**DANGER PELIGRO**

**Oxidizer Corrosive**

**PRECAUTIONARY STATEMENTS**

Hazards to Humans and Domestic Animals

**DANGER**: Corrosive. Causes irreversible eye damage or skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or clothing. Do not breathe spray mist.

**KEEP OUT OF REACH OF CHILDREN**

**FIRST AID**

- **If in eyes**: Hold open eyes and rinse slowly and gently with water for 15-30 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.

- **If swallowed**: Call a poison control center or doctor for treatment advice.

- **If contacted by skin or clothing**: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-30 minutes. Call a poison control center or doctor for treatment advice.

- **If inhaled**: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth. If possible, call a poison control center or doctor for further treatment advice.

**NOT FOR USE**

- Discontinue use immediately after contact with Vaprox Hydrogen Peroxide Sterilant. Do not re-use or re-fill Vaprox Hydrogen Peroxide Sterilant in validated and non-validated applications. Do not use this product without development of an appropriate fumigation plan (see package insert). Not for use as a terminal sterilant or high-level disinfectant for reprocessing of critical or semi-critical medical devices. Not for residential use.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, feed by storage or disposal. Store container upright. Do not freeze. Do not expose to cyanide, hexavalent chromium compounds, other oxidizers, reducers, combustible materials, or flammable vapors. Shade from radiant heat and direct sunlight. Stow away from powdered metals and peroxides.

**PESTICIDE DISPOSAL**: Rinse containers with 20 parts water and then empty into sink with running water. Hydrogen Peroxide is classified as a nonrefillable container. Do not reuse or refill this container. Offer for recycling if available.

**PRODUCT MADE IN U.S.A.**

**LOT NUMBER**: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available.

**PRODUCT INGREDIENTS**: Hydrogen Peroxide (312)

**PRODUCT STABILIZERS**: Hydrogen Peroxide Sterilant

**PRODUCT FORMULA**: Hydrogen Peroxide Sterilant

**PRODUCT PACKAGE DESIGN**: PMS 279 BLUE HEXAWAVE

**PRODUCT MARKETING**: 3/9/12

**PRODUCT MANUFACTURER**: Steris-PB006US-21E

**PRODUCT LABELING**: PMS 3425 GREEN COLOR BAND

**PRODUCT MANUFACTURING**: Mentor, OH 44060

**PRODUCT DISTRIBUTION**: 800-548-4873

**PRODUCT RECYCLING**: 5906 Wesley Road Mentor, OH 44060 U.S.A.

**PRODUCT MANUFACTURING**: 800-548-4873 | www.steris.com
**2. User Safety Requirements:**

- **Respirator Requirements** – When a respirator is required for use with this product, the trained applicator supervising the fumigation must make sure that:
  a. Respirators must be fit tested and fit checked using a program that conforms with OSHA's requirements described in 29 CFR Part 1910.134.
  b. Respirators must be trained using a program that conforms with OSHA's requirements described in 29 CFR Part 1910.134.
  c. Respirator users must be examined by a qualified medical practitioner to ensure the physical ability to safely wear the style of respirator to be worn.
  d. Respirators must be maintained according to a program that conforms with OSHA's requirements described in 29 CFR Part 1910.134.
- **Liquid hydrogen peroxide is corrosive and will cause irreversible eye damage or skin burns and may be fatal if inhaled at higher concentrations. It is also harmful if inhaled or exposed through skin. Do not get in eyes, on skin or clothing. Do not breathe spray mist or vapor. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. User should remove contaminated clothing and wash before reuse. Discard clothing and or absorbent material that has been heavily drenched or contaminated with liquid hydrogen peroxide.**

3. **Follow manufacturer’s instructions for cleaning/maintaining protective eyewear and respirators.**

4. **User Safety Recommendations:**
   a. User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
   b. User should not remove clothing/PPE immediately if hydrogen peroxide gets inside.
   c. Wash thoroughly and put on clean clothing.
   d. User should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as practical, wash thoroughly and change into clean clothing.

5. **Efficacy:**

- **VAPROX Hydrogen Peroxide is effective as a Sterilant, Sporicide, Bactericide, Virucide, and Fungicide under the following conditions on exposed, pre-cleaned, dry, porous surfaces including production equipment:**
  - For 40 ft³ or smaller enclosures a Sterilization Cycle was developed for the VHP Generator and validated for both 2 ft³ and 40 ft³ pre-cleaned, sealed enclosures using an Association of Official Analytical Chemists (AOAC) standardized test protocol to validate sterilization and validated for both 2 ft³ and 40 ft³ pre-cleaned, sealed enclosures up to 4,000 ft².
  - As a Sterilant, Sporicide, Bactericide, Virucide, and Fungicide at a minimum of 400 ppm of VHP sterilant for 30 minutes in sealed enclosures up to 4,000 ft².
  - For larger than 40 ft³ enclosures as a Sterilant, Sporicide, Bactericide, Virucide, and Fungicide when used in a validated application in accordance with use instructions provided in Section 6. This product is not to be used as a terminal high level disinfectant or sterilant for reprocessing of any critical/semi-critical medical device in a healthcare setting. Not for use in residential applications.

6. **Fumigation Management Plan**

- **The STERIS Corporation trained applicator is responsible for working with the owners and/or responsible employees of the site to be fumigated to develop a site specific Fumigation Management Plan (FMP) for each site that will be treated with VHP.**
  - The applicator is responsible for all tasks of the fumigation process unless otherwise noted in the FMP and must be on site during the entire fumigation treatment process. The FMP must address characterization of the site, and include appropriate monitoring and notification requirements, consistent with, but not limited to, the following:
    1. **Inspect the structure and or area to determine its suitability for fumigation.**
    2. **When sealing is required, consult previous records for any changes to the structure, seal leaks, and monitor any occupied adjacent rooms and/or buildings to ensure safety.**
    3. **Before each fumigation, review any existing MSDS, Equipment Manual and other relevant safety procedures with company officials and responsible employees.**
    4. **Consult with company officials in the development of procedures and appropriate safety measures for nearby workers who will be in and around the area during application and aeration.**
    5. **Consult with company officials to develop an appropriate monitoring plan that will confirm that nearby residents and bystanders are not exposed to levels above the allowed limits during application and fumigation. This plan must also demonstrate that nearby residents will not be exposed to concentrations above the allowable limits.**
    6. **Consult with owners and responsible employees at the site who will be responsible for development of procedures for local authorities to notify nearby residents in the event of an emergency.**
    7. **Confirm the placement of placards to secure entrance into any area under fumigation.**
    8. **Confirm the required safety equipment is in place and the necessary manpower is available to complete fumigation.**

These factors must be considered in putting a FMP together. It is important to note that some plans will be more comprehensive than others. All plans should reflect the expertise of the applicator and circumstances of and around the structure and/or area. In addition to the plan, the applicator must read the entire label and equipment manual and follow all directions carefully. If the applicator has any questions about the development of an
1. GUIDELINES FOR PREPARATION OF A FUMIGATION MANAGEMENT PLAN

A Fumigation Management Plan (FMP) is an organized, written description of the required steps involved to help ensure a legal and effective fumigation. It will also assist you and others in complying with pesticide product label requirements. The guidance that follows is designed to help you plan any fumigation that you might perform PRIOR TO ACTUAL TREATMENT. It is meant to be descriptive, prescriptive, yet flexible enough to allow the experience and expertise of the fumigator to make changes based on circumstances that may exist in the field. By following a step-by-step procedure, yet allowing for flexibility, an effective fumigation can be performed.

Before any fumigation begins, carefully read and review the label and the Equipment Manual. This Information must also be given to the appropriate company officials (supervisors, foreman, safety officer, etc.) in charge of the structure or area. Preparation is the key to any successful fumigation. If the type of fumigation, for example, is not listed in this Guidance Document you will want to construct a similar set of procedures. Finally, before any fumigation begins, you must be familiar with and comply with all applicable state and local laws. The success of the fumigation is not only dependent on your ability to do your job but also upon carefully following all rules, regulations, and procedures required by governmental agencies.

2. A CHECKLIST GUIDE FOR A FUMIGATION MANAGEMENT PLAN

This checklist is provided to help you take into account factors that must be addressed prior to performing any fumigations. It emphasizes safety steps to protect people and property.

The checklist is general in nature and cannot be expected to apply to all types of fumigation situations. It is to be used as a guide to prepare the required plan. Each item must be considered, however, it is understood that each fumigation is different and not all items will be necessary for each fumigation structure and/or area.

A. PLANNING AND PREPARATION

1. Determine the purpose of the fumigation.
   a. Sterilization of rooms or enclosure.
   b. Sterilization of vehicles.

2. Determine the type of fumigation. For example:
   a. Pharmaceutical Operations, clean rooms, medical device sterilization manufacturing
   b. Laboratories, animal research facilities.
   c. Patient rooms, hotel rooms, offices, recreational facilities.
   d. Create equipment in addition to the Equipment Manual, read the US Coast Guard Regulations.

3. Evaluate the structure or area to be fumigated, and develop a site-specific plan that includes the following points, as applicable:
   a. The general structure layout, construction (materials, design, age, maintenance, of the structure, fire or combustion hazards, ventilation system, property line, etc.).
   b. Cruise ship rooms, (In addition to the Equipment Manual, read the US Coast Guard regulations).
   c. Patient rooms, hotel rooms, offices, recreational facilities.
   d. Create equipment in addition to the Equipment Manual, read the US Coast Guard Regulations.

4. Equipment requirements.
   a. The need for buffer zones in rooms adjacent to the treated enclosure to limit access to only trained applicators. This would include adjacent rooms that could be occupied when using VHP in areas such as: clean rooms, patient rooms or offices. Additional considerations should also be given to adjacent rooms above or below the enclosure if the structure does not have contiguous spaces (i.e., contiguous rooms or spaces adjacent to the enclosure) that would preclude exposure if the treated enclosure was not properly sealed.
   b. An approved and validated personnel access plan that identifies those who routinely enter the area to be fumigated (i.e., employees, visitors, customers, etc.).
   c. The identity and responsibilities of those employees, including those who enter the area.
   d. The need for communication of any changes to the plan that may occur.
   e. Nearest telephone or other means of communication, and mark the location of these items on the drawing/sketch.
   f. Emergency exit stations for electricity water and gas. Mark the location of these items on the drawing/sketch.
   g. Create a telephone numbers of local Health, Fire, Police, Hospital and Physician responders.
   h. Name and phone number (both day and night) of appropriate company officials.
   i. Checkmark and prepare the points of fumigation application.
   k. Exposure time considerations.

B. PERSONNEL

1. Confirm that all personnel in and around the area to be fumigated have been notified prior to application of the fumigant. Consider using a checklist that each employee initially indicating they have been notified.

2. Induct all fumigation personnel about the hazards that may be encountered, and about the selection of personal protection devices, including detection equipment.

3. Confirm that all personnel have had/are trained for the use of this fumigant.

4. Induct all personnel on how to report any accident and/or incident related to the fumigation exposure. Provide a telephone number for emergency response reporting.

5. Induct all personnel to report to proper authorities any theft of fumigant or equipment related to fumigation.

C. CRIteria FOR SUCCESSFUL FUMIGATION:

1. All VHP fumigation process conditions (vapor concentration, temperature, relative humidity) are achieved throughout the fumigation cycle.

2. Exposures to bystanders are allowed to occur with appropriate monitoring and protective gear.

3. Induct all personnel to report to proper authorities any theft of pesticidal or equipment related to fumigation.

4. Documentation of exposure.
   a. Cubic footage or other appropriate space/location calculations.
   b. Structure sealing capability and methods.
   c. Perimeter Safety.
   d. Aeration requirements.
   e. Nearest telephone or other means of communication, and mark the location of these items on the drawing/sketch.
   f. Emergency exit stations for electricity water and gas. Mark the location of these items on the drawing/sketch.
   g. Detailed layouts of the structure to be fumigated, delineating features, hazards, and other structural issues.
   h. The need for buffer zones in rooms adjacent to the treated enclosure to limit access to only trained applicators. This would include adjacent rooms that could be occupied when using VHP in areas such as: clean rooms, patient rooms or offices. Additional considerations should also be given to adjacent rooms above or below the enclosure if the structure does not have contiguous spaces (i.e., contiguous rooms or spaces adjacent to the enclosure) that would preclude exposure if the treated enclosure was not properly sealed.
   i. An approved and validated personnel access plan that identifies those who routinely enter the area to be fumigated (i.e., employees, visitors, customers, etc.).
   j. The identity and responsibilities of those employees, including those who enter the area.
   k. The need for communication of any changes to the plan that may occur.

5. Training and Certification of Applicators

Prior to use, applicators must be adequately trained and certified by STERIS Corporation on the hazards and label directions for VAPROX Hydrogen Peroxide. On the use and operation of the VAP application equipment, hydrogen peroxide monitoring procedures and where appropriate, validation procedures.

6. Preparation of Enclosures

a. Cleaning: Remove gross filth and visible soil prior to application. Wash soiled surfaces...
Steris Corp.
Steris-PB006-INC Vaprox Insert, cp
Port Size 7.25gal, Lead 7.4gal
Vaprox/US/Insert/Design/PB006-INC, 3/13/12

DO NOT PRINT SPOT RED TEMPLATE

with a compatible detergent using a cloth, sponge or appropriate cleaning device to ensure visible soils are removed. Rinse with potable water and allow to dry. All the surfaces in the treatment area must be completely dry to the touch or visibly dry prior to VHP sterilization.

b. The VHP Application Equipment: Position or connect the VHP application equipment for optimum VHP distribution into the treatment enclosure. See Equipment User’s Manual for proper equipment preparation and set-up.

c. Sealing: Seal the treatment enclosure adequately to assure that hydrogen peroxide levels outside the enclosure are kept at acceptable levels (a ppm time weighted average for eight hours (TWA)) and ensure sufficient concentration of VHP sterilant in the treatment area. The installation must allow for proper equipment placement and disconnection.

1. Close and seal windows and doors. Sealing techniques can vary, but most often includes polyethylene sheeting and adhesive tape. Verify effectiveness of the sealing process by conducting an air draft potential analysis using a smoke stick test to ensure there are no leaks where openings have been sealed in the enclosure.

2. Turn off all ventilation systems including HVAC and seal any supply or return ducts/ductwork.

3. Monitor areas immediately adjacent to the fumigated space to ensure levels are below TWA for hydrogen peroxide.

d. Securing Enclosure: All personnel who have vacated the treatment enclosure prior to VHP application.

1. Provide signage and lockout泰心

2. Applicators must not re-enter the treated enclosure until exposure levels of hydrogen peroxide are less than or equal to one ppm.

e. Placing of Treatment Enclosure: The applicator must place or post all entrances to the treatment enclosure and designated buffer zones with signs in English bearing:

1. The signal word "DANGER/HAZARD" in red.

2. "Area under treatment. DO NOT ENTERING ENTER." or "Do not enter.

3. The statement "This sign may only be removed after the treatment enclosure has been aerated to hydrogen peroxide levels less than or equal to one ppm.

4. Identification of hydrogen peroxide as hazard associated with the treatment process.

f. Information for the applicator

1. All persons must be advised that VHP sterilization involves the introduction of a liquid that is toxic, corrosive and highly reactive.

2. VHP sterilization must be initiated only by appropriately trained and certified applicators.

3. VHP sterilization must be conducted in a controlled environment.

4. Positive control BIs demonstrate growth following incubation*

5. Only use BIs that are approved by STERIS.

6. Positive control BIs demonstrate growth following incubation*

Criteria for Successful Fumigation:

1. All VHP fumigation process conditions (vapor concentration, temperature, relative humidity) are achieved throughout the fumigation cycle.

2. All OIs that are properly recovered and evaluated exhibit a visible color change following exposure to VHP.

3. All BIs that are properly recovered (no breach of aseptic technique) are negative for growth**

4. Positive control BIs demonstrate growth following incubation*.

5. Negative control BIs exhibit no growth following incubation*.

* [not applicable to areas not requiring validation]

Reentry Instructions:

1. Early reentry in the case of an emergency requires wearing a Self Contained Breathing Apparatus (SCBA) operated in pressure-demand mode. Full hydrogen peroxide resistant body suits, gloves and boots to protect from the inhalation hazard as well as the corrosive action of hydrogen peroxide to tissues. When entering into the area under fumigation always work with two or more people under the direct supervision of a trained applicator wearing appropriate respirators.

2. Reentry to the sealed enclosure by a trained and certified applicator is allowed with a self contained breathing apparatus at VHP concentrations up to 1 ppm to allow for windowed to be opened and to augment the aeration process in accordance with the specific reentry requirements outlined in the training by the trained and certified applicator. Otherwise, do not reenter the treated enclosure until exposure levels of hydrogen peroxide are at or below one ppm.

Releasing Treated Sealed Enclosure for Return to Service:

a. Once VHP levels are determined to be at or below one ppm, applicators may re-enter the treated enclosure and remove any sealing materials and disconnect/ remove VHP Generator from the treated sealed enclosure.

b. Turn on ventilation systems including HVAC.

c. Remove placards and release the treated enclosure for normal operation and use once the level of hydrogen peroxide are determined to be at or below one ppm.

The following steps are required in developing a validated application process:

1. Introduction

a. The VHP sterilization process is defined as the intentional application of VHP at a prescribed concentration and contact time (See Section 8 “Sites Not Requiring In Sterilization”).

b. This process must be validated to ensure that the target VHP concentration is achieved in the sealed enclosure required to achieve a 10^6 of kill of all pre-established period of time.

2. Aeration

- This step involves the airflow of dry air over a fixed period time to remove the hydrogen peroxide from the treated enclosure.

- The chosen enclosure temperature and humidity conditions must be appropriate for the VHP sterilization process.

- Condensation can result in damage to enclosure surfaces and reduced cycle effectiveness.

- It is important to perform the aeration phase in a manner that results in complete removal of VHP from the enclosure.

3. Sterilization

- This process involves the intentional application of VHP at a prescribed concentration and contact time (See Section 8 “Sites Not Requiring In Sterilization”).

- The desired VHP concentration in the sealed enclosure is achieved by adjusting the VHP injection rate to maintain the target VHP concentration in the sealed enclosure required to achieve a 10^6 kill of all pre-established period of time.

- Criterion for Successful Fumigation:

1. All VHP fumigation process conditions (vapor concentration, temperature, relative humidity) are achieved throughout the fumigation cycle.

2. All OIs that are properly recovered and evaluated exhibit a visible color change following exposure to VHP.

3. All BIs that are properly recovered (no breach of aseptic technique) are negative for growth**

4. Positive control BIs demonstrate growth following incubation*.

5. Negative control BIs exhibit no growth following incubation*.

* [not applicable to areas not requiring validation]

* Positive control BIs demonstrate growth following incubation*.

* Negative control BIs exhibit no growth following incubation*.**
8. Application to Sealed Enclosures of Up to 4,000 ft³ Not Requiring Validation of Use Conditions:

VAPROX sterilant may be applied to dry, sealed pre-cleaned enclosures without prior validation when the area is treated on a routine basis or enclosures being treated vary in configuration, materials of construction and content of items located in the treatment enclosure.

The use of the VAPROX sterilant requires the applicator to apply a fixed VHP concentration over a set contact time. In addition the enclosure must be dehumidified and conditioned as part of the applications procedure and monitored after sterilization. VAPROX sterilant may be applied at a set concentration and contact time to sealed enclosures of up to 4,000 ft³ in industrial, commercial and retail space, as long as there is no concentration gradient in the enclosure. In this application, the VHP sterilant concentrations must be verified throughout the enclosure to ensure an adequate concentration level is maintained during the STERILIZATION phase of the process. In addition, hydrogen peroxide chemical indicators must be placed throughout the enclosure to be treated to verify distribution of hydrogen peroxide throughout the enclosure. If more than one room of a consistent dimension is being treated, the applicator may use the same VHP cycle settings as established in the initial room without use of a VHP sensor to confirm the distribution of the VHP sterilant. Once the DEHUMIDIFICATION phase is complete initiate a STERILIZATION phase to achieve ≤0.1% relative humidity. Ensure the ambient temperature is ≤21°C or 70°F initially and throughout the fumigation process. Once the STERILIZATION phase, monitor areas adjacent to the sealed enclosure with devices such as Dräger tubes to assure hydrogen peroxide levels do not exceed one ppm. If this level is exceeded outside the treatment enclosure, the applicator should immediately shut the treatment process and ensure completion of the STERILIZATION phase to begin the AERATION phase to reduce levels of hydrogen peroxide at or below one ppm (TWA).

Sterilization of Sealed, Dry Preconditioned Enclosures at 250 ppm VAPROX Sterilant for 90 minutes:

Prepare the treatment enclosure as defined above (Preparation of Enclosures Section) including pre-cleaning, drying and preparation of VHP Generator (refer to User’s Manual for VHP Generator Unit), sealing the enclosure and placing of the enclosure to be treated. Place VHP sensor in a location most difficult for VHP target concentration to be reached in the treatment enclosure. This is typically in a corner in the enclosure farthest away from the VHP generation unit. All drawers, closets and cabinet doors, etc. must be opened to permit exposure to VHP sterilant. Placed chemical indicators throughout the enclosure to verify effective distribution of VHP sterilant. The number of indicators placed throughout the enclosure must be based on the formula of one chemical indicator per 100 ft³. The chemical indicators must be placed in room corners and in areas difficult for the VHP sterilant to access such as closets, dressers, cabinets or other partially occluded areas. Place osculating fans throughout the enclosure to facilitate effective distribution of the VHP sterilant. Program the VHP Generator to initiate a DEHUMIDIFICATION phase to achieve ≤0.1% relative humidity. Ensure the ambient temperature is ≤21°C or 70°F initially and throughout the fumigation process. Once the DEHUMIDIFICATION phase is complete initiate a STERILIZATION phase to achieve ≤0.1% relative humidity. If the concentration of the treatment cycle. These operations should be carried out by STERIS trained and certified applicators familiar with the set up and operation of VHP application equipment.

Sterilization of Sealed, Dry Preconditioned Enclosures at 400 ppm VAPROX Sterilant for 30 minutes:

Prepare the treatment enclosure as defined above (Preparation of Enclosures Section) including pre-cleaning, drying and preparation of VHP Generator (refer to User’s Manual for VHP Generator Unit), sealing the enclosure and placing of the enclosure to be treated. Place VHP sensor in a location most difficult for VHP target concentration to be reached in the treatment enclosure. This is typically in a corner in the enclosure farthest away from the VHP generation unit. All drawers, closets and cabinet doors, etc. must be opened to permit exposure to VHP sterilant. Placed chemical indicators throughout the enclosure to verify effective distribution of VHP sterilant. The number of indicators placed throughout the enclosure must be based on the formula of one chemical indicator per 100 ft³. The chemical indicators must be placed in room corners and in areas difficult for the VHP sterilant to access such as closets, dressers, cabinets or other partially occluded areas. Place osculating fans throughout the enclosure to facilitate effective distribution of the VHP sterilant. Program the VHP Generator to initiate a DEHUMIDIFICATION phase to achieve ≤0.1% relative humidity. If the concentration of the treatment cycle. These operations should be carried out by STERIS trained and certified applicators familiar with the set up and operation of VHP application equipment.

Monitoring of H₂O Concentrations in the Sealed Enclosure and Instructions Following Aeration:

VHP Monitoring: Dräger tubes or other VHP monitoring devices are utilized by means of an intrinsically safe technique for VHP sampling to determine the VHP concentration in the sealed enclosure during and after the aeration phase. Once the VHP concentration within the treated enclosure is at or below the OSHA Permissible Exposure Limit (PEL) of one ppm, the enclosure may be released to normal operations.

9. Application to Sealed Enclosures Between 2 ft³ and 40 ft³ that Require Validation:

Use of VHP in sealed enclosures of this size, such as isolation chambers where reentry by applicators or other individuals is not possible does not require a fumigation management plan (FMP). All other applicator precautions for use of hydrogen peroxide should be adhered to when applying VHP in these chambers.

Applications Not Requiring Validation of Use Conditions:

VAPROX Sterilant may be used at 250 ppm for 90 minutes or 400 ppm for 30 minutes using a hydrogen peroxide sensor and chemical indicators to verify these use conditions are met. See Section 8 above for specific instructions regarding use under these conditions.

Validation of Alternate Use Conditions:

VAPROX Sterilant may be used in validated custom cycles for treatment of pre-cleaned, dry sealed enclosures when the enclosure to be treated is of a fixed volume configuration and contains materials of composition that remain consistent in comparison to the VHP validation run. The custom cycle developed for the treatment enclosure must be capable of consistently achieving the desired log reduction in the number of control aerobic spores (30°C, 7-day) present in the bacterial indicator substrate. See Section 7 above for specific instructions regarding development of validated cycle conditions for alternate use conditions.

Releasing Treated Sealed Enclosure for Return to Service:

a. Once VHP levels are determined to be at or below one ppm, applicators may re-enter the treated enclosure and remove any sealing materials and disconnect/remove VHP Generator from the treated sealed enclosure.

b. Turn on ventilation systems including HVAC.

c. Remove placards and release the treated enclosure for normal operation and use after the levels of hydrogen peroxide are determined to be at or below one ppm.

d. Release the treated enclosure for general public use after hydrogen peroxide levels are determined to be at or below one ppm.

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