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Standard Specification for Barrier Face Coverings¹

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INTRODUCTION

This is the first ASTM standard to address this type of product. The standard was primarily established in response to the global COVID-19 pandemic beginning in 2019 to address a product that is neither a medical face mask per ASTM Specification **F2100** for providing source control, nor a respirator for providing inhalation protection as defined by regulatory requirements specified in the United States under 42 CFR Part 84.

This specification is intended to establish a national standard baseline for a source control device. This standard brings value by specifying minimum design, performance, and testing requirements and allowing comparison of products by end users where current guidelines have been limited. Evolving literature suggests that barrier face coverings could reduce the potential for disease transmission, as well as offering a reduction of inhalation particulate matter by the wearer. The focus of this specification is to identify how the device should perform in terms of source control/protection, comfort, and reuse potential. The level of source control/protection depends on how well particles are blocked from going through the barrier face covering and minimizing the amount of leakage that may occur around the perimeter of the barrier face covering. The specific performance property for filtration efficiency provides a greater challenge than most other particulate filtration tests, including BFE, based on the use of smaller particles and more rigorous test conditions. Barrier face coverings must be comfortable enough for individuals to be willing to wear them for long periods of time. Requirements for breathing resistance were incorporated into the specification. The final performance criterion was the potential for reuse of the barrier face covering, so the possibility of reuse was identified in the specification.

Users of this standard are directed to Section 1 (Scope) and Section 4 (Significance and Use) to understand the specific areas addressed by this standard and its limitations, along with the reasons for choice of specific requirements. Users of this standard are further directed to the specific caveats for this standard that are included in 1.3 – 1.11. The subcommittee responsible for this standard intends to further evolve this specification for addressing new knowledge about disease transmission reduction and barrier face covering design, performance, labeling, conformity assessment, and other aspects of these products' safety, health, and environmental impact as this information becomes available.

1. Scope

1.1 This specification is intended to help ensure barrier face coverings meeting the stated requirements provide (1) a means of source control for individual wearers by reducing expelled aerosols from the wearer's nose and mouth into the air; and (2) a degree of particulate filtration that potentially reduces the amount of aerosols inhaled by the wearer.

¹ This specification is under the jurisdiction of ASTM Committee **F23** on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee **F23.65** on Respiratory.

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NOTE 1—The source control/protection provided by barrier face coverings depends on several factors not considered in this specification, such as material degradation from wearer challenges including perspiration, talking, sneezing, and the length of time the barrier face covering is worn. Further research is needed to expand the evidence base for the protective effect of face coverings and, in particular, to identify the combinations of materials that maximize both their blocking and filtering effectiveness, as well as fit, comfort, durability, and consumer appeal. (<https://www.cdc.gov/coronavirus/2019-ncov/more/masking-science-sars-cov2.html>.)

NOTE 2—There are currently no established methods for measuring outward leakage from a barrier face covering, medical mask, or respirator. Nothing in this specification addresses or implies a quantitative assessment of outward leakage and no claims can be made about the degree to which a barrier face covering reduces expired human-generated aerosols.

1.2 This specification establishes minimum design, performance (testing), labeling, user instruction, reporting and classification, and conformity assessment requirements for barrier face coverings.

1.2.1 Design criteria include setting minimum areas of face coverage over the wearer's nose and mouth, prohibiting open vents or valves, requiring a means for retaining the barrier face covering on the wearer's head, and providing a representation of product sizing. Manufacturers are further required to perform a design analysis for assessing leakage of exhaled air from the barrier face covering. Manufacturers are permitted to conduct quantitative testing as specified in this standard specification to supplement the design analysis. Accessories, such as braces or other devices that allow the barrier face covering to better conform to the wearer's face, are addressed as part of this specification if used for the purpose of reducing leakage.

1.2.2 Performance and testing criteria define minimum barrier face covering filtration efficiency and airflow resistance performance properties. Sub-micron particulate filtration efficiency represents the ability to capture and reduce respirable aerosols that potentially contain viruses and bacteria. Airflow resistance represents the wearer's ease of breathing or breathability while wearing the barrier face covering. The impact of repeated cleaning or laundering on continued performance is applied for measuring performance properties for those barrier face coverings that are intended for reuse. Manufacturers are permitted to also provide test results for bacterial filtration efficiency (BFE) as supplemental information to the mandatory performance measurement of sub-micron particulate filtration efficiency.

NOTE 3—The principal performance criteria for barrier face covering determined by testing are sub-micron particle filtration efficiency and airflow resistance. Quantitative leakage assessment testing is optional for information purposes and is not required. This testing is not likely to be representative of outward leakage from the barrier face covering and should not be claimed to represent the amount of source control offered by the face covering. Bacterial filtration efficiency testing is also optional and not required. It is significantly different than sub-micron filtration efficiency, and the results of BFE testing cannot be interchanged or directly compared. ~~The scope of this standard does not include accessories to barrier face coverings.~~

<https://standards.iteh.ai/catalog/standards/sist/1459627a-dcaf-45c8-a831-b4c21277-cb26/astm-f3502-23a>

1.2.3 Labeling requirements specify the minimum content for labels that appear on the barrier face covering, its immediate packaging, and if different, point-of-sale packaging.

1.2.4 User instructions are required to guide selection and sizing, proper use (positioning and adjustment), and care including cleaning or laundering if product reuse is intended; inform on product cautions and limitations; and describe product replacement and disposal procedures.

1.2.5 Conformity assessment is demonstrated with a Supplier Declaration of Conformity (SDOC) following Guide F3050, Annex A3, Model A. The SDOC states that each barrier face covering labeled as compliant has met all of the requirements of this specification including design criteria, performance criteria, test methods, labeling, and user information. Additionally, conformance to this specification requires that sub-micron particulate filtration efficiency and airflow resistance tests have been performed by a laboratory accredited for conducting these tests.

NOTE 4—This specification does not provide for any form of provisional, limited, or partial conformance of barrier face coverings since their compliance with this specification is a function of meeting all performance requirements, including specific filtration efficiency and breathability requirements, as well as all applicable design, labeling, reporting, and user information requirements.

1.3 This specification addresses barrier face coverings that are either disposable or reusable.

1.4 This specification does not address the unique additional performance attributes of barrier face coverings that exist for certain applications, such as flame-resistant apparel used in environments where there are flame, high heat, electrical arc, or related hazards, but does recommend that barrier face coverings also conform to other standards as applicable.

1.5 This specification does not address the use of antimicrobial or antiviral materials, finishes, or mechanisms, nor the use of drugs, biologics, or nanoparticles in barrier face coverings. This specification also does not address the efficacy of cleaning agents or other chemicals for cleaning, disinfecting, or sanitizing barrier face coverings.

NOTE 5—Claims made about the use of antimicrobial materials, finishes, or mechanisms; or the use of drugs, biologics, or nanoparticles in any product subject the manufacturer to regulatory oversight by government agencies, including the U.S. Food and Drug Administration in the United States, which applies additional safety and efficacy requirements to these products. See 5.1.2 for the requirement of nontoxic and non-irritating materials used in the construction of barrier face coverings.

1.6 This specification does not address requirements for medical face masks, which are covered in Specification F2100.

1.7 Nothing in this specification is intended to contradict or replace criteria that are established in 42 CFR Part 84 for air-purifying respirators or requirements for use of respirators in accordance with 29 CFR 1910.134.

1.8 Nothing in this specification is intended to imply that barrier face coverings qualify as approved respiratory protection devices or have FDA clearance for use in a healthcare setting.

1.9 Nothing in this specification is intended to imply that barrier face coverings should be placed on very young children (<2 years), anyone who has trouble breathing, or anyone who is unconscious, incapacitated, or otherwise unable to remove barrier face coverings without assistance.

1.10 The values stated in SI units or in other units shall be regarded separately as standard. The values stated in each system must be used independently of the other, without combining values in any way.

~~1.11 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.~~

NOTE 6—There are several aspects that relate to the material composition and design of barrier face coverings that are not addressed in this specification but warrant attention relative to their safety, health effects, and impact on the environment, including but not limited to: leaching of potentially toxic finishes, inhalable toxic substances from materials, and bioburden inhibitors subject to regulatory oversight.

1.11 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.

1.12 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

- D3938 Guide for Determining or Confirming Care Instructions for Apparel and Other Textile Products
- D5489 Guide for Care Symbols for Care Instructions on Textile Products
- F1494 Terminology Relating to Protective Clothing
- F1506 Performance Specification for Flame Resistant and Electric Arc Rated Protective Clothing Worn by Workers Exposed to Flames and Electric Arcs
- F2100 Specification for Performance of Materials Used in Medical Face Masks
- F2101 Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*
- F2302 Performance Specification for Labeling Protective Clothing Which Provides Resistance to Incidental Exposures to Heat or Open Flame
- F3050 Guide for Conformity Assessment of Personal Protective Clothing and Equipment
- F3407 Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators

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.

2.2 *AATCC Monograph*.³

M14 Guidance and Considerations for General Purpose Textile Face Coverings: Adult

2.3 *ANSI/ASQC Standard*.⁴

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

2.4 *ISO Standards*.⁵

ISO 2859-1 Sampling Procedures for Inspection by Attributes—Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-Lot Inspection

ISO/ANSI/AAMI 10993-5 Biological Evaluation of Medical Devices—Part 5: Tests for In Vitro Cytotoxicity

ISO/ANSI/AAMI 10993-10 Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Skin Sensitization

ISO 16900-5 Respiratory Protective Devices—Methods of Test and Test Equipment—Part 5: Breathing Machine, Metabolic Simulator, RPD Headforms and Torso, Tools and Verification Tools

ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories

2.5 *Federal Regulations*.⁶

16 CFR Part 1610 Standard for the Flammability of Clothing Textiles

16 CFR Part 303 Rules and Regulations Under the Textile Fiber Products Identification Act

16 CFR Part 423 Care Labeling of Textile Wearing Apparel and Certain Piece Goods as Amended

29 CFR 1910.134 Respiratory Protection

42 CFR Part 84 Approval of Respiratory Protective Devices

2.6 *NPPTL Standard Test Procedure*.⁷

TEB-APR-STP-0059 Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates for Non-Powered, Air-Purifying Respirators

2.7 *NFPA Standard*.⁸

NFPA 2112 Standard on Flame-Resistant Clothing for Protection of Industrial Personnel Against Short-Duration Thermal Exposures from Fire

3. Terminology

3.1 Definitions:

3.1.1 *aerosol, n*—a suspension of solid or liquid particulate matter in a gas.

3.1.2 *airflow resistance, n*—in the testing of a barrier face covering, the measured pressure drop across the barrier face covering under specified test conditions.

3.1.2.1 *Discussion*—<https://standards.iteh.ai/catalog/standards/sist/1459627a-dcaf-45c8-a831-b4c2f277cb26/astm-f3502-23a>

This specification involves measuring airflow resistance of the barrier face covering during initial portion of sub-micron particulate filtration efficiency test for which specific sample mounting and airflow conditions are set.

3.1.3 *bacterial filtration efficiency (BFE), n*—the effectiveness of a material in preventing the passage of aerosolized bacteria, expressed as the percentage of a known quantity that does not pass through the barrier face covering at a given aerosol flow rate.

3.1.3.1 *Discussion*—

In this specification, BFE is only an optional reported test and not part of the requirements. BFE testing primarily involves the evaluation of larger sized particles and lower exposure conditions as compared to sub-micron particulate filtration efficiency.

3.1.4 *barrier face covering, n*—a product worn on the face, specifically covering at least the wearer’s nose and mouth, with the primary purpose of providing source control and to provide a degree of particulate filtration to reduce the amount of inhaled aerosols.

3.1.4.1 *Discussion*—

In this specification, barrier face coverings are assessed for airflow resistance; filtration performance using sub-micron particulate filtration efficiency testing; and the degree of face coverage per a leakage assessment using a product design analysis that can be supplemented by quantitative testing using test subjects.

³ Available from American Association of Textile Chemists and Colorists (AATCC), P.O. Box 12215, Research Triangle Park, NC 27709-2215, <http://www.aatcc.org>.

⁴ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, <http://www.asq.org>.

⁵ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

⁶ Available from U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, <http://www.access.gpo.gov>.

⁷ Available from National Personal Protective Technology Laboratory (NPPTL), <https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0059-508.pdf>.

⁸ Available from National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02169-7471, <http://www.nfpa.org>.

3.1.5 *conformity assessment, n*—demonstration that specified requirements relating to a product, process, system, person, or body have been fulfilled. **F3050**

3.1.6 *design analysis, n*—a process ~~applied to represent the coverage and~~ intended to verify that the barrier face covering provides coverage of at least the wearer’s nose and mouth and to identify potential leakage pathways in the design of a barrier face covering as worn by an ~~individual~~ intended population.

3.1.6.1 *Discussion*—

In this specification, a design analysis is used by the manufacturer for assessing the coverage provided and leakage associated with a barrier face covering when worn by the ~~general user population~~ intended user population. A design analysis does not provide quantitative measurements of leakage around the perimeter of the barrier face covering.

3.1.7 *flammability, n*—a quality of a product related to its rate of flame spread when contacted by a flame source.

3.1.7.1 *Discussion*—

In this specification, flammability applies to barrier face coverings as determined by 16 CFR Part 1610 as part of the Consumer Product Safety Commission regulations for wearing apparel. However, products that comply with these regulations by having Class 1 or 2 flammability are considered not flame resistant when exposed to flame, high heat, electrical arc, or other thermal hazards.

3.1.8 *leakage assessment, n*—the evaluation of a barrier face covering for its potential to fit snugly to the wearer’s face by at least ~~over~~covering their nose and mouth and to reduce the likelihood of leakage of unfiltered air ~~from~~ between the wearer ~~to~~ and the outside environment.

3.1.8.1 *Discussion*—

In this specification, the leakage assessment addresses ~~particulates passing through the barrier face covering and~~ the potential for aerosol passing around the perimeter of the barrier face ~~covering~~ covering and applies to both inward and outward leakage. When quantitative testing is performed, performed according to 8.3, the leakage assessment is permitted to be will also include the measurement of any aerosol that passes through the barrier face covering. This quantitative testing measures inward leakage that is presented as the ratio of the particulate level upstream (outside) of a aerosol concentration outside the barrier face covering to the level downstream (inside) of aerosol concentration inside the barrier face covering on test subjects.

NOTE 7—~~The Quantitative testing supplementing the barrier face covering leakage assessment represents the total inward leakage likely to occur during wear. Whether measured quantitatively or assessed qualitatively, the leakage assessment does~~ measured during laboratory testing. During wearing of barrier face coverings outside the laboratory, leakage is a dynamic condition and may be greater or lesser. A quantitative leakage assessment may not represent the likely outward leakage of particles generated by the wearer. This is wearer because there are currently no specific accepted techniques that are available to measure outward leakage from a barrier face covering or any other products. Thus, no claims may be made with respect to the degree of source control offered by the barrier face covering based on the a quantitative leakage assessment.

NOTE 8—~~Leakage assessment, if measured quantitatively on a A barrier face covering that rests closely directly on the face and thus has minimal inward volume, may not be representative of true inward leakage or particles that come through or around the barrier face covering.~~ nose and mouth is likely to have limited interior volume (that is, space between the barrier face covering and the nose and mouth). In this case, a quantitative leakage assessment may not adequately measure inward aerosol leakage.

3.1.9 *medical face mask, n*—an item of protective clothing designed to protect portions of the wearer’s face, including the mucous membrane areas of the wearer’s nose and mouth, from contact with blood and other body fluids during medical procedures.

3.1.9.1 *Discussion*—

Medical face masks include surgical masks, procedure masks, isolation masks, laser masks, dental masks, and patient care masks. Isolation masks, laser masks, dental masks, and patient care masks are considered isolation masks. For many user groups, the term “mask” has become synonymous with any product worn on the wearer’s face that offers a level of filtration efficiency; however, in the context of this specification, “mask” refers only to medical face masks that are different from barrier face coverings. Requirements for medical face masks are provided in Specification **F2100**. This specification is not intended to address regulatory requirements.

3.1.10 *respirator, n*—personal protective equipment (PPE) designed to protect the wearer from inhalation of hazardous contaminants.

3.1.10.1 *Discussion*—

Barrier face coverings are not designed to meet the performance requirements of NIOSH-approved respirators. For the purpose of this specification, healthcare workers are typically instructed to wear filtering facepiece respirators with N95 or higher levels of

filtration efficiency as defined in 42 CFR Part 84 that are intended to protect the wearer from exposure to pathogenic biological aerosols. See also the definition for *surgical N95 respirators*.

3.1.11 *reusable, adj*—referring to the ability of a product to be used and laundered or cleaned multiple times and maintain its specified performance characteristics.

3.1.11.1 *Discussion*—

The use of the term “reusable” in this specification is intended to distinguish types of barrier face coverings that are durable and that can be further subjected to laundering or cleaning which permits their use multiple times until they are damaged, cannot be effectively cleaned, or have surpassed the expiration date or are beyond the manufacturer’s designated service life.

3.1.12 *service life, n*—in the specification of barrier face coverings, the maximum number of use and laundering or cleaning cycles that barrier face coverings can undergo and still maintain their performance properties.

3.1.12.1 *Discussion*—

For the purpose of this specification, the service life is the maximum number of cleaning or laundering cycles that can be applied to a reusable barrier face covering as specified by the manufacturer.

3.1.13 *shelf life, n*—in the specification of barrier face coverings, the length of time after the date of manufacture that a barrier face covering can be stored as specified by the manufacturer.

3.1.14 *source control, n*—the use of a barrier face covering over the wearer’s nose and mouth that is intended to contain the wearer’s respiratory secretions, including aerosols, to help prevent the transmission from infected individuals who may or may not have symptoms of a specific respiratory disease.

3.1.15 *sub-micron particulate filtration efficiency, n*—a measure of the ability of a barrier face covering to capture aerosolized particles smaller than one micron, expressed as the percentage difference between the concentration of particles that do not pass the barrier face covering versus the particle challenge concentration at a given face velocity for flat samples or flow rate for whole article testing.

3.1.15.1 *Discussion*—

In this specification, a specific form of sub-micron particulate efficiency testing is performed as described in 8.1. This test method is based on NPPTL Standard Test Procedure TEB-APR-STP-0059 that involves the use of poly-disperse sodium chloride (NaCl) aerosols with a count median diameter of 75 ± 20 nm diameter and a geometric standard deviation of ≤ 1.86 as measured with a suitable forward-light scattering photometer. In this testing, the filtration efficiency is measured for either the barrier face covering or those portions of the barrier face covering that cover the wearer’s nose and mouth.

<https://standards.iteh.ai/catalog/standards/sist/1459627a-dcaf-45c8-a831-b4c2f277cb26/astm-f3502-23a>

3.1.16 *supplier’s declaration of conformity (SDOC), n*—a document by which a first-party or supplier conveys an assurance that the object of conformity fulfills specified requirements.

3.1.17 *surgical N95 respirator, n*—a respirator that has both NIOSH approval as an N95 filtering facepiece respirator per 42 CFR Part 84 and FDA clearance as a Class II medical device under 21 CFR Section 878.4040.

3.1.17.1 *Discussion*—

Surgical N95 respirators are N95 filtering facepiece respirators that are approved under 42 CFR Part 84 criteria and meet additional performance criteria for material biocompatibility, fluid resistance, and flammability required by the FDA.

3.2 For definitions of other protective clothing-related terms used in this specification, refer to Terminology **F1494**.

4. Significance and Use

4.1 Barrier face coverings are worn over at least the nose and mouth with the primary purpose of providing source control and to potentially reduce inhaled aerosols. It is expected that a range of barrier face covering products with different configurations, designs, and materials of construction can be developed and qualified in accordance with this specification. For this reason, a limited number of principal performance evaluations are applied. The principal performance requirements in this specification for barrier face coverings include sub-micron particle filtration efficiency and airflow (breathing) resistance, with a separate design criterion for leakage assessment.

4.1.1 Minimum requirements are set for sub-micron particulate filtration efficiency for the purpose of source control. The test for sub-micron particulate filtration efficiency is based on 42 CFR Part 84 (Subpart K), with further detail in NIOSH Standard Test

Procedure TEB-APR-STP-0059. These procedures are typically applied to air-purifying respirators with filters. The test is performed using poly-disperse sodium chloride (NaCl) aerosols with a count median diameter of 75 ± 20 nm electrical mobile diameter and a geometric standard deviation of ≤ 1.86 to give a mass median aerodynamic diameter of $0.3 \mu\text{m}$. Testing is performed on full products or, for certain products, the area of the product that fully covers the wearer's nose and mouth. Testing to this method yields a percentage reduction that can range from 0 % (no sub-micron filtration capability) to 99.97 % (practically all sub-micron aerosols are blocked by the product). For the purpose of this specification, a minimum 20 % requirement is set. This specific performance property provides a greater challenge than most other particulate filtration tests, including BFE, based on the use of smaller aerosols and more rigorous test conditions.

4.1.2 As filtration efficiency for a barrier face covering increases, airflow resistance (breathing resistance) also increases, making it more difficult to breathe. Consequently, a maximum airflow resistance for barrier face coverings is established. Measurements of airflow resistance are made with the same equipment that is used to measure sub-micron particulate filtration efficiency. This testing yields airflow resistance values in millimeters of water gauge pressure ($\text{mm H}_2\text{O}$), where lower pressures indicate easier breathing. In this standard, the airflow resistance must be at 15 mm H_2O or below. The value of 15 mm H_2O was chosen as this level is a lower breathing resistance than required for filtering facepiece respirators and is not expected to require a pre-use medical evaluation for the general user population.

4.1.3 Sub-micron Measurements of sub-micron particulate filtration efficiency and airflow resistance do not account for the leakage of air around the perimeter of the barrier face covering. A leakage assessment using a design analysis of the product is required to assess the ability of the barrier face covering design to provide appropriate coverage for a range of wearer faces of different dimensions. The design analysis can be conducted by the manufacturer in a number of different ways. The standard specification also permits the supplemental use of quantitative information obtained from a modified form of Test Method F3407 using test subjects. This test yields a reportable ratio of outside particulate aerosol concentration to the concentration of particles aerosol in the wearer's breathing zone. Thus, a an inward leakage ratio of 1.0 indicates the outside and inside environments are equal and that particulates flow through gaps in 5.0 indicates the aerosol concentration outside the barrier face covering (in addition to any particulates that pass through the filtration materials of the product) is five times higher than the aerosol concentration inside the barrier face covering. An inward leakage ratio of 1.0 is the lowest possible result and represents that the inside and outside environments are at the same aerosol concentration.

4.1.4 Additional testing requirements are included in this specification for barrier face coverings that are intended to be laundered or cleaned and reused. These tests evaluate the impact of multiple cycles of cleaning or laundering on sub-micron particulate filtration efficiency, airflow resistance, and leakage assessment. This requirement is included in this specification because it is known that certain products may shrink, stretch, become distorted, or are otherwise negatively affected in their capabilities for source control and their potential for reducing the inhalation of aerosols. For the purposes of this specification, defined performance requirements for sub-micron particulate filtration efficiency and airflow resistance in addition to the leakage assessment design analysis requirements must be met after the maximum number of laundering and cleaning cycles specified by the manufacturer.

4.1.5 A system for reporting the key performance properties is established in this specification where compliant product performance above the minimum levels is classified into two different levels that indicate differences of performance. The purpose of this classification system is to allow end users to differentiate products among the mandatory performance properties—sub-micron particulate filtration efficiency and airflow resistance. While the higher level indicates better performance for the individual property, these levels do not imply specific protection levels or applications since there is currently insufficient information to characterize how barrier face covering performance relates to all conditions of use. It is also possible for a product to have high performance for one property (sub-micron particulate filtration efficiency or airflow resistance) and low performance for the other property.

4.2 Design criteria are established in this specification to ensure the barrier face covering stays over the wearer's nose and mouth, as well as to limit the use of features that would compromise the effectiveness of the barrier face covering from providing source control and reducing the inhalation of aerosols. For example, the incorporation of vents, valves, or other features that allow for airflow to bypass the filtration elements of the barrier face covering during exhalation are prohibited.

4.3 Minimum requirements are established for labeling of barrier face coverings and for information provided by the manufacturer to the end user. The intent of these requirements is to deliver products that are clearly identified as meeting this specification and that additional pertinent information and instructions are provided to the end user.

4.4 The conformity assessment requirements for barrier face coverings in this specification have been established to provide confidence that the products labeled as compliant meet all applicable criteria of this specification. The specification for sub-micron

particulate filtration efficiency and airflow resistance performance requirements must be conducted by laboratories accredited to ISO/IEC 17025, and the testing performed must be within the scope of the laboratory's ISO/IEC 17025 accreditation.

4.5 It is the responsibility of the user of this specification to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

4.6 A number of recommendations are provided through notes to aid in the clarification of requirements or suggestions to address other areas of compliance with this specification.

5. Design Requirements

5.1 *General Construction:*

5.1.1 The barrier face covering shall be designed to cover at least the wearer's nose and mouth and fit snugly where the product contacts the wearer's face to reduce gaps, as determined by the product design analysis in 5.4.

NOTE 9—~~A leakage assessment design analysis is provided in required per 5.4 to ascertain the extent of possible assess potential leakage through or around the barrier face covering through a product design self-declaration that covering.~~ The general approach used in the design analysis is described by the manufacturer as part of the report. This can be supplemented by reporting the results of quantitative testing as specified in 8.3.

5.1.2 Portions of the barrier face covering materials that contact the wearer's skin shall be made of non-irritating and nontoxic materials.

NOTE 10—It is possible to assess these characteristics of barrier face covering materials by performing dermal irritation and skin sensitization tests according to procedures provided in ISO/ANSI/AAMI 10993-10 and by performing cytotoxicity testing per ISO/ANSI/AAMI 10993-5. This note does not imply a requirement to use any of the listed tests or any particular test for determining that the product does not irritate the wearer. It is further possible that the use of materials already evaluated to these standards satisfies this requirement. Manufacturers or material suppliers can demonstrate the absence of toxic materials by complying with national, regional, or local requirements for the use of restricted substances. There are also commercial entities that provide services to verify that materials, components, and products are free of restricted substances.

5.1.3 Barrier face coverings shall not be made of materials that pose a flammability hazard.

5.1.3.1 Where barrier face coverings are used in applications where flame, high heat, electrical arc, or other thermal hazards are present, barrier face coverings shall be qualified to the respective applicable standards, as appropriate.

NOTE 11—Barrier face coverings made of textile fabrics are considered wearing apparel and are subject to 16 CFR 1610 requirements for the measurement of textile material flammability. The application of this federal regulation is intended to limit the use of potentially dangerous, flammable materials, where acceptable performance is judged by the respective materials being classified as Class 1, "Normal Flammability," Class 2, "Intermediate Flammability," or exempt from testing. Specific standards related to flame, high heat, electrical arc, and other thermal hazard exposures include, but are not limited to: Specification F1506, Specification F2302, and NFPA 2112.

5.1.4 Barrier face coverings shall be free of any sharp edges, sharp points, or burrs.

5.1.5 Barrier face coverings shall be permitted to be either disposable (single use) or reusable (multiple uses). Barrier face covering designs that combine disposable and reusable parts shall meet the requirement in 5.1.8.

5.1.5.1 Barrier face coverings shall be constructed of materials and designed such that they will not be damaged by ordinary handling, donning, and doffing.

5.1.5.2 Barrier face coverings that are intended to be reusable shall be constructed of materials and designed such that they will not be damaged by ordinary handling, donning, and doffing after being repeatedly subjected to laundering or cleaning as specified by the manufacturer.

NOTE 12—Section 6 has specific requirements for evaluating the performance of reusable barrier face coverings for their continued performance following the manufacturer's recommended maximum number of laundering (or cleaning) cycles when using the manufacturer's recommended laundering or cleaning procedures.

5.1.6 Barrier face coverings shall be designed, shaped, or have features that aid in reducing the flow of air around the perimeter of the product.

5.1.7 Barrier face coverings shall not have vents, valves, or other open pathways as part of their design.

NOTE 13—The use of exhalation valves or other features that bypass the filtration of the product are not allowed because these features potentially diminish source control and increase the likelihood of unfiltered air to pass through into the environment.

5.1.8 Barrier face coverings with replaceable filters shall have means for reducing the likelihood of improper filter placement in the product. Where these configurations exist, the manufacturer shall provide specific instructions that address the use and care of their products relative to filter replacement and disposal of filtering components or cleaning/laundrying of reusable parts of the barrier face covering.

5.1.9 Barrier face coverings ~~that shall be permitted to include transparent materials for the purpose of allowing others to view the wearer's lips shall afford sufficient filtration material to provide the function of source control, but these configurations are still required to meet the performance requirements of Section 6 control.~~ where the transparent portions of the barrier face coverings are part of the tested samples.

5.2 Retention System:

5.2.1 Barrier face coverings shall have a means for keeping the barrier face covering over the wearer's nose and mouth for the expected period of use and range of activities.

NOTE 14—Examples of retention systems include, but are not limited to: ties, elastic ear loops, and head harnesses. In some cases where the retention system is integrated with the filtering area, such as tubular neck garments (sometimes referred to as gaiters), the area intended to cover the wearer's nose and mouth must be clearly identifiable and proper orientation described in the user instructions. The effectiveness of these systems for keeping the barrier face covering on the wearer's head and maintaining coverage of wearer's nose and mouth varies with the type of retention system in combination with the materials of construction and the overall design. Subsection 5.4 includes an assessment as a degree for how well the barrier face covering fits on individuals' faces. For adult products, the use of plastic toggles or slides is permitted but should not be able to release from the tie or free end (thus leaving the ability of the mask to fall open).

5.2.2 Where the barrier face covering uses a head harness, the head harness shall provide for adjustment to allow proper fit on the wearer's head. When the head harness is made from elastic materials, the elasticity of the harness material is considered adequate adjustability for proper use.

5.3 Sizing:

5.3.1 Where intended to be worn by a range of individuals, multiple sizes shall be permitted, but not required, to allow a single model to fit a wide variety of the end user population, excluding very young children (<2 years). Different sizing for children versus adults is permitted.

5.3.2 Barrier face coverings shall be permitted to be offered in single sizes for the general population and for specific population groups such as children.

NOTE 15—Anthropometric data for adult populations from the National Institute for Occupational Safety and Health are available as a resource for product size development.⁹ For the date of this specification, there were no known human subject panels for children's sizes.

5.4 Leakage Assessment:

5.4.1 The leakage assessment shall be reported by the manufacturer ~~through a product design analysis self-declaration as part of the supplier's declaration of conformity (see Section 12).~~

⁹ The report, "A Head-and-Face Anthropometric Survey of U.S. Respirator Users," is available from *Journal of Occupational and Environmental Hygiene*, Vol 2, No. 11, 2005, pp. 567–76. DOI: 10.1080/15459620500324727. https://www.nap.edu/resource/11815/Anthrotech_report.pdf. This report provides key facial dimensions for persons aged 18 to 55. This report may not address the full range of adult facial dimensions for all populations.

5.4.2 ~~The required self-declaration~~As part of its declaration, the manufacturer shall report that the product reduces leakage around the perimeter or other areas of the ~~product~~ barrier face covering based upon an analysis of the product design. ~~This statement is included on any self-declaration required as part of Guide F3050, under Section 12 of this specification.~~

5.4.2.1 The manufacturer is permitted to conduct quantitative testing to supplement its product design analysis self-declaration. When used, the leakage ratio shall be determined using Test Method F3407, with the modifications specified in 8.3.

5.4.3 Where barrier face coverings are reusable and intended for laundering or cleaning, the product design analysis shall be applied to barrier face coverings both in a new condition and after the maximum number of laundering or cleaning cycles as specified by the manufacturer according to the manufacturer’s care instructions.

NOTE 16—~~Examples of different means to accomplish a leakage assessment could include dimensional analysis, computer modeling, placement of~~ includes dimensional analysis or computer modeling where the product design is electronically captured and then compared to how the product can be placed on computer-generated faces of varying dimensions. An alternative approach is to physically place barrier face coverings on standardized head or head/torso forms and ~~judging~~(such as those specified in ISO 16900-5) and judge their respective areas of coverage and ~~conformity to the visually observe (or measure) any gaps between the barrier face covering perimeter and underlying face portions of the head or head-torso form face showing conformance to the fit and sizing characterizations of form.~~ However, it is important to point out that the absence or existence of visual gaps may not be truly indicative of whether leakage is likely or not. It is also possible to apply this approach to a number of human subjects representing a range of facial dimensions such as those described in Appendix X1 AATCC M14-2020, or performing a quantitative analysis. AATCC M14-2020 is an additional reference for evaluating conformity of the barrier face covering on respective wearers providing appropriate coverage with gaps that could result in leakage.

5.5 Accessories:

5.5.1 Where accessories are provided that include but are not limited to braces or similar devices that affect the leakage design analysis and quantitative testing of barrier face coverings, these items shall be explicitly disclosed in the test report and described as part of the user instructions provided by the product manufacturer as required in Section 11.

6. Performance Requirements

6.1 Barrier face coverings shall meet the requirements specified in Table 1.

6.2 Where the barrier face covering is reusable and intended to be laundered or cleaned, barrier face coverings shall meet each of the requirements in Table 1, both in a new condition and after the maximum number of laundering or cleaning cycles specified for the product in accordance with 7.3.

7. Sampling and Conditioning

7.1 *Type of Samples*—Testing shall be performed on complete barrier face coverings or materials as specified in each individual test method in Section 8.

7.1.1 Where materials are specified as the samples in the individual test method, these samples shall be taken from complete barrier face coverings unless the nature of the testing requires larger samples than what can be obtained from any particular finished product.

7.1.2 Where barrier face coverings include embellishments such as logos, emblems, embossed lines, or other additive features for appearance purposes, sample selection shall account for the maximum impact of these features on the performance of the product.

NOTE 17—It is recommended that samples be selected that include the largest affected areas of the barrier face covering where the embellishment

TABLE 1 Barrier Face Covering Minimum Performance Requirements

Performance Property	Criteria	Test Method Section
Sub-micron particulate filtration efficiency	≥20 %	8.1
Airflow resistance, inhalation	≤15 mm H ₂ O	8.2

potentially affects sub-micron particulate filtration efficiency and air flow resistance.

7.1.3 Where barrier face coverings rely on accessories, such as braces or similar devices, to achieve conformity of the product to the wearer's face for reducing leakage, the selected samples shall include those accessories for the purpose of the design analysis or quantitative leakage testing.

7.1.4 The number of barrier face coverings or material samples shall be as specified in the individual test method.

7.2 *Choice of Samples*—The specific barrier face covering samples to be tested shall be representative of the barrier face coverings being manufactured.

NOTE 18—The use of a sampling plan for choosing specific representative samples of barrier face coverings for evaluation in accordance with this specification is recommended but not required. Examples of acceptable sampling plans are found in ANSI/ASQC Z1.4 and ISO 2859-1.

7.3 *Conditioning:*

7.3.1 Prior to testing, specimens shall be conditioned to the environmental conditions specified in each test method in Section 8.

7.3.2 Reusable barrier face coverings shall be further subjected to testing after the maximum number of laundering or cleaning cycles specified by the manufacturer as required in Section 11.

7.3.2.1 If the manufacturer specifies that their reusable barrier face covering is to be cleaned or laundered before use, then the barrier face covering shall be tested initially following a single cleaning or laundering cycle in lieu of testing in a new condition.

7.3.2.2 Laundering or cleaning for reuse shall be performed as specified by the manufacturer as required in Section 11.

8. Test Methods

8.1 *Sub-Micron Particulate Filtration Efficiency*—Sub-micron particulate filtration efficiency shall be measured as specified in Subpart K of 42 CFR Part 84, using an initial efficiency (no preloading) and the following modifications:

NOTE 19—Additional useful information on the performance of this testing is provided in TEB-APR-STP-0059, particularly for the generation of the sodium chloride salt aerosol.

NOTE 20—Both sub-micron particulate filtration efficiency and airflow resistance are performed using the same equipment and can be conducted on the same set of samples. It is recommended that the procedures for measuring airflow resistance described in 8.2 be measured first without the use of the challenge aerosol.

8.1.1 *Specimens:*

8.1.1.1 A total of ten (10) specimens shall be tested.

8.1.1.2 Where barrier face coverings are reusable, an additional set of specimens shall be tested after the maximum number of laundering or cleaning cycles specified by the manufacturer, according to manufacturer care instructions (ten specimens tested in each condition for a total of 20 samples).

8.1.1.3 Specimens shall include the entire product unless the style of product extends beyond the ordinary shape of a product that normally just covers the wearer's nose and mouth, such as a tubular product (for example, gaiter), in which case the specimen should include at least the portion of the product that covers the wearer's nose and mouth and be representative of the final, finished manufacturer product.

8.1.1.4 For products with filter inserts smaller than the specimen area, the area around the filter insert shall be included in the specimen area to be tested.

8.1.1.5 Specimens shall be pre-conditioned at $85 \pm 5\%$ relative humidity and $38 \pm 2.5\text{ }^{\circ}\text{C}$ for $25 \pm 1\text{ h}$. After conditioning, the filters shall be sealed in an airtight, non-hygroscopic container and tested within 10 h.

8.1.2 *Specimen Mounting and Test Setup:*