Biological Safety Cabinet Biodecontamination

With Hydrogen Peroxide Vapor

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Introduction

Safe and effective biodecontamination of biological safety cabinets is important whether it is part of equipment commissioning, decommissioning, prophylactic bioburden control, or maintenance to ensure the safety of those utilizing the equipment or the research being conducted within the equipment. There are several methods of biodecontamination technology available to the Customer depending upon the desired result which includes but is not limited to material compatibility, efficacy against organisms, ease of validation, bioburden reduction level, HEPA filter penetration, and environmental health and safety concerns. This article discusses the successful use of hydrogen peroxide vapor in the biodecontamination of Class II Type A2 biological safety cabinets. It will discuss the reasons why this process was chosen; the biodecontamination process; and the results.

Why Hydrogen Peroxide Vapor

With many methods of biodecontamination technology available on the market today from formulated chemistries to formaldehyde to chlorine dioxide to hydrogen peroxide hybrid (liquid/condensation & vapor) to hydrogen peroxide vapor, the challenge is selecting the correct method for the particular application and desired results. Hydrogen peroxide vapor was first introduced in 1991 by STERIS Corporation with the VHP® 1000 for primarily the biodecontamination of isolators and food & beverage applications.(1) Since, the technology has been expanded in scope and many companies have introduced like products. In the United States (US) the Environmental Protection Agency (EPA) regulates the safe and effective use of these products under

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). “The objective of FIFRA is to provide federal control of pesticide distribution, sale, and use. All pesticides used in the US must be registered (licensed) by EPA. Registration assures that pesticides will be properly labeled and that, if used in accordance with specifications, they will not cause unreasonable harm to the environment. Use of each registered pesticide must be consistent with use directions contained on the label or labeling.”[(2)] This gives Customers the ability to understand the claims and use of any particular product as part of the decision making process.

In particular, hydrogen peroxide vapor biodecontamination has many advantages over the other methods. Due to the fact that it is a vapor, the process has a high degree of material compatibility because the vapor is not condensing onto the surfaces within the biological safety cabinet. This is important as many of the internal surfaces of the cabinet are galvanized or painted surfaces and the cabinet has electrical components, which when exposed to moisture or other chemicals can cause harmful damage. The US EPA has done extensive studies on this and published articles accordingly for reference.[(3)] The process has a wide range of efficacy. Depending on the manufacturer, the US EPA label claims range from a disinfectant for mold remediation[(4)] to a sterilant (Fungicide, Sporicide, Bactericide, and Virucide).[(5)] In addition to this, the hydrogen peroxide vapor process can be easily validated with the use of Biological Indicators (BI) and Chemical Indicators (CI). Generally, a 6-log BI comprised of *Geobacillus stearothermophilus* spores wrapped in Tyvek® on a stainless steel carrier are used for validation. *G. stearothermophilus* spores have been proven to be the most resistant organism to hydrogen peroxide vapor. The Tyvek and stainless carrier are used as challenges to the biodecontamination process as many other processes cannot penetrate the Tyvek and/or achieve kill on a stainless steel disc. The Tyvek acts as barrier for the vapor or gas to pass through similar to a HEPA filter and the stainless steel disc acts as a catalyst to the sterilant being used. The combination simulates a worst case environment and ensures a 6-log reduction was achieved on exposed surfaces within the cabinet. The CI is used to show even distribution of the vapor throughout the cabinet. Because the process remains in the vapor phase, the vapor can effectively pass through the HEPA filters within the cabinet effectively

biodecontaminating the HEPA filter as well as both the dirty and clean sides of the cabinet. Hydrogen peroxide vapor is one of the safer forms of biodecontamination methods available. (See Table 1)

Table 1. ENVIRONMENTAL HEALTH & SAFETY GUIDELINES[6][7]

	H_2O_2 Hydrogen Peroxide	ClO_2 Chlorine Dioxide	CH_2O Formaldehyde
HEALTH HAZARD	Skin / eye irritant	Severe respiratory irritant	Human carcinogen (IARC – WHO)
PEL / REL A32 (ppm) (8 hour TWA)	1.0 / 1.0	0.1 / 0.1	0.75 / 0.1
IDLH (ppm, 30 min)	75	5	20
STEL – OSHA / NIOSH (ppm, 15 min.)	- / -	- / 0.3	2 / 0.1

Lastly, the process is green leaving no residue or residual odor after biodecontamination with natural byproducts of water vapor and oxygen as a result of the process.

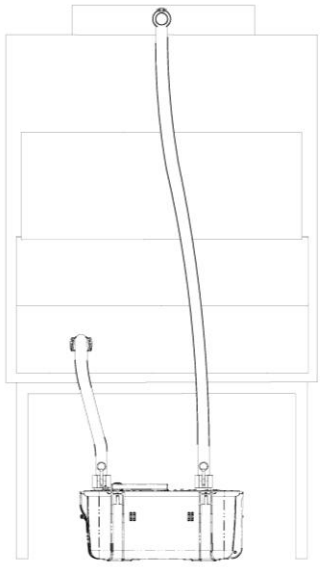
Biodecontamination Process

The hydrogen peroxide vapor biodecontamination process involves three main criteria: the preparation of the cabinet for biodecontamination; the biodecontamination process; and the release of the cabinet.

The first criterion, preparation of the cabinet for biodecontamination, is the same for all gas, liquid/vapor, and vapor processes. For a Class II Type A2 cabinet, the cabinet should be sealed as leak tight as possible with tape and plastic. If the cabinet is connected to the air handling system the damper to the cabinet should be closed or the cabinet disconnected from the system. A sash adapter and plenum adapter are installed on the cabinet to allow for the connection of the hydrogen peroxide vapor generator to the biological safety cabinet (See Figure 1). At a minimum in accordance with EPA labeling and other certifications, CIs are placed in the work zone and plenum to show distribution of the vapor in the work zone as well as penetration through the HEPA filter. BIs, depending on EPA labeling or Customer requirements, may or may not be required. If they are required, it is recommended to place them with the CIs and to double hang. Once the cabinet is properly sealed, warning placards placed, and

generator connected, the biodecontamination process can be started. Set-up takes about 15-60 minutes depending upon the particular application.

Figure 1. TYPICAL GENERATOR-CABINET SET-UP



The next criterion, biodecontamination process, consists of three distinct phases. The first phase, conditioning, involves standardizing the cabinet to an operating temperature, humidity, and hydrogen peroxide vapor concentration. This reduces the risk of condensation of the vapor and allows for maximum vapor concentration to be achieved, which decreases cycle time while increasing efficacy. If the cabinet blower is functional, it is recommended to use it as it aids in the even distribution of the vapor throughout the cabinet and speeds the entire process. Additionally, some generators do not have the ability to circulate the vapor without the use of the blower. For these generators, if the blower is broken, an auxiliary blower will need to be supplied. The cabinet is checked for any leaks during this phase using a hydrogen peroxide vapor sensor or tube to ensure that hydrogen peroxide vapor levels are less than or equal to 1 part per million in the area adjacent to the cabinet. If the result is less than the 1 part per million, depending on the generator and process, the Trained & Certified Operator (TCA) may leave to perform other tasks (e.g. prepare another cabinet, perform maintenance, etc.) within the facility or elsewhere while the biodecontamination process completes. During the second phase, biodecontamination, vapor concentration is maintained at a time and concentration sufficient enough to achieve desired results in accordance with Customer

conditions, EPA labeling, and/or validated conditions. The final phase, aeration, requires the removal and/or destruction of the sterilant. For hydrogen peroxide vapor processes, this can be achieved by various means. For vented cabinets, the damper can be opened and the vapor vented to the outside. The galvanized ducting and sunlight readily destroy the vapor. For non-vented units, the vapor is destroyed with the use of a catalyst. The biodecontamination process takes an average 1-4 hours depending upon the desired results and actions to be performed (e.g. biodecontamination, maintenance, etc).

Lastly, the criterion for release of the cabinet. Before removing placards and unsealing the cabinet, a hydrogen peroxide sensor or tube is used to determine that the hydrogen peroxide vapor concentration is less than 1 part per million as measured at the cabinet sash. Once this limit is reached, the cabinet can be completely unsealed. In addition to this criterion, the CIs are examined and if used, the BIs are processed and evaluated. If all of the necessary conditions are met, the cabinet can be released for use.

Results

At the conclusion of the biodecontamination process, the CIs and if used, BIs are collected, examined, and processed. CIs are checked for color change showing even distribution of the vapor throughout the cabinet. If all of the CIs exhibit color change, the cabinet can be released for use. If the Customer and/or registration require use of BIs as part of the process, the cabinet cannot be released for use until results are returned, which can be 24 hours to 7 days depending upon the Customer's acceptance and/or validation criteria. The positive BI control requires taking an unexposed BI and placing it in the BI media for the desired incubation period. The BI media should show turbidity and/or color change. The exposed BIs should show no turbidity and/or color change for the desired incubation period. This means that a 6-log bioburden reduction has been achieved on exposed surfaces. If the positive control and exposed BIs pass, the cabinet can be released for use.

Conclusion

When choosing a method for the biodecontamination of biological safety cabinets, it is important to understand the needs/requirements of the Customer and of the

requirements/capabilities of the various processes. The hydrogen peroxide vapor process offers Customers material compatibility, efficacy against organisms, ease of validation, 6-log bioburden reduction of surfaces, HEPA filter penetration, and environmental health and safety advantages over other processes. With its non-condensation application, it is an effective biodecontamination technology for commissioning, decommissioning, prophylactic bioburden control, or equipment maintenance to ensure the safety of those utilizing the equipment or the research being conducted within the equipment.

References

(1) www.STERISLifeSciences.com.

(2) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), www.epa.gov/oecaagct/lfra.html.

(3) Compatibility of Material and Electronic Equipment With Hydrogen Peroxide and Chlorine Dioxide Fumigation (December 2010), Assessment and Evaluation Report, www.epa.gov.

(4) EPA Reg. No. 90150-1, BIT (Binary Ionization Technology), www.epa.gov/pesticides/chem_search/ppls/090150-00001-20131230.pdffgfg.

(5) EPA Reg. No. 58779-4,Vaprox Hydrogen Peroxide Sterilant, www.epa.gov/pesticides/chem_search/ppls/090150-00001-20131230.pdffgfg.

(6) National Toxicology Program (June 2011). *Report on Carcinogens, Twelfth Edition.* Department of Health and Human Services, Public Health Service, National Toxicology Program. Retrieved June 10, 2011, from: http://ntp.niehs.nih.gov/go/roc12.

(7) The Center for Disease Control and Prevention (CDC) / The National Institute for Occupational Safety and Health (NIOSH), www.cdc.gov/NIOSH/.

