*Institute of Environmental Sciences and Technology*

# IEST-RP-CC012.4

Contamination Control Division
Recommended Practice 012.4

# Considerations in Cleanroom Design

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## ABSTRACT OF KEY REVISION AREAS

## WHAT IS IMPROVED

- Enhanced description about the "Integrity of Building Envelope and Interstitial Spaces to Prevent Insects/Pests Entry" in Section 4.3.12.
- Improved description on "Process-specific airflow patterns".
- Revised language on "Wireless sensor".
- Detail discussions about dedicated space for storing cleaning equipment, water for cleaning and wash down, etc. were added for the "Design considerations for controlling contamination" in Section 5.9.1.
- Improved and more detail discussions on "Optimization of workflow/paths in existing cleanroom spaces", "Design for facility disinfection" and "CFD" analysis.

## WHAT IS NEW

- Added discussion on "Impacts to building pressurization control".
- Added detail diagrams for 4 categories of airlocks: Cascading, single bubble and dual-compartment.
- Added "Design considerations for cleanroom entry and exit for personnel".
- Added new discussion section on "Room pressurization strategy".
- Detail discussion about grounding connections for wrist straps, footwear, work surfaces, metal walls and ceiling grids to avoid charging and ESD, impacts by RF generator and ionizers, etc. were added in the "Grounding systems" in Section 5.16.
- Added more discussion on "Airflow turn-down and reset" to reflect new ISO 14644-4 (2022) standard.
- Added discussion section for "Cleanroom enclosure airtightness".
- Added discussion on "Demand based airflow control" to reflect ISO 14644-4 (2022).
- In the Appendix C of "Cleanroom Modeling Approach", a new terminology called "contaminant removal effectiveness" was added to reflect the new 14644-4 (2022) and 14644-16 (2019) modeling equations, this correctional factor can increase the predictability in estimation and calculation airflow rate.
- New discussion about ground filters, personnel grounding plan, ESD tester, etc. were added into the "Grounding systems" in Section 5.16.
- Many new references (articles, books and standards) were added in the Bibliography of Appendix E.

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## 1 SCOPE AND LIMITATIONS

### 1.1 Scope

This Recommended Practice (RP) makes recommendations regarding factors to consider in the design of cleanroom facilities. This discussion is limited to those environmental conditions that typically confront cleanroom designers and users.

### 1.2 Limitations

This RP is limited to the design of cleanroom facilities. Equipment design is not within the scope of this RP, nor does this RP address process or operational considerations, except as those considerations relate to cleanroom design.

This RP is intended to provide users with factors to consider for cleanroom design, but discussion of these factors is not intended to be all-inclusive. The specified ranges and recommended criteria are intended only to provide a framework. Specific process or other needs may dictate requirements beyond the scope of this document. This RP is not intended to supersede specific requirements established by a recognized national or international regulating body.

## 2 REFERENCES

The following publications were used in the preparation of this document or are considered critical to its content; their citation in no way represents an endorsement or recommendation.

The cited editions of these documents are incorporated into this RP to the extent specified herein. Subsequent revisions of these publications do not automatically supersede the cited editions. Users should investigate the applicability of revised editions of the references.

### 2.1 FM Global

*Cleanroom Materials Flammability Test Protocol (Class 4910) October 2013*

### 2.2 Food and Drug Administration (FDA)

*Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice. FDA (2004)*

### 2.3 Institute of Environmental Sciences and Technology (IEST)

*IEST-RP-CC001.7: HEPA and ULPA Filters*