

Institute of Environmental Sciences and Technology

IEST-RP-CC012.3

Contamination Control Division
Recommended Practice 012.3

Considerations in Cleanroom Design



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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 these considerations relate to cleanroom design.

This RP is intended to provide users with a means to establish performance criteria for cleanrooms. The factors considered are those commonly encountered in cleanrooms, 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 Material Flammability Test Protocol (Class 4910) June 2009

2.2 Food and Drug Administration (FDA)

Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice, FDA

2.3 Institute of Environmental Sciences and Technology (IEST)

IEST-RP-CC001.5: HEPA and ULPA Filters

IEST-RP-CC006.3: Testing Cleanrooms