Utilizing Integrated Vapor Phase Hydrogen Peroxide (VPHP) for Decontamination of Cleanrooms and other Critical Environments

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360° solutions
Agenda

- WHY??
- History
- Introduction to Vapor Phase Hydrogen Peroxide
- Variables Affecting Efficacy
- Integrated Systems & Design Considerations
- Validation
WHY??- When manual disinfection is not enough...

- Large scale contamination
- Flood, earthquake, hurricane, power failure
- Renovation, new construction, shutdowns
History

• For over 100 yrs.: liquid hydrogen peroxide is used as a germicide.
• In the late 1980s, American Sterilizer Company (now STERIS) discovered that hydrogen peroxide in vapor phase kills spores at low concentrations and short contact times.
• The first commercial portable VHP® generator was available in 1991 and used primarily for isolator applications.
History

- Integrated systems for isolators became available in the late 90s.
- Anthrax attacks in 2001 resulted in a huge increase for decontamination of laboratories.
- Now large capacity integrated units are being installed for large volume critical environments as a built-in utility.
Vapor Phase Hydrogen Peroxide Process

Vaporization

35% Hydrogen Peroxide

2H₂O₂

Sporicidal at Low Concentrations (Typically 0.2-2 mg/L at 25°C)

+ O₂

Non-Toxic Residues

Ambient Temperature Process

‘Vapor’ is defined as a substance that has an ambient state in the liquid phase; it does not mean that it cannot exist in a dry, gaseous phase.
Limitations

• Does not work well on highly absorptive materials
• Penetration can be limited due to instability
• Surfaces must be reasonably clean
• Surfaces must be dry
Advantages

- DRY; Penetrates HEPA filters
- Great Alternative to other toxic chemicals
- Ambient Temperature
- No Lengthy Aeration compared to other chemicals
- Non-Toxic By-Products (water vapor and oxygen)
- Residue Free
- Excellent Material Compatibility
- Repeatable
Effective

- Highly sporicidal even as low as 0.2 mg/L
- Able to achieve sterility in minutes
- Destroys a wide range of microorganisms
Variables Affecting Efficacy

- Temperature and humidity affect how much can be generated in the gas state
- Concentration
- Saturation
  - Inject as much as possible but below dewpoint
  - Humidity is good for microbial kill
How Is it Dry?

- Low humidity air thru vaporizer for max. gaseous generation
- Begin enclosure at known humidity
- Constantly remove humidity
  - 35% Hydrogen peroxide/ 65% water
Vapor Phase Hydrogen Peroxide

Microbial Kill Matrix

\[
\text{Avg. D-Value (min)} \quad \text{Vapor Conc. (mg/L)}
\]

- \( Geobacillus\ stearothermophilus \) spores inoculated on Stainless Steel Coupons at 30\(^{0}\)C
D-value for 1.6 mg/L Versus Percent Saturation
Four Phase
Vapor Phase Hydrogen Peroxide Cycle

1. Dehumidify
2. Condition
3. Decontaminate
4. Aerate
If the humidity is controlled throughout the cycle, the hydrogen peroxide will remain in the dry, gaseous phase.
Closed Loop Configuration

- Sealed Enclosure
- H₂O₂ Reservoir
- H₂O₂ Cartridge
- Vaporizer
- HEPA Filter
- Pre-Heater
- HEPA Filter
- Catalytic Converter
- Desiccant Chamber
Single Pass & Integrated Configuration

- H₂O₂
- Vaporizer
- Controls
- Blower
- Enclosure
- Valve
- Dry Air In
- Air Out
Principle Diagram for Integrated System

- Dryer
  - Warm Wet Air Exhaust
  - Reactivation Air Inlet
  - Process Air Inlet
  - Dry Air Outlet
  - Sterilant Outlet

- Generator
  - Air Inlet
  - Process Air Inlet
  - Dry Air Outlet
  - Sterilant Outlet

- Optional Catalytic Converter
  - Extraction Fan

- Rooms:
  - Room 1
  - Room 2
  - Etc...

- 360° Solutions
Integration

1. Pipework separate from the HVAC
2. Using HVAC system
Integration

1. Pipework separate from the HVAC

Application Example
Integration

1. Pipework separate from the HVAC

- Pipework is CPVC/PP.
- Inlet pipes are insulated (not heat traced).
- HVAC is stopped and the airtight dampers are closed during Dehumidification and Injection Phases. HVAC system is restarted for Aeration.
- Flow between rooms will have to be adjusted during commissioning and simple adjustable butterfly dampers will be needed per room.
- Butterfly valves will be installed at each room or the pipe will be installed at the back of the room’s HEPA filter entry.
- Pressure (Positive or Negative) control during Decontamination can be achieved on small and/or leaktight rooms by the exhaust fan.
Integration

2. Using HVAC system

Application Example
Integration

2. Using HVAC system

- Pipework to HVAC is made of CPVC/PP.
- Inlet pipes are insulated (not heat traced).
- HVAC is running in a closed loop only, no fresh air is admitted during Dehumidification and Injection Phases. Then maximum fresh air for Aeration.
- Recirculation with the HVAC will allow an equal distribution of the gas.
- The cooling and heating of the HVAC will be stopped (Aluminum, Stainless Steel or Epoxy coated; no copper).
Large Room Capacity

>32,000 ft³ (900m³) volume and
28 ft. (8.5 m) ceiling height
Pass-through Chamber

- Integrated VPHP can be used for:
  - Equipment/Packaging/Other Cleanroom /Heat sensitive items

  ✓ Achieving shortest cycle times
  ✓ To achieve 6 log kill: 15 minutes – 1 hr.
Validation: Efficacy

• Methods:
  – *Geobacillus stearothermophilus* Biological Indicators (BI)
    • Packaged in Tyvek® or ‘naked’
    • Inoculated side face up
    • Hang with paper clips/tape
  – User Made Inoculated Coupons
    • Can be inconsistent
    • Issues with reusing stainless steel
    • Material properties affect resistance

*Photos are Courtesy of Advanced Barrier Concepts*
Validation: Efficacy

• Population
  – $10^6$ is most common
  – Lower population can be justified for low bioburden isolators
  – Population verification
• Locations
  – Worst case
  – Critical areas
  – Indicator cannot be blocked
• Multiple indicators per location
  – Potential outliers
• D-value testing
  – Actual vs. Vendor’s
Concentration Monitoring

- Room monitors for outside of space
- Low end sensor to detect levels inside space before entry
- High end sensor to measure decontamination levels

**Humidity Study Using 31% H2O2**

- **UOP H2O2 Monitor S/N 1011**
  - 20 SCFM at 2.2 g/ml

![Graph](image)

- **VHP Exposure Average = 1.05 ± 0.02**
- **Water Vapor Exposure Average = 3.51 ± 0.05**
Concentration Monitoring

Hand held Sensor

Low end Sensor

High end sensor
QUESTIONS???