Decon 2.0: Emerging Decontamination Technologies

Vaporized Hydrogen Peroxide (VHP) and Chlorine Dioxide Gas Decontamination Case Studies:

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Exposing a confined space to a gas or vapor with sporicidal capability

Space can be manufacturing or research rooms and/or laboratories, HVAC systems, entire buildings, containment suites, LARs

Equipment within space i.e. biological safety cabinets (BSCs), laminar flow hoods, incubators, refrigerators, freezers, computers, and other electronic devices
Why Space Decontamination?

- Eradication or sufficient reduction of known bioburden
- Preventative periodic bioburden reduction
- Preventative pre-start up bioburden reduction
- Decommissioning of facility
- Product change
What Defines a Successful Decontamination?

- Bioburden reduction – typically demonstrated via 4-6 log kill of bacterial endospore biological indicators (BIs) with controls growing out
- Distribution of disinfectant to all target surfaces including HVAC, through HEPA filters where applicable
- Control of conditions: temperature/humidity/room pressurization
What Defines a Successful Decontamination? contd.

- Containment of fumigant
- Disposal of fumigant via ventilation, neutralization, filtration
- Material compatibility
- Safety – all fatally toxic at use concentrations
- Regulatory compliance with FIFRA
Why Gas/Vapor vs. Liquid/Fog

- Limitation of liquid/fogging agents to reach some surfaces vs. gas/vapor, i.e. internal equipment surfaces, porous surfaces, HVAC, interstitial and tough to reach spaces, plenums within BSCs
- Difficulty in uniform application of liquid/fogging agents vs. gas/vapor
- Material compatibility, liquids and corrosion
Why Gas/Vapor vs. Liquid/Fog, contd.

- Difficulty maintaining sufficient contact time for sporicidal disinfectants for liquid/fogging agents vs. gas/vapor
- Difficult to validate with biological indicators with liquid/fogging agents vs. gas/vapor
- Gas/vapor systems can be integrated into facilities
- Gas/vapor systems can be automated
Gas/Vapor Decontamination Options

- Formaldehyde gas
- Vaporized Hydrogen Peroxide
- Chlorine Dioxide Gas
Formaldehyde Gas, Overview and Advantages

- 50+ years of use and data
- Via methylization of DNA
- Typically @ .3 grams/ft³ (NSF/ANSI 49) yielding ~ 10,000 ppm
- Rh > 60%, typical ambient temp., target contact time six log ≥ 6 hours (NSF)
- Industry Accepted and Validated
- Good – excellent material compatibility
- Relatively inexpensive (depolymerization of paraformaldehyde)
Formaldehyde Gas Challenges

- Requires neutralization with ammonium carbonate or bicarbonate
- WHO carcinogen
- Low PEL (.75 ppm)
- OSHA regulated
- Residue
- Not FIFRA compliant
Vaporized Hydrogen Peroxide 
\((H_2O_2)\)

- Developed early 1990s AMSCO, Steris VHP
- Mechanism – oxidation, attacks cell membrane
- Sporicidal (broad spectrum) at low concentrations, typically @ 150 - 700 ppm
- Start Rh < 50%, typical ambient temp., target dosage 6 log typically 250 – 500 ppm-hours (d value ~ 10 min @ 350 ppm)
- Cycle phases: dehumidification, conditioning, decontamination, aeration
Typical Vaporized Hydrogen Peroxide Bio-decontamination Cycle

By Courtesy of Steris Corporation
Vaporized Hydrogen Peroxide (VHP)

Hydrogen Peroxide 31% or 35%

Vaporization

$2\text{H}_2\text{O}_2$

$\text{O}_2 + 2\text{H}_2\text{O}$

Sporicidal at Low Concentrations

By Courtesy of Steris Corporation
Vaporized Hydrogen Peroxide ($H_2O_2$) contd.

- Good – excellent material compatibility with some exception (nylons, galvanized aluminum with prolonged exposures)
- Absorptive materials slow down process
- Internal, external or integrated introduction of VHP
- IDLH 75 ppm; PEL 1 ppm
Vaporized Hydrogen Peroxide ($H_2O_2$) contd.

- FIFRA-compliant STERIS Vaprox EPA-registered sterilant
- Non-toxic byproducts; no residue
- Multiple generators needed for larger spaces
- Materials must be dry
- Typical cycle time 4 – 7 hours including aeration
- Integrated concentration monitoring option
Chlorine Dioxide Gas

- US Senate anthrax remediation, food industry, water treatment, medical device, Life Sciences
- Mechanism – oxidation, (not chlorination) attacks cell membrane, no chlorine by-products
- Sporicidal (broad spectrum) at low concentrations, typically @ 100 – 1800 ppm
Chlorine Dioxide Gas contd.

- Start Rh > 65%, typically at ambient room temp., target dosage six log typically 700 - 1000 ppm-hours (d value ~ 20 min @ 400 ppm)
- Ventilated or scrubbed
- Mild corrosion/discholoring to cold steel, copper, brass ++ H2O present; potentially corrosive if Cl2 present
Chlorine Dioxide Gas contd.

- External introduction
- Low PEL .1 ppm
- FIFRA – compliant ClorDisys EPA-registered sterilant
- Scalable
- Integrated concentration monitoring option
- CD gas cycle time 3 – 7 hours typically (humidification, charge, exposure, aeration)
Field Studies: VHP and ClO$_2$
Decontamination Planning Issues

- Define purpose and scope: rooms, equipment, HVAC
- Identify the players, area production managers, EH &S, facilities engineering, QC validation, security
- Establish responsibilities
- Select decontaminating agent
- Establish the schedule and ordering
- Write SOPs, fumigation management plan
- Define success: BIs, full PQ, target dosage
Decontamination Planning Issues contd.

- Containment Issues, Ventilation, Circulation, Humidification/de-humidification
- Communication
- Health and Safety Planning and Coordination, PPE, Emergency Providers
- Clean up and release of area
Decontamination Execution

- Prepare area; pre-clean, BI placement, fan distribution, monitor readiness, seal area, safety perimeter, signage
- Reach target temp/humidity; monitor
- Create safety perimeter/signage
- Introduce chemical and bring to target concentration for target exposure time; monitor
- Monitor surrounding areas for leakage
- Ventilate and/or neutralize to below PEL
- Incubate/analyze BIs as specified
Space Decontaminations

- Pharma aseptic production areas
- Laboratory Animal Research areas
- Pilot plant production areas
- Cold Rooms
VHP Case Study: Pharma

240,000 ft³ manufacturing space
VHP Case Study: Pharma Manufacturing contd.

- Emergency scenario
- Two days planning
- 65 rooms
- Emergency remediation
- 66 liters of Vaprox 35%
- Eight STERIS VHP generators
- Twelve technicians/engineers for 3.5 days
VHP Case Study: Pharma Manufacturing contd.

- Issues: old facility, unpredictable HVAC, pressure schemes
- 165 BIs, A and B samples
- 95 Chemical Indicators
- Managing the process: QC/EH&S/Facilities
Conditions and Cycle Parameters

- Humidity (RH): 25-40%
- Temperature: 22°C
- Room to Exterior Pressurization: 0.0” w.g.
- Injection Rate: 12 g/min
Pharma VHP Concentration Room

VHP Concentration

Average Reading: 214 ppm
Peak Reading: 357 ppm
4 Hours
VHP Case Study: Pharma Manufacturing contd.
VHP Case Study: Pharma Results

- All CIs changed color
- 96% BIs ≥ 6 log kill, with remaining ≥ 5 log kill
- Those < 6 log in rooms with VHP loss due to HVAC
Case Study: 20,000 ft³ Pharma Pilot Plant ClO₂ Gas Decontamination
Pharma Pilot Plant ClO₂ Decontamination

Average: 0.5 mg/L
ppm-hours: 900
Pharma Pilot Plant ClO$_2$ Decontamination

Chlorine Dioxide

![Graph showing the concentration of chlorine dioxide over time.](image-url)
Pharma Pilot Plant ClO$_2$ Decontamination Results

Results
- All 20 BIs no growth
Viable alternatives to formaldehyde gas exist for efficacious and safe decontamination of pharmaceutical production space and other space.

It is important to understand the physical properties and behavior of your decontaminant of choice to ensure efficacy and safety.

Different decontaminants may be appropriate for different applications.

Planning is paramount!!
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