Validation Report for a Medical Waste Autoclave

Testing Date **November 27-29, 2011**

A. Installation Site

Contact Name:	Dale Sullivan	Title:	General Manager
Facility Name:	MedWaste Solutions, NC		
Address:	148 Boxwood Lane		
City, State, Zip:	Gastonia, NC 28054		
Phone:	704-865-7550	E-mail:	medwastesolutionnc@gmail.com

Permit No.	Scan Date	DIN
3615	December 14, 2011	15766

RECEIVED
December 13, 2011
Solid Waste Section
Asheville Regional Office

B. Equipment

1. Equipment Information

Manufacturer:	OnSite Sterilization, LLC		
Model Number:	VariClave VC250	Serial No:	02-0005
Rated Capacity (lbs/hour or lbs/cycle):	Varies according to Characterization, Containerization and Weight		
Vessel Size:	12 feet x5 feet		
Cart/Bin Size:	1.75 cubic yards	Carts/Bins per cycle:	2

2. Manufacturer's Recommended Operating Parameters

Pressure Set Point:	15 psig (Operating at 18.1 – 19.5psig)		
Temperature Set Point:	250 degrees F (operating at 254-263 degF)		
Pre-Vacuum	Yes X No ❑	Vacuum Set Point:	15 inHg + timer setting
Length of Vacuum:	Variable	Number of Pre-Vacuum Pulses:	1 to 5
Length of Residence Time:	Variable – Heavier weight results in longer residence time.		
Maximum Weight Criteria	Per Bin/Cart: By Validation	Per Load:	By Validation

C. Regulatory Requirements

Log Reduction of Spores:	4 log 10		
Organism:	*Geobacillus Stearothermophilus*		
Minimum Residence Time:	45 minutes, or other parameters shown to be effective [15 ANCAC 13B.1207.2(a)]		
At Temperature:	250 Deg F	At Pressure:	15 psig

D. Testing Information

1. Biological Indicators

Manufacturer:	Raven Labs	Type:	ProSpore Ampoules, Cat # PS1-6-100
Lot Number:	244	Organism:	*Geobacillus Stearothermophilus*
ATCC#:	7953	Population:	4.0x10^6 cfu

2. Tested By:

Name(s):	Timothy Barrett	Title:	Vice President of Engineering Services
Company:	OnSite Sterilization, LLC		
Address:	319 Commerce Ct., Suite 103		
City, State, Zip:	Pottstown, PA 19464		
Phone:	610-495-8214	E-mail:	tbarrett@askonsite.com

E. General Description of Testing

Testing was performed in accordance with the attached protocol for waste types:

Red Bag & Large Sharps Waste Suction Canister Waste

F. Results

Use blank Results Tables as needed to record results of each Validation Cycle. Mark each set of Tables with an Exhibit Number and record below. Mark all temperature/pressure graphs for all sensors with an Exhibit Number and corresponding validation cycle and include in list below.

Exhibit Number	Description
1 a-c	Red Bag & Large Sharps Cycle #7; (a)Results, (b)Chart, (c)Cycle Report
2 a-c	Suction Canister Cycle #6; (a)Results, (b)Chart, (c)Cycle Report

G. Validated Operating Parameters

Type of Waste	**A** (Red Bag& Lg. Sharps)	B (Suction Canister)	
Cycle Time *(Not including cool down)*	1 hrs or more	8.5 hrs or more	
Residence Time:	.50-.54 hrs or more	6.39-7.76 hrs or more	
Temperature:	250 Deg F	250 Deg F	
Pressure:	15 – 18.1 psig	15 – 18.1 psig	
Number of Vacuum Pulses:	1	5	
Vacuum Set Point:	15 inHg plus 420 sec	15 inHg plus 420 sec	
Maximum Weight:	1,000	1,000	

NV = Not Tested or Validated

H. Recommendations/Comments

1) The VariClave VC250 automatically adjusts the cycle residence time according to the weight of the load to ensure proper treatment. Heavier loads will automatically have longer residence times. The weights of the loads tested are at random and determined only by the density of the waste available at the time of testing.

2) The VariClave VC250 automatically adjusts the number of vacuum pulses according to waste type in order to ensure steam penetration through waste packaging and throughout the waste.

3) Suction Canister Test performed with 2,400ml polycarbonate canister supplied by OnSite. These results validate the cycle for suction canisters up to and including this very large size.

4) Municipal Waste was used for testing in lieu of genuine Regulated Medical Waste, which was not available at the facility at the time of testing.

5) The VariClave VC250 has been validated to be efficacious with a pressure and temperature residence time of less than 45 minutes in accordance with 15 ANCAC 13B.1207.2(a).

J. Attachments

Attachments Include:

A. Test Protocol

B. Photographs

I. Attested

November 30,2011

Signature *Date*

Name: Timothy A. Barrett Title: VP Engineering Services Company: OnSite Sterilization, LLC

Exhibit ___1a____ Validation Cycle ___7_____

Internal Waste Temperature Results (Graphs Attached)

	Bin Weight	Test Package Type	Recorder Number	Time to Reach 250°F	Time at 250°F	Minimum Time at 250°F for Treatment (based on D-Value) 4log10	6log10	Cycle Successful (Y or N)
Cart 1	274	Red Bag	02600	48 min	30.5 min	12 min	18 min	Y
		Red Bag	18921	48 min	30 min	12 min	18 min	Y
		Large Sharps	02609	48 min	28 min	12 min	18 min	Y
Cart 2	315	Red Bag	02625	48.5 min	33 min	12 min	18 min	Y
		Red Bag	21964	48 min	30 min	12 min	18 min	Y

dnrt= Did Not Reach Temperature
na = Not Applicable

Internal Waste Biological Indicator Results

	Bin Weight	Test Package Type	Sample Number	Sample Population	24 Hour Observation	48 Hour Observation
Cart 1	274	Red Bag	B1	4.0 X 10^6	NG	NG
		Red Bag	B2	4.0 X 10^6	NG	NG
		Large Sharps	S1	4.0 X 10^6	NG	NG
Cart 2	315	Red Bag	G1	4.0 X 10^6	NG	NG
		Red Bag	G2	4.0 X 10^6	NG	NG
Control	na	Unprocessed	C1	4.0 X 10^6	G	G

G = Growth
NG = No Growth
na = Not Applicable

Exhibit 1b

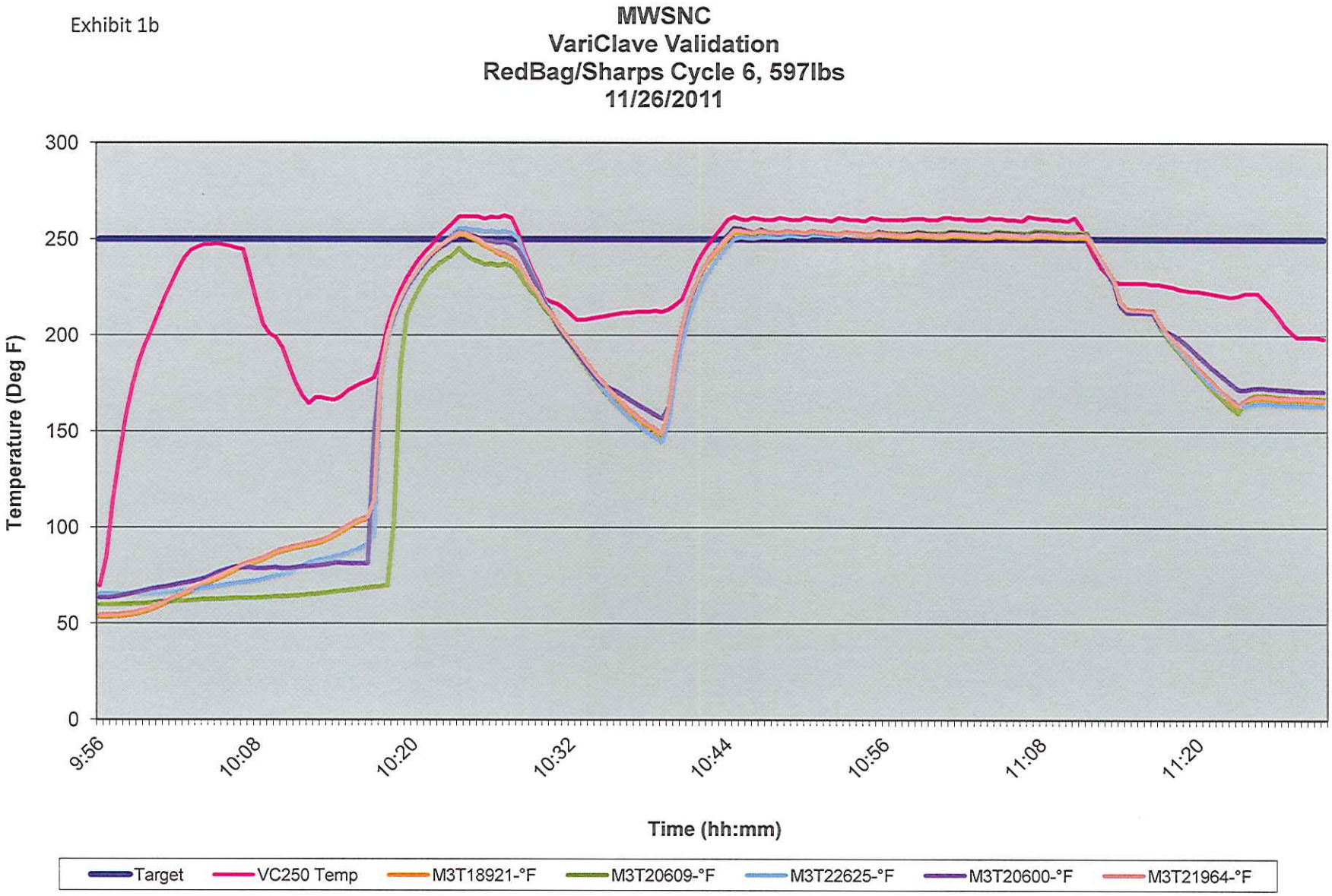

MWSNC
VariClave Validation
RedBag/Sharps Cycle 6, 597lbs
11/26/2011
Temperature (Deg F)
300
250
200
150
100
50
0
9:56
10:08
10:20
10:32
10:44
10:56
11:08
11:20
Time (hh:mm)
Target
VC250 Temp
M3T18921-°F
M3T20609-°F
M3T22625-°F
M3T20600-°F
M3T21964-°F

Exhibit 1c

Cycle Number:	7	
Cycle Type:	Red Bag	
Weight:	597	
User ID:	1	
User Name:	OnSite	
Start Time Stamp:	9:56:46	11/26/2011
End Time Stamp:	11:31:46	11/26/2011
Spore Test:	No	

Time Stamp	Pressure	Tempeature
11/26/2011 9:56	0.33498767	69.6136322
11/26/2011 9:57	1.882095456	84.56689453
11/26/2011 9:57	1.300274611	113.8649597
11/26/2011 9:58	2.935536861	136.5806427
11/26/2011 9:58	4.41432333	158.1163025
11/26/2011 9:59	5.734437466	173.6964417
11/26/2011 9:59	7.047933102	186.2343292
11/26/2011 10:00	8.105787277	195.1952209
11/26/2011 10:00	9.322313309	202.9576416
11/26/2011 10:01	10.7349844	211.3285217
11/26/2011 10:01	11.97355366	219.6993866
11/26/2011 10:02	13.412673	226.8902283
11/26/2011 10:02	15.0082655	234.0626373
11/26/2011 10:03	16.25785255	240.0365601
11/26/2011 10:03	17.03360939	244.2220001
11/26/2011 10:04	17.27823639	246.0289307
11/26/2011 10:04	17.17465401	247.2274017
11/26/2011 10:05	17.20550919	247.2274017
11/26/2011 10:05	17.17245102	247.8174286
11/26/2011 10:06	17.12837601	247.2274017
11/26/2011 10:06	17.02258873	246.6373901
11/26/2011 10:07	16.98732758	245.4389191
11/26/2011 10:07	16.1961441	244.8488922
11/26/2011 10:08	9.183470726	231.6656952
11/26/2011 10:09	4.658953667	217.9293365
11/26/2011 10:09	2.228101254	205.9814758
11/26/2011 10:10	1.110744476	200.8741455
11/26/2011 10:10	0.804405272	198.7906342
11/26/2011 10:11	-3.153720856	193.4251709
11/26/2011 10:11	-8.211572647	184.4273987
11/26/2011 10:12	-11.76694489	175.4849396
11/26/2011 10:12	-14.33057785	168.9025574
11/26/2011 10:13	-17.19669342	164.7171173
11/26/2011 10:13	-23.18181801	167.6856384
11/26/2011 10:14	-27.13884163	167.7040863
11/26/2011 10:14	-29.19173622	167.1140594
11/26/2011 10:15	-28.69586754	166.5056
11/26/2011 10:15	-26.14710617	168.2940979

11/26/2011 10:16	-26.05289268	171.2810669
11/26/2011 10:16	-26.20661163	173.0879974
11/26/2011 10:17	-26.39999962	174.894928
11/26/2011 10:17	-26.55867958	176.0749512
11/26/2011 10:18	-18.45619774	177.8634491
11/26/2011 10:18	-10.69091034	188.0412598
11/26/2011 10:19	-4.487604141	204.1745453
11/26/2011 10:19	0.361433059	214.9239349
11/26/2011 10:20	2.704130888	223.3132477
11/26/2011 10:20	4.815425873	229.8956299
11/26/2011 10:21	6.433058262	235.2611084
11/26/2011 10:21	8.191735268	240.0550079
11/26/2011 10:22	9.826997757	244.240448
11/26/2011 10:22	11.40275383	247.8174286
11/26/2011 10:23	12.97190094	252.0213013
11/26/2011 10:23	14.34710884	255.0267029
11/26/2011 10:24	15.99559212	258.0136719
11/26/2011 10:24	17.70578384	261.5906372
11/26/2011 10:25	17.38842964	261.5906372
11/26/2011 10:25	17.84903526	261.6090698
11/26/2011 10:26	17.43030357	261.6090698
11/26/2011 10:26	17.00936699	260.410614
11/26/2011 10:27	17.56473923	261.6090698
11/26/2011 10:27	17.14600563	261.0006409
11/26/2011 10:28	17.81377602	262.1990967
11/26/2011 10:28	17.37520599	261.0006409
11/26/2011 10:29	13.50743675	253.8097992
11/26/2011 10:29	9.234161377	243.0604095
11/26/2011 10:30	6.325067043	234.707962
11/26/2011 10:30	4.271075249	228.0518341
11/26/2011 10:31	1.26721704	219.1278076
11/26/2011 10:31	0.251239151	217.3577576
11/26/2011 10:32	-2.618183136	216.1777191
11/26/2011 10:32	-5.166942596	213.7623444
11/26/2011 10:33	-7.185123444	210.7753754
11/26/2011 10:33	-9.198345184	207.7884064
11/26/2011 10:34	-11.04793358	207.7699738
11/26/2011 10:34	-13.00661087	208.3784332
11/26/2011 10:35	-15.16859627	208.9684448
11/26/2011 10:35	-16.9685936	209.5584564
11/26/2011 10:36	-18.22809982	210.1853638
11/26/2011 10:36	-19.3537178	210.7753754
11/26/2011 10:37	-20.67272949	211.365387
11/26/2011 10:37	-21.54545593	211.3838348
11/26/2011 10:38	-22.19008255	211.9554138
11/26/2011 10:38	-23.10743713	211.9554138
11/26/2011 10:39	-24.87272835	211.9738464

11/26/2011 10:39	-28.53719139	212.5823059
11/26/2011 10:40	-28.00165367	211.9554138
11/26/2011 10:40	-11.00330734	213.1723175
11/26/2011 10:41	-4.368595123	215.550827
11/26/2011 10:42	1.34215045	218.537796
11/26/2011 10:42	4.163087368	226.9086761
11/26/2011 10:43	6.856200218	235.2979889
11/26/2011 10:43	9.40826416	241.8803711
11/26/2011 10:44	11.40716267	247.2458496
11/26/2011 10:44	13.30247974	251.4497223
11/26/2011 10:45	15.34104729	255.6351624
11/26/2011 10:45	17.28925705	259.8390503
11/26/2011 10:46	18.07823563	261.6090698
11/26/2011 10:46	17.61101723	260.4290466
11/26/2011 10:47	17.21212196	259.8021545
11/26/2011 10:47	18.17741203	261.0190735
11/26/2011 10:48	17.61322403	260.4290466
11/26/2011 10:48	17.34435081	259.8390503
11/26/2011 10:49	17.08209419	259.8390503
11/26/2011 10:49	17.85785103	261.0190735
11/26/2011 10:50	17.55592346	260.4290466
11/26/2011 10:50	17.31790543	259.8390503
11/26/2011 10:51	17.1019268	259.8390503
11/26/2011 10:51	17.95482063	261.0190735
11/26/2011 10:52	17.64187241	260.4290466
11/26/2011 10:52	17.43250656	259.8021545
11/26/2011 10:53	17.22313881	259.8390503
11/26/2011 10:53	17.03581238	259.2305908
11/26/2011 10:54	17.82699585	261.0190735
11/26/2011 10:54	17.59118462	260.4290466
11/26/2011 10:55	17.39944839	259.8390503
11/26/2011 10:55	17.22534561	259.8390503
11/26/2011 10:56	17.06446457	259.2305908
11/26/2011 10:56	17.88429642	261.0190735
11/26/2011 10:57	17.65289307	260.4290466
11/26/2011 10:57	17.46335983	259.8390503
11/26/2011 10:58	17.29366302	259.8390503
11/26/2011 10:58	17.13057899	259.8390503
11/26/2011 10:59	17.60000038	259.8390503
11/26/2011 10:59	17.75647545	260.4290466
11/26/2011 11:00	17.56694221	260.4475098
11/26/2011 11:00	17.39944839	260.4290466
11/26/2011 11:01	17.23856735	259.8390503
11/26/2011 11:01	17.09531784	259.8390503
11/26/2011 11:02	18.06941986	261.0190735
11/26/2011 11:02	17.72121239	261.0375061
11/26/2011 11:03	17.5449028	260.4290466

11/26/2011 11:03	17.39063263	260.4290466
11/26/2011 11:04	17.24077225	259.8390503
11/26/2011 11:04	17.09752083	259.8390503
11/26/2011 11:05	17.77851105	259.8390503
11/26/2011 11:05	17.74545479	261.0375061
11/26/2011 11:06	17.57355499	260.4475098
11/26/2011 11:06	17.47658539	260.4475098
11/26/2011 11:07	17.33113098	259.8390503
11/26/2011 11:07	17.18787956	259.8390503
11/26/2011 11:08	17.06005478	259.2305908
11/26/2011 11:08	17.91735458	261.627533
11/26/2011 11:09	17.70137787	261.0375061
11/26/2011 11:09	17.54049683	260.4475098
11/26/2011 11:10	17.4016552	260.4475098
11/26/2011 11:10	17.28264618	259.8390503
11/26/2011 11:11	17.17245102	259.8390503
11/26/2011 11:11	17.05785179	259.2305908
11/26/2011 11:12	17.90413284	261.0375061
11/26/2011 11:12	15.13608646	256.2620544
11/26/2011 11:13	11.51955986	247.8911743
11/26/2011 11:13	8.714050293	240.7003326
11/26/2011 11:14	6.549860954	235.3164215
11/26/2011 11:14	3.548208952	231.7394409
11/26/2011 11:15	1.190083861	228.1440277
11/26/2011 11:15	1.090908051	226.9455414
11/26/2011 11:16	1.068871856	226.9455414
11/26/2011 11:16	1.053441405	226.9455414
11/26/2011 11:17	1.040220261	226.9455414
11/26/2011 11:18	-0.426446915	226.9455414
11/26/2011 11:18	-3.173553467	226.3555298
11/26/2011 11:19	-5.434713364	226.3555298
11/26/2011 11:19	-7.209917068	225.7470703
11/26/2011 11:20	-8.791736603	225.1570587
11/26/2011 11:20	-10.22975159	223.9401398
11/26/2011 11:21	-11.51405144	223.3501282
11/26/2011 11:21	-12.67438126	222.7601166
11/26/2011 11:22	-14.1619854	222.7601166
11/26/2011 11:22	-15.72396755	222.1700897
11/26/2011 11:23	-17.32066154	221.5800781
11/26/2011 11:23	-18.55537224	220.9716187
11/26/2011 11:24	-19.52727127	220.3631592
11/26/2011 11:24	-14.28595352	219.7546997
11/26/2011 11:25	-10.87438011	220.3631592
11/26/2011 11:25	-5.469421387	221.5800781
11/26/2011 11:26	-0.927272797	221.5431976
11/26/2011 11:26	0.982920349	221.5800781
11/26/2011 11:27	0.698623717	217.966217

11/26/2011 11:27	0.676584303	214.3892365
11/26/2011 11:28	0.66336	210.2037964
11/26/2011 11:28	0.669972122	205.4098969
11/26/2011 11:29	0.683193266	201.8329163
11/26/2011 11:29	0.833059967	198.8275146
11/26/2011 11:30	0.760329604	198.8275146
11/26/2011 11:30	0.343799621	198.8275146
11/26/2011 11:31	-4.10578537	198.8275146
11/26/2011 11:31	-7.864465714	198.2375031

Exhibit ___2a____ Validation Cycle ___6_____

Internal Waste Temperature Results (Graphs Attached)

	Bin Weight	Test Package Type	Recorder Number	Time to Reach 250°F	Time at 250°F	Minimum Time at 250°F for Treatment (based on D-Value) 4log10	6log10	Cycle Successful (Y or N)
Cart 1	242	Suction Canister	02600	354 min	76..5 min	12 min	18 min	Y
Cart 2	349	Suction Canister	22625	348 min	82.5 min	12 min	18 min	Y

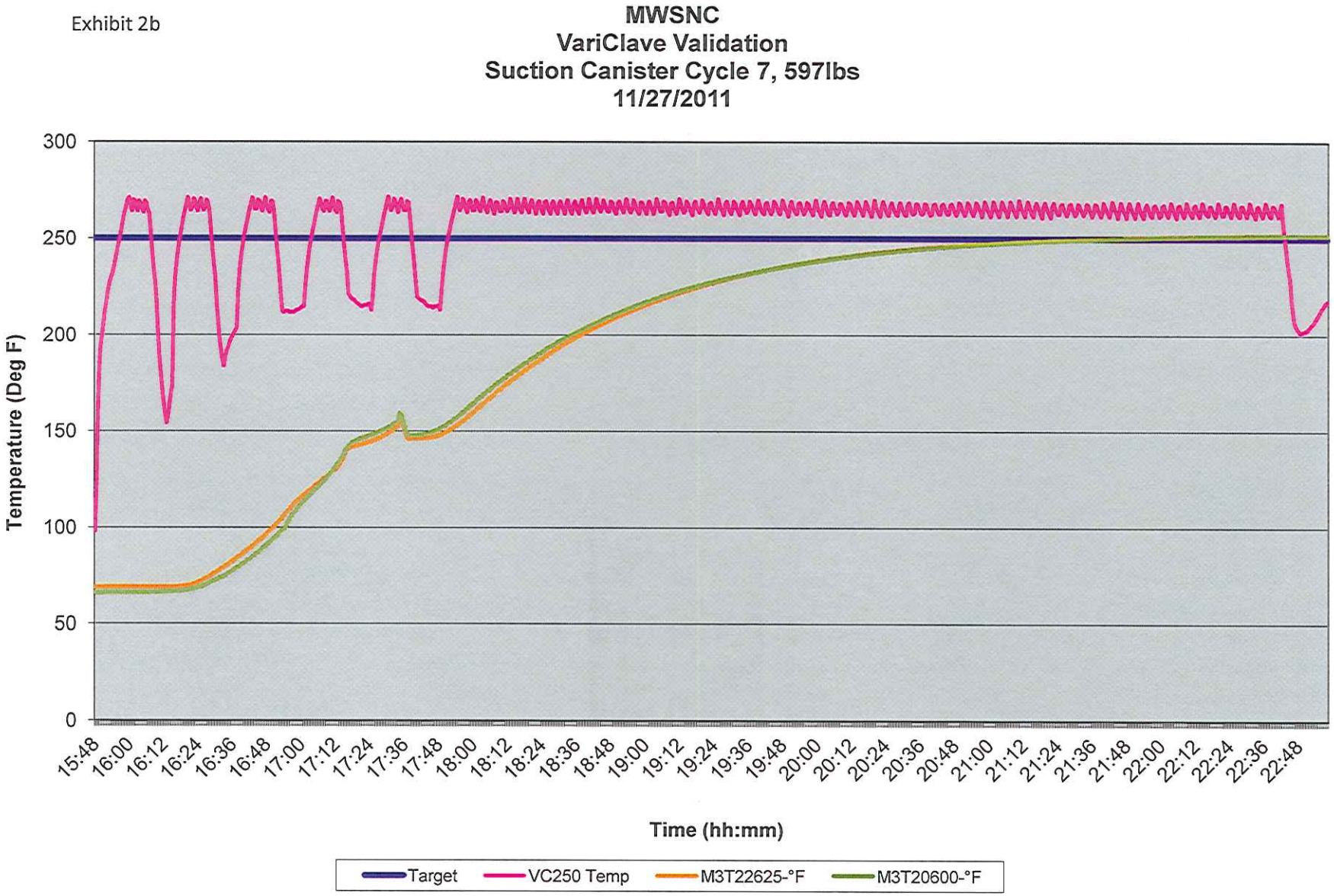
dnrt= Did Not Reach Temperature
na = Not Applicable

Internal Waste Biological Indicator Results

	Bin Weight	Test Package Type	Sample Number	Sample Population	24 Hour Observation	48 Hour Observation
Cart 1	242	Suction Canister	SC1	4.0 X 10^6	NG	NG
Cart 2	349	Suction Canister	SC2	4.0 X 10^6	NG	NG
Control	na	Unprocessed	C2	4.0 X 10^6	G	G

G = Growth
NG = No Growth
na = Not Applicable

Exhibit 2b


MWSNC
VariClave Validation
Suction Canister Cycle 7, 597lbs
11/27/2011
Temperature (Deg F)
300
250
200
150
100
50
0
15:48
16:00
16:12
16:24
16:36
16:48
17:00
17:12
17:24
17:36
17:48
18:00
18:12
18:24
18:36
18:48
19:00
19:12
19:24
19:36
19:48
20:00
20:12
20:24
20:36
20:48
21:00
21:12
21:24
21:36
21:48
22:00
22:12
22:24
22:36
22:48
Time (hh:mm)
Target
VC250 Temp
M3T22625-°F
M3T20600-°F

Cycle Number:	6		
Cycle Type:	Red Bag && Canister		Exhibit 2c
Weight:	597		
User ID:	1		
User Name:	OnSite		
Start Time Stamp:	15:48:08	11/27/2011	
End Time Stamp:	22:58:12	11/27/2011	
Spore Test:	No		

Time Stamp	Pressure	Tempeature
11/27/2011 15:48	1.197520494	97.93946838
11/27/2011 15:48	2.796692848	123.9799728
11/27/2011 15:49	2.868593931	160.9172516
11/27/2011 15:49	2.990083694	184.5362549
11/27/2011 15:50	3.148759604	194.2222748
11/27/2011 15:50	3.451237679	200.2760468
11/27/2011 15:51	3.493387699	206.3484344
11/27/2011 15:51	3.808264732	212.9982605
11/27/2011 15:52	4.123141766	217.2452087
11/27/2011 15:52	4.581817627	222.7029114
11/27/2011 15:53	4.90165472	226.3351746
11/27/2011 15:53	5.447108746	229.3713684
11/27/2011 15:54	6.203305721	231.1968079
11/27/2011 15:54	7.147933006	234.195755
11/27/2011 15:55	8.37768364	237.8466339
11/27/2011 15:55	9.766116142	241.4788971
11/27/2011 15:56	11.38016224	245.7072144
11/27/2011 15:56	13.04132271	249.3394775
11/27/2011 15:57	14.82148647	252.9903564
11/27/2011 15:57	16.63140488	257.218689
11/27/2011 15:58	18.45372009	260.8509521
11/27/2011 15:58	20.15454483	263.887146
11/27/2011 15:59	21.90743637	266.9047241
11/27/2011 15:59	23.73718834	269.940918
11/27/2011 16:00	23.82148933	271.1516724
11/27/2011 16:00	21.79586601	266.9047241
11/27/2011 16:01	20.91818047	263.887146
11/27/2011 16:01	24.01735497	269.940918
11/27/2011 16:02	23.4223156	269.3448486
11/27/2011 16:02	21.61239624	266.3086548
11/27/2011 16:03	21.18842888	263.887146
11/27/2011 16:03	24.23305702	269.3262329
11/27/2011 16:04	23.23884201	268.1340942
11/27/2011 16:04	21.53553391	265.1165161
11/27/2011 16:05	21.0520649	263.2910767
11/27/2011 16:05	24.2082634	269.3262329
11/27/2011 16:06	23.22148514	268.1340942
11/27/2011 16:06	21.53553391	265.0979004

11/27/2011 16:07	20.57355118	262.6763916
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11/27/2011 22:12	23.81652832	267.5380249
11/27/2011 22:12	22.7132206	265.0979004
11/27/2011 22:13	21.51818275	263.2724609
11/27/2011 22:13	20.29090691	261.4470215
11/27/2011 22:14	22.8074379	265.0979004
11/27/2011 22:14	24.53553581	268.7301636
11/27/2011 22:15	23.24132347	266.3086548
11/27/2011 22:15	22.07107544	263.8685303
11/27/2011 22:16	20.91818047	262.6763916
11/27/2011 22:16	21.20578384	262.0617065
11/27/2011 22:17	24.09173393	266.9047241
11/27/2011 22:17	23.79917336	266.9047241
11/27/2011 22:18	22.66611481	265.1165161
11/27/2011 22:18	21.50082779	263.2724609
11/27/2011 22:19	20.30826378	261.4470215
11/27/2011 22:19	22.72562027	264.5018311
11/27/2011 22:20	24.58760262	268.7301636
11/27/2011 22:20	23.16198349	265.6939697
11/27/2011 22:21	22.07107544	263.887146
11/27/2011 22:21	20.90578461	262.0617065
11/27/2011 22:22	21.29751968	262.0617065
11/27/2011 22:22	24.17603302	266.9047241

11/27/2011 22:23	23.80413246	266.9047241
11/27/2011 22:23	22.62644577	265.0979004
11/27/2011 22:24	21.45371628	263.2724609
11/27/2011 22:24	20.30578423	261.4470215
11/27/2011 22:25	22.76280975	265.0979004
11/27/2011 22:25	24.56032944	268.7301636
11/27/2011 22:26	23.25123978	266.3086548
11/27/2011 22:26	22.10082626	263.8685303
11/27/2011 22:27	20.91818047	262.0803223
11/27/2011 22:27	21.03223038	261.4470215
11/27/2011 22:28	24.01487541	266.9047241
11/27/2011 22:28	23.87851334	266.9047241
11/27/2011 22:29	22.73553658	265.0979004
11/27/2011 22:29	21.56528854	263.2724609
11/27/2011 22:30	20.41487503	261.4470215
11/27/2011 22:30	22.53718948	264.4645996
11/27/2011 22:31	24.7289257	268.7301636
11/27/2011 22:31	23.28842926	266.3086548
11/27/2011 22:32	22.12313843	263.887146
11/27/2011 22:32	20.99256325	262.6763916
11/27/2011 22:33	20.84379959	260.8509521
11/27/2011 22:33	23.90578461	266.3086548
11/27/2011 22:34	23.87603378	266.9047241
11/27/2011 22:34	22.72562027	265.0979004
11/27/2011 22:35	21.5677681	263.2724609
11/27/2011 22:35	20.39504242	261.4470215
11/27/2011 22:36	22.58181763	264.5018311
11/27/2011 22:36	24.6768589	268.7301636
11/27/2011 22:37	23.24132347	266.3086548
11/27/2011 22:37	22.04380226	263.887146
11/27/2011 22:38	20.89834595	262.0803223
11/27/2011 22:38	21.20578384	261.4470215
11/27/2011 22:39	24.08677673	266.9047241
11/27/2011 22:39	23.77933884	266.9047241
11/27/2011 22:40	22.56694031	265.0979004
11/27/2011 22:40	21.40909195	263.2724609
11/27/2011 22:41	20.25123978	261.4470215
11/27/2011 22:41	22.9066124	265.0979004
11/27/2011 22:42	24.06446075	268.1340942
11/27/2011 22:42	19.29669571	260.2362671
11/27/2011 22:43	15.28512192	252.9903564
11/27/2011 22:43	11.858675	246.3032837
11/27/2011 22:44	8.965287209	239.6534576
11/27/2011 22:44	6.84545517	234.195755
11/27/2011 22:45	5.042974949	229.3527374
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11/27/2011 22:47	-6.193387985	205.1376801
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11/27/2011 22:48	-10.1355381	202.7161713
11/27/2011 22:48	-11.86115646	201.5054169
11/27/2011 22:49	-13.40330505	201.5054169
11/27/2011 22:49	-14.66281033	202.1201172
11/27/2011 22:50	-15.90248108	202.1014862
11/27/2011 22:50	-16.92396545	202.7161713
11/27/2011 22:51	-17.84628105	202.7161713
11/27/2011 22:51	-18.64958572	203.9082947
11/27/2011 22:52	-19.37355232	204.504364
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11/27/2011 22:54	-21.54545593	208.7699432
11/27/2011 22:54	-21.94215012	209.9806976
11/27/2011 22:55	-12.53553581	211.191452
11/27/2011 22:55	-0.044628143	212.4021912
11/27/2011 22:56	0.21818161	214.2276459
11/27/2011 22:56	0.342149734	214.8237
11/27/2011 22:57	0.4859519	216.0158234
11/27/2011 22:57	0.557849407	217.2452087
11/27/2011 22:58	-5.290910721	217.8598938

Procedure for the Validation
VariClave VC250
MedWaste Solutions, NC
148 Boxwood Lane Gastonia, NC

Background

The purpose of validation testing is to determine the operating parameters required to achieve the efficacy standard [minimum required log reduction of spores] of the state wherein the system is operated. The testing is done at the system's maximum loading capacity; with test packages simulating the facility's specific waste stream; and using the services actually provided at that facility [steam pressure, steam quality, air pressure etc.].

The operating parameters, loading capacity, and residence time recommended by the equipment manufacturer for the facility's waste stream will be used as the initial testing point for the system.

The use of sealed spore suspension ampoules is specified.

Test packages and samples should always simulate a "representative challenge" that is anticipated for the facility.

Based on the results of the initial testing, additional tests may be required to provide sufficient data to determine the actual operating parameters specific to the facility. These additional tests may include variations in operating parameters as necessary to achieve the required efficacy.

Upon completion of the testing, a detailed report will be provided. This report will include temperature, pressure and biological indicator results. The report will also state the proper operating parameters, maximum loading capacity and waste stream components certified for the system as determined by the testing.

Test packages will be prepared as follows:

Select the test packages that are appropriate for the facility's specific waste stream from those listed below. For example, a facility that uses an outside sharps service may not require the testing of large (laboratory) sharps containers [Test Package Type B]. The remainder of the weight, in excess of the test package weight, required to achieve the manufacture's recommended maximum weight should consist of medical waste from the facility. Commercial facilities should place the test packages inside the boxes or containers consistent with the packaging in which it is processed.

Test Package Type A - "Red Bag" - e.g. Patient Rooms

1. Prepare Biological Indicators
    a. Wrap 1 ampoule and 1 programmed temperature recorder in a sheet of paper, tape with colored tape and mark with the sample number.

2. Fill an autoclavable bag (31x43-1.2mil) with a mixture of surrogate RMW to a weight typical of those found at the facility.
3. Bury the prepared Biological Indicator card in the bag of mixed material.
4. Loosely tie the bag closed.
5. Mark the outside of the bag with "TYPE A" & "PKG #"

Test Package Type B - "Suction Canister" - e.g. OR/ER/CIC

1. Prepare 1 Biological Indicators
    a. Mark ampoules for identification
        i. Wire markers work well on the neck of the ampoule
2. Obtain unused suction canisters typically in use at the facility.
3. Suction Canister Assembly (prepare canisters, one with solidifier, one with water only)
    a. Fill the first suction canister with water and solidifier following the solidifier manufacturer's directions.
    b. Using a thin dowel or rigid tube, press an ampoule into the center of the solidified water and work solidified material to fill the hole above the ampoule.
    c. Program and similarly press a temperature recorder into the solidified material.
    d. Attach the lid to the canister and plug or cap all of the holes according to the manufacturer's directions.
    e. Fill the second canister with water only, insert ampoule and temperature recorder, then seal.
6. Fill an autoclavable bag (31x43-1.2mil) with a mixture of surrogate RMW to a weight typical of those found at the facility.
4. Bury the prepared suction canister in the bag of mixed material.
5. Loosely tie the bag closed.
6. Mark the outside of the bag with "TYPE C" & "PKG #"

Test Package Type C - "Large Sharps Container" - e.g. Laboratory

1. Prepare Biological Indicators
    a. Tape 1 ampoule onto a 3x5 card
    b. Program and affix temperature recorder (if used) to the card.
    c. With permanent marker note the sample number, recorder number and position on each card.
2. Package Assembly
    a. Place 3 inches of clean, unused, "sharps" material into a 17 gallon sharps container.
    b. Place the prepared Biological Indicator card in the container
    c. Fill the balance of the container with the same mixture of surrogate material.

d. Add 32 ounces of liquid to the container

3. Secure and close the lid onto the container
4. Mark the outside of the bag with "TYPE B" & "PKG #"

The test load will be prepared as follows:

1. If bin liners are used, fit the liner into the bin.
2. Place the prepared Test Packages A, B and C, into the bins marking each bin to identify it, recording the weight of each bin and the total load weight.
3. The bag packages (A and C) are placed on the bottom of the bin and the large sharps package (B) is placed standing in the upright position.
4. Fill the balance of each bin with bagged waste material of RMW. {If the equipment is a 'Chamber Only' design [i.e. does not use bins] the test packages should be placed in the center of the load, surrounded on all sides by waste}
5. Place one temperature recorder and one pressure recorder each near the appropriate fixed sensors inside the vessel.
6. Close door and initiate the cycle as per manufacture's recommended procedure. (If machine is equipped with multiple cycle capability, separate tests must be completed or each cycle type)

Upon completion of the initial testing cycle:

1. Retrieve the ampoules and temperature/pressure recorders from the test packages and vessel, being certain to identify each by it's location within the load.

2. Download the data from the temperature and pressure recorders preparing time versus temperature or pressure graphs for all sensors.

3. Place all ampoules into the dry-bath incubator, noting or flagging each to identify it's location from with the test load.

4. Identify and place three unprocessed ampoules from each Lot used in the dry-bath incubator to serve as a positive control samples.

5. After 48 hours of incubation read and record the ampoule results. Yellow being a positive or "growth" result and purple or dark purple being a negative or "no growth" result.

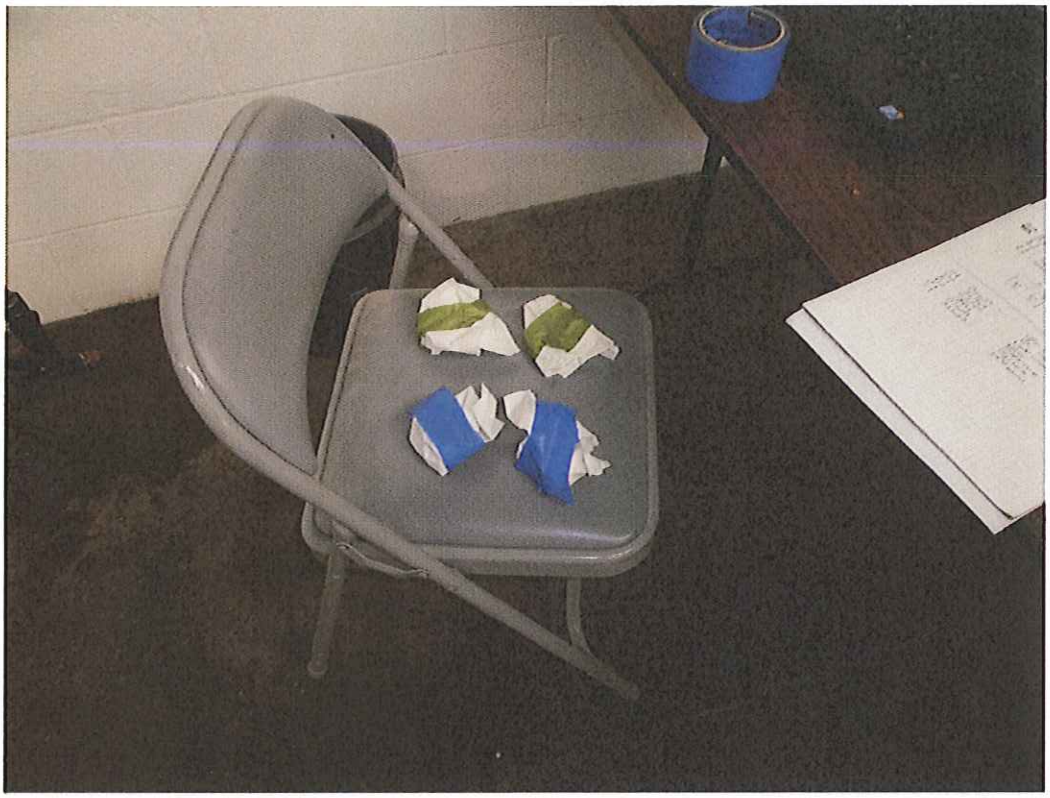
6. If any test fails adjust manufacturer's recommended operating parameters adjust the parameters as appropriate to meet the required efficacy standard. Maintain integrity of maximum loading consistent with the specific facility's waste stream.

7. Adjustments to "cycle time" will be based upon the longest time required to achieve 250 degrees Fahrenheit temperature within any of the test packages used plus an additional "residence time" of 3 minutes for each 1 log reduction required by the efficacy standard.

8. Prepare Validation Test Report with specific operating parameter recommendations.

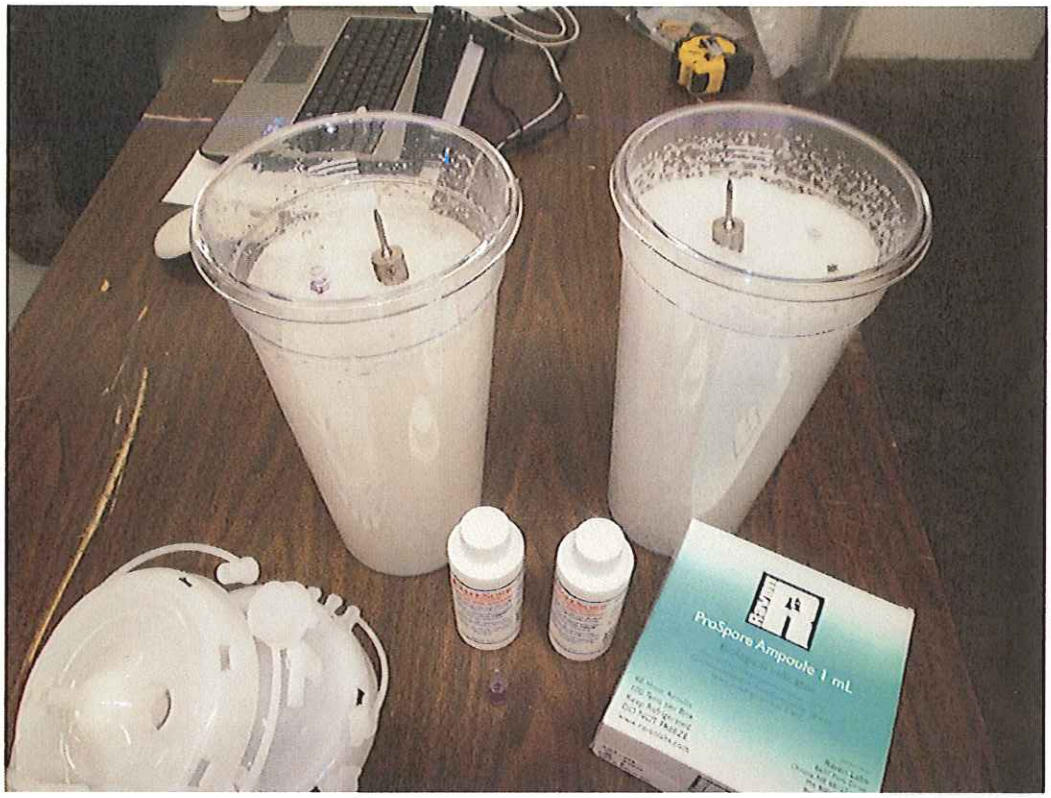
VariClave VC250 - Unit 1

VariClave VC250 Systems Installed

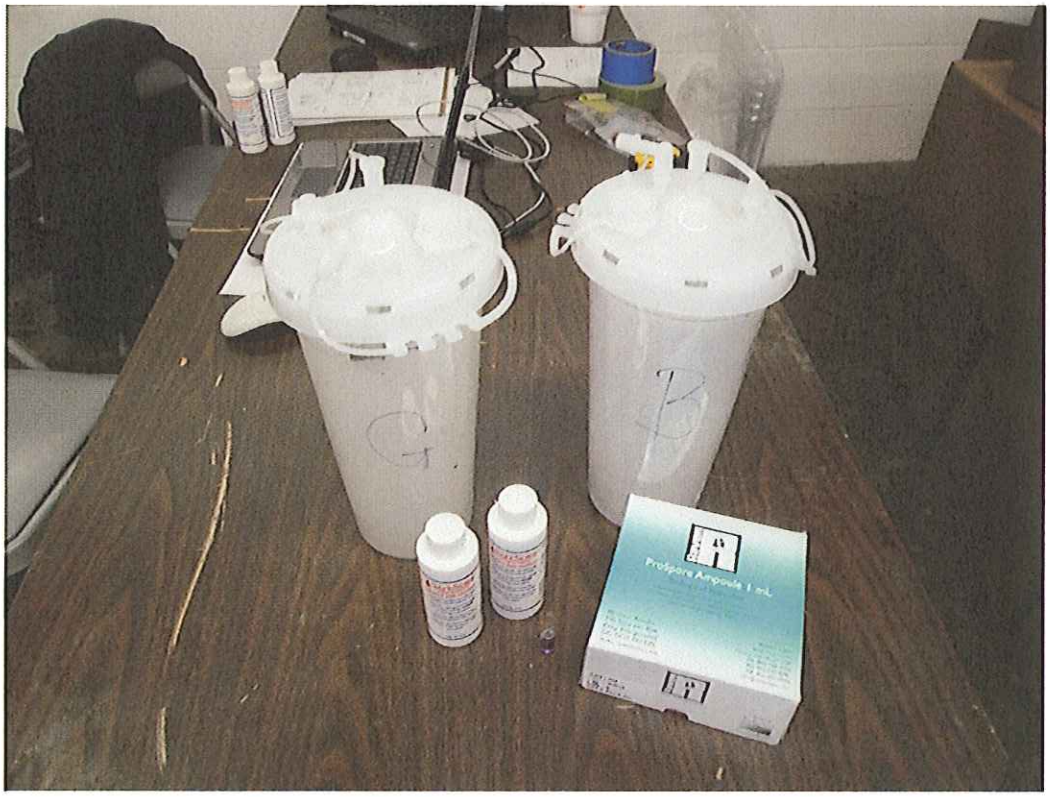


Red Bag Validation Test Bundles

Waste prepared for Validation Cycle



Suction Canister Test Packages



Suction Canister Test Packages

Suction Canister Test Packages after processing

Test Load ready for processing