Institute of Environmental Sciences and Technology

IEST-RP-CC049.1

Contamination Control Division
Recommended Practice 049.1

Controlled Environments for Regulated Industries

1827 Walden Office Square, Suite 400
Schaumburg, IL 60173
Phone: (847) 981-0100 • Fax: (847) 981-4130
E-mail: information@iest.org • Web: www.iest.org

This Recommended Practice was prepared by and is under the jurisdiction of Working Group 049 of the IEST Contamination Control Division. The following WG voting members contributed to the development of this edition of this Recommended Practice.

Anne Marie Dixon, Cleanroom Management Associates, Inc.
WG-CC049 Chair

Gordon Ely, MiMedx Group, Inc.

Leticia Fabiano, Genzyme Biosurgery

Jennifer Galvin, DuPont Protection Solutions

Leo Gubenko, Vileda Professional, FHP

Brad Lyon, ITW Texwipe

Rick Meyer, Superior Laboratory Services, Inc.

Jay Postlewaite, ITW Texwipe

Matt Smyers, TSS, Inc.

The Working Group also wishes to acknowledge the contributions of members who prefer to remain anonymous.

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1 SCOPE AND LIMITATIONS

1.1 Scope

This Recommended Practice (RP) provides criteria for the control of non-classified environments in industries such as pharmaceuticals, biologics, medical devices, nutraceuticals, healthcare, research and development, laboratories, component manufacturing, and emerging industries. The criteria are intended to assist manufacturers in implementing production methods and process controls, including facility environmental controls.

1.2 Limitations

This RP is not associated with cleanroom requirements or related documentation and does not apply to the unregulated industries, including but not limited to semiconductor, electronics, aerospace, automotive, and nanotechnologies.

IMPORTANT NOTE: This RP does not address sterile compounding as defined by *United States Pharmacopeia General Chapter <797> Pharmaceutical Compounding—Sterile Preparations* (USP <797>).

2 REFERENCES

2.1 Normative references

IEST-RP-CC003: Garment System Considerations for Cleanrooms and Other Controlled Environments

IEST-RP-CC012: Considerations in Cleanroom Design

IEST-RP-CC018: Cleanroom Housekeeping, Operating, and Monitoring Procedures

IEST-RP-CC023: Microorganisms in Cleanrooms

ISO 14644-1 Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness by particle concentration

ISO 14644-2 Cleanrooms and associated controlled environments—Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

ISO 14644-3 Cleanrooms and associated controlled environments—Part 3: Test methods

ISO 14698 Cleanrooms and associated controlled environments—Biocontamination control

ISO 14971 Medical Devices: Application of risk management to medical devices

