UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 9, 2020

Jennifer Reeder
Director, Regulatory Affairs
Steris Corporation
P.O. Box 147
St. Louis, MO 63166

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Vaprox Hydrogen Peroxide Sterilant
EPA Registration Number: 58779-4
Application Date: March 20, 2020
Decision Number: 560928

Dear Ms. Reeder:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.

3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
   a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.

      i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:

         A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
         B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
         C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)

      ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).

         A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is small non-enveloped, large non-enveloped, enveloped.

         B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.

4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Geobacillus stearothermophilus spores (ATCC 7953) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

Steven Snyderman

Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

Vaprox®
HYDROGEN PEROXIDE STERILANT

ACTIVE INGREDIENT:
Hydrogen Peroxide 35%
INERT INGREDIENTS: 65%
Total:…… ….100%

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

OXIDIZER CORROSIVE

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

FIRST AID	
If in eyes	•Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. •Call a poison control center or doctor for treatment advice.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip a glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.
If on skin or clothing	•Take off contaminated clothing. •Rinse skin immediately with plenty of water for 15-20 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.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

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 on clothing. Do not breathe spray mist. 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.

Personal Protective Equipment PPE
Applicators and all other handlers must wear:
- Long-sleeved shirt and long pants
- Socks and chemical resistant footwear
- Goggles or face shield
- Chemical-resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton
-A self contained breathing apparatus if concentrations exceed 1 ppm during handling and or application of Vaprox Hydrogen Peroxide Sterilant. Do not use oxidizable sorbants such as activated carbon.

Physical or Chemical Hazards
Liquid hydrogen peroxide is a strong oxidant and poses a FIRE, EXPLOSION OR CONTAINER RUPTURE HAZARD. Avoid excessive heat, contamination, or contact with combustible materials. Clothing, shoes, or other combustible materials that have come in contact with hydrogen peroxide must be immediately and thoroughly washed with water. If allowed to dry in the materials, a fire may result. Discard shoes in a fireproof container.
IN CASE OF FIRE use water only.
CONTAIN SPILLS and dilute with 20 parts of water.

After diluting the spill, sodium metabisulfide or sodium sulfite (1.9 lbs. of SO2 equivalent per 500 ml of peroxide) may be used to destroy the peroxide.
SEE EQUIPMENT MANUAL AND MATERIAL SAFETY DATA SHEET FOR ADDITIONAL INFORMATION.

Environmental Hazards
Do not discharge effluent containing these products into lakes, streams, ponds, oceans, or public waters unless these products are specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage authority. For guidance contact your State Water Board or Regional Office U.S. Environmental Protection Agency.

DIRECTIONS FOR USE
It is a violation of federal law to use this product in a manner inconsistent with its labeling.

For use as a microbial sterilant in validated (up to 250,000ft^3)and non-validated (up to 4,000 ft^3) applications for sterilization of sealed, dry pre-cleaned enclosures located in industrial, commercial and institutional settings (including production operations in pharmaceutical manufacturing including clean rooms, medical device sterilization as part of a manufacturing process, laboratories, animal research facilities, patient rooms, hotel rooms, offices, cruise ships, recreational facilities and emergency response vehicles). Use only with STERIS VHP application equipment.

This product is for use in STERIS VHP® application equipment only, and by trained personnel trained by STERIS Corporation. Read and follow package insert for complete directions on cleaning, sealing and use of Vaprox Hydrogen Peroxide Sterilant in validated and non-validated applications. See Equipment User Manual for operating procedures of the STERIS VHP application equipment. 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 containers 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 permanganates.

PESTICIDE DISPOSAL
Rinse containers with 20 parts water and then empty into sink with running water. Hydrogen Peroxide is classified as a DOT oxidizer and a hazardous waste under U.S. EPA hazardous waste regulations and it is a violation of federal law to improperly dispose of pesticides.
CONTAINER DISPOSAL
Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available.

LOT NUMBER:
Not for sale or use after:

ACCEPTED
04/09/2020
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 58779-4

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060 □ U.S.A.
440-354-2600
800-548-4873

EPA Reg. No. 58779-4

04/08/2020

Package Insert for Vaprox® Hydrogen Peroxide Sterilant
EPA Registration No. 58779-4
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General Information

Restrictions:

VAPROX® Sterilant has been registered by STERIS in accordance with Federal Regulations for the specific uses described in this package insert. Uses other than as specified and described are not permitted and may not be effective in the sterilization of exposed surfaces in pre-cleaned sealed enclosures.

Review the Vaporized Hydrogen Peroxide (VHP®) User's Equipment Manual for proper instructions on how to operate the VHP Generator prior to utilizing the equipment for sterilization. VAPROX Sterilant should be applied only by properly trained and certified personnel who are thoroughly trained in the use and operation of the VHP Generator.

1. VAPROX Application Process:

Effective application of vaporized hydrogen peroxide requires adequate VHP concentration and exposure time. The VHP Generator is utilized to achieve the concentration and contact time of hydrogen peroxide on exposed surfaces in the enclosed area. The process parameters are controlled through the use of the control panel on the VHP Generator. See the VHP Generator Equipment User's Manual prior to initiating the application process to determine the appropriate steps to take in development and application of the process.

The VHP Generator uses air as a carrier to deliver hydrogen peroxide vapor to exposed surfaces inside a sealed enclosure. This allows the process to take place at, or near, atmospheric pressure. Since the VHP process relies only on the contact of the VHP sterilant with exposed surfaces, the transfer of heat and moisture required by steam or chemical processes is not necessary.

The VHP sterilant is continuously injected for the required exposure time to maintain the desired concentration of hydrogen peroxide vapor. Once the VHP sterilant leaves the enclosure, it is typically broken down into water vapor and oxygen.

The VHP process consists of four phases:

• DEHUMIDIFICATION – Dry air is circulated in the sealed treatment enclosure to reduce humidity to a predetermined level in the 10-70% relative humidity range. This permits the target VHP concentration to be maintained below condensation levels during the CONDITIONING and STERILIZATION phases. The time to reach the targeted dehumidification level increases with the volume of the enclosure, and is dependant on environmental conditions.

• CONDITIONING – The VHP sterilant is injected into the air stream. The CONDITIONING phase facilitates reaching the desired VHP concentration in the sealed enclosure. CONDITIONING time is affected by VHP target concentration, injection rate, enclosure materials, environmental conditions and enclosure volume.

• STERILIZATION – The Vaprox Sterilant is continuously injected at a selected rate to maintain the target VHP concentration over a pre-established period of time.

• AERATION – The VHP injection is stopped and the flow of dry air continues to reduce the VHP concentration within the enclosure to at or below one ppm level ($\leq$ 1.0 ppm TWA 8 hr.) prior to reentry into the enclosure by trained applicators. Treated enclosures may not be released for general public use until the level of hydrogen peroxide is at/or below one ppm in the enclosure.

2. User Safety Requirements:

1. 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. Respirator users 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).

2. 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 swallowed or absorbed through skin. Do not get in eyes, on skin or on 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. Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
   b. Users should remove clothing/PPE immediately if hydrogen peroxide gets inside. Then wash thoroughly and put on clean clothing.
   c. Users 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.

3. Efficacy:

VAPROX Hydrogen Peroxide is effective as a Sterilant , Sporicide, Bactericide, Virucide, and Fungicide under the following conditions on exposed, pre-cleaned, dry, porous **[NOT APPROVED IN CALIFORNIA FOR EFFICACY ON POROUS SURFACES]** and non-porous surfaces including floors, walls, furniture, equipment and other items in sealed enclosures in industrial, commercial and institutional settings (including production operations in pharmaceutical manufacturing, manufacturing clean rooms, medical device sterilization as part of a manufacturing process, laboratories, animal research facilities, patient rooms, hotel rooms, offices, cruise ships, recreational facilities and emergency response vehicles) when used with STERIS VHP application equipment:

- For 40 ft^3 or smaller enclosures a Sterilization Cycle was developed for the VHP Generator and validated for both 2 ft^3 and 40 ft^3 pre-cleaned, sealed enclosures using an Association of Official Analytical Chemists (AOAC) sporicidal test protocol to validate sterilization when applied at 2.2 grams of Vaprox Sterilant per minute for 90 minutes (Should yield a theoretical value of 930 ppm).
- As a Sterilant, Sporicide, Bactericide, Virucide, and Fungicide at a minimum of 250 ppm of VHP sterilant for 90 minutes in sealed enclosures up to 4,000 ft^3.
- 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 ft^3.
- For larger than 40 ft^3 enclosures as a Sterilant, Sporicide, Bactericide, Virucide, and Fungicide when used in a validated application in accordance with use instructions provided in Section 8.

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.

4. 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 for 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. Prior to each fumigation, review any existing FMP, MSDS, Equipment Manual and other relevant safety procedures with company officials and appropriate 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 workers and bystanders are not exposed to levels above the allowed limits during application, fumigation and aeration. This plan must also demonstrate that nearby residents will not be exposed to concentrations above the allowable limits.
6. Consult with owners and or 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 experience and expertise of the applicator and circumstances at 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 FMP, contact STERIS Corporation for further assistance. An FMP must be developed for each treated site. In the event of an emergency application, a generic FMP which can be updated may be used and updated after fumigation. The STERIS Corporation trained applicator must sign the plan indicating it was followed. The signed FMP and related documentation, including monitoring records, must be maintained by the applicator for a minimum of 2 years and a copy provided to the owner of the treated site.

1. GUIDANCE 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 assist you in addressing all the necessary factors involved in preparing for and fumigating a structure and/or area.

This guidance is intended to help you plan any fumigation that you might perform PRIOR TO ACTUAL TREATMENT. It is meant to be somewhat 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 and/or area. Preparation is the key to any successful fumigation. If the type of fumigation that you are to perform 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 all 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 room enclosures
    b. Sterilization of emergency 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.
   e. Cruise ship rooms, In addition to the Equipment Manual, read the US Coast Guard Regulations 46CFR 147A.
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 combustibility hazards, connecting structures and escape routes, above and below ground, and other unique hazards or structure characteristics. Meet with the owner/operator/person in charge. Draw or have a drawing or sketch of structure to be fumigated, delineating features, hazards, and other structural issues.
   b. 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 hotel rooms, patient rooms or offices. Additional consideration should also be given to adjacent rooms above or below the enclosure if the structure does not consist of solid construction (i.e. Floors/walls adjacent to the enclosure) that would preclude exposure if the treated enclosure was not properly sealed.
   c. The number and identification of persons who routinely enter the area to be fumigated (i.e., Employees, visitors, customers, etc.).
   d. Accessibility of utility service connections.
   e. Nearest telephone or other means of communication, and mark the location of these items on the drawing/sketch.
   f. Emergency shut-off stations for electricity water and gas. Mark the location of these items on the drawing/sketch.
   g. Current emergency 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.
   j. Review labeling and Equipment Manual.
   k. Exposure time considerations.

      1. Fumigant to be used.
      2. Minimum fumigation period, as defined and described by the label use directions.
      3. Down time required to be available.
      4. Aeration requirements.

   l. Determination of dosage.
      1. Cubic footage or other appropriate space/location calculations.
      2. Structure sealing capability and methods.
      3. Label directions.
      4. Past history of fumigation of structure
      5. Exposure time.

B. PERSONNEL

1. Confirm in writing 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 initials indicating they have been notified.
2. Instruct 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 are aware of and know how to proceed in case of an emergency situation.
4. Instruct all personnel on how to report any accident and/or incidents related to fumigant exposure. Provide a telephone number for emergency response reporting.
5. Instruct all personnel to report to proper authorities any theft of fumigant and/or equipment related to Fumigation.
6. Establish a meeting area for all personnel in case of emergency.
7. Confirm that all applicators have been trained in the use of Vaprox Hydrogen Peroxide Sterilant and are in good standing including the required refresher training.
8. Develop a Worker Health and Safety Plan as required by OSHA for applicators. The owner/operators of the facility being treated should have a Worker Health and Safety Plan as required by OSHA developed for their employees located within close proximity of the application process.

C. MONITORING

1. Perimeter Safety

a. Monitoring of hydrogen peroxide concentrations must be conducted immediately adjacent to the fumigated space to prevent excessive exposure and to determine where exposure may occur. Document where monitoring will occur.

b. Keep a log or manual of monitoring records for each fumigation site. This log must at a minimum contain the timing, number of readings taken and level of concentrations found in each location.

c. When monitoring for leaks, document there is no hydrogen peroxide present above the one ppm levels. Subsequent leak monitoring is not routinely required. However spot checks must be made, especially if conditions significantly change.

d. Monitoring must be conducted during aeration and corrective action taken if gas levels exceed the allowed levels in an area where bystanders and/or nearby residents may be exposed.

2. Efficacy –

a. Hydrogen peroxide readings should be taken from within the fumigated structure to ensure proper vapor concentrations. This can be safely achieved outside the structure through the use of a remote sensor reading.

b. All reading of hydrogen peroxide concentration, temperature and relative humidity must be documented.

D. NOTIFICATION

1. Confirm that all appropriate local authorities (fire departments, police departments, etc.) have been notified as per label instructions, local ordinances if applicable, or instructions of the client.
2. Prepare written procedure ("Emergency Response Plan") which contains explicit instructions, names, and telephone numbers so as to be able to notify local authorities if hydrogen peroxide levels are exceeded in an area that could be dangerous to bystanders and/or domestic animals.
3. In the event of a breach or leak of the enclosure where levels of hydrogen peroxide are above oneppm in adjacent areas to the enclosure, abort the application process and initiate the aeration process in the sealed enclosure. Ensure that the adjacent areas where levels have exceeded one ppm are evacuated by general personnel and that proper respiratory protection is utilized by applicators that enter the area. Continue monitoring the area until levels are below one ppm hydrogen peroxide. The treated enclosure and adjacent areas must remain unoccupied until hydrogen peroxide levels are at or below one ppm. Early reentry into the sealed treated enclosure at use concentration levels in the case of an emergency requires wearing a Self Contained Breathing Apparatus (SCBA) operated in pressure-demand mode, full hydrogen peroxide resistant body suit, gloves and boots to protect from the inhalation hazard as well as the corrosive action of hydrogen peroxide to tissues.

E. SEALING PROCEDURES

1. Sealing must be adequate to prevent any leaks. Care should be taken to ensure that sealing materials will remain intact until the fumigation is complete. Verify effectiveness of the sealing process by conducting a smoke stick test to ensure there are no leaks where openings have been sealed in the enclosure.
2. If the structure and/or area has been fumigated before, review the previous FMP for previous sealing information.
3. Make sure that construction/remodeling has not changed the building in a manner that will affect the fumigation.
4. Warning placards must be placed on every possible entrance to the fumigation site.

F. APPLICATION PROCEDURES & FUMIGATION PERIOD

1. Plan carefully and apply all fumigants in accordance with the label requirements.
2. 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.
3. Apply fumigant from outside the fumigation space.
4. Provide watchmen when a fumigation site cannot otherwise be made secure from entry by unauthorized persons.
5. When entering structures always follow OSHA rules for confined spaces.
6. The applicator should verify compatibility of item surfaces to be treated prior to the application process.

G. POST-APPLICATION OPERATIONS

1. Provide watchmen when you cannot secure the fumigation site from entry by unauthorized persons

during the aeration process.
2. Ventilate and aerate in accordance with structural limitations.
3. Turn on ventilating or aerating fans where appropriate.
4. Use a suitable VHP detector before reentry to determine fumigant concentration.
5. Keep written records of monitoring to document completion of aeration.
6. Consider temperature when aerating.
7. Ensure aeration is complete before moving vehicle into public roads.
8. Remove warning placards when aeration is complete.
9. Inform business/client that employees/other persons may return to work or otherwise be allowed to reenter the aerated structure.

H. CRITERIA FOR SUCCESSFUL FUMIGATION:

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

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 VHP application equipment, hydrogen peroxide monitoring procedures and when appropriate, validation procedures.

6. Preparation of Enclosures

a. Cleaning: Remove gross filth and visible soil prior to application. Wash soiled surfaces 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 air dry. All the surfaces in the treatment area must be completely dry to the touch or visibly dry prior to VHP application.

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 [≤ one ppm time weighted average for eight hours (TWA)] and ensure sufficient concentration of VHP sterilant in the treatment enclosure.

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

d. Securing Enclosure:

1. Assure all personnel have vacated the treatment enclosure prior to VHP application. Remove all plants, animals, beverages and food.
2. Applicators must not reenter the treated enclosure until exposure levels of hydrogen peroxide are at/or below one ppm.

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

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

2. “Area under treatment, “DO NOT ENTER/NO 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.
5. Contact information for the applicator.

All entrances to the treatment enclosure must be placarded. Placards must be placed in advance of the treatment in order to keep unauthorized persons from entering the treated enclosure. Placards are removed after the treatment enclosure contains concentrations of hydrogen peroxide at/or below one ppm.

7. Applications to Sealed Enclosures Requiring Validation of Use Conditions:

Vaprox Hydrogen Peroxide has been registered by STERIS in accordance with Federal Regulations for the specific uses described in this package insert. Vaprox Sterilant is used with enclosures that have been pre-cleaned of visible soils and any gross contamination. Uses other than as specified and described are not permitted: Vaprox Sterilant may not be effective in sterilization without careful, thorough development and validation. In addition, the ability of the VHP sterilant to decontaminate obstructed or covered surfaces is limited. The instructions that follow explain how to define appropriate use conditions and validate these conditions for use in a dry, pre-cleaned sealed enclosure of a fixed size, location and materials of composition. This includes sealed enclosures in industrial, commercial and institutional settings (including production operations in pharmaceutical manufacturing, manufacturing clean rooms, medical device sterilization as part of a manufacturing process, laboratories, animal research facilities, patient rooms, hotel rooms, offices, cruise ships, recreational facilities and emergency response vehicles). Process conditions must be properly validated prior to use to achieve sterilization of the treated enclosure. For use in applications where the enclosure configuration, size, materials of composition and construction will vary, please see instructions for use in applying VHP sterilant at a prescribed concentration and contact time (See Section 7 “Sites Not Requiring In Use Validation”). For additional guidance, in-service, and training on how to develop and validate custom cycles, contact STERIS Corporation.

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 *Geobacillus stearothermophilus ATCC 7953* spores inoculated on biological indicator substrates.

System Characterization:

Several factors need to be considered when validating an application. The volumetric size, materials of construction, the physical nature of the contents and the temperature range of the treatment enclosure will affect application time and concentration. In general, large enclosures will take longer to reach the target VHP concentration due to a longer conditioning phase. Absorptive materials present in the construction of an enclosure or in the contents will also increase the conditioning time and the time required to aeration of the enclosure. Vaporized hydrogen peroxide is a surface sterilant; therefore the enclosure and its contents should be prepared to maximize VHP exposure. Working temperature and humidity ranges must be established to ensure that the VHP sterilant does not condense on exposed surfaces in the treated enclosure. The chosen enclosure temperature and humidity conditions must not reach the enclosure dew point. Condensation can result in damage to enclosure surfaces and result in reduced cycle effectiveness. Placement of fans or other devices to assist VHP distribution must be documented. Standard Operating Procedures (SOPs) must be written to describe the physical preparation of an enclosure and its contents required to achieve reproducible results.

Biological Indicator Selection and Distribution:

The VHP sterilant effectiveness for applications must be validated using Biological Indicators (BIs) containing *Geobacillus stearothermophilus* spores. This organism has been shown to be the most VHP resistant organism. Additionally, biological indicators consisting of other organisms of interest to the user may be utilized to verify product performance. Use BIs with spore populations of 10^6 when validating enclosure application processes. It is important to utilize BIs that are suitable for evaluating VHP sterilant. STERIS Corporation supplies BIs designed for these applications and should be consulted regarding proper use and selection of BIs for validation of the VHP

process.

Numerous BI locations are used when validating a new application. Biological Indicators are often geometrically distributed, but should also be placed in areas considered to be most difficult for the VHP sterilant to reach. Additional BIs may be placed in areas considered to be critical such as a product contact point in an aseptic area. Location and justification of BI placement should be documented. In addition to BIs, Chemical Indicators (CIs) must be used during validation to provide qualitative information about VHP sterilant exposure. The number of BIs and CIs used during validation varies, depending on the size and complexity of the application. The number of biological indicators used to validate the process must at a minimum be based on the following:

Number of BIs = one per 100 ft^2 of floor space in the enclosure.

Process Development:

Typically the initial step in validating the VHP process is to determine the effectiveness of the process against *Geobacillus stearothermophilus* BIs of a known population. This is achieved by application of the sterilant at varying contact times and concentrations while keeping constant other VHP cycle parameters in order to determine the level of surviving organisms remaining on the BI at each exposure time. One approach to establishing effective kill times is the characterization of a "D value" which is the number of minutes or time required for a one log reduction of the target organism. This information can be utilized to extrapolate cycle parameters to achieve the desired level of BI kill.

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

• DEHUMIDIFICATION – Reduce humidity to a predetermined level in the enclosure. A typical range for relative humidity is 10-70%. This permits the necessary VHP concentration to be maintained below condensation levels during the CONDITIONING and STERILIZATION phases. The time to reach the targeted dehumidification level increases with the volume of the enclosure, and is dependant on environmental conditions such as temperature and humidity in the sealed enclosure. The chosen enclosure temperature and humidity conditions must not reach the enclosure dew point.. This may result in condensation on enclosure surfaces. Condensation can result in damage to enclosure surfaces and reduced cycle effectiveness.

• CONDITIONING – The VHP sterilant is injected into the sealed enclosure. The injection rate is adjusted and controlled based on guidelines established for the VHP equipment (refer to VHP Generator Equipment User's Manual). The CONDITIONING phase facilitates reaching the desired VHP concentration in the sealed enclosure. CONDITIONING time is affected by VHP target concentration, injection rate, enclosure materials, environmental conditions and enclosure volume.

• STERILIZATION – A constant flow of VHP sterilant is maintained at a selected Vaprox injection rate to maintain the target VHP concentration in the sealed enclosure required to achieve a 10^6 level of kill over a pre-established period of time.

• AERATION – The VHP injection is stopped and the flow of dry air continues to reduce the VHP concentration within the enclosure to an acceptable level ($\leq$ 1.0 ppm TWA 8 hr.) prior to reentry into the enclosure by trained applicators. Treated enclosures may not be released for general public use until after the level of hydrogen peroxide is at or below one ppm in the enclosure.

Once acceptable cycle parameters have been determined, three VHP cycle replicates must be conducted to verify the performance of the process. After successful validation of the process, the applicator must use the validated cycle conditions and contact time for VHP application. Significant changes to the enclosure such as major modifications to room dimensions and materials of composition will require additional validation or modification of application parameters.

Monitoring of H_2O_2 Concentrations in the Sealed Enclosure and Reentry Instructions Following Aeration.

VHP Monitoring: Dräger tubes or other VHP monitoring devices are utilized by means of a minimally invasive technique for VHP sampling to determine the VHP concentration in the sealed enclosure during and after the aeration phase. After 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 and general public use.

Criteria for Successful Fumigation:

1. All VHP fumigation process conditions (vapor concentration, temperature, relative humidity) are achieved throughout the fumigation cycle.
2. All CIs 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 suit, 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 5 ppm to allow for windows to be opened and to augment the aeration process if deemed appropriate at the specific location 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 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.

8. Application to Sealed Enclosures of Up to 4,000 ft^3 Not Requiring Validation of Use Conditions:

VAPROX sterilant may also be applied to dry, sealed pre-cleaned enclosures without prior validation when the area is treated on a non-routine basis or enclosures being treated vary in configuration, materials of composition and content of items located in the treatment enclosure. The use of the VHP process in these conditions 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 application process and aerated after sterilization. Vaprox sterilant may be applied at a set concentration and contact time to sealed enclosures of up to 4,000 ft^3 in industrial, commercial and institutional settings (including production operations in pharmaceutical manufacturing, manufacturing clean rooms, medical device sterilization as part of a manufacturing process, laboratories, animal research facilities, patient rooms, hotel rooms, offices, cruise ships, recreational facilities and emergency response vehicles). In these applications, the VHP concentration should be monitored using a hydrogen peroxide sensor 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 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 Precleaned 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 Generating Unit), sealing the enclosure and placarding of the enclosure to be treated. Place VHP monitor 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 & cabinet doors, etc. must be opened to permit exposure to VHP sterilant. Place 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 ft^2. 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 oscillating fans throughout the enclosure to facilitate effective distribution of the VHP sterilant. Program the VHP Generator to initiate a DEHUMIDIFICATION phase to achieve $\leq$ 70% relative humidity. Assure the ambient temperature is not less than 21˚ C or 70˚ F initially and throughout the fumigation process. Once the DEHUMIDIFICATION phase is complete initiate a CONDITIONING phase to achieve a 250 ppm VHP sterilant concentration in the sealed enclosure. When a 250 ppm VHP sterilant concentration is achieved initiate the STERILIZATION phase and maintain this concentration for 90 minutes. During the STERILIZATION phase, monitor areas adjacent to the sealed enclosure with devices such as Drager tubes to assure hydrogen peroxide levels do not exceed one ppm. If this level is exceeded outside the treatment enclosure, the applicator should immediately abort the treatment process and ensure the enclosure is properly sealed. Upon completion of the STERILIZATION phase, begin the AERATION phase to reduce levels of hydrogen peroxide at or below one ppm (TWA).

Sterilization of Sealed, Dry Precleaned 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 Generating Unit), sealing the enclosure and placarding of the enclosure to be treated. Place VHP monitor 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 & cabinet doors, etc. must be opened to permit exposure to VHP sterilant. Place 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 ft^2. 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 oscillating fans throughout the enclosure to facilitate effective distribution of the VHP sterilant. Program the VHP Generator to initiate a DEHUMIDIFICATION phase to achieve $\leq$ 70% relative humidity. Assure the ambient temperature is not less than 21 C or 70 F initially and throughout the fumigation process. Once the DEHUMIDIFICATION phase is complete initiate a CONDITIONING phase to achieve a 400 ppm VHP sterilant concentration in the sealed enclosure. When a 400 ppm VHP sterilant concentration is achieved initiate the STERILIZATION phase and maintain this concentration for 30 minutes. During the STERILIZATION phase, monitor areas adjacent to the sealed enclosure with devices such as Drager tubes to assure hydrogen peroxide levels do not exceed one ppm. If this level is exceeded outside the treatment enclosure, the applicator should immediately abort the treatment process and ensure the enclosure is properly sealed. Upon completion of the STERILIZATION phase, begin the AERATION phase to reduce levels of hydrogen peroxide at or below one ppm (TWA).

Monitoring of H_2O_2 Concentrations in the Sealed Enclosure and Reentry Instructions Following Aeration.

VHP Monitoring: Dräger tubes or other VHP monitoring devices are utilized by means of a minimally invasive technique for VHP sampling to determine the VHP concentration in the sealed enclosure during and after the aeration phase. After 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 and general public use.

Criteria for Successful Fumigation:

a. All VHP fumigation process conditions (vapor concentration, temperature, relative humidity) are achieved throughout the fumigation cycle.
b. All CIs that are properly recovered and evaluated exhibit a visible color change following exposure to VHP.

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 suit, 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 5 ppm to allow for windows to be opened and to augment the aeration process if deemed appropriate at the specific location 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 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.

9. Application to Sealed Enclosures Between 2 ft^3 and 40 ft^3 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 applicable 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 400ppm 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 *Geobacillus stearothermophilus ATCC 7953* spores inoculated on biological indicator substrates. See Section 7 Above for specific instructions regarding development of validated cycle conditions for alternate use conditions.

Monitoring of H_2O_2 Concentrations in the Sealed Enclosure and Instructions Following Aeration.

VHP Monitoring: Dräger tubes or other VHP monitoring devices are utilized by means of a minimally invasive technique for VHP sampling to determine the VHP concentration in the sealed enclosure during and after the aeration phase. After 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.

Criteria for Successful Sterilization:

a. All VHP sterilization process conditions (vapor concentration, temperature, relative humidity) are achieved throughout the sterilization cycle.
b. All CIs that are properly recovered and evaluated exhibit a visible color change following exposure to VHP.
c. For validated processes, all BIs that are properly recovered (no breach of aseptic technique) are negative for growth*.
d. For validated processes, positive control BIs demonstrate growth following incubation*.
e. For validated processes, negative control BIs exhibit no growth following incubation*.

* [not applicable to chambers not requiring validation]

Reentry Instructions:

1. Early reentry or opening of the chamber in the case of an emergency requires wearing a Self Contained Breathing Apparatus (SCBA) operated in pressure-demand mode, full hydrogen peroxide resistant body suit, gloves and boots to protect from the inhalation hazard as well as the corrosive action of hydrogen peroxide to tissues.

Releasing Treated Sealed Enclosure for Return to Service:

a. Once VHP levels are determined to be at or below one ppm, applicators may open the isolator/chamber and remove any sealing materials and disconnect/remove VHP Generator from the treated sealed enclosure.
b. Remove placards and release the treated enclosure for normal operation.

10. Aseptic Food Processing Operations

VAPROX® Sterilant is a ready to use solution. It may be used to achieve commercial sterility of food packaging materials and food processing equipment.
Apply VAPROX® Sterilant on the exterior and interior of food containers and closure systems (caps, seals, etc.), or appropriate food processing equipment surfaces. Use techniques such as, but not limited to, immersion, coarse spray, or circulation to sterilize the equipment. Apply VAPROX® Sterilant at a minimum temperature of 75˚C. This product must remain in contact with the packaging surface for a minimum of 20 seconds. Use in an aseptic food processing operation includes testing required for the process validation. Food subject to these FDA regulations may not be sold in a treated package until after the scheduled process for the food processing operation has been accepted by the FDA.

Emerging Viral Pathogens Not on EPA Registered Disinfectant Labels (These statements shall not appear on marketed (final print product labels).

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category [ies].

-Enveloped Viruses
-Large Non-Enveloped Viruses
-Small Non-Enveloped Viruses

For an emerging viral pathogen that is a/an…	*…**follow** the sterilant directions for use in conjunction with the STERIS Vaporized Hydrogen Peroxide Generator application equipment. Use this product for sterilization as instructed in the Vaporized Hydrogen Peroxide (VHP®) User's Equipment Manual.*
Enveloped virus	
Large, non-enveloped virus	
Small, non-enveloped virus	

***[Product name]** has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, **[porous and/or non-porous surfaces]**. Therefore, **[product name]** can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus(es)]** on **[hard, porous/non-porous surfaces]**. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.*

***[Name of illness/outbreak]** is caused by **[name of emerging virus]. [Product name]** kills similar*

viruses and therefore can be used against ***[name of emerging virus]*** *when used in accordance with the directions for use against* ***[name of supporting virus(es)]*** *on* ***[hard, porous/non-porous surfaces]****. Refer to the* ***[CDC or OIE]*** *website at* ***[website address]*** *for additional information.*"