



Biodecontamination Project: BSL-3 Laboratory Suite with VHP Integrated System Case Study

Project:

BSL-3 Laboratory Suite

Location:

Maryland, USA

Requirements:

6-log Biodecontamination of 18,000 ft³ (510m³), 11-room BSL-3 suite

Products:

VHP® M100X Biodecontamination Unit

Vaprox® Hydrogen Peroxide Sterilant

Steraffirm® [VH2O2] Process Indicators

The Challenge:

Biological Safety Level 3 (BSL-3) laboratories handle some of the most infectious and dangerous organisms on the planet. Effective biodecontamination of these facilities ensures the safety of the laboratory personnel, service personnel, and the surrounding environment. A US Government Research Center in Maryland wanted to biodecontaminate an eleven (11) room, 18,000 ft³ (510m³) enclosure and exhaust HEPA filters using hydrogen peroxide vapor with no additional equipment within the enclosure.

The Solution:

Through extensive coordination, STERIS Life Sciences worked together with the Engineering Company, Building Contractor, and Customer teams to put together a comprehensive integrated system for the facility using a combination of STERIS Life Sciences VHP products including the M100X Biodecontamination Unit, Vaprox Hydrogen Peroxide Sterilant, and Steraffirm [VH2O2] Process Indicators (PCC051) working with the facility's HVAC system.

The Result:

Within 12 hours, the entire 18,000 ft³ (510m³) BSL-3 enclosure was biodecontaminated and aerated. Sensors and Steraffirm [VH2O2] Process Indicators confirmed that a 6-log bioburden reduction was achieved throughout the facility. By using STERIS Life Sciences, the Customer was able to create an effective biodecontamination cycle and fumigation management plan for proof of biodecontamination and confirmation of adequate safety standards in support of regulatory compliance.

STERIS Life Sciences Biodecontamination Technologies:

STERIS' patented, world renowned VHP® Process Technology was introduced in 1991 by AMSCO and utilizes hydrogen peroxide vapor sterilant, which is highly effective against a wide range of microorganisms and compatible with a wide range of materials including sensitive electronics and other lab equipment often found in research facilities. The process is non-carcinogenic and environmentally friendly, breaking down into water vapor and oxygen with no residue.

STERIS's Vaprox Hydrogen Peroxide Sterilant is a United States Environmental Protection Agency registered product (EPA. Reg. No. 1043-123) compatible with STERIS VHP Biodecontamination Units.

STERIS's VHP M100X Biodecontamination Unit with its high output and integration capability allows VHP to be part of a building's utility system.

STERIS's Steraffirm [VH2O2] Process Indicators are specially formulated chemical indicators that aid in validation and routine monitoring of applications using VHP Process Technology.



The Biodecontamination Process

After a bid proposal process, a project proposal was given and agreed upon. A fumigation management plan was then developed for integration into the building based on the Customer's specific requirements.

The Customer wanted to perform a 6-log biodecontamination of an 11-room, BSL-3 suite 2-4 times per year as a prophylactic purpose for organism study change-over and general bioburden maintenance as well as have a response for emergency purposes. The integrated approach allowed a quick turnaround time and most importantly, meant that no additional mobile equipment, labor, or distribution systems were required to be brought into the BSL-3 suite. The system included a STERIS VHP *M100X*, dehumidifier to feed the VHP system, high volume distribution blower, HEPA filter, extraction blower, VHP high concentration sensor, and VHP safety monitors in the mezzanine and outside the BSL-3 entrances. The hydrogen peroxide vapor was distributed through insulated CPVC piping and exhausted through the suite's HEPA filtration system using a main exhaust bypass. Due to STERIS's unique VHP Process Technology featuring no condensation or "dry process," heat tracing of the distribution system was not required. An additional benefit to this system was that the hydrogen peroxide vapor penetrated and biodecontaminated the BSL-3 suite HEPA filters prior to exhaust. A manual valve system was employed to save cost versus an automated system with direct injection ports in the BSL-3 suite to allow for optimal hydrogen peroxide vapor distribution and isolation when the system was not in use.

Prior to use, the STERIS Life Science Service Team performed installation verification, start-up, and calibration of the VHP system. The STERIS VHP Application Engineering Team then performed cycle development using chemical and biological indicators in 24 challenge locations throughout the BSL-3 suite.

The building HVAC system was used to condition the BSL-3 suite prior to biodecontamination and was shut off while hydrogen peroxide vapor was being dispersed throughout the enclosure. The facility was treated with a hydrogen peroxide vapor concentration of 200 ppm over a 6-hour period. During the biodecontamination cycle, the BSL-3 suite was held at a slight negative pressure using the extraction blower to ensure lab integrity. Aeration was conducted overnight using the Customer's HVAC System down to a hydrogen peroxide vapor concentration of ≤ 1 ppm.

After biodecontamination cycle completion, the Trained & Certified Applicator entered the enclosure and checked with a Dräger hydrogen peroxide sensor for ≤ 1 ppm hydrogen peroxide vapor concentration. Biological and chemical indicators were collected for evaluation.

All Steraffirm (PCC051) process indicators showed color change indicating exposure to hydrogen peroxide vapor. Biological indicators were sent out for growth analysis with all reporting negative for growth after 7 days.

A final report was provided for the Customer showing a successful biodecontamination process. After three (3) successful biodecontamination cycles, the biodecontamination cycle was validated for use.

About STERIS Corporation

STERIS Corporation is a leading provider of infection prevention and surgical products and services, focused primarily on critical healthcare, pharmaceutical and research markets around the world. The Company supplies a broad array of equipment, consumable and service solutions that help assure productivity and quality. STERIS is listed on the New York Stock Exchange under the symbol STE. For more information, visit www.steris.com.

STERIS has a comprehensive offering of detergents, disinfectants, skin care products and sterility assurance products that support your needs. We also have world class technical support to design the most effective cleaning program for your facility.

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