Decon 2.0: Emerging Decontamination Technologies

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

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Space Decontamination

- 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 $\geq$ 6 hours (NSF)
- Industry Accepted and Validated
- Good – excellent material compatibility
- Relatively inexpensive (depolymerization of paraformaldehyde)

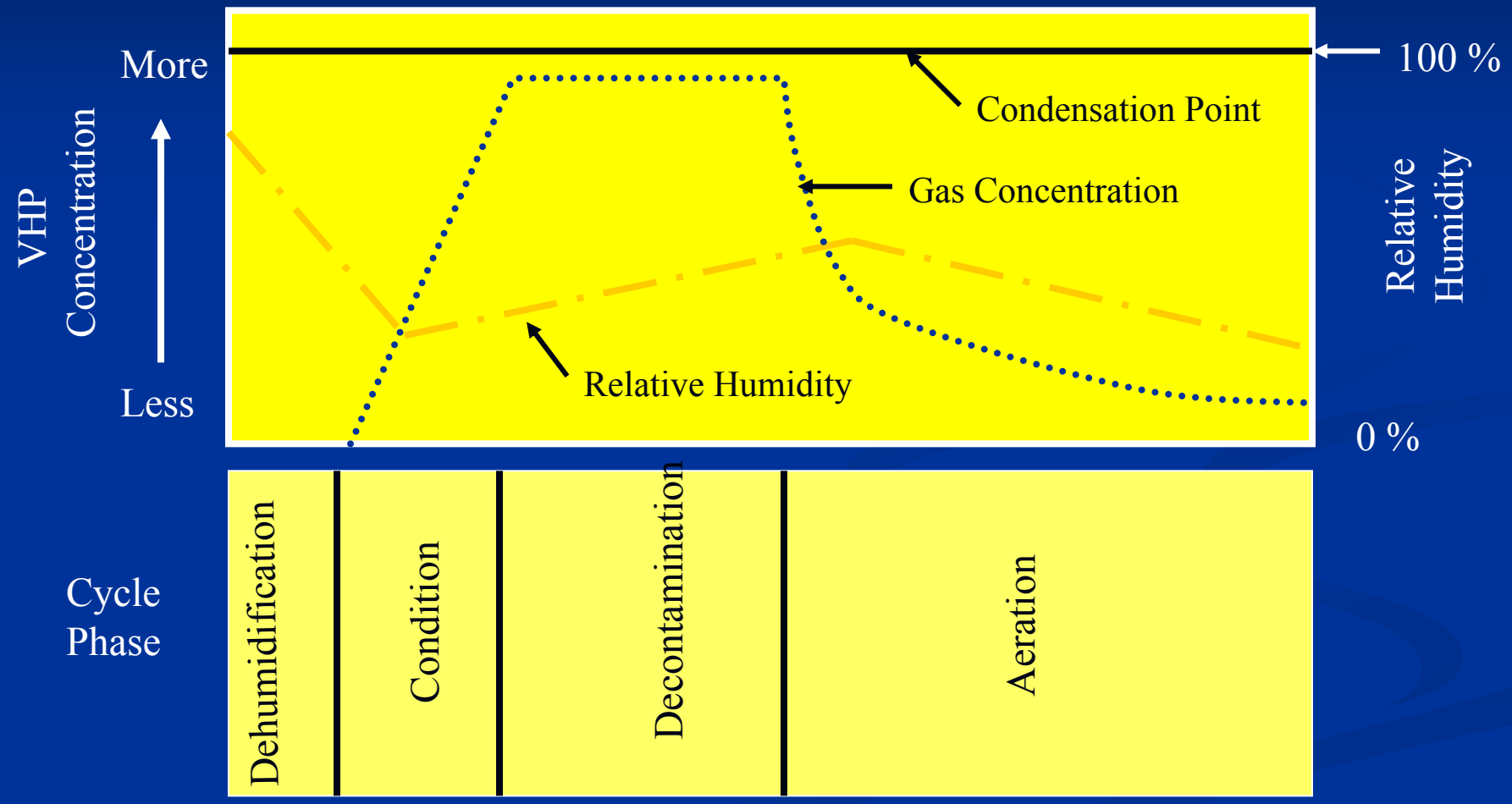
Formaldehyde Gas Challenges

- 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

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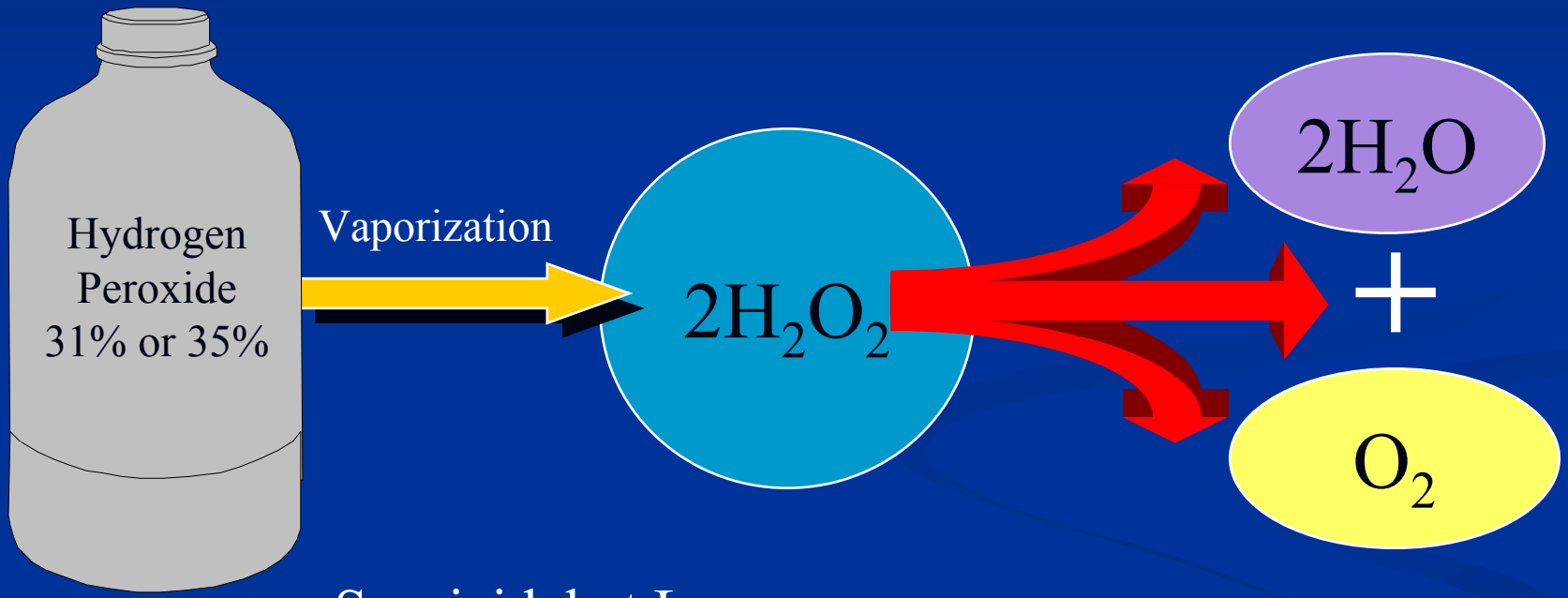
Vaporized Hydrogen Peroxide (VHP)



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

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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/discoloring to cold steel, copper, brass ++ H_20 present; potentially corrosive if Cl_2 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

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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

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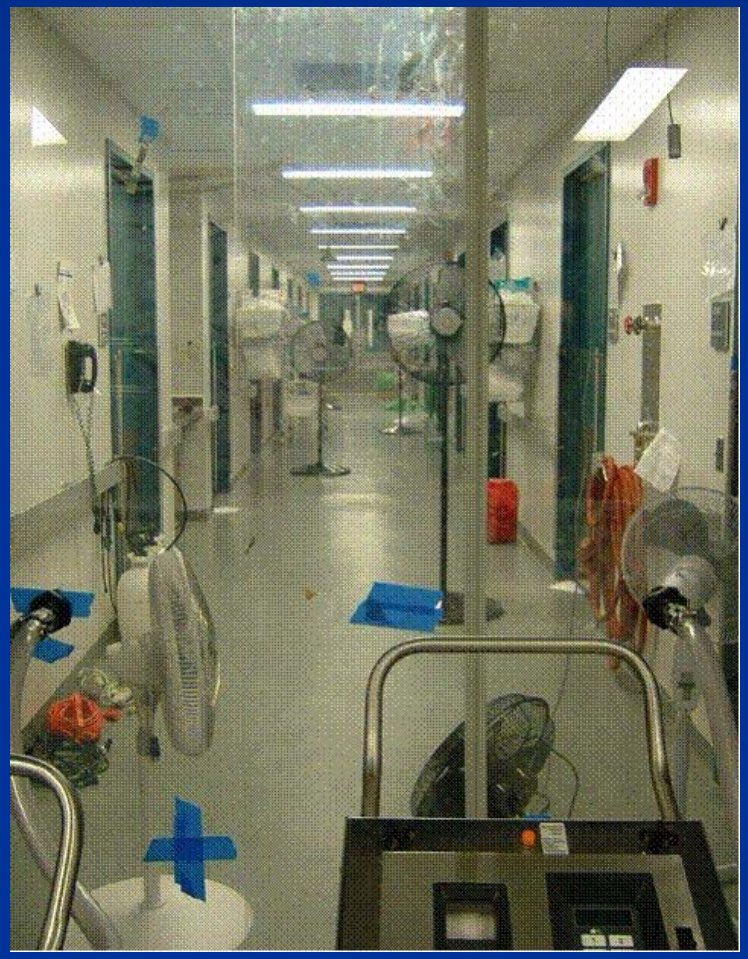
VHP Case Study: Pharma



240,000 ft^3 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

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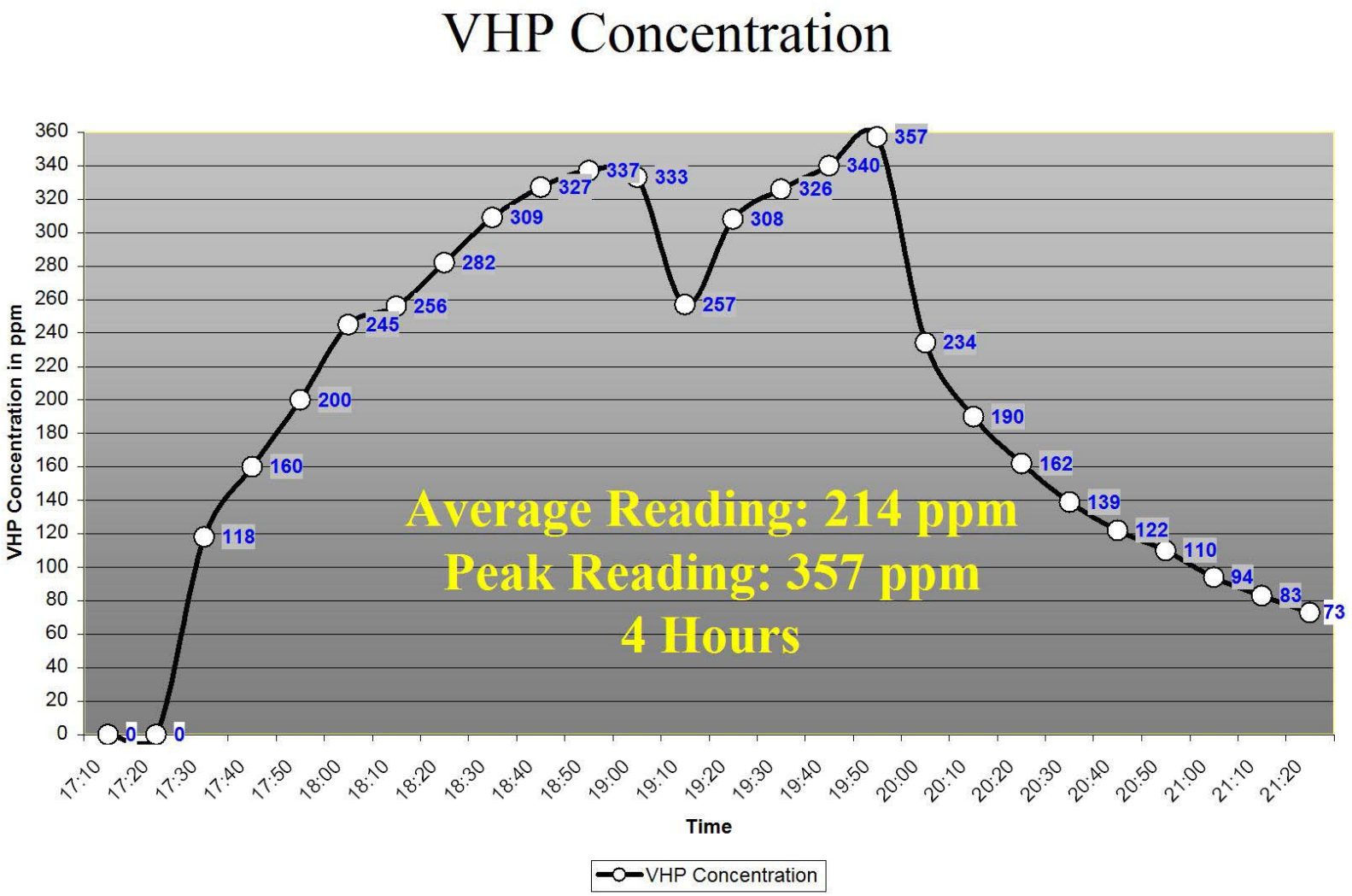
VHP Case Study: Pharma Manufacturing contd.

- 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

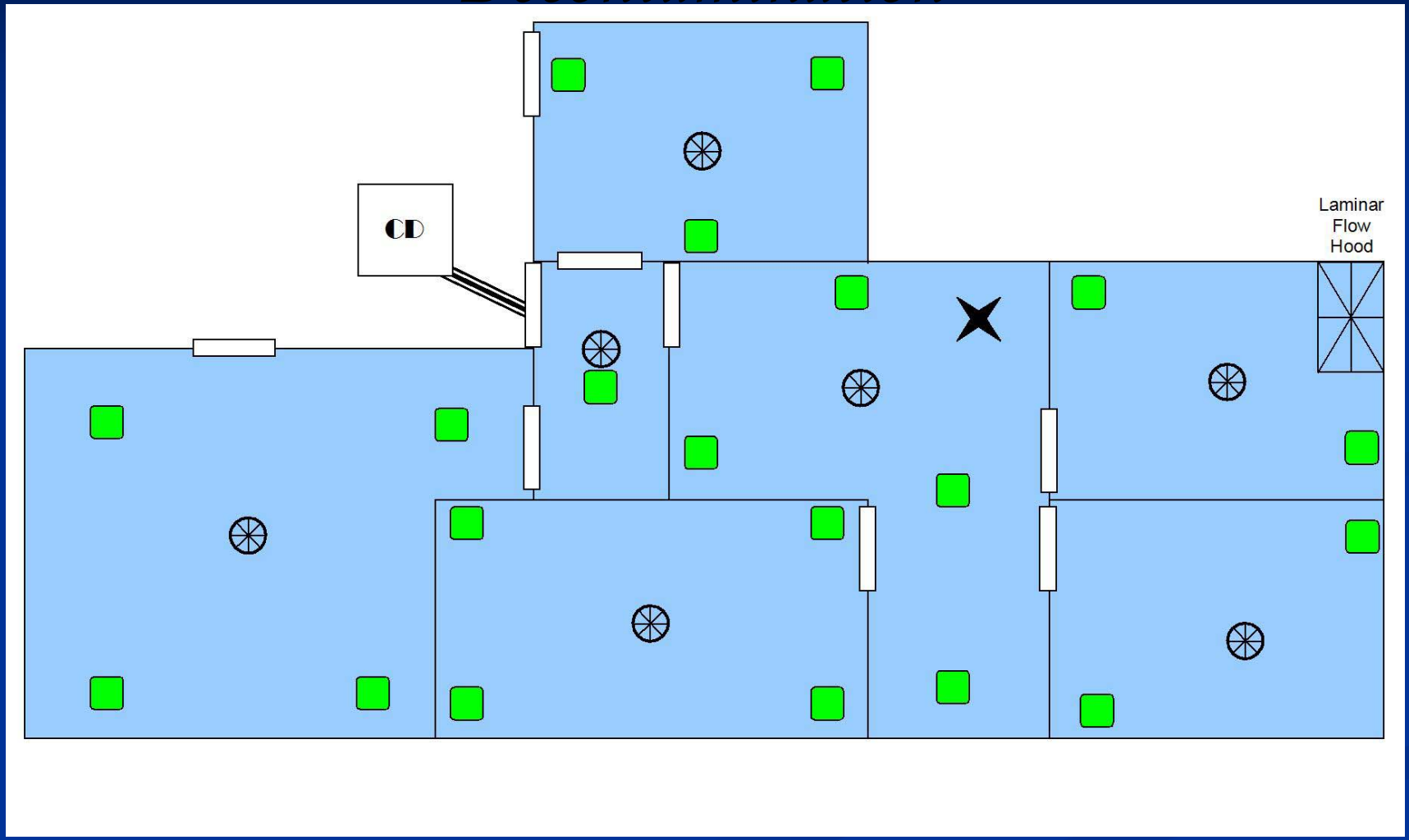


VHP Case Study: Pharma Manufacturing contd.

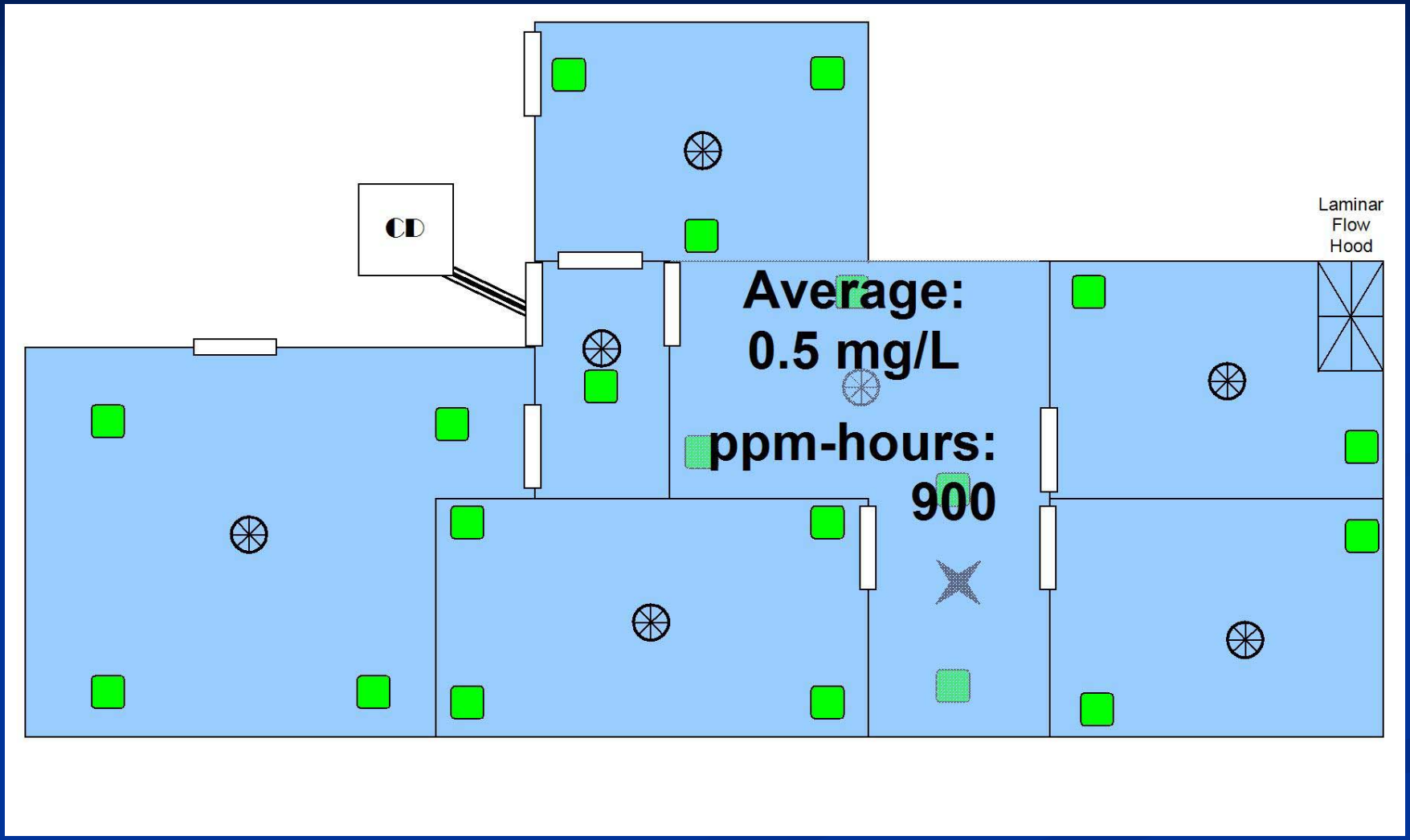
VHP Case Study: Pharma Results

- 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 ft^3 Pharma Pilot Plant ClO_2 Gas Decontamination



Pharma Pilot Plant ClO_2 Decontamination



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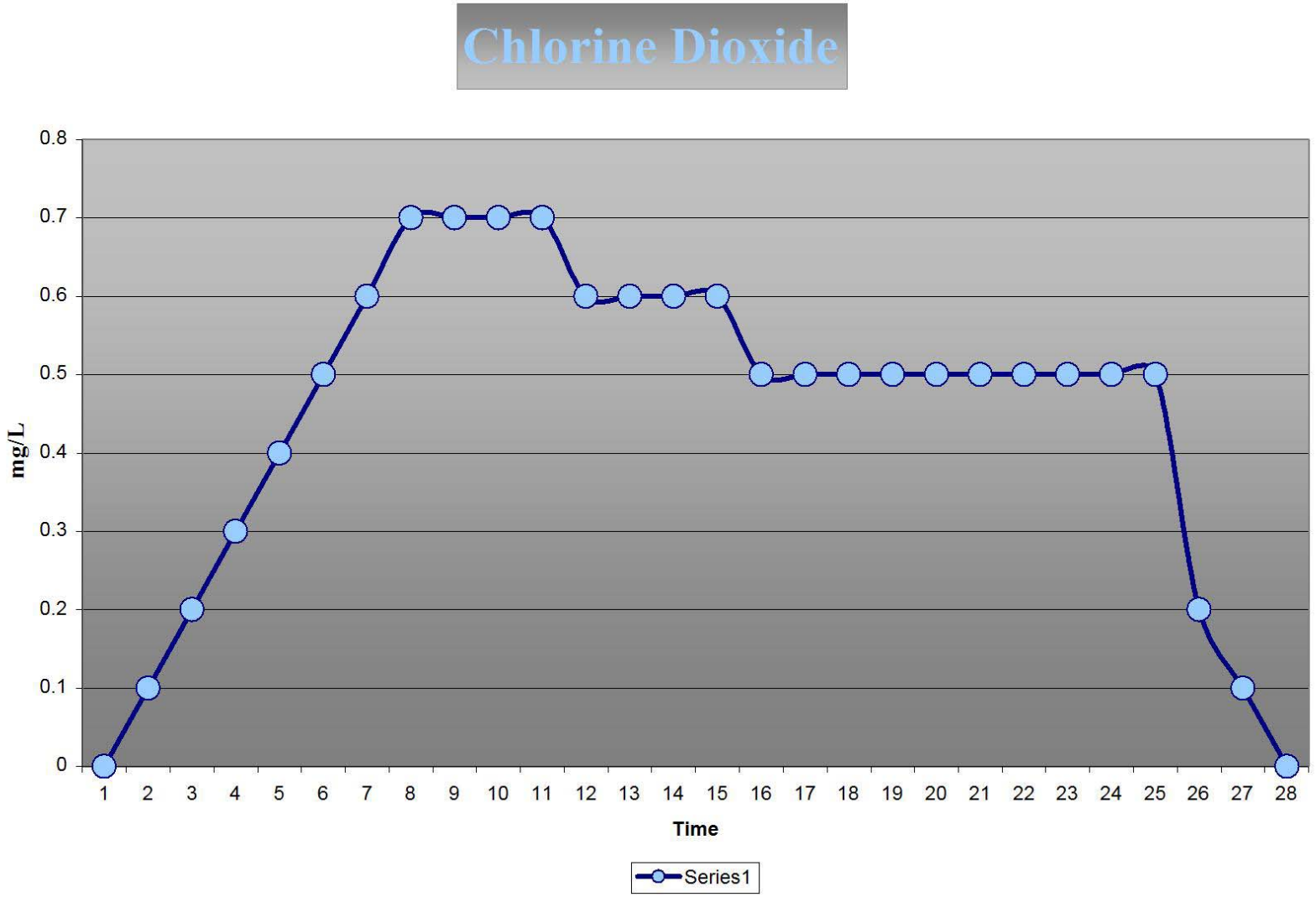
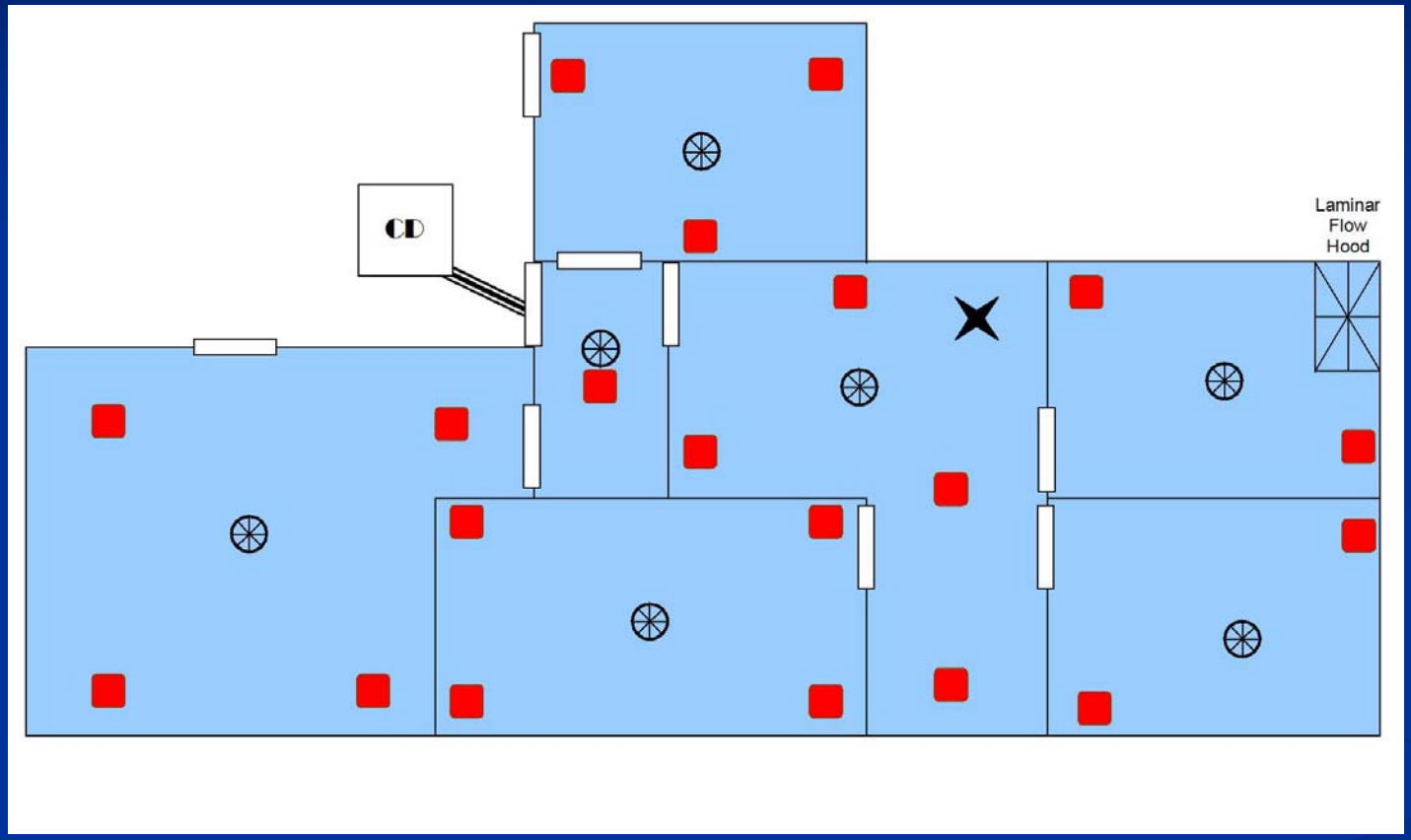


Pharma Pilot Plant ClO_2 Decontamination Results



Results

- All 20 BIs no growth

Summary

- 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!!

Acknowledgements

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