

Institute of Environmental Sciences and Technology

IENT-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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Second printing, July 2017

ISBN 978-0-9787868-6-1

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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

IENT-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

2.3 Sources and Addresses

AAMI

Association for the Advancement of Medical Instrumentation
1110 North Glebe Road, Suite 220
Arlington, VA 22201-4795, USA
Phone: 703-525-4890
Fax: 703-276-0793
www.aami.org

ANSI

American National Standards Institute
25 West 43rd Street
New York, NY 10036, USA
Phone: 212-642-4900
Fax: 212-398-0023
www.ansi.org

ASTM International

(Formerly American Society for Testing and Materials)
100 Barr Harbor Drive
West Conshohocken, PA 19428-2959, USA
Phone: 610-832-9500
Fax: 610-832-9555
www.astm.org

ASQ

American Society for Quality
600 North Plankinton Avenue
Milwaukee, WI 53203, USA
Phone: 800-248-1946
Fax: 414-272-1734
www.asq.org

CEN

European Committee for Standardization
Avenue Marnix 17
B-1000 Brussels, Belgium
Phone: 32 2 550 08 11
Fax: 32 2 550 08 19
www.cenorm.be

FDA

Food and Drug Administration
Division of Manufacturing and Product Quality
Office of Compliance
5600 Fishers Lane
Rockville, MD 20857, USA
www.fda.gov

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ISO

International Organization for Standardization
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www.iso.ch

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MIL/QQ (Military Standards)

Standardization Document Order Desk
Bldg. #4, Section D
700 Robbins Avenue
Philadelphia, PA 19111-5098, USA
http://dodssp.daps.dla.mil/

3 TERMS AND DEFINITIONS

abrasion resistance

The ability of a surface to resist wearing due to friction.

aliquot

One part of a sample that has been divided into equal parts.

ashing

A method for determining the amount of non-carbon components that remains after combustion.

AQL

Acceptable quality level. Refers to table of inspection by attributes in ANSI/ASQC Z1.4.

bag, autoclave

A type of polymer bag used in steam sterilization applications. Also called biohazard bags, some are printed with an indicator that changes color when processed.

bag, gusseted

A bag made with side or bottom pleats, with dimensions such as 10 × 4 × 16 in., or in the case of bottom gusset, 10 × 16 × 4 in.

bag, outer (also outside double-bag, dust cover)

An additional layer of protective packaging used during storage and transportation. **NOTE:** The outer bag is removed in the gowning area and has a less-stringent cleanliness requirement than the inner packaging.

bioburden

A measure of the number of microorganisms resident on or within products and inanimate objects. A common synonym is microcount.

chemical degradation

The change in materials that occurs when the materials come into contact with chemicals. Degradation may take such forms as swelling, loss of tensile strength, deformation, or loss of abrasion resistance.

colony forming unit (CFU)

An individual or an aggregate of multiple microbial cells, which, when cultivated on solid media, will develop into a single visual colony.

contaminant

Any unwanted substance present in or on a material or any surface within a clean zone.

electrostatic discharge (ESD)

The transfer of electrostatic charge between bodies that have different electrostatic potentials.

electrostatic discharge shield

A barrier or enclosure that limits the passage of current and attenuates an electromagnetic field resulting from an electrostatic discharge.

film, gas barrier

A film designed with either single or multiple layers of films to prevent gas transmission through the film and onto the product.

film, moisture barrier

A film designed with either single or multiple layers of films to prevent moisture transmission through the film and onto the product.

gel marks (also known as carbon marks)

The result of exposure of molten resin to time and heat that causes the resin to burn. As the burning process continues, the resin breaks free, resulting in clear, brown, or black round markings on the material.

laminate

A material formed by bonding together two or more layers to achieve an effect not otherwise attainable from each of the component layers separately.

nonvolatile residue (NVR)

Any solid or liquid phase remaining after the evaporation of a volatile liquid from a solution. **NOTE:** NVR is generally expressed in units of mass per unit of liquid. If the volatile liquid was used to remove soluble contamination from a specific area of surface, the NVR units may be expressed as mass per unit area.

outgassing

The liberation of a gas from any material other than by change of state.

NOTE: Per ISO 14624-3, NASA coined the term “offgassing” to describe outgassing into the spaceship cabin atmosphere. The term has also been used in standards for test methods related to materials out-

gassing into room air. However, the physical and chemical processes for “outgassing” and “offgassing” are the same. The surrounding atmosphere affects the net outgassing rate, but there is no obvious point where “offgassing” becomes “outgassing” as the atmospheric pressure decreases.

particle

An object that is solid, liquid, or both, usually between 1 nanometer (nm) and 1 millimeter (mm) in size.

particle size

The apparent maximum linear dimension of a particle in the plane of observation as observed with an optical microscope, or the equivalent diameter of a particle detected by automatic instrumentation. The equivalent diameter is the diameter of a reference sphere having known properties and producing the same response in the sensing instrument as the particle being measured.

permeability

A quantitative measure of the ability of a material to transfer mass (solid, liquid, or gaseous) through its pores or capillaries, or both, under the influence of a pressure gradient.

primary barrier

A surface that is in direct contact with the product. The primary barrier should be as clean as or cleaner than the product it contains.

polymer

A high-molecular-weight substance, natural or synthetic, whose structure can be represented by repeated small units.

releasable particles

Particles present on the surface of a substrate that are readily releasable there from by wetting the surface with a liquid, but without imparting mechanical energy to the substrate.

3.1 Packaging material abbreviations

ABS – Acrylonitrile butadiene styrene

EVA – Ethyl vinyl acetate

FEP – Fluorinated ethylene polypropylene co-polymer

HDPE – High-density polyethylene

HIPS – High-impact polystyrene

LDPE – Low-density polyethylene

LLDPE – Linear low-density polyethylene

MDPE – Medium-density polyethylene

NY – Nylon-polyamide

PCTFE – Polychlorotrifluoroethylene

PE – Polyethylene

PET – Polyethylene terephthalate

PP – Polypropylene

PS – Polystyrene

PTFE – Polytetrafluoroethylene
PU – Polyurethane
PVC – Polyvinyl chloride
PVDC – Polyvinylidene chloride
SBHDPE – Spun bond high-density polyethylene

4 BACKGROUND AND PURPOSE

4.1 Background

Packaging of products within the contamination-sensitive environment of a cleanroom or other controlled environment requires a systematic approach to achieve the protective environment needed for the product. Packaging applications in cleanrooms are used for protection, handling, and storage of products to ensure preservation of cleanliness. Contamination from improperly chosen packaging can migrate into critical products and cause product malfunction or damage. The product can react with the packaging, causing damage to the product.

4.2 Purpose

This RP provides a structured method for selecting flexible packaging for use with products manufactured or processed in cleanrooms and other controlled environments.

5 DETERMINATION OF PACKAGING REQUIREMENTS

Proper packaging should be designed to maintain the cleanliness of products until opened by the intended user. Many requirements should be considered to address contamination concerns. The following partial list of considerations is intended as a starting point for making the proper packaging choice.

5.1 General characteristics of product and packaging

When choosing materials appropriate for the product being packaged, various packaging properties should be considered along with the specifications and goals to be met. End users of clean, flexible packaging materials (i.e., film or bags) should consider the following characteristics:

- Abrasion resistance
- Biodegradability
- Chemical reactivity/resistance/compatibility
- Cleanliness
- Density
- ESD protection (static generation and static dissipation)
- Flammability

- Flexibility
- Humidity range
- Ion-free
- Moisture barriers
- Moisture permeability (moisture transmission of barrier material)
- Outgassing
- Sloughing/shedding
- Opacity
- Oxygen or gas permeability
- Porosity
- Product visibility
- Sealability
- Shelf life
- Sterilization capability
- Temperature range

The following product characteristics also should be considered:

- Configuration
- ESD sensitivity
- Fragility
- Quantity
- Sharp or protruding features
- Size
- Sterility
- Surface texture

5.2 Compatibility of packaged product environment

5.2.1 Chemical compatibility

Chemical resistance ratings of packaging materials should be obtained from the manufacturer of the packaging materials.

5.2.2 Material compatibility

Material compatibility may be specific to the industry or application. Such requirements are typically defined by regulatory standards or industry specifications and standards. The packaging material manufacturer should be consulted for the material compatibility of film or bags used with specific substances or in situations that might cause products to react with the packaging materials, including the effects of exposure time, chemical temperature, chemical concentration, material thickness, and UV exposure.

5.2.3 Sterilization compatibility

Sterilization compatibility is critical, depending on the process chosen. Requirements are process application-specific and irreversible damage may occur if material compatibility is ignored. Compatibility with the sterilization method(s) is a property of the pack-

aging material and of the complete package. Incompatibility of the package or packaging material with the sterilization method may have detrimental results such as non-sterile product, product damage, or package damage.

Packaging material should permit both penetration and removal of the sterilant. Manufacturers of the materials may provide data concerning the compatibility of the materials with various sterilization methods. Literature is also available that contains information on materials and compatibility with sterilization methods. Attainment of sterilizing conditions should be demonstrated either prior to or in conjunction with the sterilization validation for the product. Sterilization may not be achieved if the packaging material limits or inhibits penetration.

5.3 Requirements for protection of packaged product

Conditions affecting packaging include the following:

- Required cleanliness level
- Composition of material being packaged
- Composition of packaging material
- Configuration of item being packaged, including projections or cavities to be covered or protected
- Future use, handling, environment, storage, and transport of the packaged item

5.3.1 Cleanliness requirements of packaged product

Selection of packaging materials should consider the sensitivity of the product to factors that can affect cleanliness. The following is a partial list of such factors:

- Abrasion/sloughing
- Fibers/foreign objects
- Humidity
- Ionics
- Labeling
- Leaching/migration
- Light/radiation
- Microorganisms
- Moisture sensitivity
- NVR
- Organics
- Oxygen/gas sensitivity
- Particles (inherent in the material or generated from the material during packaging)
- Shelf life of the packaging
- Shock/vibration
- Static discharge
- Sterilization compatibilities
- Temperature

For desired cleanliness levels, refer to applicable standards for the specific industry (e.g., IEST-STD-CC1246).

5.3.2 Preservation of physical integrity of packaged product

Clean packaging has been available since the need arose to preserve products manufactured in a clean environment. The process of packaging clean parts, components, and systems has become an important aspect in the fabrication of high-tech manufactured parts in all industries. Critical items such as cleaned parts, assemblies, and pharmaceutical products are wrapped or sealed in clean packaging materials for protection during non-process periods of manufacturing. Flexible packaging has replaced pre-cleaned metal or glass enclosures by providing a cost-effective, user-friendly method of protecting products during different stages of processing.

Packaging protects against (according to need):

- Contamination – particulate and non-volatile residue (NVR)
- Corrosion
- Temperature
- Light
- Humidity and moisture damage
- Gas and oxygen damage
- Electrostatic discharge/electromagnetic interference (ESD/EMI)
- Chemicals
- Physical damage
- Damage during shipping
- Vectors
- Flammability
- Bio-organisms

5.3.4 Types of seals of flexible barrier material

The appropriate closure should be selected to provide optimum contamination control and protection for the internal product. Types of seals include the following:

- Heat seal
- Zipper lock
- Self-adhesive
- Tape seal
- Staple
- Moisture barrier
- Glue
- Vacuum pack
- Twist tie or cable tie