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An Overview of Specification F3502-21 on Barrier Face Coverings

Understanding and applying requirements of the new standard

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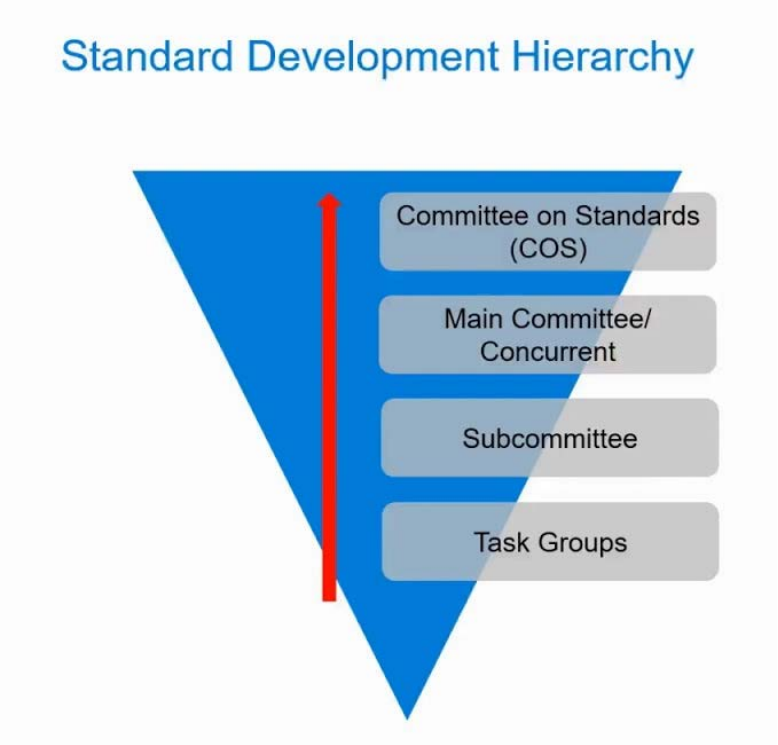
“An open and transparent consensus standards development process”

- Organization engaged in creating standards on range or products and services
  - 140+ committees
  - 12,800+ standards
- Committee F23 on Protective Clothing and Equipment
  - 12 subcommittees
  - 290 + voting members
- Subcommittee F23.65 on Respiratory Protection
  - 100 + voting members
- Work Group WK73471 on Barrier Face Coverings
  - 85+ members
  - 12 + meetings to achieve final standard



Origin of the Standard

COVID-19 Driven Need

- NIOSH initiated effort in June 2020 to address a standards gap identified during the COVID-19 response
- ASTM Work Item Initiated under F23 July 2020
- Two committee leads determined July 2020
  - NIOSH NPPTL representative
  - Private sector subject matter expert
- Standard will
  - Provide a consistent way to benchmark products to inform user selection decisions
  - Define performance requirements for source control and protective capability

Scope of the Standard

Why a specification (and not a guide)?

- ***Purposes***
  - First: Source control (protect the public)
  - Second: Offer protective capability (protect the wearer)
- ***Performance Requirements*** – Protection, Comfort, Potential for Re-Use
  - Protection: (1) how well the particles are blocked going through the face covering, and (2) leakage assessment, how well it seals to the face and prevents particles going around its perimeter
  - Comfort: face coverings must be comfortable enough for people to wear for long periods of time
  - Re-use: the potential that products could be used over again
- ***Test Methods*** – use /tailor existing test methods to evaluate performance to accommodate expected range of products
- ***Conformity Assessment*** – approach based on risk; oversight on the most important parts

Understanding Product Differences

Respirators

"3.1.8 *respirator, n*— Personal protective equipment (PPE) designed to protect the wearer from inhalation of hazardous atmospheres."

Medical Face Masks

"3.1.7 *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."

Barrier Face Coverings

"3.1.3 *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."

Areas Not Addressed by of the Standard

Specification does not set regulatory requirements or cover all safety issues

- 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
- Does not address the use of antimicrobial or antiviral materials, finishes, or mechanisms
- Does not address requirements for medical face masks, which are covered in Specification F2100
- Does not address requirements for use of respirators in accordance with 29 CFR 1910.134 or 42 CFR Part 84
- Does not address barrier face coverings qualify as approved respiratory protection devices or have FDA clearance for use in a healthcare setting
- Does not 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
- Does not purport to address all the safety concerns, if any, associated with its use

Design Requirements

Keeping criteria to a minimum to promote innovation

- General Construction

  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 minimize gaps as determined by the product design analysis

- Retention System

  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

- Sizing

  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

Leakage Assessment for Covering Design

Adequate coverage of product on wearer's face must be evaluated

- "3.1.6 *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 offered from the wearer to the outside environment."
- Product manufacturer reports a product design analysis self-declaration
- Product design analysis could include:
  - Dimensional analysis
  - Computer modeling
  - Use of head forms and judgement of coverage to fit and sizing characteristics
  - Quantitative analysis

Optional Quantitative Leakage Ratio Testing

Measure of leakage around/through product demonstrates effectiveness

Permits the use of modified version of ASTM Test Method F3407

- The reportable leakage ratio replaces the respirator fit capability result referred to in Test Method F3407
- Leakage Ratio, as defined by the standard, is the RFC result, not an overall fit factor
- The leakage ratio of the BFC is determined through the calculation of an RFC result using the equation identified in F3407. The leakage ratio is determined by averaging the results of 10 test subjects
- The standard does not identify a pass/fail criteria.
- The standard identifies the possibility of evaluating multiple sizes. It uses the NIOSH Bivariate Panel for definition of facial dimensions used for sizing. 10 subjects need to be considered for each size represented by the manufacturer

The use of the F3407 is an adaptation of a respirator testing method that measures inward leakage of particulates through the BFC material and around its perimeter

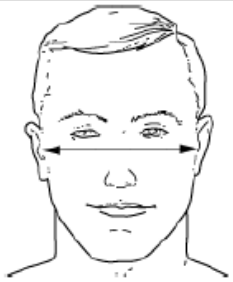
There is no expectation that the representation of the leakage ratio would imply outward leakage performance, and by using the N99 mode, the test indicates a better indication of the overall product performance by looking at particles coming through, and around the perimeter of the device.

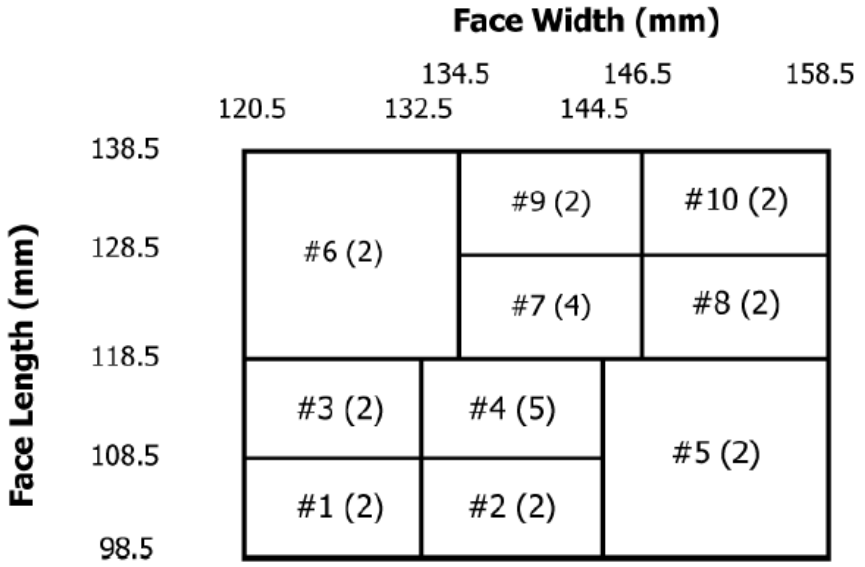
Quantitative Leakage Ratio Test Methodology

Use of reduced bivariate panel helps assess fit across intended population

FIG. X1.1 NIOSH Panel Based on Face Length and Width

TABLE X1.1 Measured Face Dimensions

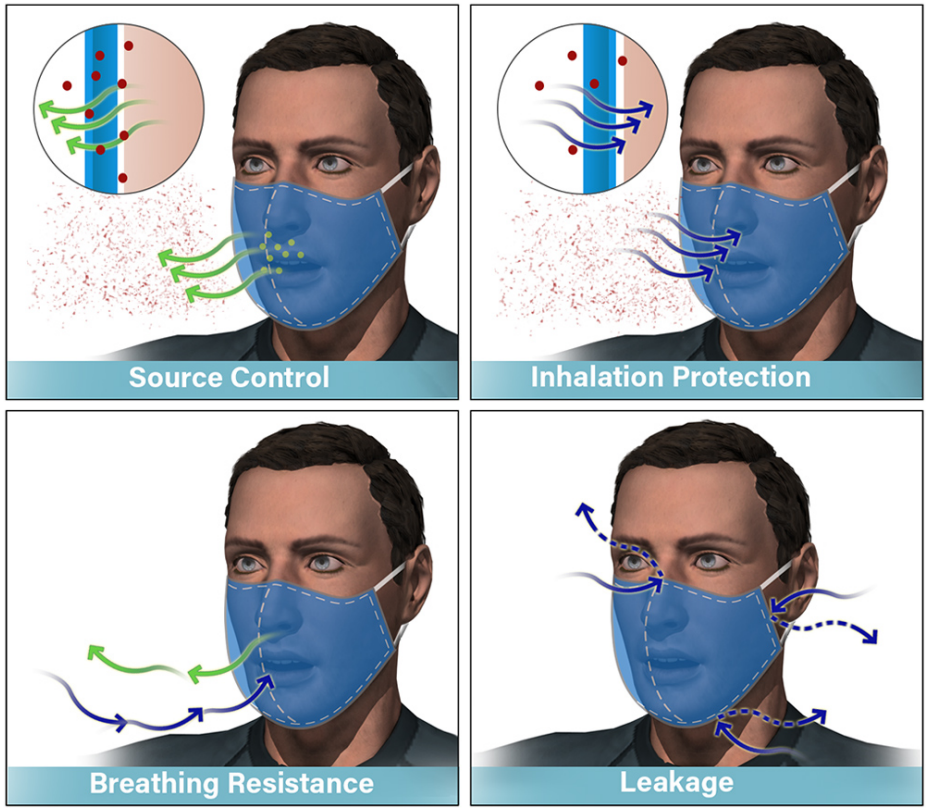
Description	Definition	Diagram
Bizygomatic Breadth (face width)	Maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches	
Menton-Sellion Length (face length)	Distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark	



Mandatory Performance Requirements

Essential criteria to define wearer source control and limited protection

- Sub-micron particulate filtration efficiency
  - Establishes percentage of particles blocked by product
  - Higher values are better
- Airflow resistance (inhalation)
  - Measures resistance to air passing through product
  - Lower values are better
- Applies to single use and reusable products
  - Reusable products are evaluated before and after maximum number of laundering or cleaning cycles specified by manufacturer using manufacturer specified laundering/cleaning procedures



Sub-Micron Particulate Filtration Efficiency

Use of the smallest particle size to discriminate filter performance

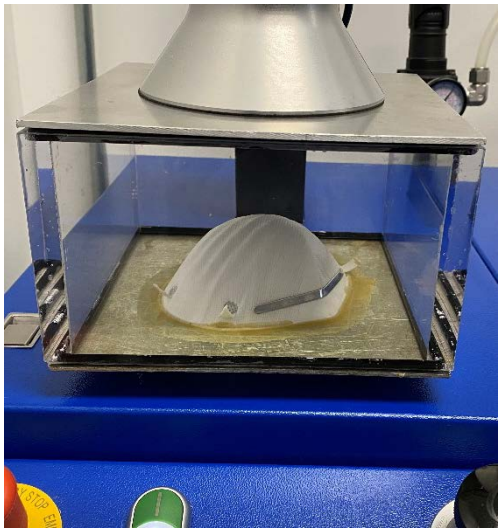
- Test method based on 42 CFR Part 84 (Subpart K)
  - Other details provided in NIOSH TEB-APR-STP-0059 (same test method used to measure performance of N95 respirators)
  - Uses poly-disperse sodium chloride particles
  - Count medium diameter of 75 nm diameter
  - Mass median aerodynamic diameter of 0.3 microns
  - Airflow rate of 85 Liters/minute adjusted to face velocity of 10 cm/second
- Evaluates full product (not just material)
- Utilizes holder to position face covering test sample on test apparatus
- Provides greater challenge than other filtration tests (much better at discriminating filtration performance)
- Minimum performance is ≥ 20%

Photograph courtesy of NIOSH/NPPTL

Airflow Resistance

Ease of breathing through face covering is addressed for whole product

- Test is performed on same equipment and sample as sub-micron particulate filtration efficiency test
  - Airflow resistance measured before filtration efficiency
- Test apparatus calculates initial resistance (pressure differential) for air being pulled through face covering
- As with filtration efficiency, airflow resistance relies of test sample being mounted on test platform to seal around its edges and evaluate entire product
- Maximum airflow is ≤ 15 mm H_2O



Photograph courtesy of NIOSH/NPPTL

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

Classification of Performance

Each performance property is separately classified

- ASTM F3502 sets two separate classifications of both sub-micron particulate filtration efficiency and airflow resistance
  - Intended to differentiate products among mandatory performance properties
  - Products may have mixed performance
- Performance levels do not imply specific protection levels or applications (currently, insufficient information is available to characterize how barrier face covering performance relates to all conditions of use)

Performance Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)
Sub-micron particulate filtration efficiency (Effectiveness of barrier face covering for capturing small particles; larger percentages indicate higher performance)	≥ 20%	≥ 50%
Air flow resistance (Indicative of ease of breathing while wearing barrier face covering; lower resistances indicate more breathable products)	≤ 15 mm H_2O	≤ 5 mm H_2O

Reporting of Results

Required documentation offers a means of demonstrating compliance

- Report documents results and other details of testing
- Provides
  - Manufacturer name
  - Product name or model number
  - Laboratory name/address
  - Laboratory accreditation info.
  - Specific test values
  - Laundering/cleaning method and maximum number of cycles, if reusable barrier face covering
  - Other test documentation
  - Performance classifications
- Recommended test report form provided in Appendix X2 (other formats may be used)

REPORT OF TESTING AND OTHER INFORMATION REQUIRED BY ASTM F3502-21 SPECIFICATION ON BARRIER FACE COVERINGS											
Manufacturer Name											
Product Name or Model number											
Laboratory Name/Address											
Laboratory Accreditation Credentials											
Sub-micron Particulate Filtration Efficiency (Section 8.1)						Date of Testing					
Test Values (%) by Specimen											
Condition	1	2	3	4	5	6	7	8	9	10	Report Value†
Pristine*											
After Wash**											
Air Flow Resistance (Section 8.2)						Date of Testing					
Test Values (mm H_2O) by Specimen											
Condition	1	2	3	4	5	6	7	8	9	10	Report Value†
Pristine*											
After Wash**											
* Description of Condition if Other than Pristine (identify where performed)											
** Description of Laundering or Cleaning Conditions Applied (identify where performed)											
Description of Approach Applied as Part of Product Design Analysis (provide supporting documentation, as needed)											
Results of quantitative leakage assessment with leakage ratio (if applicable – document full findings in separate report)											
PERFORMANCE CLASSIFICATION***	Sub-micron Particulate Filtration Efficiency							Air Flow Resistance			

Product Labeling

Communicating minimum information to the consumer

- Product label (must be printed or affixed anywhere on face covering)
  - Manufacturer name
  - Product name or model
  - “MEETS ASTM F3502”
- Package label (smallest saleable unit/package)
  - Same information as above except full compliance statement is given
  - Separate classifications of performance properties
  - Primary materials of construction
  - Month and year of manufacture
  - Lot or trace number (if applicable)
  - Indication of single use or reusable product
  - Expiration date (if applicable)

MEETS ASTM F3502, SPECIFICATION ON BARRIER FACE COVERINGS.

THIS PRODUCT IS PRIMARILY INTENDED AS A MEANS OF SOURCE CONTROL FOR MINIMIZING THE PROJECTION OF THE EXPELLED MATERIALS FROM THE WEARER’S NOSE AND MOUTH.

WARNING: THIS FACE BARRIER COVERING IS NOT A MEDICAL FACE MASK AS DEFINED IN ASTM F2100, IS NOT INTENDED FOR USE IN MEDICAL PROCEDURES, AND IS NOT A RESPIRATOR

Full Compliance Statement

Visual Rating Methods – Part 1

Suggested Scheme for Indicating Face Covering Performance – Tabular

Option 1

Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)	"My Mask"
Filtration Efficiency	≥ 20%	≥ 50%	Level 2: 60%
Breathability	≤ 15 mm H_2O	≤ 5 mm H_2O	Level 1: 8 mm H_2O

Option 2

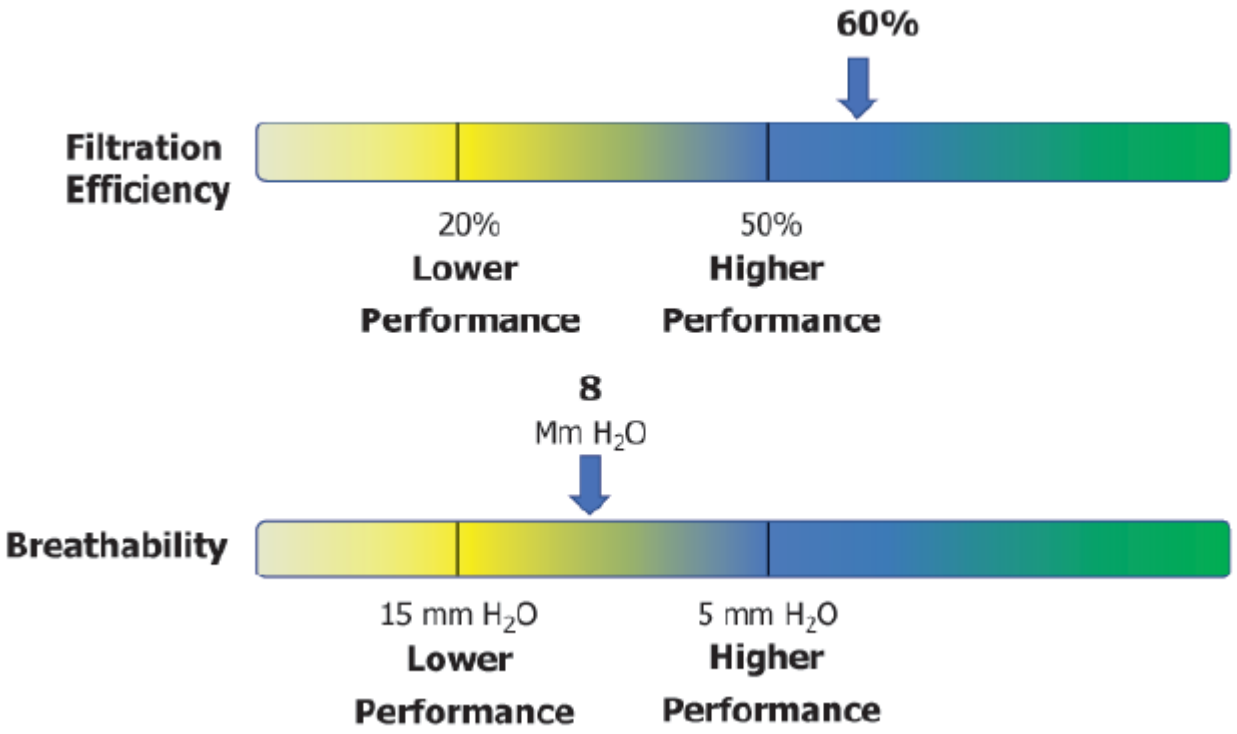
Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)	"My Mask"
Filtration Efficiency	≥ 20% F1	≥ 50% F2	F2
Breathability	≤ 15 mm H_2O B1	≤ 5 mm H_2O B2	B1

Option 3

Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)
Filtration Efficiency	F1	F2
Breathability	B1	B2

Visual Rating Methods – Part 2

Suggested Scheme for Indicating Face Covering Performance – Continuum



User Instructions

Important information to be conveyed to the end user

- User instructions required for smallest saleable unit/package
- Content
  - Repeat of product label information
  - Information on how to select correct size or make adjustments (if applicable)
  - How sizes are defined
  - How to put on and take off barrier face covering including proper orientation
  - If reusable, laundering or cleaning instructions
  - Maximum number of laundering and cleaning cycles
- Content (continued)
  - Other cautions and limitations (e.g., products not suitable for young children, products with metal should not be worn during MRI procedures)
  - Conditions of storage and shelf life
  - When to replace face covering
  - Procedures for disposal follow use

Manufacturers are encouraged to use diagrams, images, or video to convey correct use

Conformity Assessment

Demonstrating compliance with the standard

- Conformity assessment encompasses how a manufacturer product meets the ASTM F3502 standard
- The barrier face covering must apply “Model A” Requirements of ASTM F3050-17 Standard Guide for Conformity Assessment of Personal Protective Clothing and Equipment (Annex 3)
  - These requirements has manufacturer self-declare conformance, set the frequency of testing, and address product quality
- Filtration efficiency and airflow resistance must be performed by laboratory accredited to ISO 17025 having test methods as part of their accreditation scope
  - Quantitative leakage testing is not subject to this requirement
- Manufacturers are permitted to meet more rigorous requirements (e.g., 3rd party certification)

Further Development of the Specification

Intent is to evolve standard immediately as new information becomes available

- Potential work group to develop a separate test method for filter efficiency and air flow resistance
- Potential work group to develop a test method for measuring outward leakage
- Potential work group to address comments provided during the balloting process

Additional Communications

Subcommittee will be engaged in providing additional information on standard

- ASTM to develop training package geared toward (1) manufacturers and (2) users
- Development of a NIOSH/NPPTL blog about the standard
- Preparation of a FAQ document about the standard
- Discussions on identifying a database associated with listing conforming products

Potential for Enforcement Mechanisms

Potential ways that standard could be implemented

- OSHA is responsible for enforcement in the workplace and could consider adopting the standard
- Federal agencies who have jurisdictions not covered by OSHA should consider adopting the ASTM standard for workers under their jurisdiction
- FDA could consider dual certification of a facemask for medical use compliant with the ASTM Standard
- Options for the general public could be defined
- NIOSH or another agency should list the information on a trusted source website
- PPE purchases for barrier face coverings (e.g., SNS) could adopt the ASTM standard

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Questions?

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Thank you

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