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Standard Guide for Writing a Specification for Flexible Barrier Rollstock Materials¹

This standard is issued under the fixed designation F99; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide defines the requirements and considerations for flexible barrier materials.

1.2 This guide addresses some critical printing requirements for flexible barrier materials.

1.3 Guidance is provided on specification requirements and considerations for flexible barrier materials intended to be purchased as rollstock.

1.4 If the flexible barrier material is intended to be purchased in the form of a pre-made sterile barrier system, Guide **F2559** should be referenced.

1.5 The values stated in SI units are to be regarded as standard. The values given in parentheses after SI units are provided for information only and are not considered standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

2. Referenced Documents

2.1 *ASTM Standards:*²

D4321 Test Method for Package Yield of Plastic Film

F17 Terminology Relating to Primary Barrier Packaging

F88 Test Method for Seal Strength of Flexible Barrier Materials

F2097 Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products

F2203 Test Method for Linear Measurement Using Precision Steel Rule

F2250 Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials

F2251 Test Method for Thickness Measurement of Flexible Packaging Material

¹ This guide is under the jurisdiction of ASTM Committee **F02** on Flexible Primary Barrier Packaging and is the direct responsibility of Subcommittee **F02.50** on Package Design and Development.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[F2475 Guide for Biocompatibility Evaluation of Medical Device Packaging Materials](#)

[F2559 Guide for Writing a Specification for Sterilizable Peel Pouches](#)

2.2 *TAPPI Standard*:³

[T 213 Dirt in Pulp — Chart Method](#)

[F437T 437 Dirt in Paper and Paperboard](#)

[T 547 Transparent Chart for the Estimation of Defect Size](#)

2.3 *FDA Document*:⁴

[21 CFR 178 Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers](#)

3. Terminology

3.1 *Definitions*—For definitions and terms used in this guide, see Terminology [F17](#).

3.2 *Definitions*:

3.2.1 *carbon particles*—carbon particles are bits of parent material (resin) that have seen excessive heat in processing.

3.2.2 *gels*—small particles of resin with higher-than-average molecular weight and that appear as small, hard glassy particles. Gels are not foreign material and are inherent to many polymer-based materials.

3.2.3 *specification*—an explicit set of requirements to be satisfied by a material, product, system, or service. Examples of specifications include, but are not limited to, requirements for; physical, mechanical, or chemical properties, and safety, quality, or performance criteria. A specification identifies the test methods for determining whether each of the requirements is satisfied.

3.2.4 *telescoping*—transverse slipping of successive winds of a roll of material so that the edge is conical rather than flat.

4. Summary

4.1 This standard provides guidance for writing a specification for flexible barrier materials. Materials, method of manufacture, physical properties, performance requirements, dimensioning, appearance, printing, and labeling are all issues that need to be addressed in a flexible barrier material specification. Appropriate requirements and test methods are suggested for preparing a specification.

5. Significance and Use

<https://standards.iteh.ai/catalog/standards/sist/c8cab18f-c943-4971-8403-b249f5db32f9/astm-f99-21>

5.1 Flexible barrier materials are universally used across industries and produced by a myriad of suppliers. They may be monolayer materials or complex composite structures. However, even with the diversity of material, there are still basic requirements that all flexible barrier materials should exhibit.

5.2 Flexible barrier material requirements may be divided into two categories, initial material qualification, and routine production and receipt requirements to ensure the purchaser receives exactly what is ordered. While all requirements may be included in the written specification, initial qualification tests may only be needed prior to the first order. Routine production and receipt requirements should be adhered to on every order. Initial qualification requirements are indicated with each clause, where applicable.

5.3 This guide provides an understanding of the requirements needed for the manufacture, purchase, and acceptance of flexible barrier materials. Appropriate test methods for compliance are also cited.

NOTE 1—All test methods for a particular requirement may not be cited due to specific or unique circumstances. For additional guidance on applicable methods, refer to Guide [F2097](#).

5.4 The specification and its requirements should be mutually agreed to by the supplier and purchaser of the product. This helps ensure that the flexible barrier materials will comply with the specified requirements.

³ Available from [Technical Association of the Pulp and Paper Industry \(TAPPI\)](http://www.tappi.org), 15 Technology Parkway South, Norcross, Suite 115, Peachtree Corners, GA 30092, <http://www.tappi.org>.

⁴ Available from [U.S. Food and Drug Administration \(FDA\)](http://www.fda.gov), 5600 Fishers Ln., Rockville, MD 20857, 10903 New Hampshire Ave., Silver Spring, MD 20993, <http://www.fda.gov>.

6. Specification

NOTE 2—Sufficient requirements should be included to ensure that all batches, lots, or deliveries conform to the specification. Incorporating unnecessary requirements into the specification is likely to increase cost and should be avoided.

6.1 Material Identification:

6.1.1 A brief description of the flexible barrier material should be provided. For composite structures, key layers and their thickness should be noted.

6.1.2 The trade name of the flexible barrier material and the associated manufacturer/supplier may be included if desired.

6.2 Physical Properties:

NOTE 3—There are numerous test methods associated with determining physical properties of flexible materials. Care should be taken in selecting the most appropriate test for the user's particular application and use. For guidance in determining which methods to use, refer to Guide F2097. Commonly used test methods have been indicated where appropriate.

6.2.1 *Thickness (if applicable)*—~~the~~The total thickness of the flexible barrier material and associated thickness tolerance should be identified. (See Test Method F2251.)

6.2.2 *Yield*—If the flexible barrier material is to be purchased in weight, the yield should be indicated. (See Test Method D4321.)

6.2.3 *Seal Strength*—If applicable, a seal strength should be specified. This requirement may be a minimum ~~and/or~~or maximum value, or both, a typical value, or in the case of weld seal materials, a statement that the material will provide a destruct (material failure) seal. ~~(Test—~~(See Test Method F88).)

NOTE 4—Minimum seal strength is typically that which maintains package integrity through the processing, handling, and distribution systems. Maximum seal strength is that which, if exceeded on peelable applications, may result in the perception that the package is too difficult to open or causes fiber tear or delamination between one or more of the bonded substrates. Maximum seal strength does not apply to weld seal applications.

6.2.3.1 The sealing conditions (temperature, pressure, and dwell), and the product to which the material should be sealed should be specified.

6.2.3.2 Seal strength is generally measured using a tensile test method such as Test Method F88. Test Method F88 indicates three different tail holding methods for the test sample: unsupported, supported 90° (by hand), and supported 180°. Because the effect of each of these on the results is varied, consistent use of one technique should be negotiated with the supplier and indicated in the specification.

6.2.4 *Barrier (if applicable)*—The flexible barrier material should provide an appropriate physical barrier (oxygen, water vapor, light, and so forth) ~~and/or microbial barrier.~~or microbial barrier, or both. This requirement should be evaluated during the initial material qualification and is not typically performed on a routine production basis.

6.3 Application Requirements (incorporate if applicable):

6.3.1 *Compatibility with Sterilization Process*—The flexible barrier material should be compatible with the intended sterilization process. This requirement should be evaluated during the initial material qualification and is not typically performed on a routine production basis.

6.3.2 *Toxicity*—The flexible barrier material should be non-toxic and appropriate for the given application (see 21 CFR 178 ~~and/or~~or Guide F2475 (intended for medical device ~~applications).~~applications), or both. This requirement should be evaluated during the initial material qualification and is not typically performed on a routine production basis.

6.3.3 *Process/Application Specific Requirements*—Any specific process/application requirements should be indicated (for example, haze, treatment level, and so forth).

6.4 Appearance: