Institute of Environmental Sciences and Technology

IEST-RP-CC032.1

Contamination Control Division
Recommended Practice 032.1

Flexible Packaging Materials for Use in Cleanrooms and Other Controlled Environments

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This Recommended Practice was prepared by and is under the jurisdiction of Working Group 032 of the IEST Contamination Control Division.

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PROPOSAL FOR IMPROVEMENT: The Working Groups of the Institute of Environmental Sciences and Technology are continually working on improvements to their Recommended Practices and Reference Documents. Suggestions from users of these documents are welcome. If you have a suggestion regarding this document, please use the online Proposal for Improvement form found on the IEST website at www.iest.org.

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CONTENTS

SECTION

TABLE

APPENDIX

FIGURE

Institute of Environmental Sciences and Technology
Contamination Control Division
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1 SCOPE AND LIMITATIONS

1.1 Scope

This Recommended Practice (RP) provides guidance for the selection of flexible packaging materials for applications in cleanrooms and other controlled environments. Only packaging that protects the product integrity is discussed.

1.2 Limitations

This RP does not discuss rigid packaging materials. This RP also does not discuss packaging procedures or outer packaging required for shipping. Health, safety, and waste stream issues are not addressed.

2 REFERENCES

The following documents are incorporated into this RP to the extent specified herein. Users should apply the most recent editions of the references.

NOTE: There are multiple test methods and procedures to identify contamination properties. Users are advised to select the method best suited to their products or applications. Users should establish the physical, electrical, and contamination performance property levels needed to secure adequate protection.

2.1 Governmental

MIL-STD-3010: Test Procedures for Packaging Materials

MIL-STD-3010, Method 2065: Puncture Resistance

MIL-STD-3010, Method 3005: Contact Corrosivity

FDA 97-4179, Medical Device Quality Systems Manual, Section 13: Packaging

2.2 Non-governmental

ANSI/ASQ Z1.4: Sampling Procedures and Tables for Inspection by Attributes

ASTM D882: Standard Test Method for Tensile Properties of Thin Plastic Sheeting

ASTM D1003: Standard Test Method for Haze and Luminous Transmittance of Transparent Plastics

ASTM D3420: Standard Test Method for Pendulum Impact Resistance of Plastic Film

ASTM F88: Standard Test Method for Seal Strength of Flexible Barrier Materials

ASTM F1249: Standard Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor

IEST-STD-CC1246: Product Cleanliness Levels and Contamination Control Program

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

ISO/EN 11607-1: Packaging for Terminally Sterilized Medical Devices—Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

ISO/EN 11607-2: Packaging for Terminally Sterilized Medical Devices—Part 2: Validation Requirements for Forming, Sealing and Assembly Processes