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Technical Series

SOPs for Facility Maintenance, Cleaning, and Sanitization

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SOPs for Facility Maintenance, Cleaning and Sanitization

The purpose of rigorous standard operating procedures (SOPs) for maintaining, cleaning, and sanitizing the controlled environment is to manage the viable and non-viable particulate matter that is constantly being generated and shed by the humans working in the environment. Having documented and scheduled cleaning that is conducted according to the SOP maintains the integrity of the controlled environment and decreases the risk of product contamination. The SOP for facility maintenance, cleaning, and sanitization should also include guidance for removing gross contaminants and spills.

All SOPs for controlled environments must be thoroughly defined, executed, and monitored. Cleaning of the controlled environment requires specific instruction and must be performed by the trained operators responsible for maintaining the cleanliness of the environment and equipment. Trained operators or outside janitorial service providers who maintain, clean, and sanitize a controlled environment should adhere to the same SOPs production technicians use for gowning and personal hygiene. Appropriate cleanroom PPE (personal protective equipment) may include liquid-repellent cleanroom garment systems (masks, anti-skid shoe covers, sleeves, coveralls, bouffant caps, beard covers, etc.), and gloves.

Caution should be taken when cleaning Ultra-Low Particulate Air (ULPA) and High-Efficiency Particulate Air (HEPA) filter surfaces. Avoid touching the filter media. If the filter is punctured or otherwise compromised, its ability to remove particles is weakened. Gross contamination and spills must be removed prior to sanitizing and/or disinfecting any surface.

The frequency of cleaning areas within the controlled environment will vary depending on cleanroom classification and the production schedule. For example, the walls and ceiling may be cleaned once a month whereas the equipment and floors are cleaned after each production shift. This frequency should be scheduled to maintain cleanliness to your environment's specification.

Selecting **Cleaning Materials**

Cleanroom wipers, mops, swabs, and all cleaning chemicals must be compatible with the controlled environment's walls, floors, equipment, and all other possible surfaces. When cleaning and sanitizing the controlled environment, use only facility-approved wipers, mops, and swabs with approved cleaning chemistry that are compatible with each surface. The use of corrosive disinfectants can potentially rust metal table legs, cartwheels, etc. It's imperative that your approved cleaning chemistries do not create contamination. Cleaning chemistries include a variety of disinfectants, chemical formulations, sterilants and decontaminants dependent on the sensitivities of the controlled environment.

Appendix A: Guidance for Wiper Selection by Environmental Cleanliness or Application in **IEST-RP-CC004.4** Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments are resources for selecting the correct wiper for the appropriate application in your specific controlled environment.

The most common cleanroom wiper substrates are poly-cellulose, polypropylene, polyester, and microfiber. For general facilities and environmental cleaning, high absorbency is the most important factor to trained operators, because it can hold the most cleaning solution, clean the largest surface area, and clean most effectively. A thicker wiper with a higher basis weight will hold more chemistry. Basis weight is measured in grams per square meter (GSM). Therefore, the higher the GSM of the wiper, the higher the absorbent capacity.

One highly absorbent wiper material is poly-cellulose (also called non-woven or engineered fabric). Non-woven wipers are constructed from a hydro-entangled, nonwoven blend of cellulose and polyester. This composite substrate combines the highly absorbent properties of a natural fiber with the cleanliness and strength of a synthetic yarn, which has a low level of particulate and extractable counts. Non-woven sterile and non-sterile wipers are acceptable for non-critical cleaning and sanitizing.

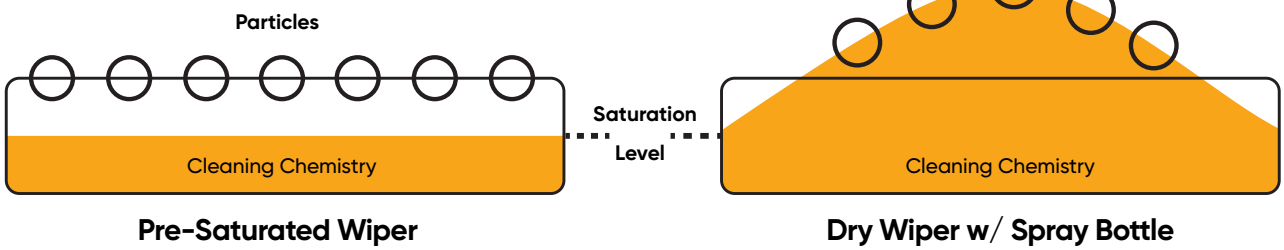
Cleaning Chemistries **and Application**

The selected wiper must be compatible with the approved cleaning chemistry. Using a squeeze bottle to apply the cleaning chemistry to a dry wiper is more effective than simply using a dry wiper. A dry wiper only "moves" particles and doesn't effectively "capture" them.

For the most effective cleaning, the chemistry should be uniformly saturated throughout the wiper; center-to-edge. Using a pre-saturated wiper that is properly dosed, vacuum packed, and uniformly saturated with the specified chemistry is more effective at capturing particles, resulting in a cleaner surface.

There is a wide range of cleaning and sanitizing chemistries depending on the specific controlled environment and the processes performed. The most common chemistry found in controlled environments is a mixture of 18 megohm/cm deionized (DI) water and ultra-pure isopropyl alcohol (IPA). Concentrations range from 6% IPA to 100% IPA, depending on application. In most life science cleanrooms (e.g. pharmaceutical, medical device, tissue banks, biotech R&D, etc.), sterile and non-sterile wipers are pre-saturated with a 70% IPA/30% DI water solution. 70% IPA is the most common because the solution has a desirable "saturation" dwell time before drying out and is an effective sanitizer.

Cleaning **Efficacy**



Pre-Saturated Wiper **Dry Wiper w/ Spray Bottle**

Cleaning **Frequency**

The SOP should define a daily, weekly, and monthly cleaning schedule depending on the ISO classification of the controlled environment. For example:

Daily task

Wipe down each worksurface, even if they were unused, with a pre-saturated wiper at the beginning and end of each shift.

Weekly task

Mop the floors.

Monthly task

Clean the ceilings, walls, floors, and equipment.

Quarterly/semi-annually tasks

Perform a facility deep clean, typically conducted by outside janitorial service providers.

SOPs also include as-needed cleaning tasks, such as how and when to replace tacky mats and how to handle gross contamination and spills.

Cleaning **Sequences**

The SOP should specify the exact cleaning sequences, down to the stroke and direction of mopping and wiping.

A variety of mopping systems are used for cleaning floors, walls, and ceilings. There are single-use, multi-use, flat heads, polyester heads, pre-saturated heads, and more. The type of mop used is dependent on the air cleanliness classification of controlled environment and should be specified in the SOP. Mopping systems should also be compatible with the environment. For example, using a polyester fantail mop on a raised-grid floor creates contamination as the edges fray with agitation. Cleaning chemistry will also drip through the grid to the subfloor.

To ensure janitorial/facility/maintenance technicians achieve specified cleanliness standards, they should follow the SOP guidance, including the tools (i.e. mopping system) and the chemistry (i.e. disinfectants, chemical formulations, sterilants, decontaminants, etc.) approved by the facility. Mops should be properly labeled and identified for use exclusively in the controlled environment to prevent cross contamination.

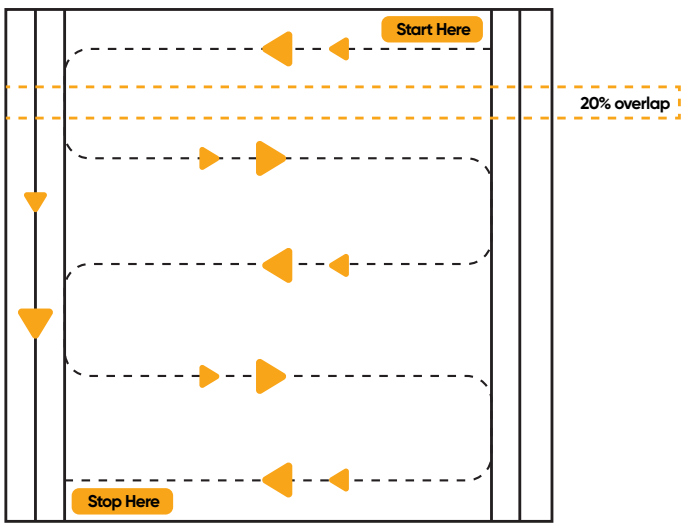
Here is an example of proper mopping techniques:

1. Pre-clean walls and floors with a tacky roller and/or cleanroom HEPA vacuum. Ceilings typically do not need pre-cleaning.
2. For walls and ceilings, use the pull-lift technique (just like wiping a worktop surface). Walls should be wiped from top to bottom, starting from the ceiling and pulling toward the floor.
3. Mop the floors following the crisscross method.

Mopping Techniques

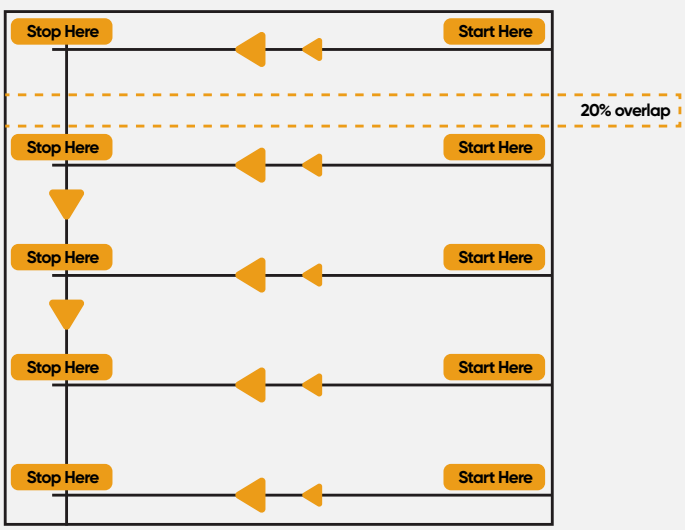
Crisscross/S-Curve mopping method:

1. First, mop the edges on either side of the controlled environment.
2. Start from the top corner of the controlled environment and mop in a crisscross formation, keeping lines neat and moving back toward the exit.
3. Do not step on any cleaned areas.
4. Overlap mop strokes by 20%.
5. Finish mopping at the exit.



Place and Pull mopping method:

1. Place the mop at the edge of the controlled environment, furthest away from you.
2. Pull the mop toward you in a straight line.
3. Repeat the process, overlapping strokes by 20%.
4. Do not step on any cleaned areas.
5. Finish by mopping along the edge.



Cleaning **Task Sequence**

The sequence in which general facilities cleaning tasks take place must be specified in the SOP. For example:

1. Clean the gown room.
2. Clean the ceiling.
3. Clean the equipment.
4. Clean the window frames and sills.
5. Clean the tops and edges of doors.
6. Clean the walls, including windows and doors with continuous strokes.
7. Clean the floor as you move from the clean side to the dirty side of the room using the place and pull mop method.
8. Clean furniture, carts, and chairs; moving from the clean side to the dirty side of the room.
9. Clean the remaining part of the floor, ending at the cleanroom entrance.

Here is an example of a partial checklist for cleaning the controlled environment:

Surfaces

- Wipe Down All Surfaces (tables, cabinets, benches, etc.) with nonwoven wiper.
- Wipe all door and cabinet handles.
- Remove one layer of tacky mats.

Floors

- Vacuum floors with HEPA-filter vacuum to remove large particles.
- Mop all floors. ONLY USE THE MOP IN THE ROOM IT KEPT.

Supplies

- Replace any wipes, cleanroom paper, etc. that have been used.
- Refill all Acetone, Methanol, Ethanol, etc. spray bottles for benches.
- Notify management of chemicals running low.

Trash

- Remove all trash from the controlled environment and replace trash bags.
- RED BAGS INDICATE CHEMICAL WASTE AND MUST BE DISPOSED FOLLOWING CHEMICAL HANDLING SOP.

After Cleaning is **Complete**

When leaving the controlled environment, all personnel (production, facility, janitorial, etc.) must doff and change cleanroom garments and any cleaning material used per the gowning SOP. No cleanroom garments are allowed to be worn outside the controlled environment.

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