



Biodecontamination Project: New Lab Animal Research Facility Commissioning Case Study

Project:

Lab Animal Research Facility Commissioning

Location:

Miami, FL - USA

Requirements:

6-log Biodecontamination of 120,000+ft³, 30+ room facility

Products:

VHP® *VICTORY-PRO*™ Biodecontamination Unit

VHP® *TS1000*™ Tri-Scale Sensor Steraaffirm™ Process Indicator (PCC051)

Vaprox® 59 Hydrogen Peroxide Sterilant

The Challenge:

Whether it is a new building or a small renovation, the process of commissioning is an integral tool in support of applications required for many accreditation and certification organizations. Accreditation bodies are concerned not only with regulatory accuracy and competency of staff, but also with ensuring a safe, functioning laboratory facility that has documented proof of operational accuracy. Because commissioning is a broad, comprehensive process that requires extensive coordination, this new 120,000+ft³ lab animal research facility at a prominent University in the Miami area knew it was only logical to turn to STERIS Life Sciences to help with their biodecontamination needs in order to prepare the facility for animal integration and operation.

The Solution:

The STERIS Life Sciences Biodecontamination Services Team worked together with the Customer's safety, scientific, and engineering teams to put together a comprehensive biodecontamination process for the research facility using a combination of STERIS Life Sciences technology and products including ten VHP *VICTORY-PRO* Biodecontamination Units; ten VHP *TS1000* Tri-Scales Sensors; Vaprox 59 Hydrogen Peroxide Sterilant; Steraaffirm Process Indicators (PCC051); 6-log *Geobacillus stearothermophilus* biological indicators; and 24-hour biological indicator media. This process included but was not limited to biodecontaminating the equipment within the facility, which included biological safety cabinets, laminar airflow benches, cage & rack systems, computer equipment, and office furniture.

The Result:

In less than 24 hours, the research facility (120,000+ft³) and equipment within it were successfully treated with STERIS's proprietary VHP process technology. Sensors and Process Indicators confirmed that a 6-log bioburden reduction was achieved throughout the cycle. By using STERIS Life Sciences Biodecontamination Services, the facility 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's patented, world renown 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 equipment often found in lab animal research facilities. The process is environmentally friendly, breaking down into water and oxygen with no residue.

STERIS's Vaprox 59 Hydrogen Peroxide Sterilant is registered with the United States Environmental Protection Agency (EPA. Reg. No. 1043-123) and is compatible with STERIS VHP Biodecontamination Units.

STERIS's VHP *VICTORY-PRO* Biodecontamination Unit with its high output, shortened cycle time, and easy operation, establishes a new standard for room and facility decontamination.

STERIS's VHP *TS1000* Tri-Scale Sensor Boosts VHP *VICTORY-PRO* biodecontamination system cycle efficiency and effectiveness by ensuring that hydrogen peroxide vapor sterilant is adequately distributed.



The Biodecontamination Process

After an evaluation of the University's research facility, a project proposal was presented and agreed upon.

Upon arrival, a STERIS Life Sciences Biodecontamination Services Team assessed the area and began preparing the facility for successful biodecontamination by ensuring that all surfaces were dry and clean; all items within the facility were set-up for biodecontamination; and potential hazardous materials were removed from the facility. The *VICTORY-PRO*s, *TS1000* Tri-Scales, Steraffirm chemical indicators and 6-log *Geobacillus stearothermophilus* biological indicators were placed throughout the facility in accordance with the fumigation management plan. VHP Units were connected via Ethernet through a router for remote monitoring, remote control, and simultaneous operation. Vaprox 59 Hydrogen Peroxide Sterilant was loaded into each *VICTORY-PRO* Unit. A last walk-through was conducted before sealing the facility and performing the biodecontamination cycle.

The biodecontamination cycle was initiated from outside the enclosure. The *VICTORY-PRO* Biodecontamination Units and *TS1000* tri-scale sensors were operated remotely, utilizing RealVNC® software via laptop with a wireless Ethernet connection. The biodecontamination cycle was monitored by utilizing the *VICTORY-PRO* and *TS1000* tri-scale sensor inputs (measuring temperature, percent relative humidity and hydrogen peroxide vapor concentration) to ensure a minimum of a 6-log bioburden reduction. Aeration was conducted overnight using the Customer's Building Management HVAC System down to a residual hydrogen peroxide vapor concentration of ≤ 1 ppm.

The facility was unsealed and checked with a Dräger hydrogen peroxide monitor for ≤ 1 ppm hydrogen peroxide vapor concentration. Biological and Steraffirm process indicators were collected. All biodecontamination equipment and accessories were removed from the facility. The facility was then released to the Customer pending results from the biological and chemical indicators.

All Steraffirm process indicators showed color change indicating exposure to hydrogen peroxide vapor. The biological indicators were checked for growth analysis using a 24-hour biological indicator media with all reporting negative for growth after 24-hours.

A final report and Certificate of Successful Biodecontamination were prepared and presented to the Customer.

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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