Designing a CCS that Focuses on Materials Transfer into Cleanrooms, RABS, and Isolators

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ABSTRACT

Effective materials transfer is essential for cleanroom contamination control. Items entering from warehouses or other cleanrooms pose a high risk of introducing fungal and bacterial spores. A robust decontamination procedure is key to minimizing this risk. Options include wiping or spraying items with a sporicide or disinfectant or using vaporized hydrogen peroxide (VHP) pass-through chambers or room decontamination. VHP is especially suitable for sensitive items like electronics and soft metals due to its excellent material compatibility and efficacy.

Introduction

Figure 1: CCS Flow Chart

Contamination Control Strategy (CCS)

A CCS is a risk-based approach to prevent contamination— microbial, particulate, or pyrogenic—throughout a process. Control measures, such as isolators or RABS (Restricted Access Barrier System), are selected based on contamination risk assessment.[1,3,4]

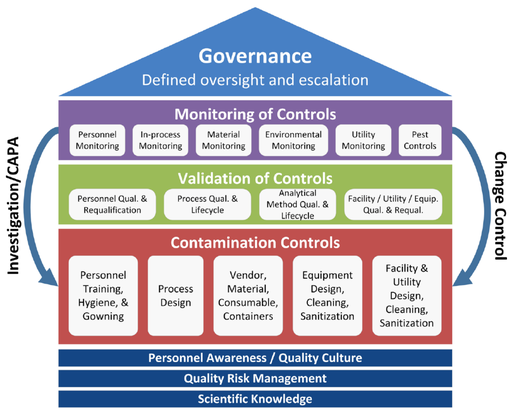

Figure 2: Elements of a Contamination Control Strategy[3]

Materials transfer process is a critical part of a successful CCS.

Annex 1 4.10 - Transferring equipment and materials into and out of cleanrooms—especially critical zones—is a major contamination risk. "Any activity that could compromise cleanroom integrity must be assessed, and if it can't be avoided, proper controls should be put in place."[1]

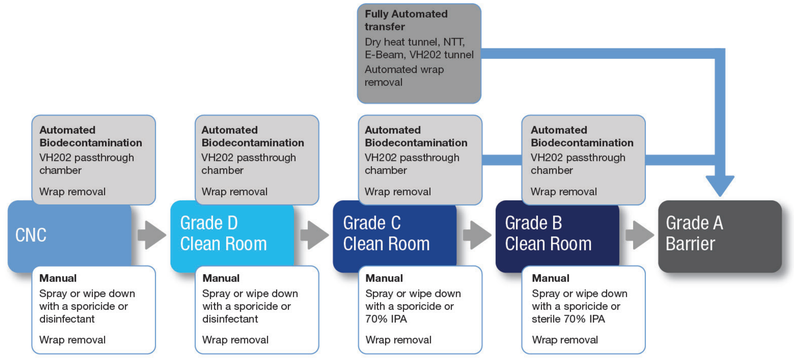

Figure 3: Material Transfer Map-Manual and Automated Processes

Each transfer step requires a defined wrapping and/or decontamination strategy (Figure 3). Pressure differentials, handling methods, sterile barriers, hold times, monitoring, and technology (e.g., isolators, RABS) must align with EU Annex 1 guidance (Sections 4.14, 4.18, 8.46-8.49). Hydrogen peroxide (H2O2)/peracetic acid wipes and trigger spray are long term viable options to control incoming bioburden on pass thru items into the cleanroom.[1,3]

Vaporized Hydrogen Peroxide for Material Transfer

VHP is an effective option for safeguarding material transfer processes and minimizing the risk of contamination in aseptic environments. Traditional VHP applications are residue-free producing only non-condensing water vapor and oxygen as byproducts (Figure 4).

VHP can be applied to pre-sterilized wrapped components and other materials moving into and through critical environments.

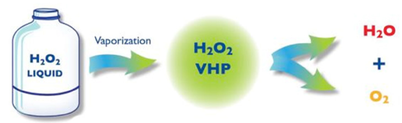

Figure 4: Depiction of Liquid H2O2 Vaporizing and Post Application VHP Breakdown into Water Vapor and Oxygen

VHP Usage: Validated using 6-log *Geobacillus stearothermophilus* biological indicators (BIs). Lower reduction levels (4- or 5-log) may be acceptable based on a bioburden risk assessment for material transfer.[2]

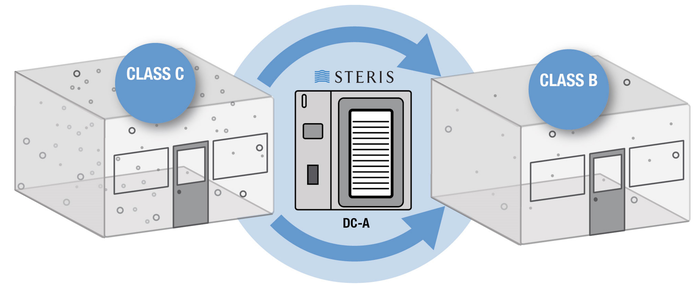

Figure 5: VHP Pass Through Decontamination Chamber

MALs (Material Air Locks) or chamber technologies pictured in Figure 5 create an automated method of decontamination, minimizing human error and personnel contamination risks. Standalone style chambers are designed with VHP generation, HEPA (High Energy Particulate Air) filtration, and aeration built into the chamber. VHP can also be applied directly to cleanrooms, RABS, and isolator environments.

Conclusion

Robust material transfer procedures are fundamental to maintaining cleanroom integrity and minimizing contamination risk. Items introduced from external environments must undergo validated decontamination processes[1]—such as wiping, spraying, or VHP treatment—based on risk assessment and material compatibility. VHP is particularly suitable for sensitive components due to its broad efficacy and material safety. A well-structured CCS, supported by clearly defined transfer protocols and integrated into SOPs (Standard Operating Procedures), is essential for meeting regulatory expectations and ensuring product quality.

References

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2. PDA Technical Report No. 51: *Biological Indicators for Gas and Vapor-Phase Decontamination Processes*. Bethesda, MD: PDA; 2010.
3. PDA. Technical Report No. 90: *Contamination Control Strategy Development*. Bethesda, MD: PDA; 2023.
4. PDA. *Environmental Monitoring Series No. 9: Best Practices in Maintaining Contamination Control*. Bethesda, MD: PDA; 2025.