CLEAN AIR SOLUTIONS

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Challenges Encountered in Decontamination of Small Spaces and Tubes

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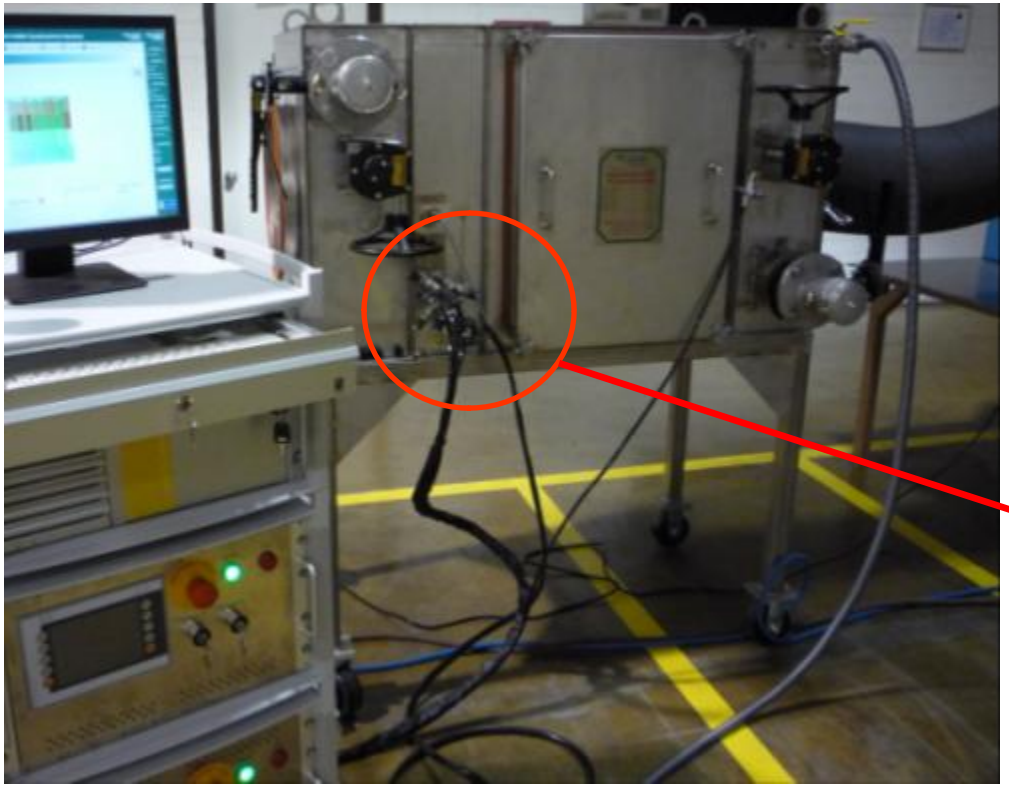
Purpose: Prospective Validation of Decontamination in HEPA Filter Containment Housings and Filter Test System

New Products: HEPA Filter Containment Housings with built-in automatic HEPA filter scanning capability

New Concept: “Hot Testing” whereas laboratory operations do not need to be interrupted for decontamination prior to filter testing. Decontaminate the filter test equipment after filter testing, without disruption to laboratory activities.

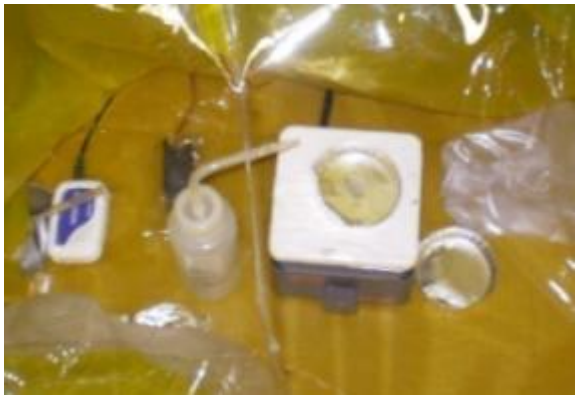


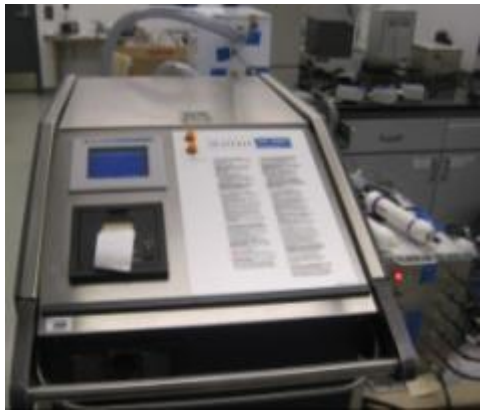
For “Hot Testing” we must decontaminate test equipment after scanning using special ports

Housing connected to Filter Scanning Equipment via Tubes

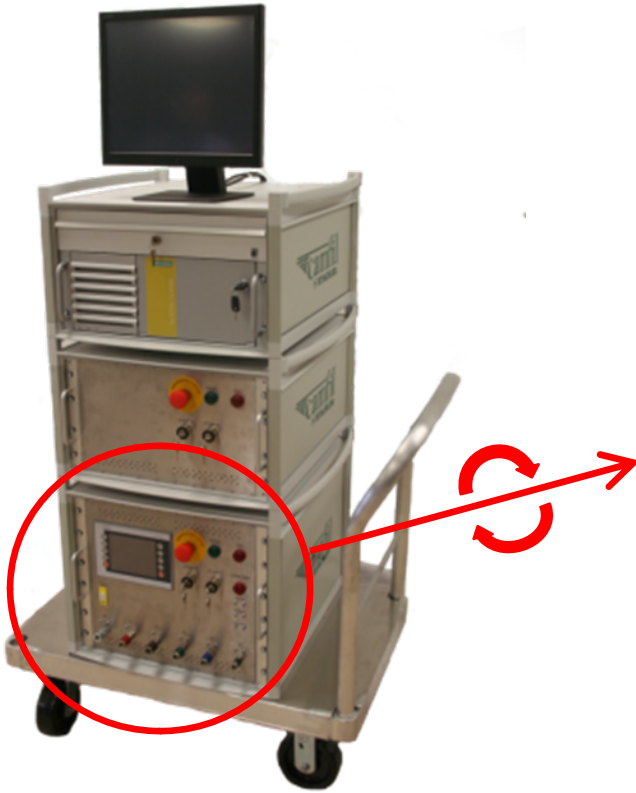
Decontamination Agents

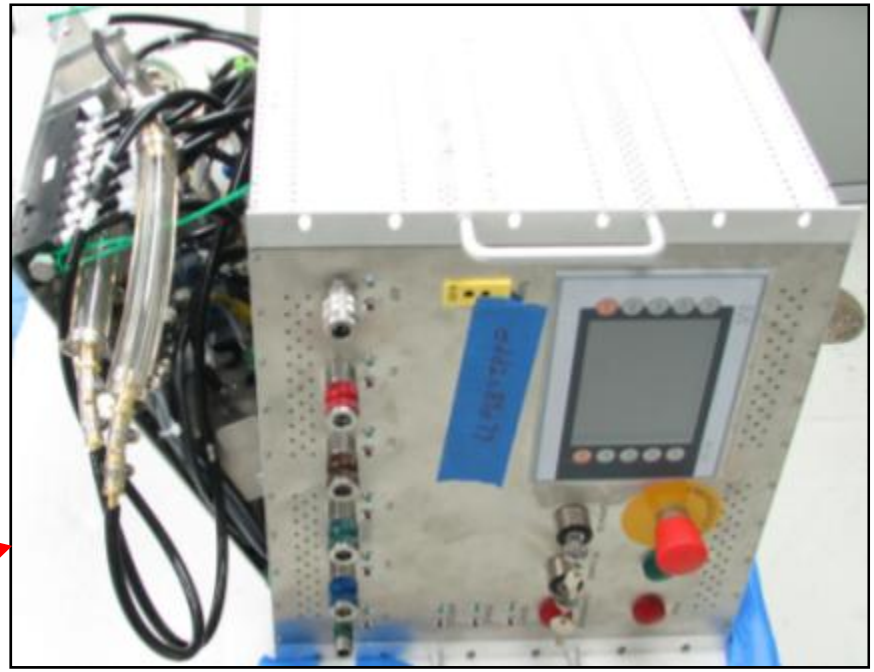
- Formaldehyde (CH_2O)
- Hydrogen Peroxide (H_2O_2)
- Chlorine Dioxide (ClO_2)





Mobile Filter Testing Equipment





Test equipment on it's side and disassembled for validation trials

HEPA Housings - Method

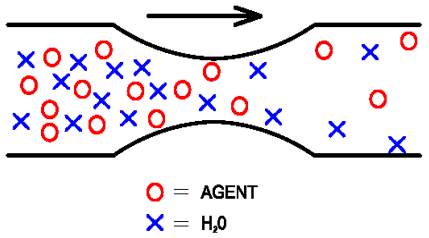
- 3 Agents Used
- 2 Housing types (CamContain and CamContain CS)
- Cycles depended upon agent type

Housing Type	Agent Type	Approximate Target Concentration	Exposure Phase (min)	Total Cycle Time (min)
CC	Formaldehyde	10.5 g/m^3	900	1150
CC - CS	Hydrogen Peroxide (VHP)	1500 ppm	30	60
CC	Chlorine Dioxide	5.0 mg/l	120	170

Physics and Chemistry

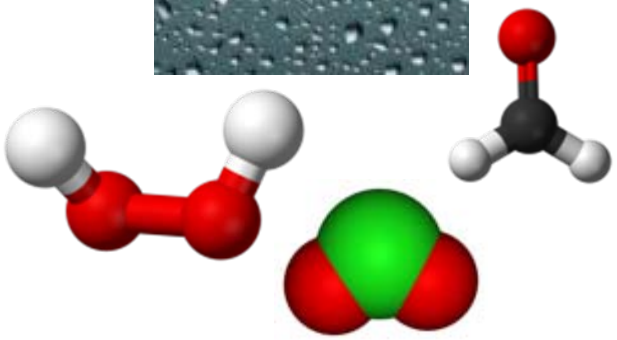
Relative Humidity needed to kill spores (Typ. >60%)
Adequate Decon Agent concentration and exposure time is required

- Low pressure areas create zones of low Relative Humidity and low Decon Agent concentration
- High pressure areas of the system raise RH levels

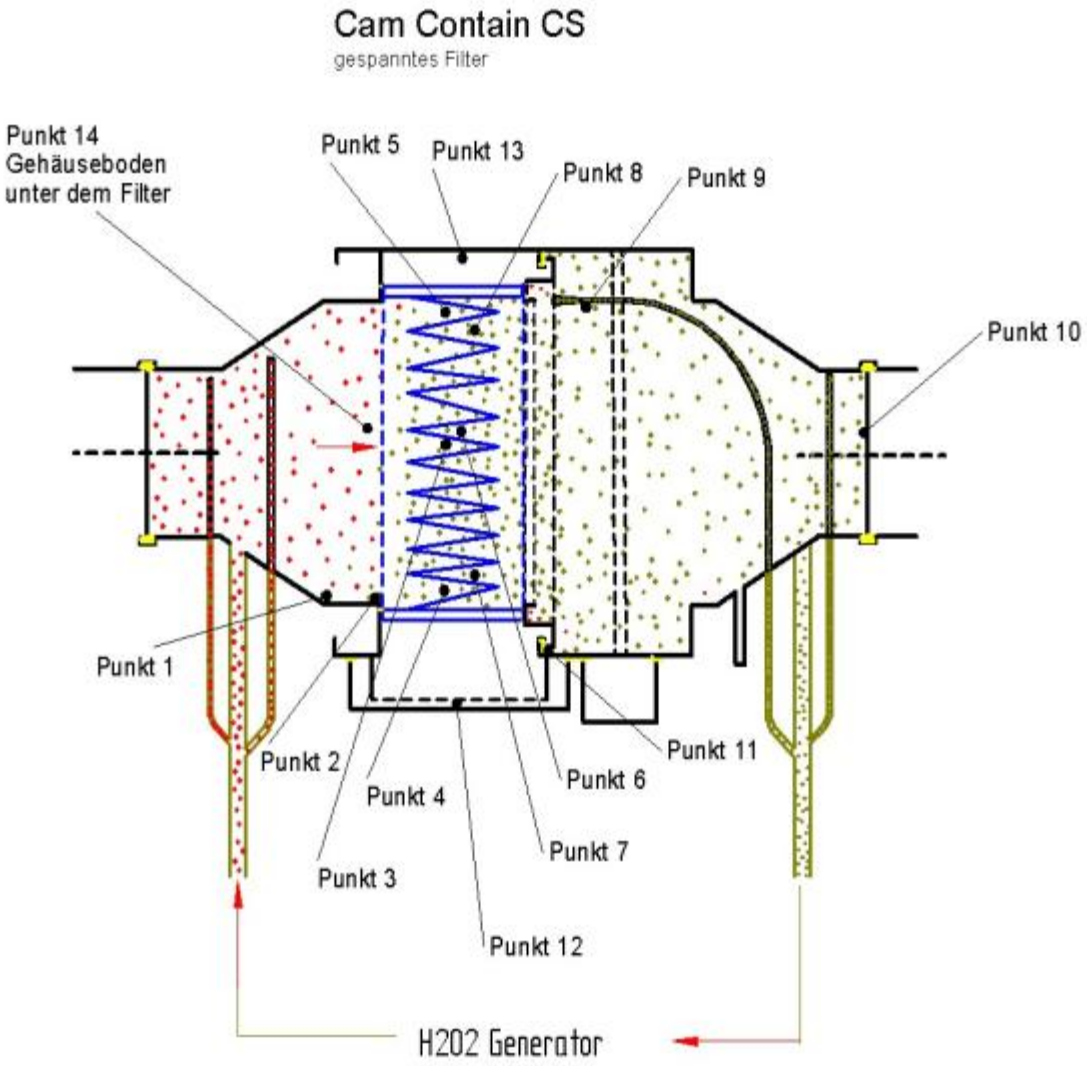


- Condensation can occur. Decontamination agent can go into solution with water
- Adsorption of moisture and decontamination agent onto surface materials can significantly reduce Relative Humidity and Agent Concentration

- Chemical reactions can occur that consume Decontamination agent



HEPA Housings – VHP Method Validation



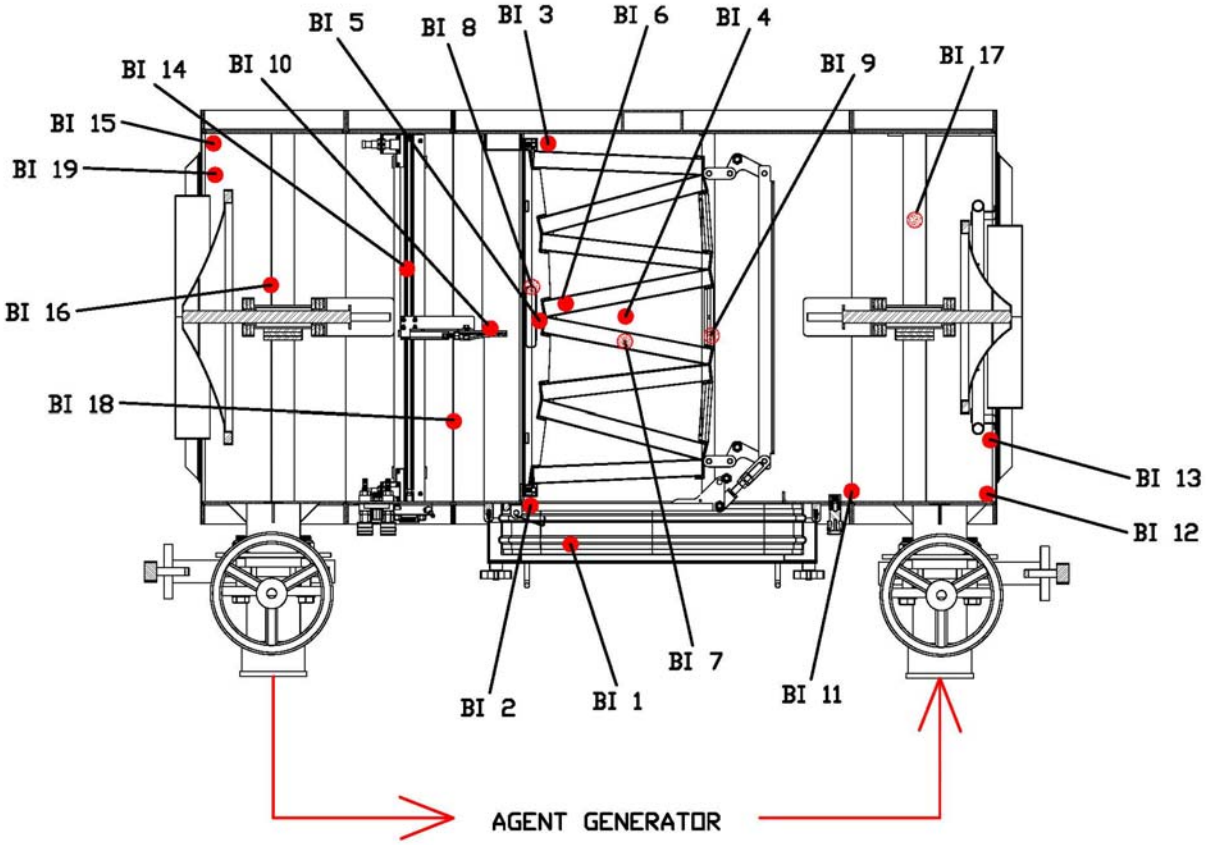
- 14 BI Locations selected
- BI's were 10^6 *G. stearothermophilus*
- Housing constructed as one unit. Non-Modular

HEPA Housing (CamContain CS) – VHP Result

Location	Description	B.I. Type		
		G. stearothermophilus 10^6 Run A3	*G. stearothermophilus* 10^6 Run B3	*G. stearothermophilus* 10^6 Run C3
1, 2	Upstream Housing Locations	0/2	0/2	0/2
3, 4, 5	Upstream Filter Pack Between Pleats	0/3	0/3	0/3
6, 7, 8	Downstream Filter Pack Between Pleats	0/3	0/3	0/3
9, 10	Downstream Housing Locations	0/2	0/2	0/2
11 - 14	Difficult locations, behind filter, clamp	0/4	0/4	0/4
	Trial Result	Pass	Pass	Pass
	Net Result	PASS		
	Negative Control	-		
	Positive Control HMV-091 (SS Disc - Apex)	+		
	Positive Control SBC-327 (SS ribbon - Apex)	+		

30 min Exposure, 1500 ppm, 85% RH

HEPA Housings – Formaldehyde and Chlorine Dioxide Method Validation



- 19 BI Locations selected on CamContain housing
- BI's were 10^6 *B. atrophaeus* for both CH_2O and ClO_2 studies
- Housing constructed in modular fashion. Internal joints were included as additional BI location test points.

HEPA Housing (CamContain) - Formaldehyde Result

Location	Description	B.I. Type		
		B. atrophaeus 10^6 Run 10	*B. atrophaeus* 10^6 Run 11	*B. atrophaeus* 10^6 Run 12
1-8	Upstream Housing Locations and Tight Spaces	1/17	0/8	0/8
9	Under bottom clamp (upstream)	0/2	0/1	0/1
10	Inside probe	0/2	0/1	n/t
11*	Gap 2 one third to one half way up front side	1/2	0/1	0/1
12*	Gap 1 End Plate Top Front (or back) Upstream	0/2	1/1	0/1
13	End Plate Bottom Back Upstream	0/2	0/2	0/2
14*	Between linear axis screw and extrusion	0/2	0/1	1/1
15-19	Downstream Housing Locations Tight Spaces	0/10	0/5	0/6
	Trial Result	Pass	Conditional Pass	Conditional Pass
	Net Result	PASS		
	Negative Control	-		
	Positive Control - GRS-090 (SS Disc - Apex)	+		
	Positive Control - PLN-060 (SS Ribbon - Apex)	+		

15 hr Exposure, 10.5 g/m^3 , 85% RH

* Position non-existent on CC-CS – VHP Trial. Naked BI, possible occlusion of inoculated site.

HEPA Housing (CamContain) – Chlorine Dioxide Result

Location	Description	B.I. Type: *B. atrophaeus* 10^6 Run 10	*B. atrophaeus* 10^6 Run 11	*B. atrophaeus* 10^6 Run 12
1-8	Upstream Housing Locations and Tight Spaces	0/15	0/11	0/11
9	Under bottom clamp (upstream)	0/1	0/1	0/1
10	Inside probe	0/1	0/1	0/1
11*	Gap 2 one third to one half way up front side	0/3	0/1	1/1
12*	Gap 1 End Plate Top Front (or back) Upstream	1/3	0/1	0/1
13	End Plate Bottom Back Upstream	0/3	0/2	0/2
14*	Between linear axis screw and extrusion	0/2	1/1	1/2
15-19	Downstream Housing Locations Tight Spaces	0/6	0/6	0/6
	Trial Result	Pass	Conditional Pass	Conditional Pass
	Net Result	PASS		

Negative Control	-
Positive Control - GRS-090 (SS Disc - Apex)	+
Positive Control - PLN-060 (SS ribbon - Apex)	+
Positive Control - CBATR-130 (Paper - SGM)	+

2 hr Exposure, Exposure 5 mg/l, (Run 12 = 1 hr Exposure), 70% RH

* Position non-existent on CC-CS – VHP Trial. Naked BI, possible occlusion of inoculated site.

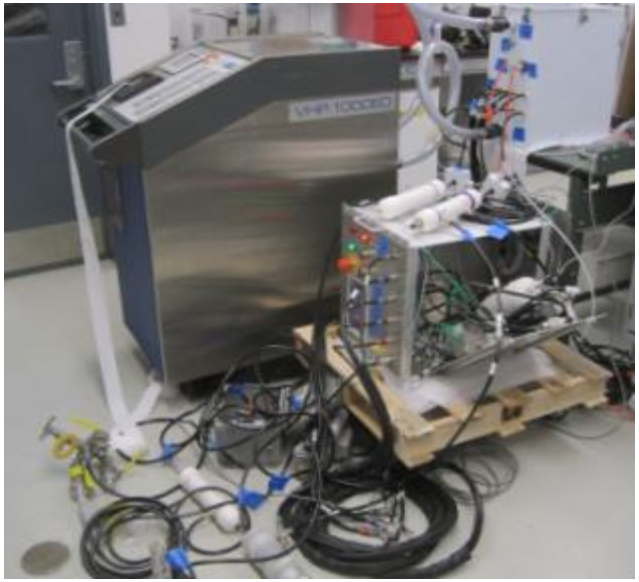
HEPA Housings - Conclusions

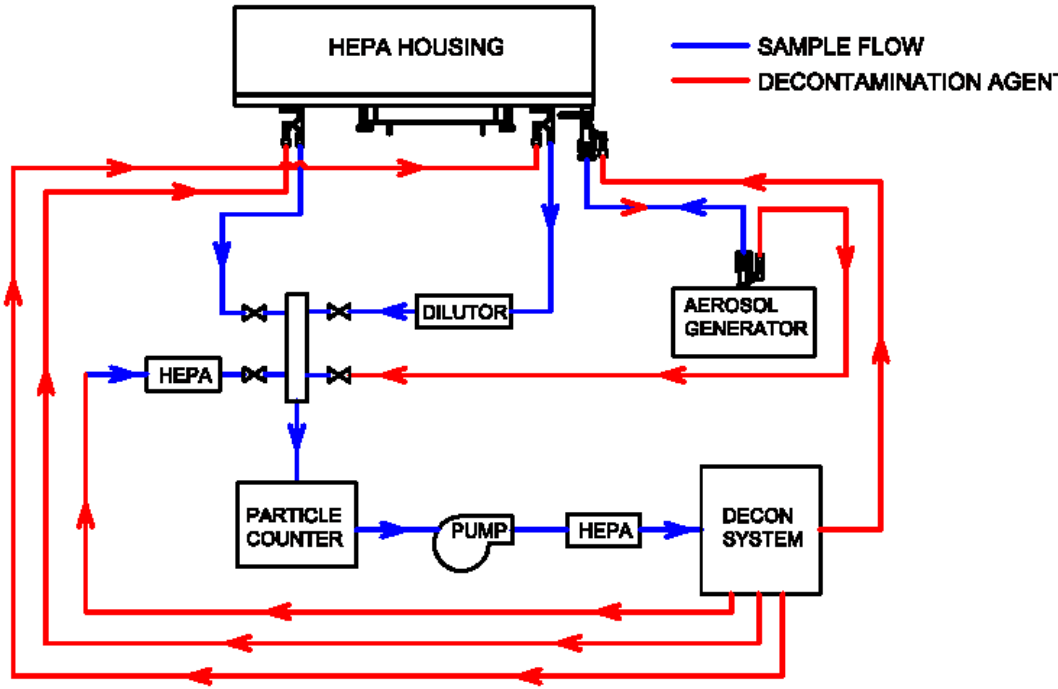
- Able to decontaminate the housings with all 3 agents
- Experience and Results similar to those reported by others with respect to BSC's and traditional containment housings.
- Possible to optimize housing design and construction for a given decontamination method.

We will now move on to the subject of:

Decontamination of Tubes

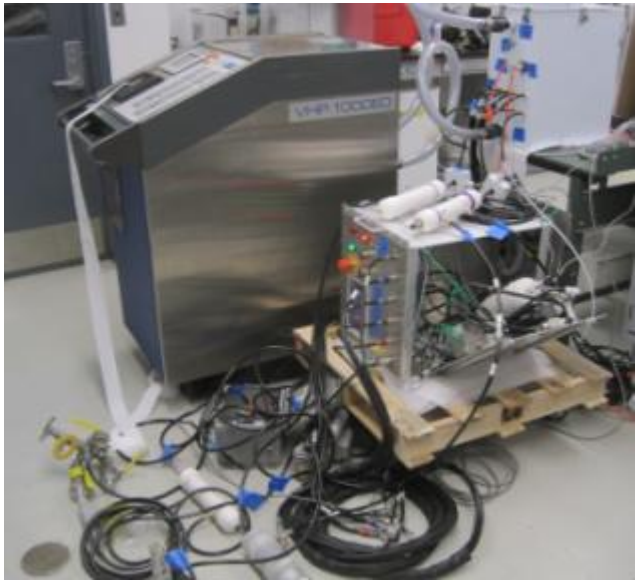
Decontamination of Tubes

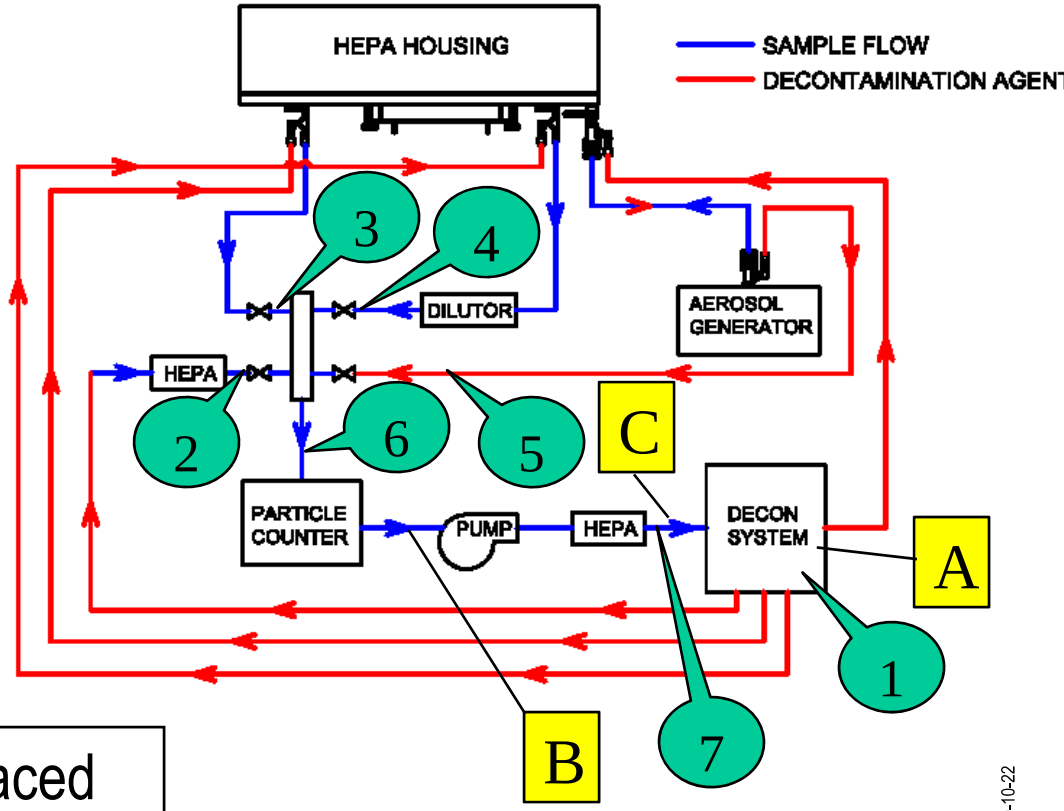




Test System Includes:
- 75 m of 6 mm tubing
- Laser Particle Counter
- Diluter
- HEPA Filters
- Solenoid Valves
- Fittings

Decontamination of Tubes





7 BI's and 3 Sensors were placed in the system

7 = BI location

3 = T, RH Sensor

Method - Formaldehyde

- Formaldehyde Concentration Target at 10.5 g/m^3 (0.3 g/ft^3)
- Conducted 2 hour, 6 hour and 15 hour exposures
- 10^6 *Bacillus atrophaeus* Biological Indicators were used in 7 locations
  - Paper BI's and SS Disc BI's were used.
  - Paper BI's were neutralized prior to incubation. (using sterile1% sodium sulfite.)

Formaldehyde Results (Typical, 2hr, 6hr and 15 hr exposure)

Location	Description	B.I. Type	
		B. atrophaeus 10^6 SS Disc GRS-090	*B. atrophaeus* 10^6 Paper ACD/6
1	In Formaldehyde Generator	0/1	0/1
2	Downstream of Clean-up HEPA	1/1	1/1
3	Downstream of Sample Probe	1/1	1/1
4	Downstream of Diluter	1/1	1/1
5	Downstream of Aerosol Generator	1/1	1/1
6	Upstream of Particle Counter	1/1	1/1
7	Downstream of Particle Counter	1/1	1/1
	Trial Result	Fail	Fail
	Net Result	FAIL	
	Negative Control	-	-
	Positive Control	+	+
	Negative Control w/ Sterile Neutralization		-
	Positive Control w/ Neutralized BI		+

2, 6, and 15 hr Exposure, 10.5 g/m^3 , 75% RH

Results - Formaldehyde

- We decided to measure formaldehyde concentration and RH in various locations in the system over time.
- 2 hour, 6 hour and 15 hour exposures gave similar, poor results. Unable to kill most BI's in placed in the system
- We probably had some zones in the system at lower RH than we expected. Micro-condensation observed on walls of isolator-generator in some locations.

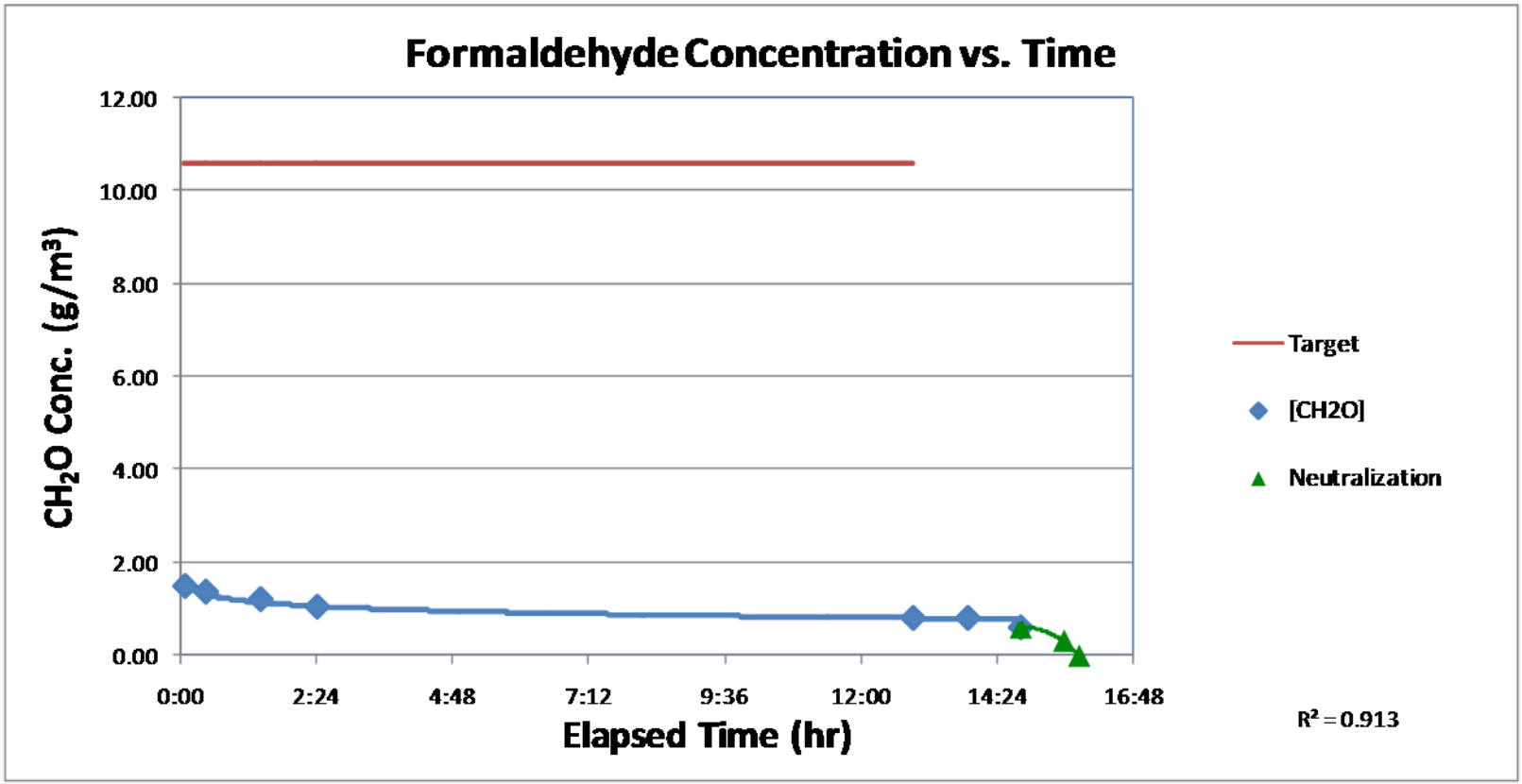
New Method - Formaldehyde

- Implemented a method to quantify formaldehyde concentration in the system
- Method was modified version of one used by Braymen and Songer (NADL, USDA, Ames, IA Appl. Micro. June 1970)
- Method required that we draw a 1 liter air sample from the system through an impinger containing a 1M sodium sulfite solution and an indicator; then titrate the impinger with 0.05N sulfuric acid to determine formaldehyde concentration.
- We previously verified the accuracy of the method *in-vitro*

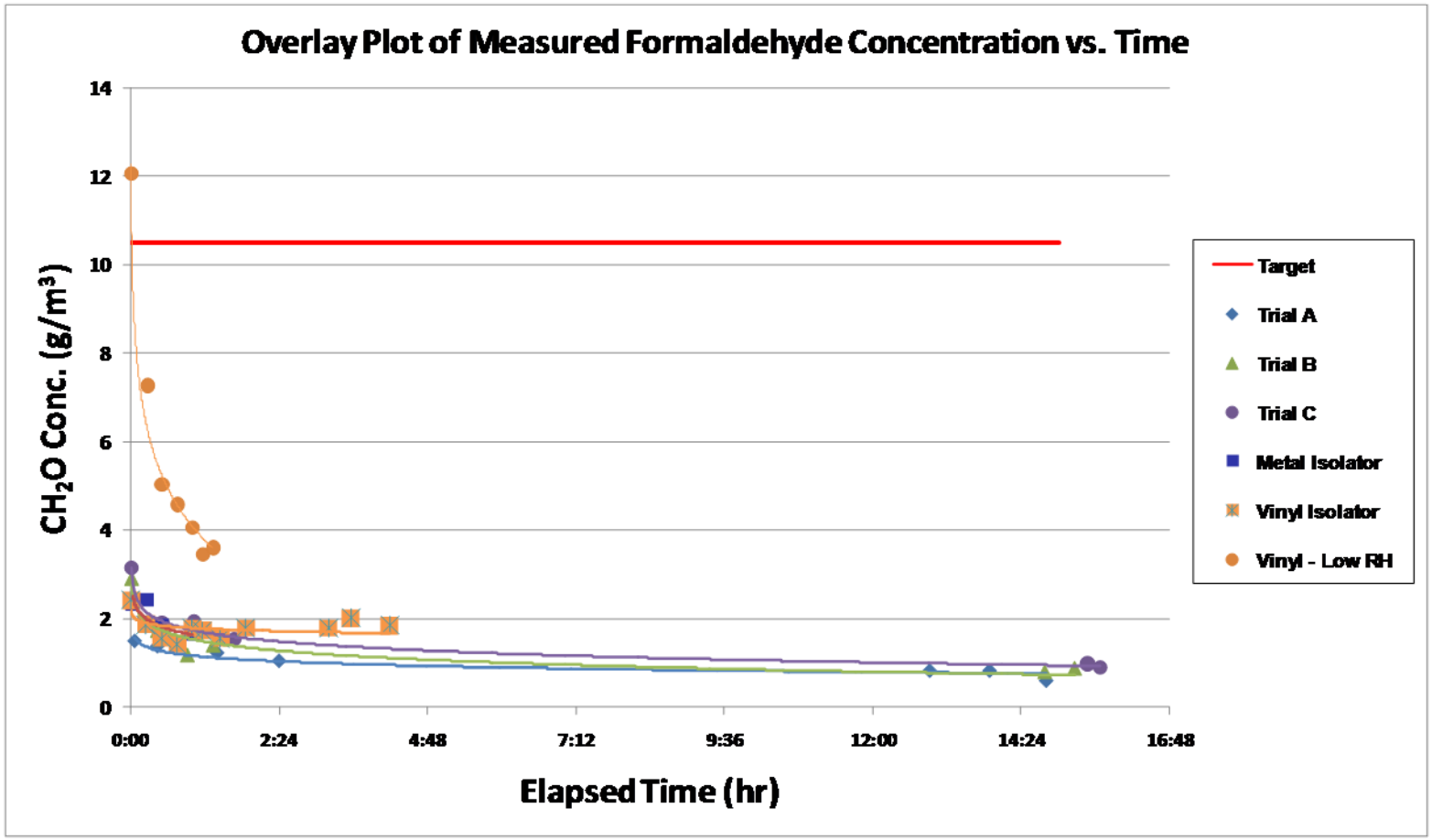
$$CH_2O + Na_2SO_3 \rightarrow NaOH + CH_2(NaSO_3)OH$$

Results - Formaldehyde

- The results obtained from our system were surprising



Results - Formaldehyde



- We verified and repeated the measurements many times

Key Points - Formaldehyde

- Actual concentration of formaldehyde in the system was much lower than expected. This finding was disturbing.
- Residues on surfaces and condensate droplets tested qualitatively positive for formaldehyde.
- There were no leaks in the system.

Method – Hydrogen Peroxide (VHP)

- Used Steris VHP 1000 ED Generator
  - Continuously Circulated VHP into a “Mix Box”
  - 14 m3/hr, 1.5 g/min, ~1200 ppm H_20_2
- Circulated from Mix Box through Scanning system at 28 l/min (1 cfm)
- Monitored T, RH and [H_2O_2] at various points in system
- Placed (7) BI’s. 10^6 *Geobacillus stearothermophilus* on SS Disc
- 2 Hour Cycle was attempted.

VHP Results (Typ. 1 hr. Exposure, 1.7 hr. Total Cycle)

Location	Description	B.I. Type *G. stearothermophilus* 10^6 SS Disc HMV-091
1	Mix Box	0/1
2	Downstream of Clean-up HEPA	1/1
3	Downstream of Sample Probe	1/1
4	Downstream of Diluter	1/1
5	Downstream of Aerosol Generator	1/1
6	Upstream of Particle Counter	1/1
7	Downstream of Particle Counter	0/1
	Trial Result	Fail
	Net Result	FAIL
	Negative Control	-
	Positive Control	+

Up to 2 hr min Exposure, 1000-1500 ppm, ~70% RH

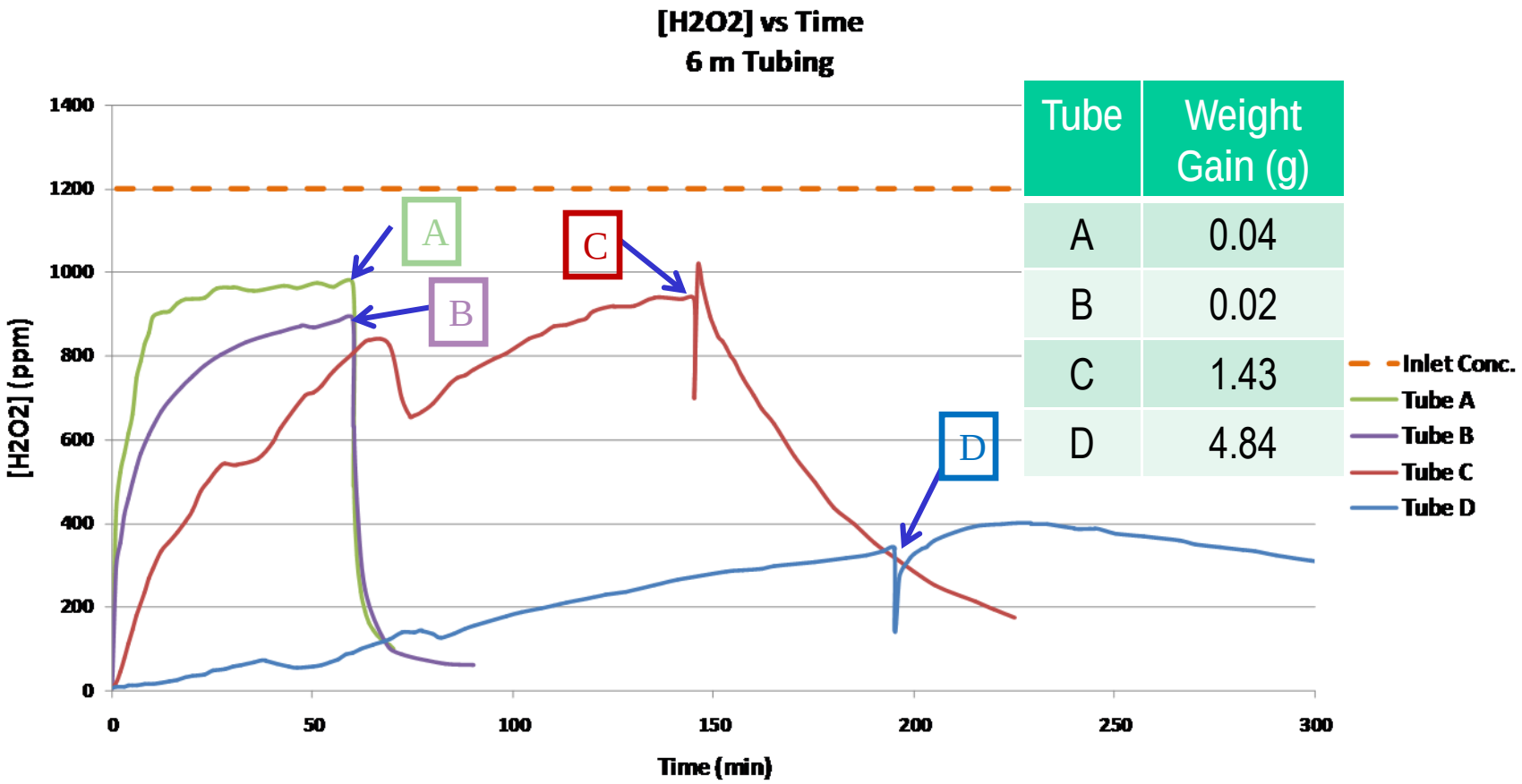
Results – Hydrogen Peroxide

- Low H_20_2 concentration detected at system outlet
- We were unable to effectively kill BI's placed in the tubing system.

Additional Work - H_2O_2

- Investigated cause for sub-lethal dose of VHP in system
- We worked with 6 m long lengths of different types of tubing including:
  - PTFE tubing
  - Vinyl tubing
  - Polyurethane tubing
- Worked with a group of Stainless Steel Fittings
- Monitored inlet and outlet concentration of H_2O_2 at 28 l/m (1 cfm) flow
- Results were surprising

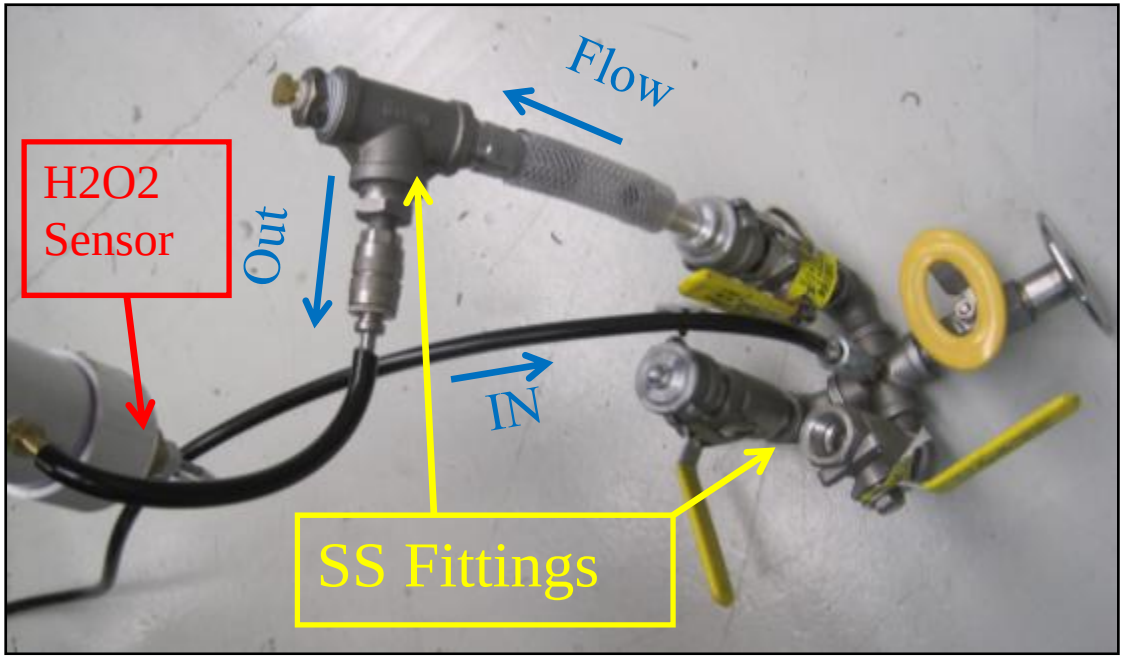
Clear evidence of adsorption-desorption process and different material properties



Tube	Weight Gain (g)
A	0.04
B	0.02
C	1.43
D	4.84

→ Start of Aeration Phase ←

Loss of H_2O_2 through SS Fittings



Loc.	$[H_2O_2]$ (ppm)
Inlet	927
Outlet	127

Catalytic Disproportionation? $2H_2O_2 \rightarrow 2H_2O + O_2$

Evidence of condensation not observed

Method – Chlorine Dioxide

- Attempted decontamination at 5.0 mg/l (0.14 g/ft^3)
- 10^6 *Bacillus atrophaeus* on paper carrier Biological Indicators were used.
- Succeeded in getting repeatable results.
  - 50 minute humidity conditioning phase
  - 60 minute exposure phase
  - 10 minute aeration phase

Chlorine Dioxide Results (Typ. 1 hr. Exposure, 2 hr. Total Cycle)

Location	Description	B.I. Type			
		B. Atrophaeus 10^6 Paper ACD/6 Run 53	*B. atrophaeus* 10^6 Paper ACD/6 Run 54	*B. atrophaeus* 10^6 Paper ACD/6 Run 55	*B. atrophaeus* 10^6 Paper ACD/6 Run 56
1	In Mix Box	0/1	0/1	0/1	0/1
2	Downstream of Clean-up HEPA	0/1	0/1	0/1	0/1
3	Downstream of Sample Probe	0/1	0/1	0/1	0/1
4	Downstream of Diluter	0/1	0/1	0/1	1/1
5	Downstream of Aerosol Generator	0/1	0/1	0/1	0/1
6	Upstream of Particle Counter	0/1	0/1	1/1	0/1
7	Downstream of Particle Counter	0/1	0/1	0/1	0/1
	Trial Result	Pass	Pass	Conditional Pass	Conditional Pass
	Net Result	PASS			
	Negative Control	-	-	-	-
	Positive Control	+	+	+	+

60 min Exposure, 5 mg/l, 65-75% RH

Key Points – Chlorine Dioxide

- High and Low pressure areas of system needed to be considered and addressed in cycle development.
- Distribution of humidity throughout system was critical
- Rapid, uniform distribution of ClO_2 throughout the system was observed
- Concentration of ClO_2 at the inlet (Mix Box) and outlet of the system were identical.
- Materials held up well to multiple exposures. No failures.
- We were able to successfully validate the decontamination of filter scanning equipment using chlorine dioxide

Lessons Learned

- Each Decon Agent has it's own characteristics, pro's and con's.
- Measure T, RH and Agent concentration during the run
- Place BI's at multiple locations
- Choose the proper BI for the agent being evaluated.
- Ensure sufficient exposure conditions in all parts of the system
- Do not assume all materials behave the same
- Keep Trying

Acknowledgements

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Thank you for your time and attention!!!

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