CLEANROOM CLEANING AND DISINFECTION

Cleaning and disinfection protocols are an essential part of any successful cleanroom operation, helping cleanrooms minimize the risk of contamination and meet their regulatory and environmental monitoring requirements. Proper cleaning and disinfection are especially important in environments where aseptic processing, healthcare applications, pharmacy compounding, animal research, and similar operations take place.

In general, cleaning and disinfection programs focus on removal of dirt and debris and minimization or elimination of microbial contamination.

Some Terms to Describe Cleaning and Control of Viable Organisms

Disinfection
A process that kills most microbes including bacteria and fungi, but not necessarily bacterial spores.

Sterilants
Agents used to kill or destroy all forms of microbial life, including viruses.

Sporicides
Agents used to deactivate microbial spores.

Sanitization
A process that reduces the number of microorganisms or pathogens present. Permissible levels of organisms after sanitization may be specified by public health or regulatory agency guidelines.

Detergents and Cleaning Agents
Chemicals used to dissolve or loosen unwanted soils or contaminants so they can be removed by mechanical means. These are often used to remove gross contamination prior to antimicrobial treatment.

Cleaning Protocols in Detail

Your facility's documented cleaning procedures should include a schedule of what to clean and when to clean it.[1] In regulated facilities, validation of cleaning and disinfection efficacy may be required.[2] This can involve testing surfaces before and after cleaning with swabs or contact plates, or evaluating cleaning efficacy via "coupon" tests of various surfaces in the room.

Selecting appropriate cleaning and antimicrobial agents involves consideration of a range of factors, including regulatory requirements, material compatibility, application method, amount and type of organisms to be killed or controlled, amount and type of soil to be removed, etc. For some end uses, regulatory agencies may require

qualification, validation and use of specific cleaning agents. Consult applicable regulations when designing or implementing a cleaning and disinfection program. Liquid cleaning agents may arrive as concentrated solutions requiring dilution prior to use or as ready-to-use formulations. Always follow the manufacturer's instructions, including dilution (if required), contact time, application method, rinsing and decontamination.

Cleaning protocols often include routine use of disinfectants and periodic use of sporicides to maintain environmental control.[3] Frequency of rotation between these agents can depend on many factors specific to a given facility: as set by schedule, as indicated by environmental monitoring, or as part of facility recovery after disruption of normal operations, such as after construction.

Hard surfaces in a cleanroom should be cleaned and/or disinfected at some frequency. Microbial death is very dependent on the time that an agent is in contact with the surface. For antimicrobial agents to be effective, surfaces must remain wet for the full contact time recommended by the manufacturer. Some cleaning chemicals and antimicrobial agents may require additional rinsing to remove any residue.

Protecting Your Employees

Employee protection is a necessary consideration for any cleaning protocol. Hazards can include skin or eye contact, respiratory exposure, and even slips, trips and falls. For cleanroom use, properties such as garment cleanliness, particle shedding, filtration efficiency, etc., should be part of your personal protective equipment (PPE) garment evaluation criteria. In aseptic cleanroom environments, sterile garments and accessories may be required.

Given the breadth of hazards, no single garment solution is appropriate for all cleaning applications, so it's important to conduct a hazard assessment to understand all potential scenarios and protect employees effectively.

In addition to a broad selection of protective garments, DuPont Protection Solutions provides a Certified Industrial Hygienist who can assist customers with these complex decisions. Here are a few real-life examples of customers who made use of this service:

Example 1: GMP Cleanroom Sporicidal Cleaning

Generally speaking, GMP (good manufacturing practices) cleanrooms are treated with a sporicidal agent on a recurring basis. Typical sporicidal products have hydrogen peroxide, peroxyacetic acid and acetic acid as their active ingredients. These products are corrosive to the eyes and skin in their concentrated form. Even when diluted, they still can be very irritating. Additionally, their vapors can cause respiratory irritation, especially in sensitive individuals. Dripping, spraying, and splashing solutions present contact risks, while aerosols and vapors present inhalation risks. There are occupational exposure limits for all three active ingredients.

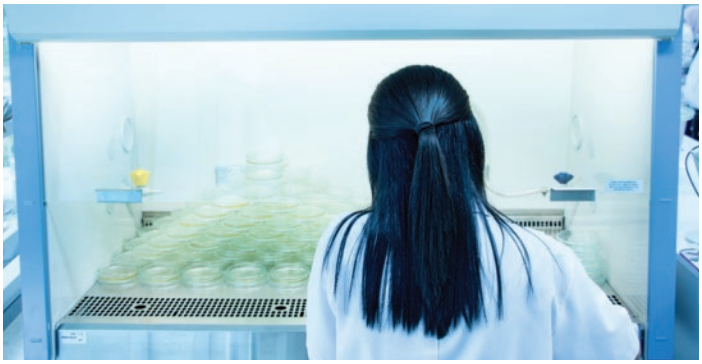
Application procedures typically involve wet mopping or spray application on the relevant surfaces, including ceilings, walls, floors, and, in some cases, cleanroom equipment. In addition to donning standard cleanroom garments, the typical ensemble may include use of a cartridge or powered respirator. Eye protection should also be worn. Avoid heavy exposures to solutions that could soak through cleanroom garments and contact the wearer's skin. Certain situations may warrant higher-level chemical-resistant garments.

The products below are examples of garments in the DuPont portfolio that might be suitable for use in Example One:

Tyvek® 800J

Tyvek® IsoClean® Coverall
IC181SWHXX002500

Example 2: Cleaning a Biological Safety Cabinet



Biological safety cabinets (BSC) are a common engineering control device found in many life science, biotech and pharmaceutical work environments. These devices, as well as other pieces of equipment that handle biological hazards, need to be cleaned on a regular basis. The level of antimicrobial cleaning agent used depends on a number of factors, including the microorganism(s) being handled and the degree of cross-contamination prevention or microbial reduction required.

Routine daily cleaning to prevent cross-contamination between tasks in the BSC may involve wiping down the interior surfaces with 70% isopropanol. If a higher level of cleaning is needed to satisfy end-of-day or weekly cleaning regimens, phenolic or even sporicidal cleaners may be applied using wet-wiping or spray application techniques. Standard PPE for this type of cleaning includes a lab coat, sterile sleeves, nitrile or latex exam gloves and safety glasses.

The products below are examples of garments in the DuPont portfolio that might be suitable for use in Example Two:

Tyvek® IsoClean® Labcoat
IC224SWHXX00300B

Tyvek® IsoClean® Sleeves
IC501BWHXX0100CS
Multiple options available.

Visit SafeSPEC.DuPont.com for More Product Details

DuPont protective apparel must be worn with other appropriate PPE, such as, but not limited to, respirators; face and eye protection; gloves; and protective footwear, as indicated during the hazard risk assessment to minimize inhalation, prevent skin contact and avoid contamination of clothing worn under the protective garment. DuPont PPE helps protect both employees and the process itself.

1. Cleaning – IEST-RP-CC018.4 Cleanroom Housekeeping: Operating and Monitoring Procedures
2. Ibid.
3. Technical Report 70 – Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities (Parenteral Drug Association)

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