Techniques for BSC Decontamination

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Outline

- General steps in performing a BSC Decontamination
- Chemical-Specific Issues
  - Methodologies
  - Advantages / Disadvantages
- Comparison
- DRS Laboratories' Position

Choice of Decontaminants

- Formaldehyde Gas
- Hydrogen Peroxide Vapor
- Chlorine Dioxide Gas
- Others
  - Methyl Bromide
  - Ethylene Oxide
  - Ozone

Typical Applications

- Clean-up of a contamination event
- Maintenance or other need to access contaminated plenums
- Moving of BSC
- HEPA filter replacement
- End of work program

Requirements for a Successful SD

- Decontamination – typically looking for a log 4-6 reduction of test bacterial spores
- Choice of decontaminant
- Penetration to all surfaces
- Penetration through HEPA filter and into “dead legs”
- Temperature and humidity control
- Containment of fumigant

Requirements for a Successful SD (Cont.)

- Disposal of decontaminator
  - Vent, neutralize, scrub
- Validation of decontamination
  - Biological indicators
- Material compatibility
- Safety

General Preparation Options

- Seal BSC when decontamination required
- Construct BSC with decontamination facilities included
- Permanently modify BSC for specific decon type
- Ensure gas-tight damper if ducted to building
- Insert recirculation (optional)

General Preparation – Biological Indicators

- Given 7 –day test time, typically assume decontamination method already validated
- If using indicators, often *B. atrophaeus* or *G. stearothermophilus*
- Use appropriate substrate (not cellulose for HP)
- Upstream and/or downstream of HEPA filters
- Log-Reduction enumeration vs. Go / No Go
- Controls

General Preparation - Final

- Establish and measure proper humidity & temperature
- Final seal
- Pressure check (neutral to adjacent area)
- Establish safety perimeter
- Meet OSHA requirements

General Procedure

- Fumigant generation to a steady state concentration
- Environmental monitoring for leakage
  - E.g., Draeger pumps, infrared analyzers
- Appropriate personnel protective equipment (PPE)
  - Full face respirator, gloves, lab coat
- Neutralization or scrubbing → Ventilation

General Procedure (Cont.)

- Validation of BSC Decontamination
  - Biological Indicators (opt.)
  - Monitoring of relative humidity, space temperature, and/or decontaminant concentration during process

Formaldehyde Gas (CH_2O)

- Typically via depolymerization of Paraformaldehyde (PF)
- NSF standard 0.3 gm/ft^3 $\longrightarrow$ ~8000 ppm
- Mechanism: methylization of DNA
- Requires relative humidity > 60%
- Target contact time > 6 hr
- Use *Bacillus atrophaeus* as BI

Formaldehyde Gas (Cont.)

- Neutralization with ammonia gas (NH_3)
  - ~ 1 hr contact time
- Vent and environmental monitoring
- Clean "fall-out"
  - Mixture of methenamine and PF
  - Can limit PF with humidity control

Formaldehyde Gas - Advantages

- “True” gas
- Relatively inexpensive
- General material compatibility
- Industry accepted

Formaldehyde Gas - Issues

- “Fall-out” residue
  - Added clean-up time
- Carcinogen
- Potential odor residual
- Polymerization on cold surfaces

Hydrogen Peroxide Vapor (H_20_2)

- Typically delivered by flash vaporization of aqueous peroxide mixture
  - The mixture is generally close to or above saturation in air
- Two major vendors of generators with significant differences
  - Mechanism : Oxidation
- Required contact time less than formaldehyde
- Use *Geobacillus stearothermophilus* as BI

HP Vapor – STERIS (VHP)

- Avoids condensation on surfaces to minimize corrosion and optimize distribution
- Typically two portals into BSC for VHP inlet and return
- Design cabinet with appropriate circulation paths
- Dehumidify to < 30% RH

HP Vapor – STERIS (Cont.)

- Typical 1-2mg/liter, 750-1500 ppm (D~1-2 min)
  - Data that D value is lower than for liquid HP
- Target 70-85% RH during decontamination
- Continually introduce HP, decomposing HP in return
- Cycle Phases
  - Dehumidification / Conditioning / Decontamination / Aeration

HP Vapor – BIOQUELL (Clarus)

- Seeks “micro-condensation”
  - BQ believes D ~2 min required liquid presence
- Swiveling source to inject high-speed droplets to all surfaces
  - Condensate “bounces”
- Monitor for onset of condensation

HP Vapor Advantages

- Safe by-products (water and oxygen)
- No residue
- Industry accepted
- Automated
- Relatively short cycle time if properly engineered

HP Vapor Issues

- Instability of HP toward decomposition
- Decomposition may block access of decontaminant
- Condensation may cause control issues
- Cellulose materials absorb or decompose
  - May effect decontamination or aeration
- Some material issues – nylon, cellulose, copper, lead, iron oxide, epoxy
  - Condensation may effect painted surfaces
- Capital equipment cost

HP Operating Conditions

- (Based on limited information)
- Typical duration from conditioning through decontamination:
  - 1-2 hours
- Typical aeration:
  - 2-4 hours

Chlorine Dioxide Gas (ClO_2)

- Mechanism: Selective oxidation (no chloridation)
- Generated on site via reaction
  - $Cl_2(g) + 2NaClO_2 \longrightarrow 2ClO_2(g) + 2NaCl$
- Visible green gas
- Humidification required, 65-90% RH
- D-value 0.1-0.8 min for 10-30 mg/L
  - (3,500-10,000 ppM)

Chlorine Dioxide Gas (Cont.)

- Scrubbing
  - Wet, with alkaline solutions
  - Dry, via absorption (e.g., charcoal)
- Direct venting option (use by paper industry)
- Monitor concentration and relative humidity
- Use *Geobacillus stearothermophilus* as BI (?)
- The Halide Group, ClorDiSys Solutions, Sabre Technologies (different reaction)

Chlorine Dioxide Gas – Advantages

- Safe by-products (oxygen and salt)
- No residue
- Not flammable / explosive
- “True gas – no condensation issues
- Reputation for use in Anthrax decontamination

Chlorine Dioxide Gas - Issues

- Less well-known or characterized
- Mild corrosion/discoloring to cold steel, copper, brass
  - Particularly in the presence of water
- Potentially corrosive if Chlorine gas (Cl_2) is present
  - Care to avoid Cl_2 in synthesized CD
  - Care to avoid Cl_2 creation by UV exposure
- Current low PEL limit (0.1 ppm)

CD Operating Conditions

- Typical duration conditioning through decontamination:
  - 1-1.5 hr
- Typical duration of aeration / scrubbing:
  - 0.25-0.5 hr

Comparison

Issue	Formaldehyde Gas	Hydrogen Peroxide Vapor	Chlorine Dioxide Gas
Sporocidal effectiveness	+	+	+
Effective through HEPA filters	+	?	+
Non Carcinogenic	-	+	+
Toxicity (TWA PEL)	0.75 ppm	1.0 ppm	0.1 ppm
Non-explosive (at used concentrations)	-	-	+
Humidity requirement (RH)	60-90%	30% (Steris) or ambient (Bioquell)	65-90%
No residue	-	+	+
Non-corrosive	+	+ (dry) / ? (cond.)	+ / - (with chlorine)
Method of removal	Neutralizer	Catalytic breakdown	Scrubbing
Limited development effort	+	-	+
Limited cost	+	-	-

NSF/ANSI 49 – 2002 Annex G

Recommended microbiological Decontamination procedure

"Prior to decontamination with an alternative [note added: other than depolymerized paraformaldehyde] *method (such as VHP), cycle parameters and validation of those parameters must be developed for each model and size of BSC."*

Baker Company in CleanRooms (Mar. 2001)

"Existing cabinets can be modified in the field to accept hydrogen peroxide vapor generators… However, these alternatives are less than optimal because:

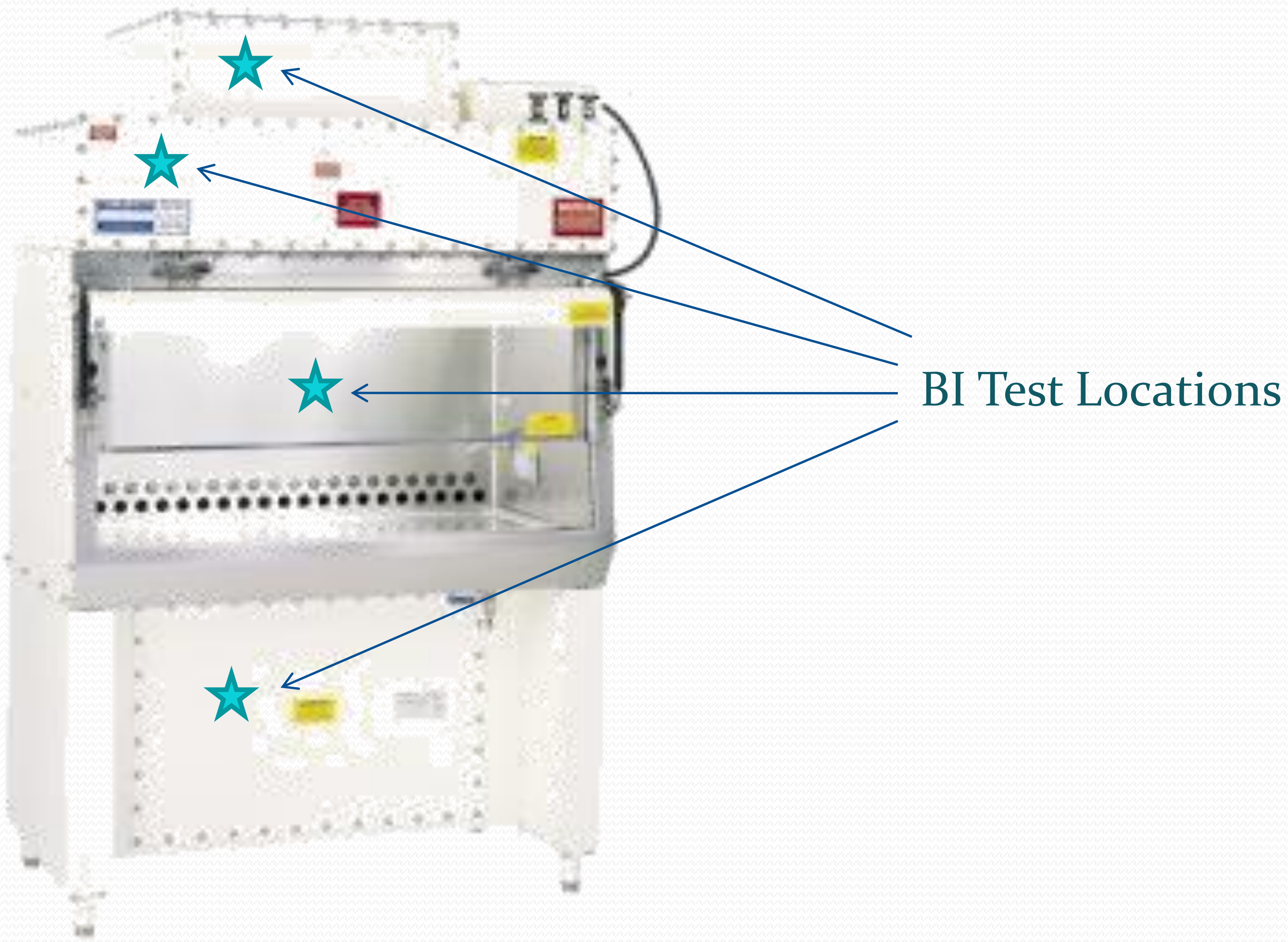
1. *Such cabinets are not designed for fast distribution of H_2O_2 and poor vapor distribution will require long cycle times – considerably longer than for formaldehyde cycle. …"*

DRS Laboratories' Position

- Safety issue in maintaining BSC following Clarus decontamination
- Need validation data for decontamination covering
  - Variation of safety cabinet
  - Variation of HEPA filter thickness
  - Demonstration of decontamination on up and down stream sides of HEPA filter
  - Demonstration of decontamination if cabinet has a failed motor

Chlorine Dioxide Alternative

- DRS Laboratories has experience with two delivery systems:
  - Direct ClO_2 insertion into BSC
    - Continuous concentration monitoring
    - Wet "scrubbing" of gas after cycle
  - Tablet generation of ClO_2 in water
    - "Bubbling" air to draw out gas
    - Dry "scrubbing" after cycle
    - No additional cost relative to PF


BI Test Locations

Current CD Data

- Four runs with four BI's each (*G. Stearothermophilus*)
- 125 min. from humidification to opening
- Exhaust plenum wo/ recirculation:
  - 3.5-5.5 log reduction
- Exhaust plenum w/ recirculation:
  - 6.0-6.2 log reduction
- Of others,
  - 11/12>6.2 log reduction, 1/12~5.6 log reduction

Chlorine Dioxide Validation

- Less of an issue, as ClO_2 is “true” gas
- Have begun process at DRS Laboratories on multiple cabinets
- Propose to monitor with BI’s on other cabinets on short term after DRS Laboratories internal validation complete
- DRS Laboratories’ technicians would not require waiting for BI results during this phase