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Standard Specification for Barrier Face Coverings[1]

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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 ~~re-use~~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 ~~re-use~~reuse of the barrier face covering, so the possibility of ~~re-use~~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 ~~primarily~~ intended to help ensure barrier face coverings meeting the stated requirements provide (*1*) a means of source control for individual wearers by reducing ~~the number of expelled droplets and~~ expelled aerosols from the

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wearer's nose and mouth into the air; and (*2*) ~~to potentially offer~~ a degree of particulate filtration ~~to reduce~~ that potentially reduces the amount of aerosols inhaled ~~particulate matter~~ by the wearer.

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 ~~standard~~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 ~~emission of~~ expired human-generated ~~particles.~~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 to supplement the design analysis.

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 ~~droplets and~~ 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 ~~to be reusable.~~ 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.

1.2.3 Labelling 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 following Guide F3050, Annex A3, Model A to issue a declaration of conformity indicating that each barrier face covering labelled as compliant has met all of the requirements of this standard specification including design criteria, performance criteria, test methods, labelling, and user information. Additionally, conformance to this standard requires that sub-micron particulate filtration efficiency and airflow resistance tests have been performed by a laboratory accredited for conducting these tests.

1.3 This specification addresses all barrier face coverings and only barrier face coverings that are intended for either a single use (disposable) or multiple uses (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.

NOTE 4—The use of antimicrobial materials, finishes, or mechanisms is generally subject to regulatory oversight by government agencies, including the U.S. Environmental Protection Agency and 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.*

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

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

[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.
[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.

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 degree to which a product worn over the wearer's nose and mouth restricts the ability of the wearer to inhale and exhale (also referred to as breathing resistance).
3.1.2.1 *Discussion*—
This specification requires the measurement of airflow resistance of the barrier face covering during inhalation. The performance requirement is set to reduce the restriction of inhaling and exhaling as much as possible.

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 ~~particulate matter.~~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.

3.1.5 *design analysis, n*—a process applied to represent the coverage and potential leakage pathways in the design of a barrier face covering as worn by an individual.
3.1.5.1 *Discussion*—
In this specification, a design analysis is used for assessing the leakage associated with a barrier face covering when worn by the general user population.

3.1.6 *flammability, n*—a quality of a product related to its rate of flame spread when contacted by a flame source.
3.1.6.1 *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.

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

[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.

3.1.7.1 *Discussion—*

In this specification, the leakage assessment addresses particulates passing through the barrier face covering and around the perimeter of the barrier face covering. When quantitative testing is performed, the leakage assessment is permitted to be presented as the ratio of the particulate level upstream (outside) of a barrier face covering to the level downstream (inside) of the barrier face covering on test subjects.

NOTE 5—The leakage assessment represents the total inward leakage likely to occur during wear. Whether measured quantitatively or assessed qualitatively, the leakage assessment does not represent the likely outward leakage of particles generated by the wearer. This is because there are currently no specific accepted techniques that are available to measure outward leakage from a barrier face covering or 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 leakage assessment.

NOTE 6—Leakage assessment, if measured quantitatively on a barrier face covering that rests closely 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.

3.1.8 *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.

3.1.8.1 *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 ~~standard~~specification is not intended to address regulatory requirements.

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

3.1.9.1 *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 ~~airborne particulates.~~ aerosols. See also the definition for *surgical N95 respirators*.

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

3.1.10.1 *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.

3.1.11 *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.

3.1.11.1 *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.

3.1.12 *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.

3.1.13 *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 ~~droplets and~~ aerosols, to help prevent the transmission from infected individuals who may or may not have symptoms of a specific respiratory disease.

~~3.1.12.1 *Discussion—*~~

~~When worn properly, barrier face coverings meeting the requirements of this specification provide a level of source control.~~

3.1.14 *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 a percentage of a known number of particles that do not pass the barrier face covering at a given face velocity for flat samples or flow rate for whole article testing.

3.1.14.1 *Discussion—*
In this specification, a specific form of sub-micron particulate efficiency testing is performed as described in 8.1.

3.1.15 *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.
3.1.15.1 *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 ~~standard,~~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 ~~particulates.~~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 µm. 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 ~~particles~~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 ~~particles~~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 (mm H_2O), 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 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 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 concentration to the concentration of particles in the wearer's breathing zone. Thus, a leakage ratio of 1.0 indicates the outside and inside environments are equal and that particulates flow through gaps in the barrier face covering (in addition to any particulates that pass through the filtration materials of the product).

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 ~~particulate matter.~~ 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 ~~particulate matter.~~ 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 labelling 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. Performance requirements in Section 6 must be performed by competent laboratories accredited to ISO/IEC 17025, and the testing performed must be within the scope of the laboratory's ISO/IEC 17025 accreditation. The manufacturer must also meet all of the Model A requirements in Guide F3050 for other aspects of conformity assessment that address testing/inspection facilities, a quality management system, records retention, ongoing conformity, recalls and safety alerts, and marking. The manufacturer is required to determine compliance with all design, performance, reporting, labeling, user information, and conformity assessment requirements in this specification and provide a declaration of conformation that indicates that their product(s) fulfills all of these requirements.

4.5 It is the responsibility of the user of this ~~standard~~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 7—A leakage assessment design analysis is provided in 5.4 to ascertain the extent of possible leakage through or around the barrier face covering through a product design self-declaration that can be supplemented by reporting the results of quantitative testing 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 8—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.

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 9—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).

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 10—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 ~~minimizing~~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 11—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 preventing the improper placement of the filters.

5.1.9 Barrier face coverings that 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.

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 12—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 13—Anthropometric data for adult populations from the National Institute for Occupational Safety and Health are available as a resource for product size development.[9]

5.4 *Leakage Assessment:*

5.4.1 The leakage assessment shall be reported by the manufacturer through a product design analysis self-declaration.

5.4.2 The required self-declaration shall report that the product reduces leakage around the perimeter or other areas of the product 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 14—Examples of means to accomplish a leakage assessment could include dimensional analysis, computer modeling, placement of barrier face coverings on standardized head or head/torso forms and judging their respective areas of coverage and conformity to the head or head-torso form face showing conformance to the fit and sizing characterizations of AATCC M14-2020, or performing a quantitative analysis.[10]

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 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.

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_2O	8.2

[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.

[10] Digital files for solid headform models are available at https://www.cdc.gov/niosh/data/datasets/rd-10130-2020-0/default.html.

NOTE 15—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 16—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 17—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 and 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 ± 5 % relative humidity and 38 ± 2.5 °C for 25 ± 1 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:*

8.1.2.1 In cases where the specimen lays flat against the filter holder in the test equipment, a mesh screen, wire frame, or similar device with at least 70 % open area shall support specimen products.

NOTE 18—The use of a mesh screen, wire frame, or similar device is intended to prevent the collapse of the product into the equipment, which can potentially affect test results and approximate at least the anatomy/area of the nose and mouth when used.

8.1.2.2 Where a mesh screen, wire frame, or similar device is used, the laboratory shall ensure that the type of support device used does not adversely affect the results of the test.

8.1.2.3 A face velocity of 10 ± 0.5 cm⁄s shall be used with the flow rate not exceeding 85 Lpm as specified in 8.1.3.5.

NOTE 19—The use of a specified face velocity affects the challenge flow rate. For example, with a filter that has an area of 100 cm^2, the challenge flow rate would be approximately 60 Lpm to achieve the face velocity of 10 cm⁄s.

8.1.2.4 The specimen shall be mounted and sealed on an adapter plate to prevent leakage, including leakage that may occur between multiple layers of the product. The specimen shall be sealed using hot melt glue, beeswax, rope caulk (for large gaps), or another appropriate sealant onto the adapter plate.

NOTE 20—Rope caulk is useful to help seal large gaps, if necessary. Beeswax has been found to better seal the perimeter of multilayered products. It is recommended to use a method of sealing that ensures that leakage does not occur through any areas of attachment, particularly for products that have irregular sealing surfaces, multiple layers, or other aspects of their design that make sealing on the test apparatus difficult. The provision of photographs from the laboratory of the specimen setup are useful for documenting how the specimen is mounted.

8.1.2.5 A small chamber shall be created by placing a container around the device and placing a cover (with a large inlet hole) over the chamber (see Fig. 1 for an example). Gasket material shall be used to seal the chamber to the plates.

NOTE 21—This step is not necessary if the specimen cannot be mounted and instead will be tested directly in the filter holder of the testing equipment.

8.1.3 *Procedures:*

8.1.3.1 The NaCl aerosol shall have a particle size distribution with count median diameter of 75 ± 20 nm and a standard geometric deviation not exceeding 1.86 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.

8.1.3.2 The test shall be conducted at 25 ± 5 °C and a relative humidity of 30 ± 10 % and the particles shall be neutralized to the Boltzmann equilibrium state. Each specimen will be challenged with a concentration not exceeding 200 mg⁄m^3.

8.1.3.3 The efficiency of the specimen will be determined by using a forward-light-scattering photometer or equivalent.

8.1.3.4 If the specimen is mounted and secured into a chamber, perform a test setup with the empty chamber to account for any loss of particles caused by the chamber.

8.1.3.5 The specimens shall be tested at a flow rate of 85 ± 4 Lpm. If the specimen lays flat in the filter holder, adjust the flow rate to achieve a face velocity of 10 ± 0.5 cm⁄s (see Note 19).

8.1.3.6 The stabilization time for the test shall be a minimum of 6 s to have stable concentrations upstream and downstream before measurement data is collected.

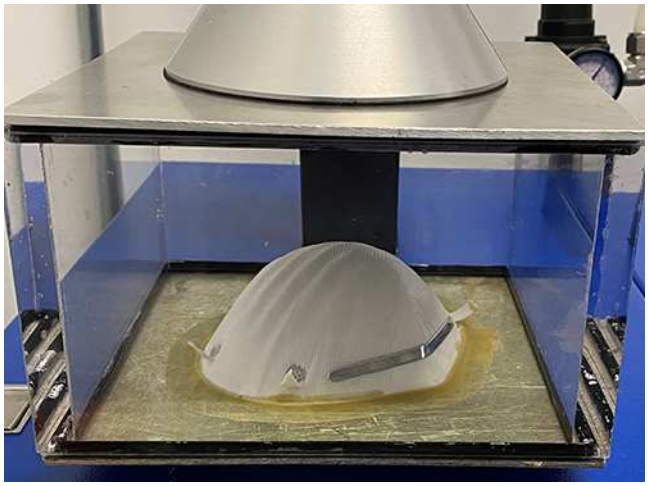

FIG. 1 Example of a Filter Holder Adapter