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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

¹ This guide is under the jurisdiction of ASTM Committee [F02](#) on 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.

[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

[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

[T 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,

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

⁴ Available from U.S. Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993, <http://www.fda.gov>.

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

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.

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 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 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. (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) 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 or Guide F2475 (intended for medical device 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:

6.4.1 Cleanliness and Particulate:

6.4.1.1 *Loose Particulate*—Loose particulate should be minimized. The level of particulate inherently present will be dependent upon the packaging material chosen. Size of particulate is frequently estimated using the Dirt Estimation Chart in TAPPI T 437, T 213, or T 547.

6.4.1.2 *Embedded Particulate*—Foreign material that is embedded between layers of a laminate or within a film, non-woven, or paper, should be minimized. Size of particulate is frequently estimated using the Dirt Estimation Chart in TAPPI T 437, T 213, or T 547. Gels and carbon particles are inherent to many polymer-based materials and should be considered separately from embedded foreign material particulate.

6.4.2 *Aesthetics:*

NOTE 5—Visual inspection of flexible barrier materials should be without magnification and under normal lighting conditions at a distance of approximately 30 to 45 cm (12 to 18 in.) and any defects should be noticeable without an extended inspection time.

6.4.2.1 The flexible barrier material should be the color specified (for example, white, silver, transparent, translucent).

6.4.2.2 The degree of scratches, scuffing, discoloration, soft wrinkles, or other defects which detract from appearance on visual inspection should be determined as appropriate for the material used.

6.4.3 *Function*—The flexible barrier material must be free from hard wrinkles that could cause channeling through a seal, or cuts, holes, or tears which impair functionality.

6.5 *Rollstock Requirements:*

6.5.1 *Roll Width*—The roll width and tolerance, typically ± 2 mm ($1/16$ in.) should be specified (Test Method F2203).

6.5.2 *Core:*

6.5.2.1 The desired core size should be specified, generally 76 mm (3 in.) or 152 mm (6 in.).

6.5.2.2 The core type may be specified.

6.5.3 *Roll Diameter*—The maximum roll diameter or maximum weight, or both, should be specified. This value is generally based upon equipment limitations or lifting (weight) restrictions.

6.5.4 *Splices:*

6.5.4.1 The maximum allowable number of splices per roll should be indicated (typically 2 on rolls less than 300 mm (12 in.), 3 on rolls with an OD of 300 mm (12 in.) to 500 mm (20 in.) and 4 on rolls with an OD of 500 mm (20 in.) or greater).

6.5.4.2 If desired, the color and width of the splicing tape may be indicated and whether the tape should be applied to a specific side of the material or to both sides of the material. Style of splice may also be indicated. Tape should be heat resistant. Selecting a tape with natural rubber free adhesive is also a good practice.

6.5.5 *Wind Direction*—Indicated the desired wind direction (for example, sealant in, sealant out). If the item is printed, the rewind figure should be specified.

6.5.6 *Telescoping*—Rolls should be wound with sufficient tension to prevent telescoping in normal handling. Maximum allowable telescoping is typically 6 mm ($1/4$ in.).

6.5.7 *Roll Edge Profile*—Maximum oscillation, peak to valley, of the edge of the roll may be specified. Maximum allowable oscillation is typically 6 mm ($1/4$ in.).

6.6 *Printing Requirements:*

6.6.1 The specification should indicate whether the copy is surface printed or buried/reverse printed.

6.6.2 *Repeat Registration*—The repeat should be indicated. The repeat tolerance is generally specified over an integral number of printing cylinder repeats.

NOTE 6—During the package forming process, the flexible barrier material is under tension and will stretch. This should be taken into consideration when developing repeat specifications. The relaxed repeat measurement will generally be less than the machine stroke.

6.6.3 *Chemical Resistance of Ink*—If the copy is surface printed, any chemical resistance requirements (for example, water, alcohol, and so forth) should be indicated (Practice F2250). This requirement should be evaluated during the initial material qualification and is not typically performed on a routine production basis.

6.6.4 *Ink Color*—The ink color should be specified and conform to agreed upon standards.

6.6.5 *Legibility*—There should be no missing, incorrect, or illegible print.

6.6.6 *Placement*—Placement and location of print should be specified. Typical copy to cut tolerance is ± 3.2 mm ($1/8$ in.).

NOTE 7—Printing should not fall into the seal area. The heat sealing process may be affected by the presence of ink. Additionally, the sealing process may affect the ink or print legibility, or both.

6.7 *Packaging and Package Marking:*

6.7.1 *Labeling*—Each roll and pallet should be labeled with the supplier name; supplier lot number; supplier or customer part number, or both; purchase order number; and quantity.

6.7.2 *Packaging*—Flexible barrier materials should be protected from dirt and contamination during shipping.

6.8 *Supplementary Requirements:*

6.8.1 Flexible barrier materials should be manufactured within a formal quality system.

6.8.2 Traceability of the raw materials used to produce each lot of flexible barrier material should be maintained back to the direct base material supplier.

6.8.3 The supplier and customer should agree on how changes to materials, processes, or sources of supply will be handled once a product is defined and qualified. This is typically documented as an agreement based upon written approvals.

7. Keywords

7.1 flexible barrier material; roll; rollstock; specification