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- 8. When we were applying for our 510K everything concerning our containers was pending. That is why we used the word "pending" in the application to describe the establishment registration number of the manufacturer and the distributor.
- The use of the word "approved" in our Sharps Disposal Service Contract was intended to refer to DOT approval, not FDA approval. We intended the phrase "510k FDA" to indicate we had received our notification from the FDA that we could market the containers. We now see how using the two items together could be misconstrued and have corrected it where we can.
- 10. To the best of my knowledge Sure-Way Systems has no violations over the past 15 years other than the ones that have been presented in this hearing by Stericycle. Medical waste is a regulatory rich environment and over 15 years to have so few fines issued shows that the severity of the violations was not considered flagrant. Sure-Way takes great effort as a small company to run a clean effective and reputable company. Reputation is everything in the medical service field. Sure-Way works hard to comply with the laws and if a problem is found we are proactive and quick to correct it.

DATED this 1st day of August, 2005 at Date leafer, Montana.

Sary Chilcott

I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 1, 2005, at Allery N. Gibbs

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1	accurate numbers possible prior to filing the return thereby minimizing amendment of returns filed, a
2	potentially costly mistake for clients.
3	DATED this 1 <sup>st</sup> day of August, 2005 at Salt Lake City, Utah.
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5	David Sullivan
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