- 20 Mr. Haffner has put in e-mail correspondence with
- 21 Mr. Chilcott and somebody else in the FDA with respect
- 22 to the same issue. This FDA fellow is not available
- 23 for cross-examination. This information very clearly
- 24 shows exactly what she's responding to in the e-mail.
- 25 JUDGE CAILLE: I'm not going to argue with

- 1 you about this, but I will point out to you that we
- 2 have stipulated to those exhibits and Mr. Haffner is
- 3 objecting to this one, so there is a bit of difference
- 4 here. If he were not objecting to this, I would look
- 5 at it in the same way. May I see a copy of that,
- 6 please?
- 7 MR. JOHNSON: Sure. Your Honor, this goes to
- 8 the exact issue that was my caveat with respect to
- 9 Mr. Haffner's prefiled exhibit, and I believe the issue
- 10 goes to the weight to be given to this material rather
- 11 than whether it should be before the Commission so that
- 12 the Commission can make an informed decision.
- 13 JUDGE CAILLE: Could you tell me again,
- 14 Mr. Johnson, why this wasn't received until yesterday?
- MR. JOHNSON: Because she didn't respond,
- 16 Your Honor, until yesterday.
- JUDGE CAILLE: When did you query her?
- 18 MR. JOHNSON: I queried her on August 12th.
- 19 I had spoken to her on the telephone some weeks prior
- 20 to that.
- 21 JUDGE CAILLE: Let's take about a five-minute
- 22 recess so I can read this.
- 23 (Recess.)
- JUDGE CAILLE: I've had an opportunity to
- 25 review the e-mail that is the subject of this proposed

- 1 exhibit. My ruling is that I'm going to deny the
- 2 admission of this exhibit. Mr. Haffner has opposed it
- 3 and Ms. Trautman is not available for
- 4 cross-examination.
- 5 I understand your argument about the weight,
- 6 but I think that would be -- if I decided to admit it
- 7 we would weigh it, and you are offered the same
- 8 opportunity, Mr. Johnson, to submit this and make it a
- 9 part of the record.
- 10 MR. JOHNSON: Is the basis of your ruling
- 11 that Ms. Trautman is not available for
- 12 cross-examination?
- JUDGE CAILLE: Yes, because what we have here
- 14 is you asking Ms. Trautman a question, or actually, you
- 15 are, in effect, testifying, and then you are saying,
- 16 "Is this correct, Ms. Trautman," and Ms. Trautman is
- 17 responding back, and I am not comfortable with the
- 18 value of this exhibit without having Mr. Haffner have
- 19 the opportunity to cross-examine. I suppose if he had
- 20 stipulated to the admission of this, I would have
- 21 allowed it in, but he hasn't, and I will not allow it
- 22 in.
- MR. JOHNSON: So Your Honor, as we've
- 24 stipulated to allow the e-mail correspondence with
- 25 somebody from the FDA for Mr. Haffner, so that will be

- 1 allowed in, but this e-mail correspondence with
- 2 somebody else from the FDA that I've offered will not
- 3 be allowed in; is that correct?
- 4 JUDGE CAILLE: It's not allowed in because
- 5 Mr. Haffner has not stipulated to it. The others you
- 6 have stipulated to. If you had raised that issue about
- 7 the other e-mail, I suppose I would have also thought
- 8 that it not be a good idea to have volumes of e-mail in
- 9 where the person who is the declarant is not available
- 10 for cross-examination. In any event, those also will
- 11 only go to weight.
- 12 MR. JOHNSON: That is my thought, Your Honor.
- 13 I don't mean to argue with you about it, but since
- 14 we've got correspondence here related to people from
- 15 the FDA interpreting the FDA's guideline that we should
- 16 put it all in front of the Commission and let the
- 17 Commission weigh it for what it's worth, but I guess I
- 18 understand your ruling.
- 19 JUDGE CAILLE: Thank you. And is that it for
- 20 your exhibit questions or issues?
- MR. JOHNSON: I guess we had one other
- 22 question. The pleadings we filed yesterday
- 23 electronically needed to be filed with the records
- 24 office.
- 25 JUDGE CAILLE: The exhibit list no, that does

- 1 not have to be filed.
- 2 MR. JOHNSON: So we are good with what we did
- 3 electronically yesterday.
- 4 JUDGE CAILLE: Yes. And Mr. Haffner, I
- 5 believe you have a remaining issue?
- 6 MR. HAFFNER: There is one other scheduling
- 7 issue that benefits me and Mr. Johnson, but Mr. Johnson
- 8 has an expert witness that will be testifying first
- 9 thing, I think, September 20. We were just going to
- 10 ask if Your Honor could possibly consider having my
- 11 cross-examination of Mr. Johnson's witnesses moved to
- 12 the 10th. Part of it is because of the expense of his
- 13 witness having to travel down here in addition to
- 14 already traveling from DC to the SeaTac area.
- 15 JUDGE CAILLE: How many witnesses do we have
- 16 coming? Would that affect other witnesses as well?
- 17 MR. JOHNSON: No, Your Honor. Kent is much
- 18 more convenient for all of our witnesses because the
- 19 Stericycle people have offices in Kent. This
- 20 particular fellow is coming across the country to
- 21 testify, so the proximity to SeaTac allows him to get
- 22 in and get out without, perhaps, involving another day,
- 23 so if Kent were available, it would be helpful.
- 24 JUDGE CAILLE: I will look into that and see
- 25 if Kent is available, and you are agreeable to that,

- 1 Mr. Haffner?
- 2 MR. HAFFNER: Yes, Your Honor.
- JUDGE CAILLE: How about you, Mr. Trautman?
- 4 MR. TRAUTMAN: This is for the September 20th
- 5 day?
- 6 JUDGE CAILLE: Is it just for that one day?
- 7 MR. JOHNSON: It would be more convenient for
- 8 our witnesses and I think for Mr. Haffner and his
- 9 witnesses to do it all three days there.
- 10 JUDGE CAILLE: I will look into it to see
- 11 what is available, and I don't know that we will do all
- 12 three days up there.
- MR. TRAUTMAN: I'm just wondering whether we
- 14 are going to need three days. I'm looking at
- 15 Mr. Haffner's estimates and I see a total of two hours,
- 16 maybe four, for all the witnesses, plus whatever Staff
- 17 has.
- 18 MR. HAFFNER: I don't anticipate needing
- 19 three days for the cross-examination of the four
- 20 Stericycle witnesses. However, I understand that
- 21 Mr. Johnson will want to have redirect, and I
- 22 anticipate that what he thinks he will need in terms of
- 23 redirect to determine that.
- JUDGE CAILLE: You won't be able to tell us
- 25 now until you hear the cross.

- 1 MR. JOHNSON: The principle reason to ask
- 2 they be in Kent is for this one fellow traveling across
- 3 the country and to testify on the 20th.
- 4 JUDGE CAILLE: Maybe we can try to
- 5 accommodate the 20th.
- 6 MR. JOHNSON: The other folks can come to
- 7 Olympia.
- 8 MR. TRAUTMAN: Staff can accommodate whatever
- 9 the Bench and the parties need.
- 10 MR. HAFFNER: Given the concerns about
- 11 traffic, it would make sense we start at 9:30 in Kent
- 12 to accommodate Staff and Your Honor.
- JUDGE CAILLE: Yes. We are going to be
- 14 driving every day.
- MR. TRAUTMAN: Are you referring to the
- 16 September date as well?
- 17 MR. HAFFNER: Yes. My preference would be
- 18 nine o'clock, but to allow you time for traffic, I have
- 19 no problem with 9:30.
- 20 JUDGE CAILLE: So everybody is clear, the
- 21 hearings next week will be starting at nine o'clock. I
- 22 will look into that and I will probably tell you next
- 23 week. Before I kind of summarize, is there anything
- 24 further from the parties?
- 25 MR. JOHNSON: There is one other thing, which

- 1 is that Mr. Haffner has requested the opportunity to
- 2 present his witness, Jeffrey Gibbs, by telephone, and
- 3 while the Administrative Procedure Act allows that in
- 4 certain cases, I think it does very much limit our
- 5 ability to cross-examine him, and I think it makes it
- 6 much more difficult for Your Honor to evaluate his
- 7 demeanor, his credibility, all the nonverbal things
- 8 that come out through testimony in person.
- 9 I also think that if we were able to see him,
- 10 we would be able to see whether he is reading things,
- 11 what he's referring to in front of him; whereas if we
- 12 are on the telephone, we don't know where the
- 13 information he's presenting to the hearing is coming
- 14 from, whether it's coming from some text he's looking
- 15 at or whether it's coming from his own knowledge and
- 16 expertise.
- 17 So for those reasons, I would like to request
- 18 that if he's going to testify by telephone that we
- 19 arrange video conferencing. I assume that the
- 20 Commission has that capability, but in any event, if we
- 21 cannot arrange video conferencing, then I would object
- 22 to having his testimony by telephone because it reduces
- 23 our ability to conduct effective cross-examination.
- JUDGE CAILLE: Any response, Mr. Haffner?
- MR. HAFFNER: Yes, Your Honor. I think the

- 1 Administrative Procedures Act clearly provides for the
- 2 allowance of testimony by telephone, and all of those
- 3 factors that Mr. Johnson raises are raised every time
- 4 this issue comes up of testifying by telephone. It's
- 5 certainly not as observant a situation as when you have
- 6 a person in front of you, but the APA allows for that.
- 7 This witness would have to be flown out from Washington
- 8 DC at great expense. Mr. Johnson has a witness that is
- 9 doing that, but I think his client is more able to fund
- 10 that expense than is my client, and again, the Act
- 11 allows for this type of testimony.
- 12 JUDGE CAILLE: Anything further, Mr. Johnson?
- 13 MR. JOHNSON: I note that under the APA, RCW
- 14 34.05.449, Subparagraph 3, the presiding officer has
- 15 the discretion to allow all or part of a hearing to be
- 16 conducted by telephone but it's limited by where the
- 17 rights of the parties will not be prejudiced thereby.
- 18 It does not say prejudiced a little or not
- 19 prejudiced a lot. It just says no prejudice, and I
- 20 think we are clearly prejudiced by allowing a critical
- 21 witness to testify telephonically when we cannot
- 22 observe his demeanor and cannot determine what
- 23 materials he may be reviewing or looking at during the
- 24 course of his testimony.
- 25 The APA provision goes on to say that each

- 1 party in the hearing must have an opportunity to
- 2 participate effectively in -- to hear and effectively
- 3 and economically feasible to see the entire proceeding
- 4 while it's taking place. That was the source of my
- 5 thought about video conferencing.
- 6 If we can arrange video conferences that will
- 7 allow us to see Mr. Gibbs while he's testifying, I
- 8 wouldn't have a problem. In the absence of that, I
- 9 believe we are prejudiced, and I do not believe that
- 10 the APA in that permits telephonic testimony.
- 11 JUDGE CAILLE: Since I don't have the APA
- 12 with me, I'm going down to my office and review that,
- 13 and also after reviewing it, I might consider or check
- 14 whether there is video conferencing available, so let's
- 15 take about a 10-minute recess.
- 16 (Recess.)
- JUDGE CAILLE: I have reviewed RCW 34.05.449
- 18 as to the rights of the parties as to hearings with
- 19 witnesses testifying over the phone, and it does read
- 20 as Mr. Johnson states.
- 21 However, this is something that is commonly
- 22 done in our hearings at the Commission, and I also
- 23 checked with our chief administrative law judge, Bob
- 24 Wallis, and he has indicated to me that at the EFSEC
- 25 hearings, they often have expert witnesses testifying

- 1 over the phone in those proceedings. So, Mr. Johnson,
- 2 your objection is overruled. Is there anything further
- 3 from the parties?
- 4 MR. HAFFNER: No, Your Honor.
- 5 JUDGE CAILLE: All right. Thank you, and --
- 6 MR. JOHNSON: Just one other thing. Just let
- 7 me be reminded of what Your Honor's prior ruling was on
- 8 this one issue. Mr. Haffner gave me, as I mentioned, a
- 9 stack of materials this morning. I believe it was your
- 10 ruling that we would be free to add these to the
- 11 cross-examination lists that we are going to be working
- 12 up.
- 13 JUDGE CAILLE: That is correct, Mr. Johnson,
- 14 and just to remind the parties, I will be sending you
- 15 the list of cross-examination exhibits that I have
- 16 provided to you in hard copy. I will send that to you
- 17 electronically so you can add your descriptions in and
- 18 add in your cross-examination exhibits under the
- 19 appropriate witnesses since I was not able to do that.
- 20 All right. Thank you everyone --
- 21 MR. HAFFNER: Your Honor, I guess to clarify
- 22 that, when we do the cross-examination exhibits, you
- 23 want us to list them first person only that they will
- 24 appear.
- 25 JUDGE CAILLE: Yes. They don't have to be in

## each, just because they will be admitted at that point or not. MR. HAFFNER: Thank you, Your Honor. JUDGE CAILLE: Thank you. (Prehearing adjourned at 11:03 a.m.)