

MMV Decontamination of a Biologics Production Facility

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Overview

1. Facility Description
2. Decontamination selection process
3. CD Gas Process
4. Protocol Generation
5. Example Pictures of other Decon Projects

The Facility

- 2.0 million cu ft. (57,000 cu m) facility dedicated to the production of biologics.
- A biologic is manufactured in a living system such as a microorganism, or plant or animal cells. They include:
 - vaccines
 - blood and blood products for transfusion and/or manufacturing into other products
 - allergenic extracts, which are used for both diagnosis and treatment (for example, allergy shots)
 - human cells and tissues used for transplantation (for example, tendons, ligaments and bone)
 - gene therapies
 - cellular therapies
 - tests to screen potential blood donors for infectious agents such as HIV
- Since this is a living system facility, a contamination can cause cost \$\$\$\$ (millions)

What is an Effective Decontamination?

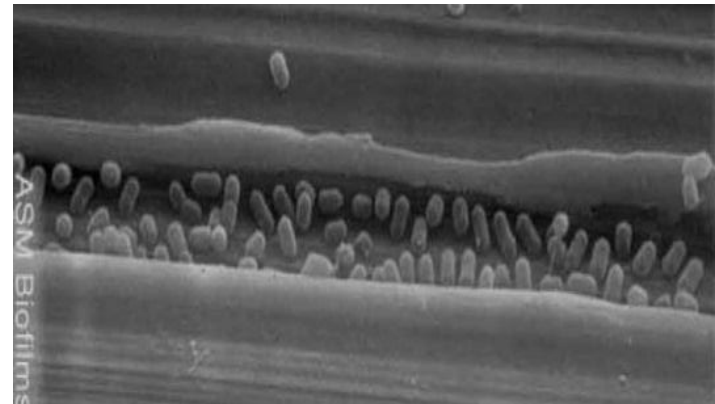
All Decontamination methods can work based on the following:

Must reach ALL surfaces for a prescribed amount of time, which means you must have:

- ✓ Good and Complete Distribution
- ✓ Thorough and Total Penetration
- ✓ Sufficient Contact Time
- ✓ Specified Concentration

**= Successful
Decontamination**

Any decontamination method requires a complete and thorough distribution of the sterilant or high level liquid disinfectant to get an effective decontamination

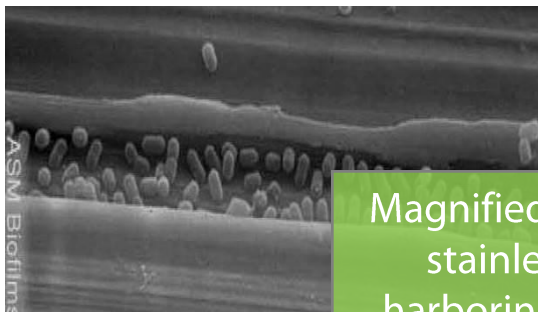


Effectiveness – Spray and Wipe/Fogging

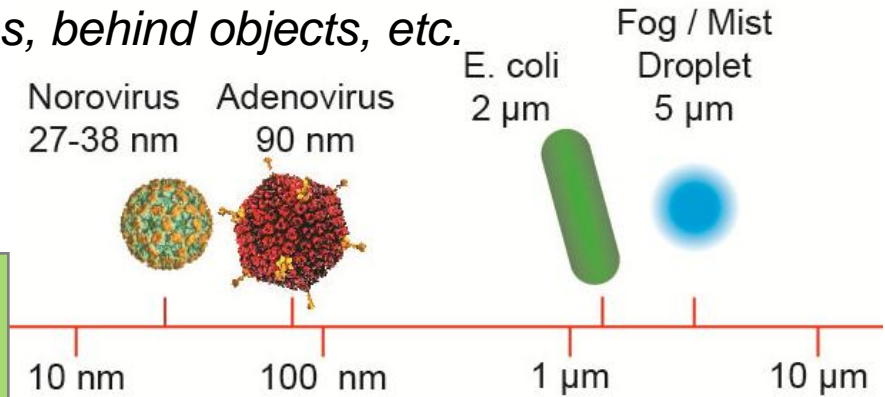
Spray & Wipe: Impractical for every surface in a LARGE facility to be wiped (threads of screws, crevices, HVAC grills)

Mists & Fogs: Difficult reaching ALL organisms:

- *Particle size is larger than organisms,*
- *Affected by gravity,*
- *Difficult to reach under surfaces, behind objects, etc.*



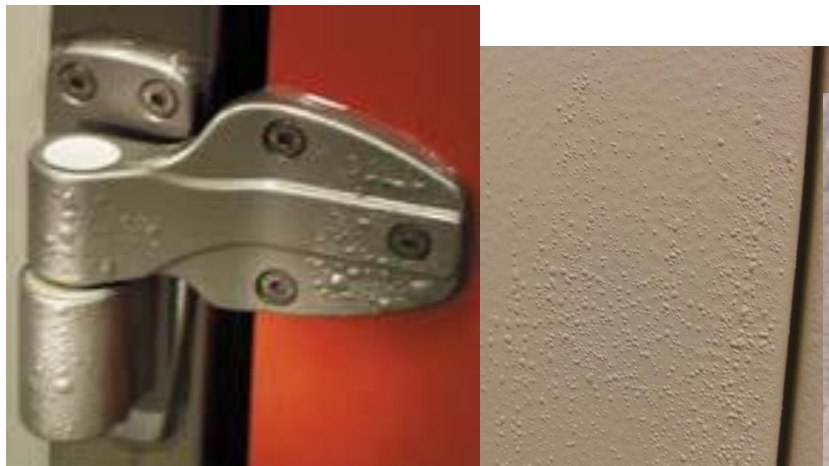
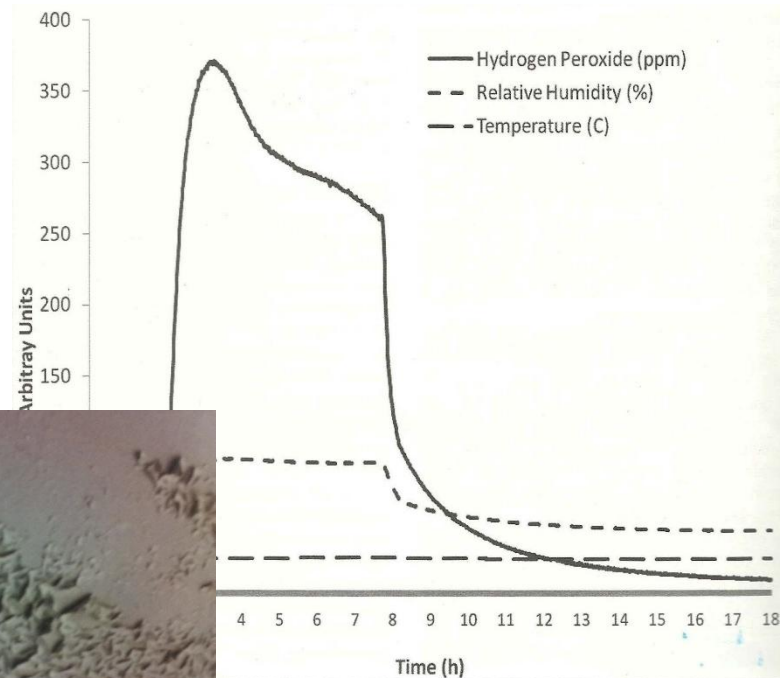
Magnified scratch in stainless steel harboring bacteria



1. Beswick Alan J., Farrant J., Makison C., Gawn J., Frost G., Crook B., and Pride J. 2011. Comparison of Multiple Systems for Laboratory Whole Room Fumigation. Applied Biosafety Vol. 16, No. 3.
2. Andersen BM, Syversen G, Thoresen H, Rasch M, Hochlin K, Seljordslia B, Snevold I, Berg E. **Failure of dry mist of hydrogen peroxide 5% to kill Mycobacterium tuberculosis.** J Hosp Infect. 2010 Sep;76(1):80-3

Effectiveness - VPHP

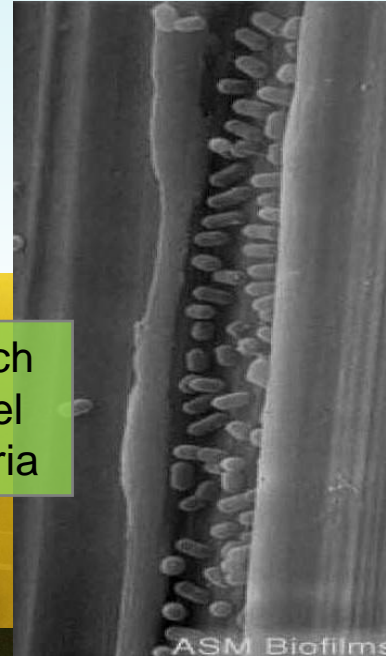
- Vapors want to condense before distributing completely
- Difficult in large volumes
- Requires extensive cycle development
- Corrosive (bubbles paint)
- Not reproducible - issues with temperatures, RH, condensation, volume, room geometry, equipment, HEPA's, etc.
- Vapors also clump, like clouds, restricting distribution.



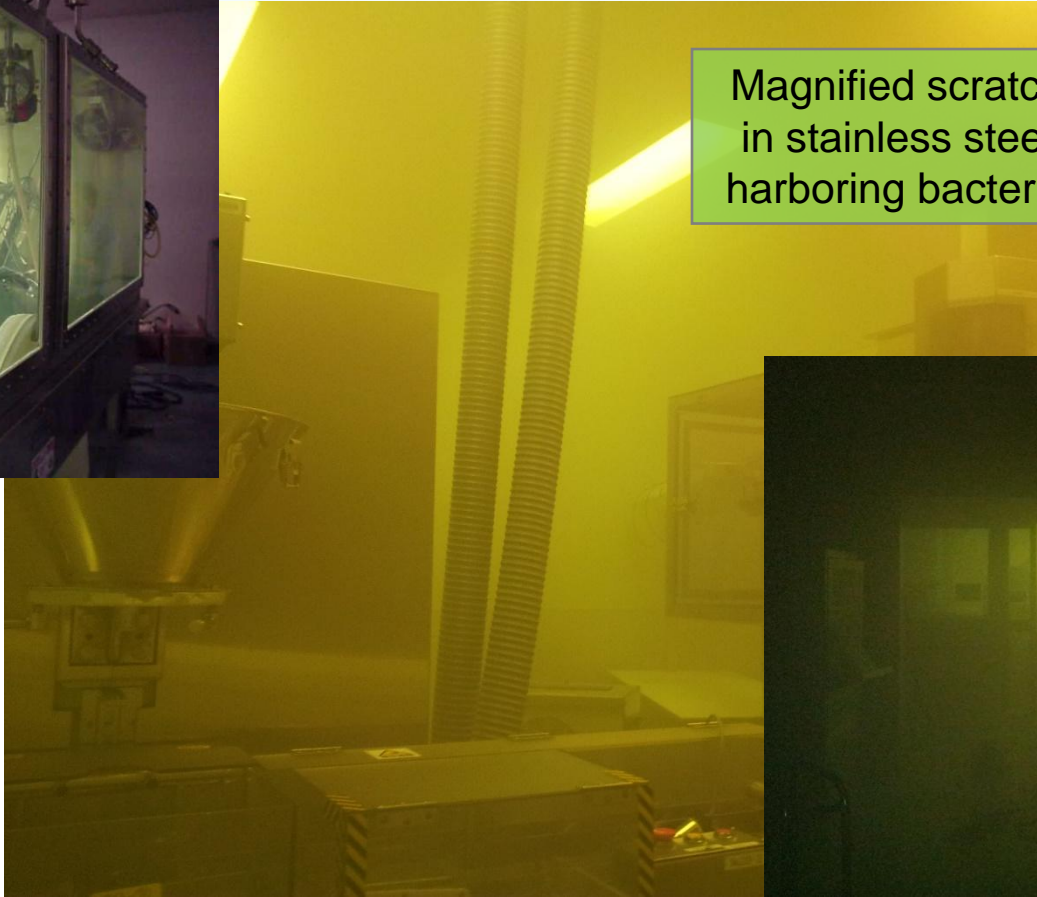
Effectiveness – True Gas

True Gas: Chlorine Dioxide and Formaldehyde

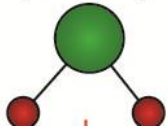
- Gasses are able to reach **EVERY** organism, even in crevices / scratches.



Magnified scratch
in stainless steel
harboring bacteria



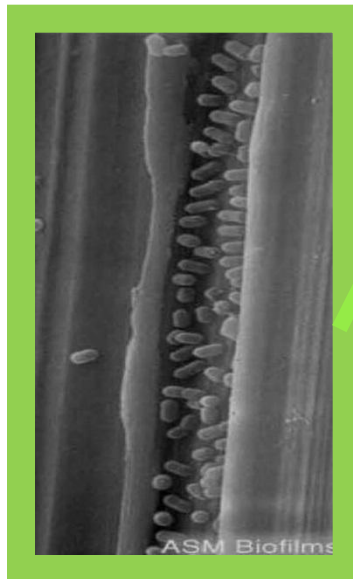
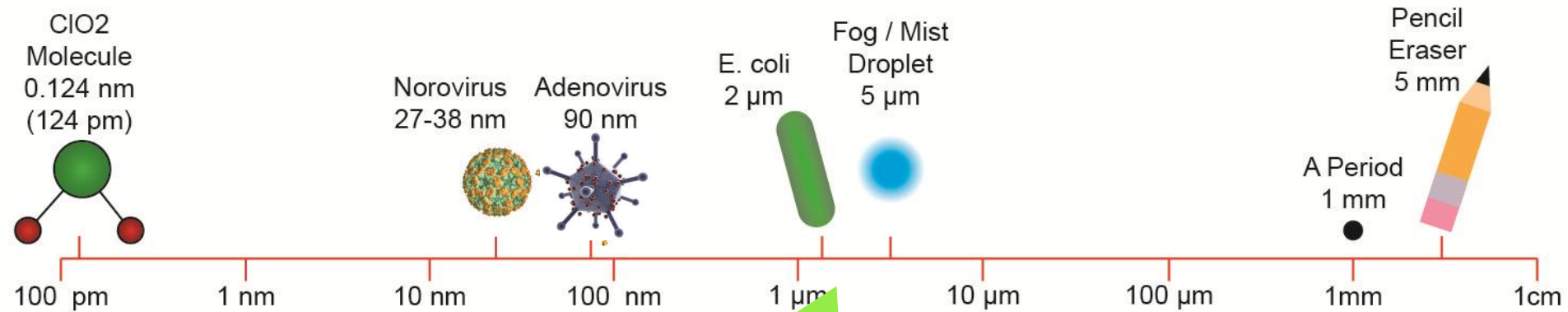
ClO₂
Molecule
0.124 nm
(124 pm)



Why Does
CD so well?

Size Comparisons

Organism sizes vs. ClO₂ molecule

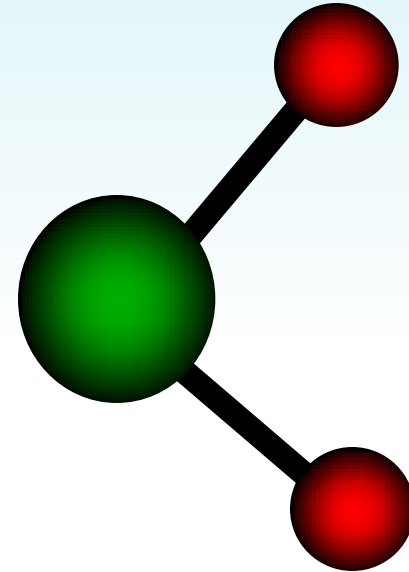


Showing the tight areas where organisms can hide, this is a scratch in stainless steel which is harboring bacteria

What is Chlorine Dioxide (CD) ?

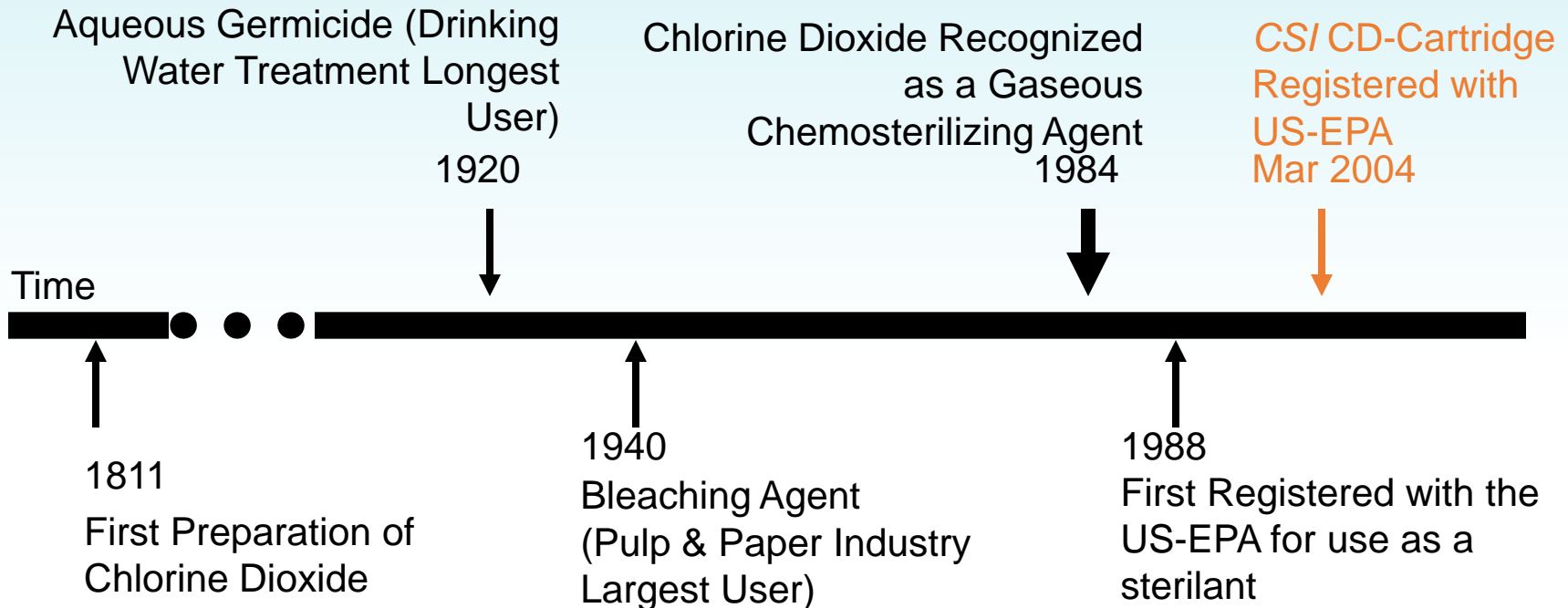
Properties:

- Yellow-Green Gas¹
- Water Soluble²
- Boiling Point 11°C³
- Tri-atomic Molecule
- Molecular Weight 67.5



1. Ability to be monitored in real time with a photometric device.
Not subject to condensation or affected by temperature gradients.
2. Ability to penetrate water (not all sterilants can penetrate water, *vapors can not*)
3. Chlorine dioxide is a “true gas” at room temperatures; which means excellent distribution and penetration.

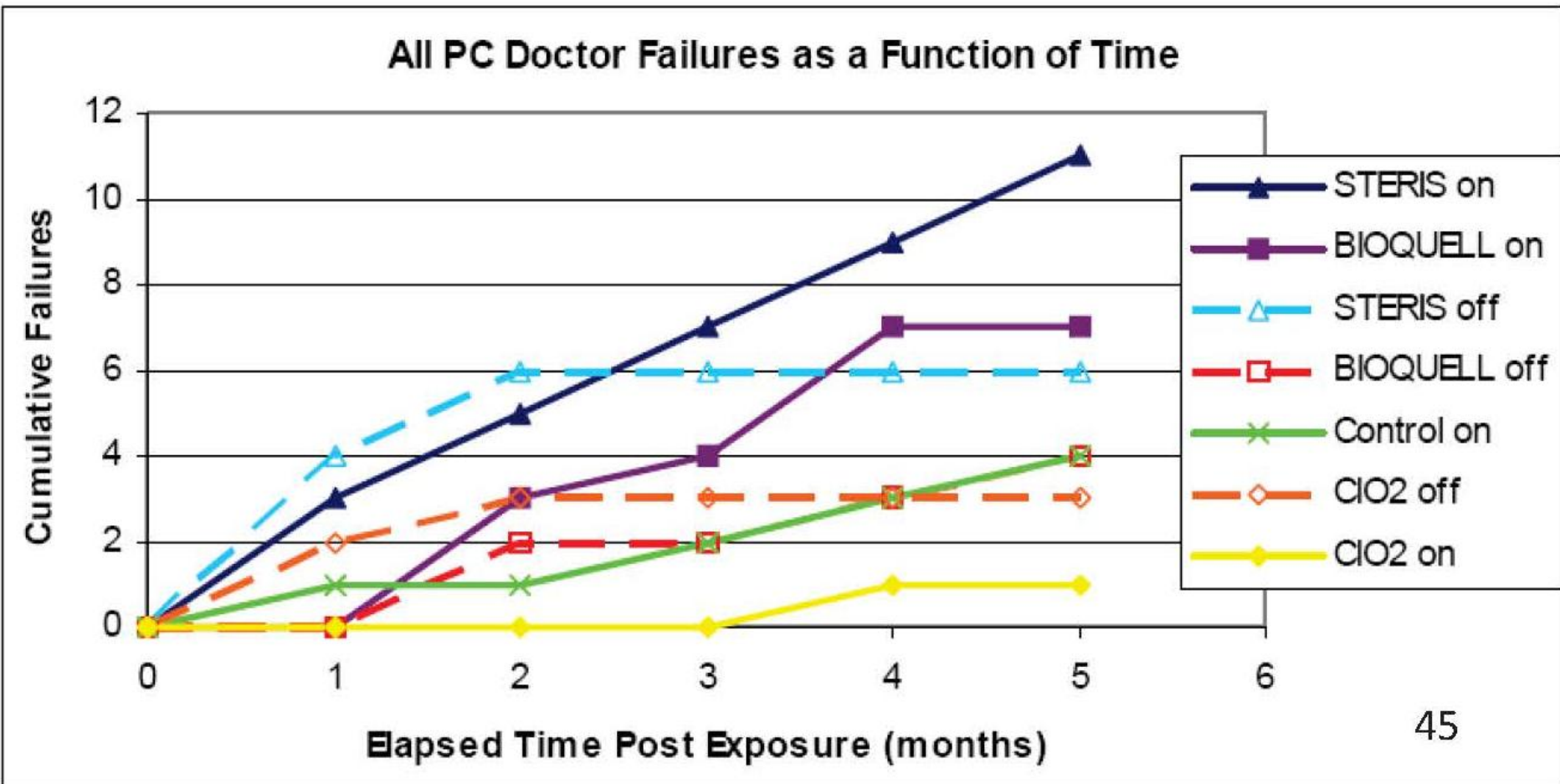
Chlorine Dioxide Time Line



- World wide consumption of chlorine dioxide – 4.5 million lbs/day (2.04million kg/day).
- 743,000 lbs (337,000 kg) released to atmosphere in 2000.
- Example: Maine allows 3 lb's / hour (1.4kg / hour)of CD to be emitted
- 2004 Ontario reported releases of 114 tonnes (103,419kg)
- CD is not listed in the California Air Pollution Control Officers Association Air Toxics "Hot Spots" Program Revised 1992 Risk Assessment Guidelines as having health values (cancer or non-cancer) for use in risk assessments (CAPCOA, 1993)CD

Material Compatibility

EPA Comparison of Decon Agents



45

Snyder, Emily, "Indoor and Outdoor Decontamination" Presentation at EPA Region 9 / ORD Homeland Security Research Workshop, July 14, 2011 San Francisco, CA. Accessed from http://www.epa.gov/osp/presentations/homesec11/hs_Snyder1.pdf . Accessed on 1-10-2013

Cycle Development Questions

	CD Gas	VPHP
Are Cycle Development Studies and Room Specific Evaluation Runs Required?	No	Yes
Does the chamber size affect cycle development?	No	Yes
Does the load pattern affect cycle development?	No	Yes
Do shadow areas affect cycle development?	No	Yes
Do multiple rooms affect cycle development?	No	Yes
Do odd shaped rooms affect cycle development	No	Yes
Does temperature affect cycle development	No	Yes
Does the Starting RH affect cycle development?	No	Dry - Yes Wet – No

CD cycle is 720 PPM-Hours for any shape, load pattern, volume

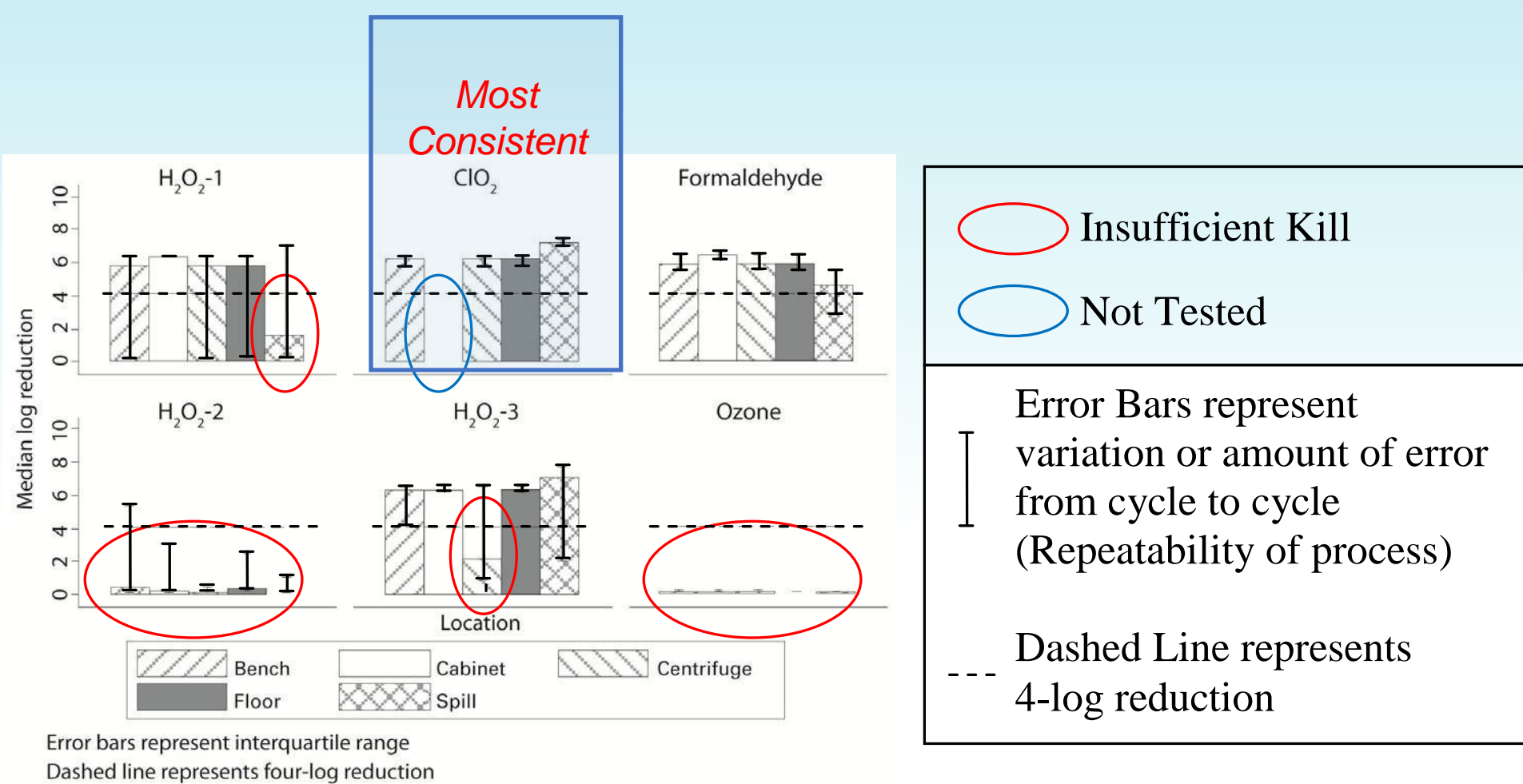
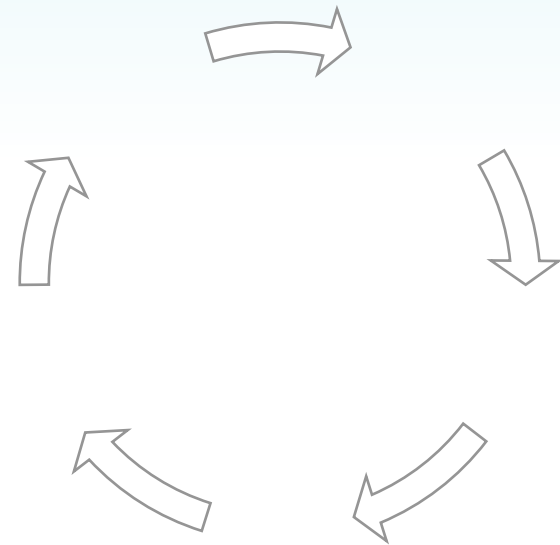


Figure 1: Observed median Log reduction by fumigation system and location

Ref. Beswick Alan J., et al, "Comparison of Multiple Systems for Laboratory Whole Room Fumigation", Applied Biosafety Vol. 16, No. 3, 2011.

The Chlorine Dioxide Decontamination Process

- **Pre-Conditioning**
Raise RH 65%-75%
- **Conditioning**
Dwell time at RH SP
- **Charge**
Raise CD Concentration 1mg/L
- **Exposure**
Dwell time at CD SP
- **Aeration**
Remove CD Gas 12-15 air exchanges



CD Dry Gas Generation Process

MIXTURE
UN1956, Compressed gas, n.o.s.

Concentration	Component
2.00 %	(CHLORINE)
BALANCE	(NITROGEN)

Certified
CAUTION! HIGH PRESSURE GAS
if inhaled. May cause
system damage. May
drowsiness.
TLV: Chlorine 0.5 ppmv

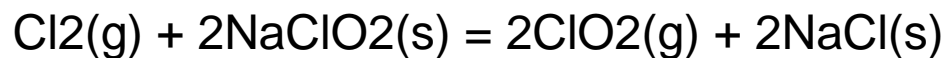
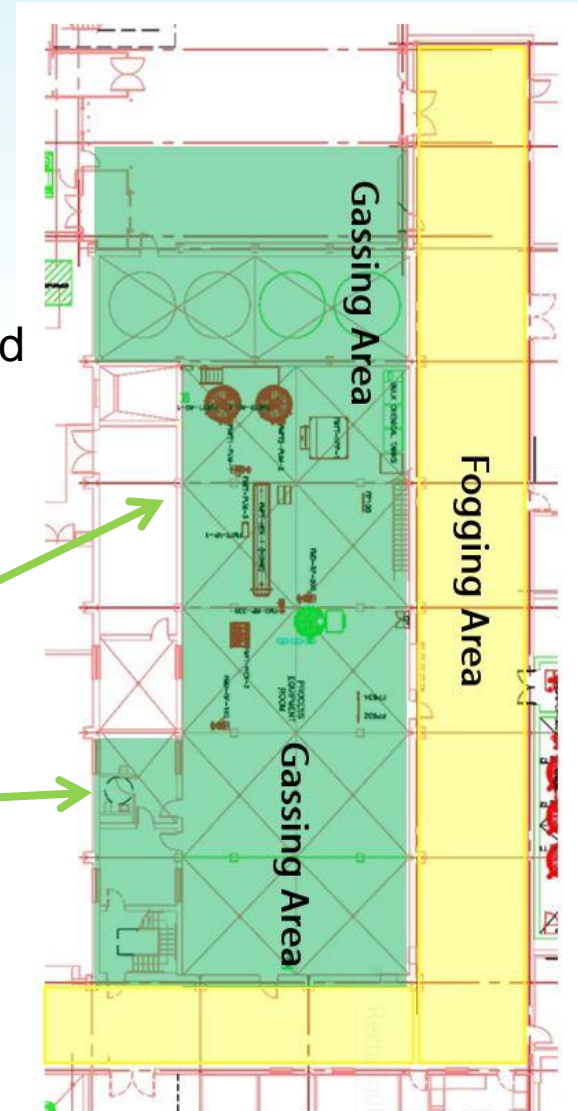


2% Cl₂ and 98% N₂
Reagent Gas



PURE
4% ClO₂ and
96% N₂ as
the inert
carrier

Technical Grade Sodium
Chlorite Flakes

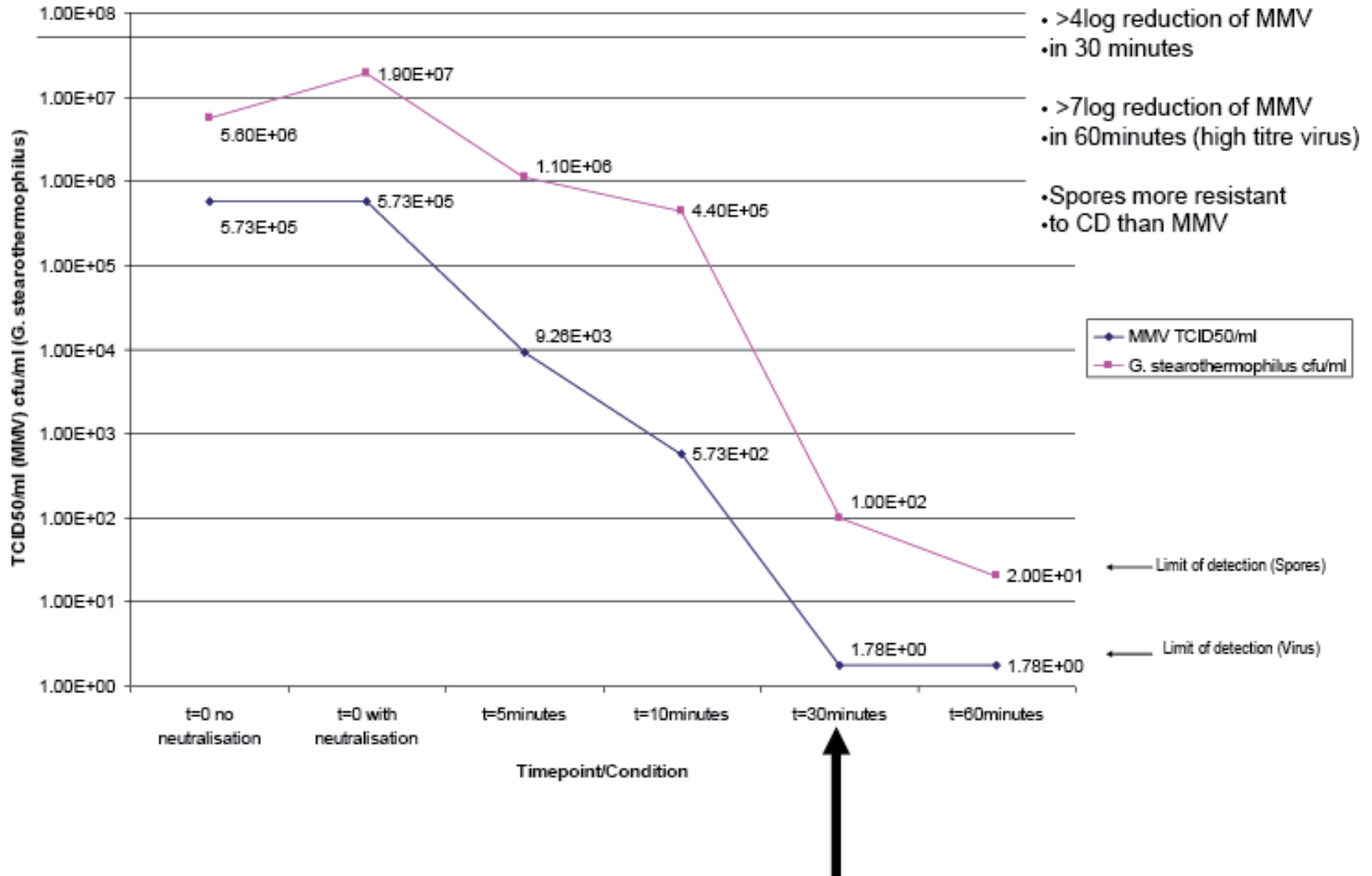


Pre-Planning

- Do as much as you can to prevent the contamination
- Put methods in place to detect contamination as soon as possible to minimize the effect / distribution
- Develop a pre-approved Decontamination protocol and put it in place **BEFORE** the contamination occurs:
 - This minimizes downtime.
 - This allows the best method to be investigated.
 - This can be done more effectively when focus is not on the contamination and potential recall discussions.

Chlorine Dioxide Efficacy on MMV

Chlorine dioxide mediated kill curve for MMV and *G. stearothermophilus*

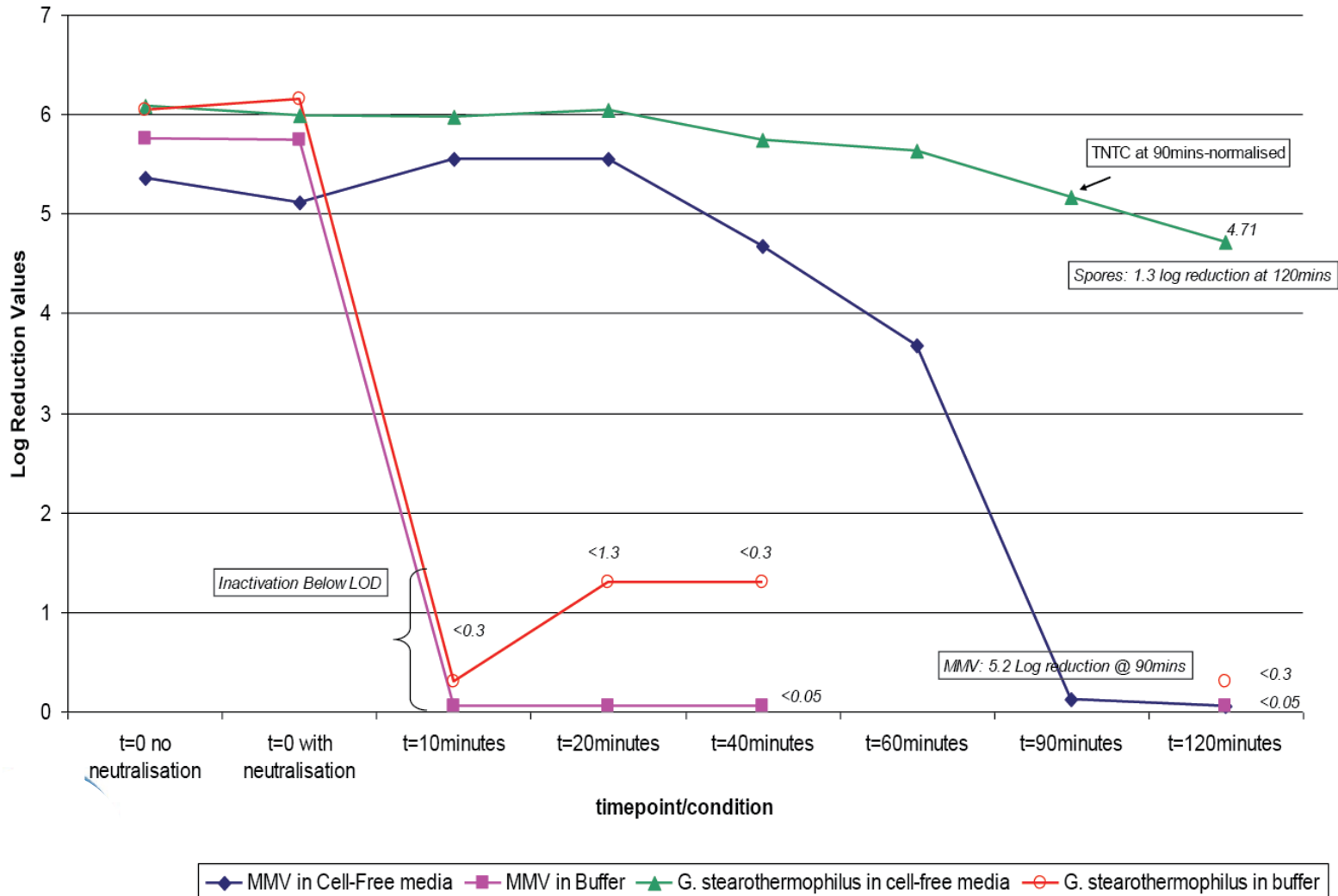


Chlorine dioxide Efficacy Log Reduction

Chlorine Dioxide mediated inactivation of MMV and Spores in cell-free media and buffer

- Spores more resistant than MMV to Chlorine Dioxide

- Presence of cell-free proteinaceous material inhibits effective decontamination of spores



Steps to Develop Protocol

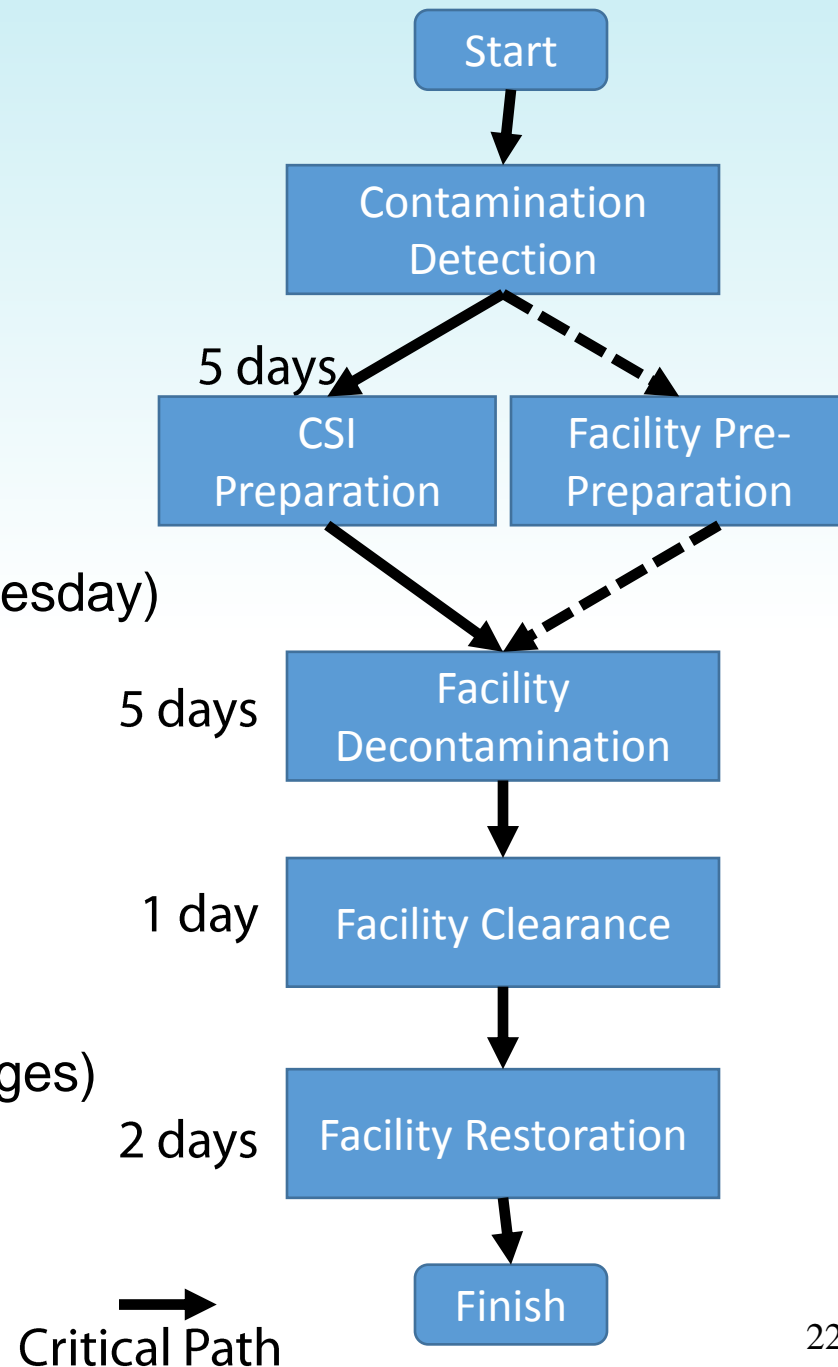
- Visit site and evaluate
- What areas will be decontaminated?
 - Sections
 - Entire building
- What are the volumes?
 - How many generators are required for volume?
- What HVAC's handle what sections?
- Are the HVAC's recirculating or 100% fresh in/out?
 - If Recirculating how much recirculation? (need some fresh air to exhaust the gas)
- Can the HVAC raise RH to 65%?
 - How many humidifiers are needed?

Protocol Development

- What is the Timeline (from contamination to decontamination)
- Determine Department Responsibilities (Site)
- Determine Company Responsibilities (CSI vs. Site)
- How much equipment is needed? (generators, humidifiers, tubing, etc.)
- Develop acceptance criteria
- How many BI will be used and where will they be placed
- Where is power for humidity generators?
- HVAC needs to be cycled once every hour for 5 minutes from a remote location
- Develop check lists

Identify Time Table

1. Ship equipment and consumables
2. Arrive on site
 1. Day 1-3
 2. Set up equipment (Monday - Wednesday)
3. DECON start Day 4 ≈ 8 am
4. Humidification end time ≈ 10 am
5. Start CD gassing ≈ 10 am
6. End CD gassing ≈ 4 pm
7. Start Aeration ≈ 4pm (12-15 air exchanges)
8. End Aeration ≈ 6 pm
9. Re-Entry 6 pm



Identify Department Responsibilities

Process Microbiology

- Prepare the decontamination protocol and associated report.
- Approve decon protocol and report.
- Assist in the execution of the decontamination protocol.
- Lead any investigation activities.

Operations

- Approve decon protocol and report.
- Support the execution of the decontamination protocol.
- Support any investigation activities.

Engineering

- Approve decon protocol and report.
- Coordinate the planning and execution of the protocol.
- Support the execution of the decontamination protocol.
- Support any investigation activities.

EHS

- Approve decon protocol and report.
- Ensure adequate safety measures are in place to support the decontamination activities.
- Support the execution of the decontamination protocol.
- Support any investigation activities.

Quality Control (QCL)

- Perform analytical testing as specified in the protocol.
- Review the decontamination protocol.
- Ensure that analytical methods are validated in accordance with Company Standards and Procedures as appropriate.
- Support any investigation activities.

ClorDiSys Solutions Inc. (CSI)

- Perform Chlorine Dioxide decontamination as per the protocol, applicable method statement and procedures.
- Support any investigation activities.

Quality Assurance (QA)

- Approve the decontamination protocol, and associated report.

Identify Site Responsibilities

- Casework ,cabinets – all drawers and doors must be opened
- BSC's, Laminar flow hoods, fume hoods, and down flow tables – turn on the units and leave running during the entire decontamination process.
- Refrigerators / Freezers – Must be at ambient temperature
- Washers – Open door fully.
- Elevators – lock the elevator doors open to allow air circulation, so RH and CD will contact this area.
- If walk-in cold or warm rooms are included in the scope of the decontamination, they will need to be shutdown prior to the decontamination and be brought to ambient temperature.
- Bump HVAC's during the process

Determine Equipment Needed

- 2,000,000 cu ft. (57,000 cu m)
- 82 generators
- 248 chlorine cylinders
- 150 Fans/Blowers
- 3 Automatic EMS CD Gas Sensor Module
- 1/4" gas inject tubing (200-red)
- 1/4" gas sample tubing (44-green)
- Duct Tape (25)
- 2 ft. Wide Tape (4)
- Plastic Sheeting (3)
- 60 Biological Indicators (spore strips)
- 12 people
- 3 Days setup
- 1 Day gassing



Determine Acceptance Criteria

ACCEPTANCE CRITERIA / VALIDATION PARAMETERS

1. The CD decontamination conditions must be met in the room/area being decontaminated:
 - CD concentration-time ≥ 720 ppm/hr
2. All BI's tested for each location should be negative for growth and the control is positive.
3. All areas of the facility have a CD concentration less than 0.1 ppm's once the decontamination is completed as documented.

Biological Indicators

Xx BI's in total

- Develop a rationale for quantity and placement
- Biological indicators *Geobacillus stearothermophilus* with a spore population of $\geq 10^6$ on a paper carrier within a Tyvek envelope will be positioned through the classified room(s) to be decontaminated
- Qty. 1 BI in each Biological Safety Cabinet (BSC)
- $< 50,000$ cu ft. use Qty. 1 BI. Rooms with a volume less than $50,000 \text{ ft}^3$ were considered small enough whereby CD gas would uniformly distribute
- $>50,000$ cu ft. and active Cell Culture Rooms use Qty. 5 BI's (one in each corner and one in center).
- $>50,000$ cu ft. and Non Cell Culture Rooms use Qty. 3 BI's (one in opposing corners and lone in the room's center).
- A minimum of 2 biological indicator strips will be placed in each classified room. The location of BIs will be documented in Attachment.

Area	Location
Cell Culture Processing Rooms:	Room 1002 -1
	Room 1002 -2
	Room 1002 -3
	Room 1002 -4
	Room 1002 -5
Processing Rooms:	Room 1011 -1
	Room 1011 -2
	Room 1011-3
Outlying areas	Hallway 1100
	Lobby 1101
	Hallway 1102
	Hallway 1103
	Hallway 1104
	Hallway 1105
	Vestibule 1102

Emergency Contacts

Emergency Contacts

This information will be populated at the time of the event, as contact information may change between protocol approval and protocol execution.

Contact Function	Contact Name	Contact Number
CSI Project Manager		
Main Contact		
Security		
Maintenance		
Fire Dept.		
Police Dept.		

Danger Signage Placement

Determine warning sign and placement of signs



KEEP OUT CHLORINE DIOXIDE IN USE
 HAZARDOUS OXIDIZING GAS
 AUTHORIZED PERSONNEL ONLY
 In Case Of Emergency
 CALL CLORDISYS AT _____

DATE: START _____ END _____
 TIME: START _____

Premises shall be vacated at least 1 hour before the operation is started and shall not be re-entered until the danger signs have been removed by the proper authorities

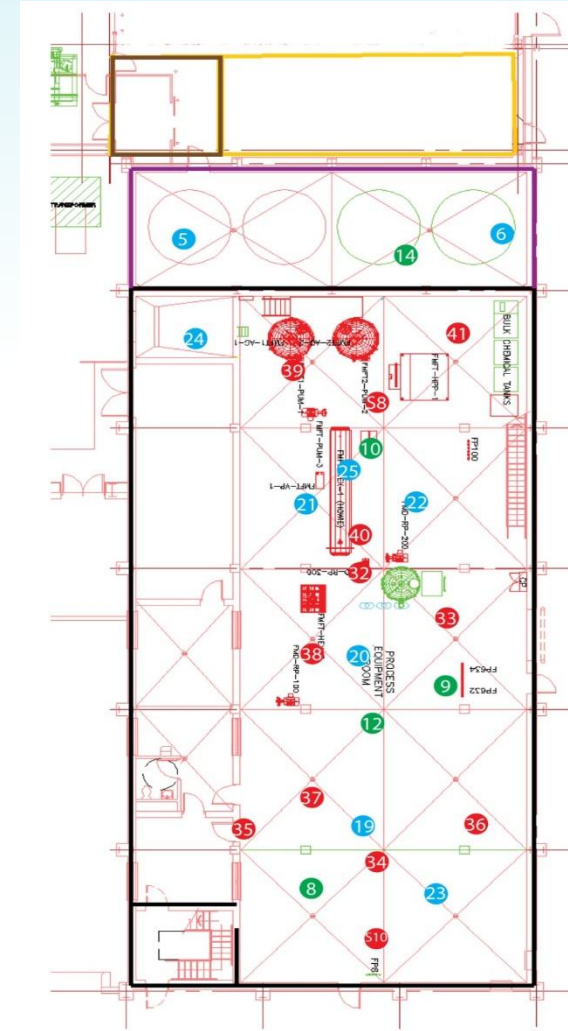
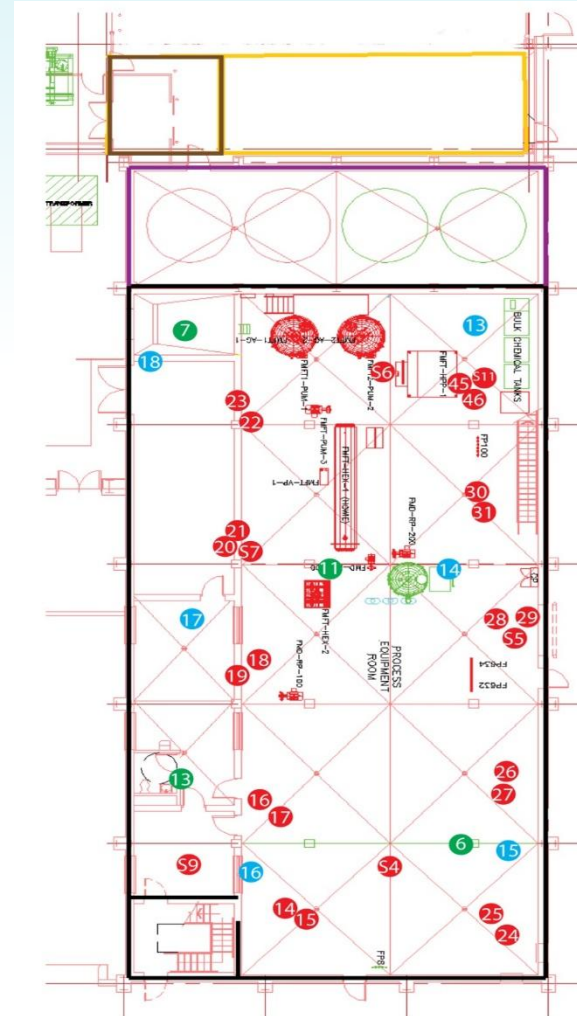
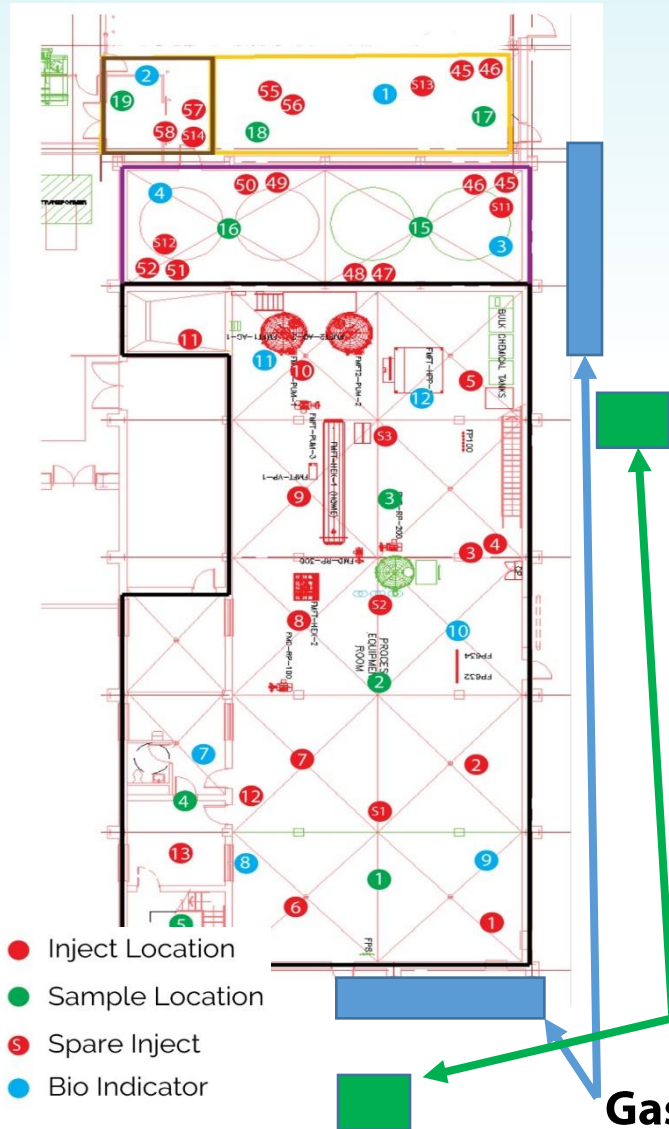
Location	Inside/Outside	Signs Placed (Y/N)	Initial/Date
222 Door	Outside		
221 Door	Outside		
223 Door	Outside		
224 Door	Outside		
230 double doors	Outside		
231 Door	Outside		
232 Door	Outside		
233 Door	Outside		
234 Door	Outside		

Gas Inject, Sample and BI Locations

Production Floor Level

Main Floor Level

Upper Levels



EMS Sensor Locations
Gas Generator Locations

Space Decontamination Checklist

Item	Description	Yes	No	Initial / Date
Warning Signs	Are all applicable and appropriate warning signs prominently posted at all possible points of entry to the site and all other places as required?			
Site Access	Is access to the site on the date of the decontamination restricted to only those individuals directly responsible for implementing the decontamination procedure?			
HVAC System	Are all HVAC systems shut down as required by the decontamination procedure?			
HVAC Sealing	Are all HVAC openings sealed off as applicable?			
Sealing	Are all openings sealed off between the decontamination areas and areas that are not in the scope of the decontamination procedure?			
Notifications	All applicable on/off-site agencies, i.e., Environmental Health & Safety, Police, Fire Dept, etc. been notified of the decontamination procedure as required			
Cleaning	All general site debris and other items that cannot be properly decontamination and been removed as appropriate.			
PPE	All applicable Personal Protective Equipment is on-site and easily accessible			

Air Handling Unit and Ductwork Decontamination

- Manual cycling of AHU's during gassing is done to draw chlorine dioxide gas mixture into the associated AHU's and ducts in order to decontaminate system air filters and the inside surfaces of AHU's and associated ductwork.
- The air handler units (AHU's) that serve the areas where live cells are present will be bumped (turned on and off) once per hour for 5 minutes for the entire decontamination process.
- De-humidification chillers are turned off.

Unit	To be Cycled on during process	Cycled (Y/N)	Shutdown	Shutdown (Y/N)	Sealed	Sealed (Y/N)	Initial/Date
AHU-001	Yes		No		Outside air in/out internal dampers		
AHU-003	Yes		No		Outside air in/out internal dampers		
AHU-100	Yes		No		Damper between Supply and Exhaust plenum		
AHU-004	No		Yes		No		
AHU-201	No		Yes		No		
AHU-208	No		Yes		No		
AHU-219	No		Yes		No		

Special Sealing

- Identify items that require special sealing.
- If room xx is not being decontaminated, CSI will seal it off and monitor it frequently for low-level leakage of chlorine dioxide gas
- Supply and return grilles in rooms 222a, 223a, and 224a require sealing.
- Supply and return grills in hallways 13, and rooms 131, 121, 175, 174, 172, 112 and 222, and stairs 142, and 166 require sealing.
- Mechanical Room 222 has some penetrations going into the ceiling above that require sealing.

Item	Location	Sealed (Y/N)	Initial/Date
Doors	Doors 234		
Doors	Stairwell 144		
Doors	Stairwell 145		
Doors	Fire Room 155		
Doors	Stairwell 147		
Doors	Corridor 13		
Doors	Receiving Dock overhead door		
Doors	Receiving vestibule 113		
Doors	Corridor 120		

Check Sheet (Before Gassing)

Site will assist with the following

Room ID & #	Procedure	Yes / No/ N/A	Performed By/Date
	Incubators (including walk in types) at room temperature and door open		
	Freezers (including walk in types) at room temperature and door open		
	Fridges/cold rooms at room temperature and door open		
	Autoclave doors Open		
	Process Equipment(e.g. tanks, bioreactors) open where possible		
	Door Interlocks disabled and doors propped open		
	All exterior windows covered with black plastic (only applicable if decontamination occurring during daylight hours)		
	All cabinet doors open		
	All drawers open		
	All pass through open		
	All Biological Safety Cabinets switched on		
	All debris (clothing, paper, rubbish etc) removed from room		
	All raw materials and consumables removed from room		

Check Sheet (Before Gassing)

- Turn off smoke detectors and differential pressure alarms
- CD gas and RH looks like smoke to some detectors
- All doors will be open and differential pressure will be 0

Differential Pressure Alarms			Smoke Detectors		
Differential Pressure Alarm Tag	Alarm OFF (Yes/No)	Performed By/Date	Smoke Detector Tag	Smoke Detector OFF (Yes/No)	Performed By/Date

Start the Decontamination Process

RH Log Sheet (Before Gassing)

- CSI turns on the humidifiers and monitors the humidity levels with hand held RH sensors. A humidity level over 65% is the goal with a target level between 65 to 75%. Results will be documented.
- Once the humidification level is held for a minimum of 30 minutes, the humidifiers are removed from the area.

Location (Room #)	Location (Room Name)	Greater than 65% (Y/N)	Steam Type	Initial/Date
N/A	Pass Elevator		NA	
222	Vestibule		Humidifier (1)	
223	Stair #1		Large Humidifier	
224	Storage		Large Humidifier	
225	Storage		Large Humidifier	
26	Conference		Large Humidifier	
226	Corridor		Large Humidifier	
227	Office		Large Humidifier	
333	Communications		Humidifier (1)	
334	Office		Large Humidifier	
335	Conference		Humidifier (2)	
336	View Alcove		Humidifier (1)	
337	Corridor		Large Humidifier	

Start the Decontamination Gassing Process

Approximately 6 hours later

End the Decontamination Gassing Process

Room Clearance Checklist (After Gassing)

- CSI verifies that the CD levels are low enough to enter the area that was decontaminated.
- CSI wears appropriate gowning before re-entering the decontaminated facility.

Location (Room #)	Location (Room Name)	CD Below 0.1 PPM (Y/N)	Initial/Date
N/A	Pass Elevator		
222	Vestibule		
225	Stair #1		
26	Sample Drop off		
226	Storage		
227	Conference		
333	Corridor		
334	Office		
335	Communications		
336	Office		
337	Conference		

Check Sheet (After Gassing)

Turn ON smoke detectors and differential pressure alarms

Differential Pressure Alarms			Smoke Detectors		
Differential Pressure Alarm Tag	Alarm ON (Yes/No)	Performed By/Date	Smoke Detector Tag	Smoke Detector ON (Yes/No)	Performed By/Date

Check Sheet (After Gassing)

Same as before gassing, but reversing status

Room ID & #	Procedure	Yes / No/ N/A	Performed By/Date
	Incubators (including walk in types) switched on and door closed		
	Freezers switched on and door closed		
	Fridges/Walk in cold rooms switched on and door closed		
	Autoclave doors closed		
	Process Equipment(e.g. tanks, bioreactors) open where possible		
	Door Interlocks enabled and doors closed		
	Black plastic from exteriors windows removed		
	All cabinet doors open		
	All drawers closed		
	All pass through closed		
	All Biological Safety Cabinets switched off		

Final (After Gassing)

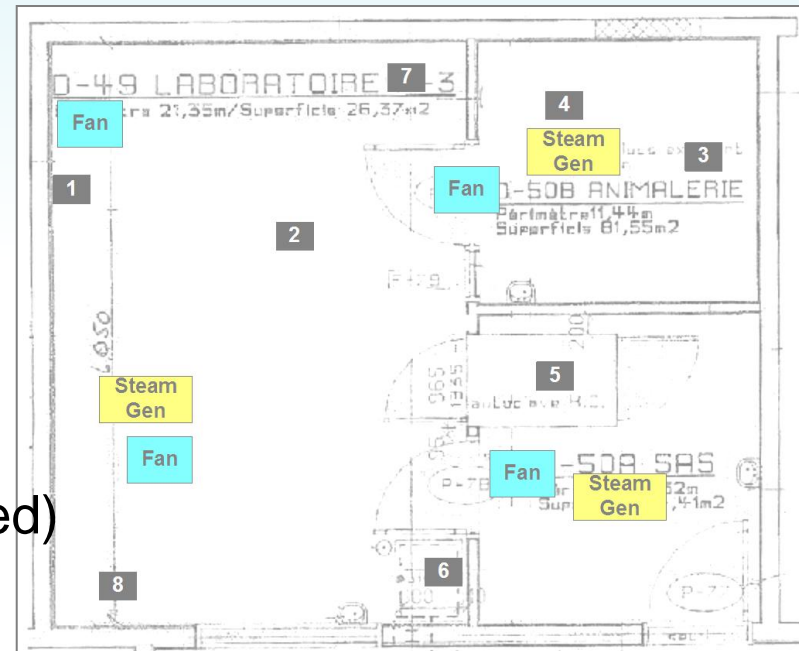
- Remove the gas generation equipment.
- Ensure the removal of the gas sample tubing, gas feed tubing, circulation fans, humidity generators, Rh probes, etc. from the area.
- Ensure removal of any sealing materials.
- Ensures removal of any signage.
- Upon completion of Decontamination Activities, Site personnel:
 - Review Clearance Form
 - Walkthrough and inspects area while decontamination personnel are still on site.
 - Release facility back to operation upon successful execution of this protocol.
- A final report to this protocol will be submitted once the BI results are obtained. It will include an overview of the process, process parameters attained, BI results, and documentation of residual CD levels.

The following slides show example
decontamination job setup

Decon Site Preparation (Place Equipment)

Steps:

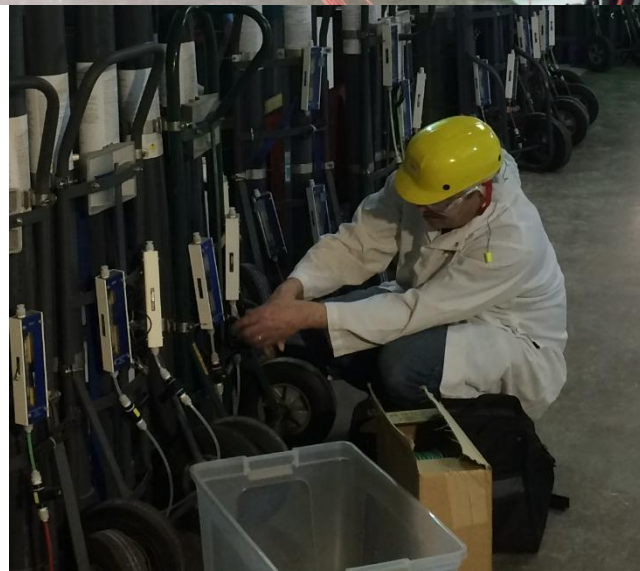
1. Run gas inject tubing
2. Run sample tubing
3. Place distribution fans / blower
4. Seal HVAC (Supply and Exhaust)
5. Seal entry/exit doors
6. Place biological indicators (If required)
7. Seal LAST doorway
8. Start RH / Gassing



Gassing Preparation (Place Generators)



Gassing Preparation (Place & Setup Generators)



Gassing Preparation (Run Tubing)



Gassing Preparation (Seal Penetrations/Doorways)



Gassing Preparation (Seal Mouse Holes)



Gassing Preparation (Seal Main Supply)



Gassing Preparation (Seal Roof Exhaust)



Gassing Preparation (Seal Penetrations/Doorways/Exhaust)



Gassing Preparation (Seal Roof Exhaust)

Surface to Seal

Access Door



Gassing Preparation (Seal Roof Exhaust)



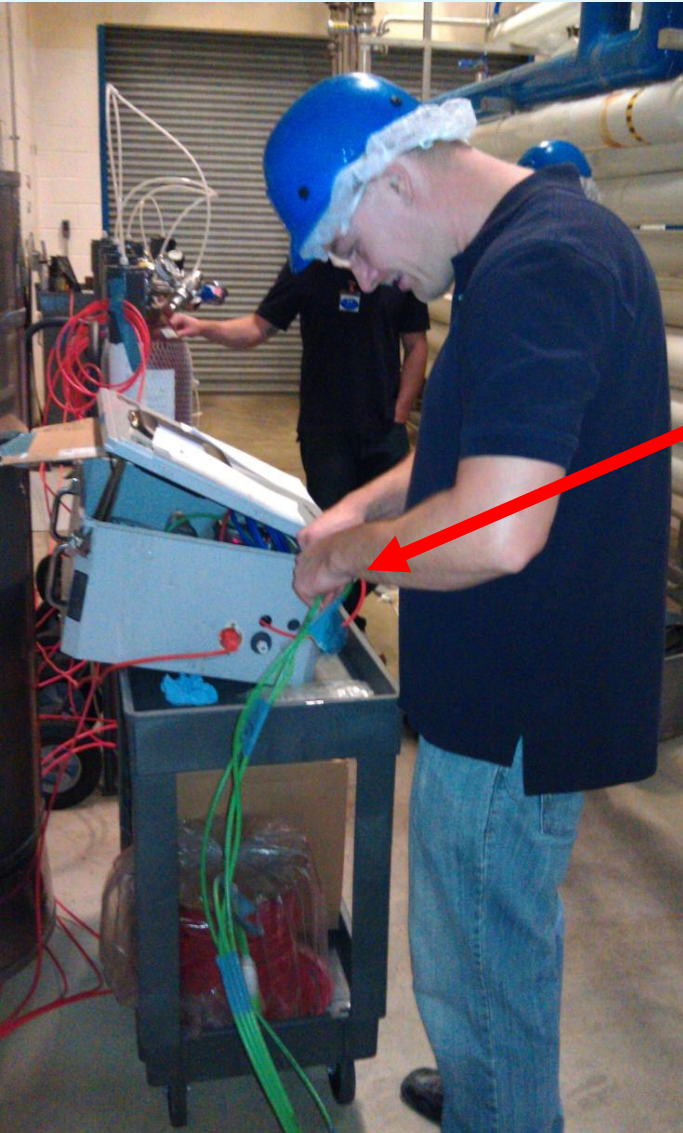
Gassing Preparation (Place Biological Indicators)



Gassing Preparation (Seal Last Doorways)



Start Gassing



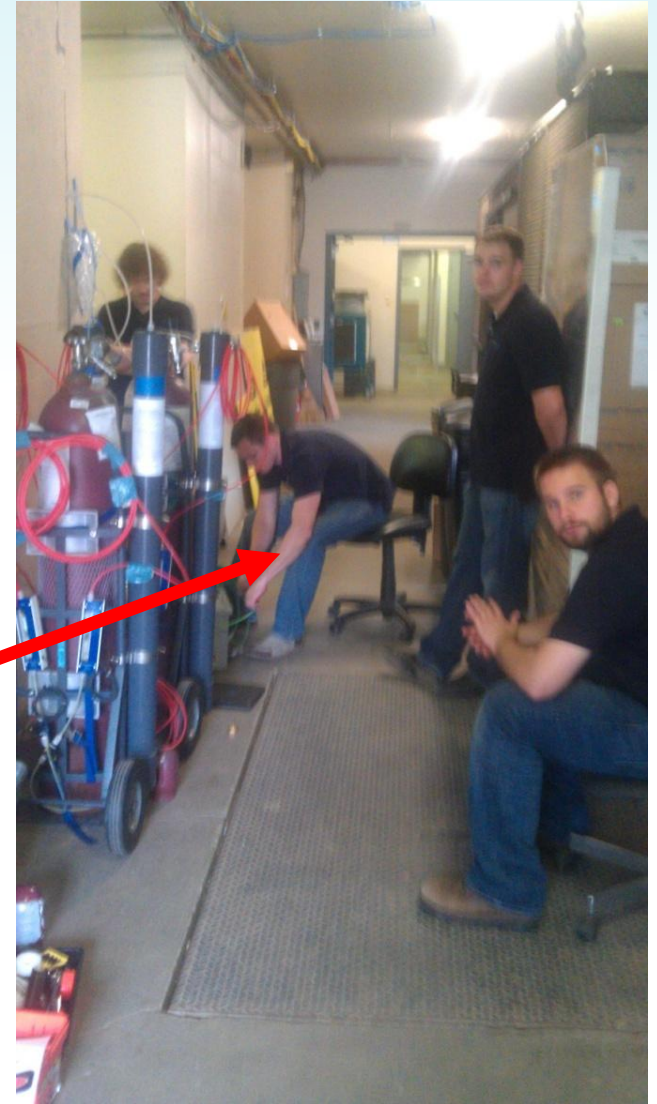
*Make Final
Connections*

And

Wait....

And

Wait...



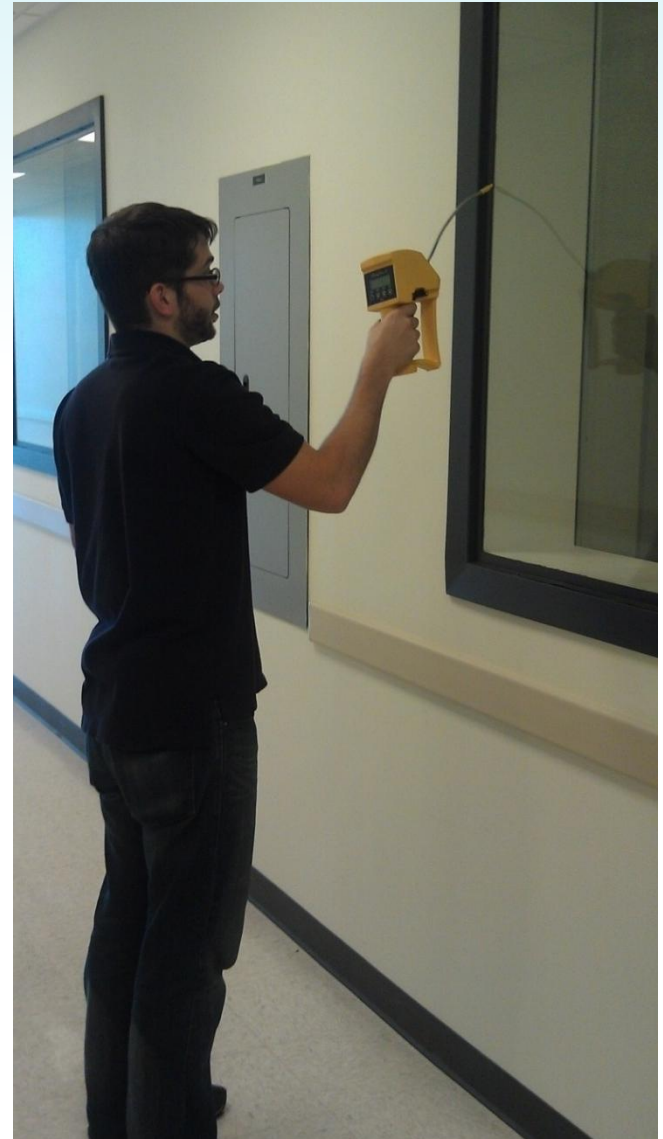
Leak Detection



- Check for Leaks During Gassing
- Gassing Complete

Then

- Clean-up



Gassing Complete (Unseal Doorways)



Gassing Complete (Remove BI's)



Gassing Complete (Remove Tubing and Fans)



Summary

- First - Don't get a contamination
- Second - Develop a plan for decontamination before the contamination occurs
- Steps for the plan
 - Survey the site
 - Determine the scope (What areas are included / excluded from the decontamination)
 - Develop a site specific protocol
 - Identify Responsibilities
 - Identify the time line

CD gas can eliminate the issue

- Biocidal at Low Concentration and Ambient Temperature
- CD gas is Size Scalable
- CD is a true gas to get distribution and penetration
- No Measurable Residuals
- Gas Concentration is Easily and Accurately Monitored
- No manual wiping required

Prevention

- Implement utilizing a Decontamination Chamber rather than using the “spray and pray” method of bringing equipment and supplies into the clean production area.
- Implement utilizing a Decontamination Chamber for pallets of raw materials when offloading trucks and bringing pallets into the building.



Other Uses

Mix-fill, measuring and packaging process Isolators



GETINGE
La Calhène



MTF Musculoskeletal
Transplant
Foundation

Lyophilizers (Freeze Dryers)



*3 hour cycle
CD cycle run every 2 weeks*

*Old steam cycle 24 hours with
heat up /cool down time*



Beta-Lactam Inactivation

Chlorine dioxide gas has been proven to provide a 3-log inactivation of eight different beta-lactams in three different beta-lactam groups.

This allows for the safe repurposing of equipment and facilities used for the production of beta-lactams for future work in non-beta-lactam applications.

Cycle Parameters	
Rh	75%
Concentration	3-5 mg/L
Exposure	4-7 hrs
Dosage	7,240 ppm-hrs for 99.9% reduction

Beta Lactams Tested


Penicillins	Cephalosporins	Carbapenems
Penicillin G	Cefadroxil	Imipenem
Penicillin V	Cefazolin	
Ampicillin	Cephalexin	
Amoxicillin		



Process Tanks and Piping



Example of Long
Distances True
Gases Can Travel



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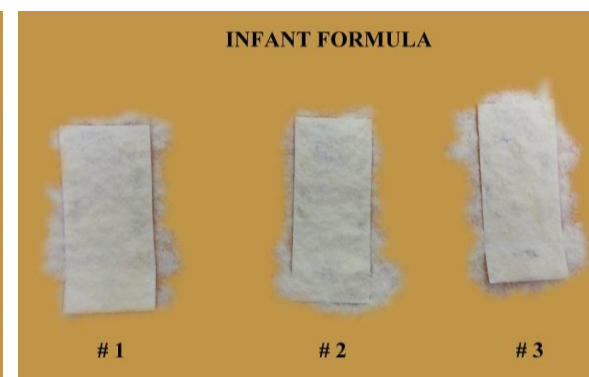
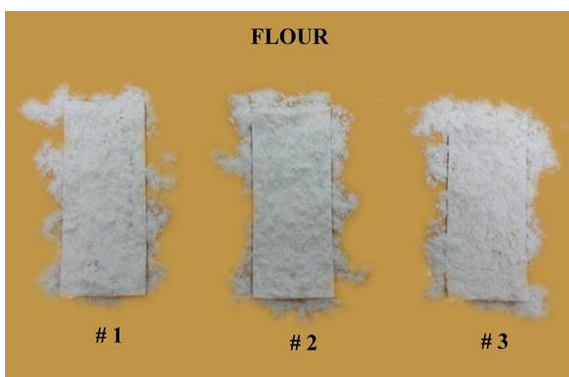
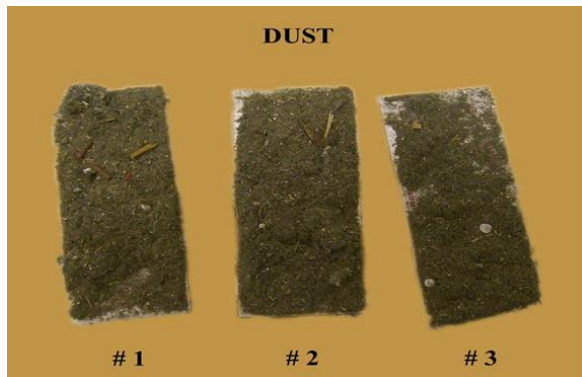
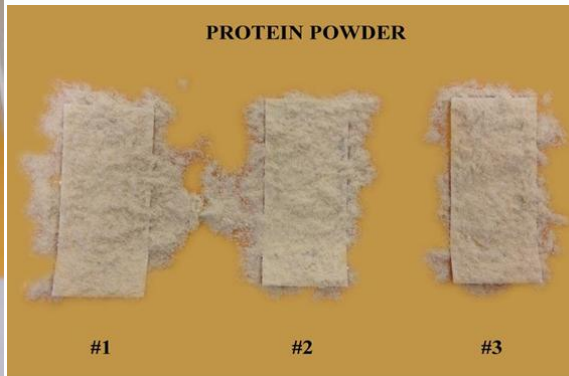


How Clean is Clean

Example of EXCELLENT Penetration Ability in dirty load



All BI's Killed



Decontamination Chambers (325 ft³)



2.5 hr cycle time

Identify Department Responsibilities

Department	Responsibilities
Validation	Review and approve the protocol.
Engineering	Review and approve the protocol.
	Bump HVAC units
	Remove any items from areas
	Replace lubricants
	Humidify rooms with HVAC
	Inhibit smoke detectors
	Notify regulators
	Notify Clordisys of project scope
Production People	Review and approve the protocol.
	Remove any items from areas
	Prepare equipment
Quality Control, Microbiology	Review and approve the protocol.
Quality Assurance	Review and approve the protocol.

BI Results log Sheet (After Gassing)

- CSI ensures that BI's or other indicators are removed from the appropriate places. Biological indicators will be incubated by CSI to ensure a quicker turnaround time. CSI validated a Reduced Incubation Time (RIT) with NAMSA who supplies the BI's and growth media.

<u>ID#</u>	<u>Location</u>	<u>Time Incubated</u>	<u>Result</u>	<u>Initial/Date</u>
1	Room 1002 -1			
2	Room 1002 -2			
3	Room 1002 -3			
4	Room 1002 -4			
5	Room 1002 -5			
6	Room 1011 -1			
7	Room 1011 -2			
8	Room 1011-3			
9	Hallway 1100			
10	Lobby 1101			
33	Hallway 1104			
34	Hallway 1105			
35	Vestibule 1102			