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Technical Series

SOPs for **Critical Cleaning**

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SOPs for Critical Cleaning

Outside janitorial service providers and facility maintenance technicians are typically responsible for general/environmental cleaning. Critical cleaning of the controlled environment and the equipment that comes into contact with the process or product is usually performed by specially trained production technicians.

As with other standard operating procedures (SOPs) for controlled environments, the process for critical cleaning must be clear and detailed. Without documented SOPs for critical cleaning, facility operations and process quality are at risk.

The SOP should document the approved cleanroom consumables and cleaning chemistries, the surface and product touch points, and the required level of cleanliness.

Approved Cleanroom **Consumables**

Critical products used inside the controlled environment must be qualified to ensure the consumables meet quality and cleanliness requirements. Gloves, wipers, and apparel are the most common consumables specified in an SOP.

The SOP should include which gloves, wipers, and apparel are approved for use inside the specific facility. Different substrates are better for different environments.

An SOP for a controlled environment where optics and lasers are manufactured may specify a microfiber wiper. A microfiber wiper can be used for sensitive surfaces that are prone to scratching. Because microfiber thread has a small diameter and is made from a combination of polyester and nylon, it's nonabrasive. The hydroentangled surface area also creates crevices to capture particles.

Semiconductor facilities often have multiple controlled environments, with different processes and cleanliness requirements. Thus, the SOP might specify a polyester knit wiper with a laser sealed edge for post-encapsulation assembly, but a pressure heat sealed edge for the most critical applications, like wafer fabrication. The most demanding applications require the cleanest wiper for product contact.

Sterile or non-sterile polyester wipers with sealed edge treatments are recommended for the most critical product, process, equipment, and tool cleaning.

When dealing with an area or component that is too small for a wiper, an approved swab can be used. Swabs can be used for cleaning cracks and crevices, hard-to-reach locations, and uneven surfaces. The typical cleaning pattern for regular surfaces is parallel, overlapping strokes in one direction. If the surface to be cleaned is irregular, modify to achieve proper cleaning.

Just like with wipers, internal SOPs should outline facility-approved specifications on the critical gloves that make contact with the product or process. SOPs for process applications provide guidance on glove selection because there are a variety of substrates, chemical compatibilities, and cuff lengths to consider. A sterile glove that works well in a compounding pharmacy may not work well in a controlled environment where electronics are manufactured.

The most popular glove substrate is nitrile, which comes in a variety of cuff lengths and cleanliness classifications depending on the application. Engineers in an advanced materials environment aren't concerned with viable particles and would never use a sterile nitrile glove. On the other hand, the life sciences industry is concerned with sterilization and preventing endotoxins from contaminating the process and products.

Coveralls, bouffant caps, shoe covers and other apparel worn inside the controlled environment should also be specified in the SOP. Apparel, whether disposable or reusable, should be made from low-linting materials such as synthetic fabrics like polyester or microporous, as these substrates minimize the release of particles that can contaminate the controlled environment. All apparel should be appropriate for the specific controlled environment and outlined in the SOP.

For example, in a pharmaceutical environment, technicians often wear Polyethylene-coated polypropylene (PCPP) lab coats or frocks because they are impervious to liquids and designed for ISO 5-6 (Class 100-1,000), medium level controlled environments.

However, in the most stringent controlled environments (ISO 3-4; Class 1-10), technicians wear microporous garments because it's the cleanest substrate that also provides protection against non-toxic particulates, liquids, spray and dust.

Approved Cleaning **Chemistries**

Each critical environment uses a different cleaning chemistry. Some critical environments use disinfectants like alcohols, aldehydes, amphoterics, biguanide, phenolics, or quaternary ammonium compounds. The specific cleaning and sanitizing solutions should be defined in the SOP.

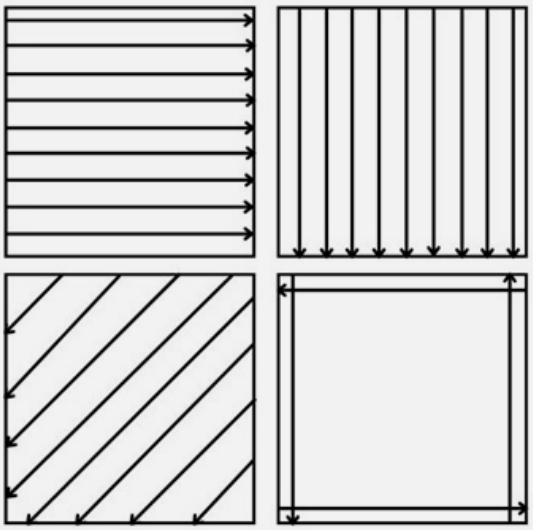
While a concentration of 70% IPA and 30% DI water is often used for general facility cleaning, there are a variety of concentrations ranging from 0% to 100% IPA are used for critical cleaning and maintenance.

In certain microelectronics and semiconductor environments, there are metallic components that cannot come into contact with water. In this specific application, water causes rust, corrosion and chemical reactions that contaminate the environment. In that case, a 100% IPA wiper is used. The SOP should outline when to use the 100% IPA wiper instead of the 70% IPA wiper which is used for surface cleaning.

Monitoring Critical **Cleanroom Cleanliness**

Because tools, equipment and processes can create contamination, it's important for the SOP to outline the testing methods that determine the air cleanliness classification. Testing a controlled environment "at-rest" vs. "in-process" when operators are present, and machines are on will yield different results. Generally, the most critical cleanrooms have continuous, 24/7 monitoring, whereas an ISO 7+ (Class 10,000+) controlled environment may only test weekly, monthly, or when required by regulatory authorities. Monitoring frequency should also be outlined in the SOP.

Swabs are often used to test cleaned surfaces for viable and non-viable particles or residues. If sampling for viable and non-viable particles or residues, swab a 10cm X 10cm area horizontally, vertically, and diagonally and the entire perimeter, rotating the surface of the swab.



The swab is placed in a transportation solution and submitted for specified analysis to verify cleaning efficacy.

There are also visual methods for monitoring the efficacy of cleaning and sanitizing the controlled environment. White wipers are used for looking for colored particles. Dark colored wipers are used for looking for white particles. Both bright white light and UV lights are used to examine surfaces for particles and residue. A surface particle probe may be attached to an air particle counter to determine both viable and non-viable particles on a surface. Sterile touch plates may be used to determine microbial contamination of surfaces.

How to Clean **a Critical Workstation**

Here is an example of a proper cleaning technique for worktop surfaces:

1. Fold the pre-saturated wiper in a quarter fold to get 8 clean surfaces.
2. Hold the quarter-folded wiper flat against four fingers on one side and the thumb on the other side.
3. Wipe unidirectionally from the cleanest area to the dirtiest area. On horizontal surfaces, like a worktop, wipe from back to front, starting away from the body and pulling toward you.
4. Change the surface fold of the wiper each time you wipe and lift. Consistently move left to right or right to left. Do not mix directions.
5. Wiping should consist of parallel, overlapping strokes in one direction. Each stroke should overlap the previous stroke by 20% for even coverage.
6. Do not use circular or S-strokes as these only spread particles and causes cross-contamination.

Pull-lift **Technique**

Stroke 1: Place wiper on the surface furthest from you and pull toward you.

Stroke 2: Lift the wiper, change the clean surface, place wiper at the start of Stroke 1, overlapping Stroke 1 by 20%. Pull toward you.

Stroke 3: Repeat.

With a clearly defined SOP for critical cleaning, in conjunction with SOPs general for facility maintenance, proper gowning protocols, and operator requirements, your controlled environment will maintain consistency, compliance, and positive outcomes.

Industry Reference Documents

Applicable reference documents for cleanroom facility testing, cleaning and sanitization SOPs are:

- **IEST-RP-CC004**, Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments
- **IEST-RP-CC018**, Cleanroom Cleaning and Sanitization: Operating and Monitoring Procedures
- **IEST- RP-CC026**, Cleanroom Operations
- **IEST-RP-CC027**, Personnel Practices and Procedures in Cleanrooms and Other Controlled Environments
- **ISO 14644-5**, Cleanrooms and Associated Controlled Environments - Operations
- **USP 795**, Pharmaceutical Compounding – Nonsterile Preparations
- **USP 797**, Pharmaceutical Compounding – Sterile Preparations
- **USP 800**, Hazardous Drugs – Handling in Healthcare Settings

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