Understanding and Applying ASTM F3502 for Face Coverings for Different Population Needs

Round Table on Standardization of Community Masks for the Current Pandemic

Jeffrey O. Stull (ASTM PPE Consultant)
Presenter – Jeffrey O. Stull, M.S. ChE

Relevant Experience and Qualifications

• 37 years of experience in PPE
  – 5 years in U.S. Coast Guard: fire and hazardous materials protection
  – 5 years Texas Research Institute: PPE research, testing & certification
  – 27 years International Personnel Protection: full range of PPE services
    o R&D projects related to PPE materials, design, development, testing
    o Positioning of products against specific standards and regulatory requirements

• Involvement in PPE standards development
  – Original author for ASTM F1862 fluid resistance test; F2100 specification on medical face masks; ASTM F1671 viral penetration resistance test
  – Technical lead for ASTM F3502 standard for “barrier face coverings”
  – Former lead U.S. Delegate to ISO TC94/SC13 on Protective Clothing
New Specification on Barrier Face Coverings

Origin and Key Attributes of ASTM F3502

• Intended to define acceptable “mask” products
• Collaboration group of over 80 individuals
  – Broad interests represented (small & large companies)
  – Many non-US participants
• Approved through full ASTM consensus process in 7 months
• Significant debates over intended use
  – Targeted end users of product
  – Appropriate level of design criteria
  – Minimum types of testing and product qualification
  – Application of conformity assessment
Preventing Transmission by Source Control

• Source control refers to use of well-fitting cloth masks, facemasks, or respirators to cover a person’s mouth and nose to prevent spread of respiratory secretions when they are breathing, talking, sneezing, or coughing
  – For face-worn products, product filtration and leakage are key factors

Preventing Transmission by Protection

- Product prevents exposure to wearer by keeping infectious droplets or aerosols from being inhaled
- Factors affecting effectiveness:
  - Droplet/aerosol size
  - Filtration media capture rates
  - Product seal or leakage on individual
  - Wear comfort and function

Performance Requirements

Key attributes are assessed

Sub-micron particulate filtration efficiency
- Establishes % 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 cycles for manufacturer specified laundering/cleaning procedures
Design Requirements

Standard avoids being design-restrictive

• Kept to a minimum to permit product type flexibility
  – Not be made of irritating or toxic materials
  – Not pose a flammability hazard
  – Cover at least nose and mouth
  – Fit snugly against the wearers face
  – Have a means of head retention
  – Not employ exhaust valves or open vents
  – Be permitted to be available in a universal or multiple sizes (including pediatric sizing)

• Manufacturer required to conduct a “design analysis” to assess leakage around edges of BFCs on intended user population
Optional Quantitative Leakage Test

Quantifies key characteristic of performance

- Allows measuring BFC leakage
  - Around edges and through material
- Can be performed to support or supplement design analysis
- References ASTM F3407 with changes:
  - Smaller test subject panel
  - Representation of different facial dimensions
  - No specific passing criteria
Test Methods

Analogous methodology as applied to respirators

- Test method based on NIOSH procedures
  - Uses NaCl particles aerosol with diameter of 75 nm (aerodynamic diameter of 0.3 μm)
  - Airflow rate of 85 Liters/min adjusted to face velocity of 10 cm/s
- 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)
- Allows for concurrent measurement of airflow resistance

Common test platform, globally available
NIOSH Filtration Testing

- Test method based on 42 CFR Part 84
  - Uses poly-disperse sodium chloride particles
  - Count medium diameter of 75 nm diameter
  - Mass median aerodynamic diameter of 0.3 μm
  - Airflow rate of 85 Liters/min
- Evaluates full product (not just material)
- Provides greater challenge than other filtration tests (much better at discriminating filtration performance)
Source: Lindsley et al., Aerosol Science and Technology; https://www.medrxiv.org/content/10.1101/2020.10.05.20207241v1
# Performance Classification

## Multiple Levels Allowing Tradeoffs

<table>
<thead>
<tr>
<th>Property</th>
<th>Level 1</th>
<th>Level 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filtration efficiency</td>
<td>$\geq 20%$</td>
<td>$\geq 50%$</td>
</tr>
<tr>
<td>Airflow resistance</td>
<td>$\leq 15$ mm H$_2$O</td>
<td>$\leq 5$ mm H$_2$O</td>
</tr>
</tbody>
</table>

Each property is classified separately.
Analysis of Total Leakage through Masks

Level 2 Breathability (≤ 5 mm H₂O)
Level 1 Breathability (≤ 15 mm H₂O)

Filtration Efficiency, PFE or TFE (%) vs Breathing Resistance (mm H₂O)

- Headform TFE
- ASTM F3502 PFE

Levels:
- Level 2 FE (≥ 50%)
- Level 1 FE (≥ 20%)
- Level 2 Breathability (≤ 5 mm H₂O)
- Level 1 Breathability (≤ 15 mm H₂O)
# Application of Leakage Information

<table>
<thead>
<tr>
<th>Outward Leakage of Face Covering From Infected Source</th>
<th>No Face Covering (100% Leakage)</th>
<th>80%</th>
<th>60%</th>
<th>40%</th>
<th>20%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Face Covering (100% Leakage)</td>
<td>15 min</td>
<td>19 min</td>
<td>25 min</td>
<td>38 min</td>
<td>75 min</td>
</tr>
<tr>
<td>80%</td>
<td>19 min</td>
<td>23 min</td>
<td>31 min</td>
<td>47 min</td>
<td>94 min</td>
</tr>
<tr>
<td>60%</td>
<td>25 min</td>
<td>31 min</td>
<td>42 min</td>
<td>1 hr</td>
<td>2 hr</td>
</tr>
<tr>
<td>40%</td>
<td>38 min</td>
<td>47 min</td>
<td>1 hr</td>
<td>1.5 hr</td>
<td>3 hr</td>
</tr>
<tr>
<td>20%</td>
<td>75 min</td>
<td>94 min</td>
<td>2 hr</td>
<td>3 hr</td>
<td>6.25 hr</td>
</tr>
</tbody>
</table>

*Assumes that, for a dose with a high probability of infection, the time to infectious dose = 15 min (CDC contact tracing time). Also assumes perfect mixing of the aerosol in the space.
Labeling and User Information

Identifies and documents compliant products

- Product label
  - Manufacturer name
  - Product name or model
  - “MEETS ASTM F3502”

- Package label (smallest unit/package)
  - Product performance property classes
  - Materials of constructions
  - Month/year of manufacture
  - Lot or trace number (if applicable)
  - Indication of single use or reusable
  - Expiration date (if applicable)
Conformity Assessment / Regulatory Oversight

ASTM F3502 has been applied in U.S. and other countries

- Specification requires ISO 17025-based testing
- FDA “recognized” standard 2 weeks following adoption
  - Considers products “medical devices” (currently unclassified)
  - Part of enforcement guidance
- CDC developed additional specifications for workers
  - Developed Workplace Protection/Workplace Protection Plus
- Referenced in OSHA Emergency Temporary Standard
  - Likely to be proposed in infectious disease regulations
- Cited by World Health Organization
- Being adopted by other countries

<table>
<thead>
<tr>
<th>Workplace Protection</th>
<th>Workplace Protection Plus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filtration efficiency</td>
<td>Filtration efficiency</td>
</tr>
<tr>
<td>≥ 50%</td>
<td>≥ 80%</td>
</tr>
<tr>
<td>Leakage ratio</td>
<td>Leakage ratio</td>
</tr>
<tr>
<td>≥ 5</td>
<td>≥ 10</td>
</tr>
</tbody>
</table>

Supplemental CDC Guidance
Current CDC/NIOSH Website F3502 Postings

https://wwwn.cdc.gov/PPEInfo/RG/FaceCoverings

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product Name or Model</th>
<th>Single Use/Reusable</th>
<th>Particulate Filtration Efficiency(%)</th>
<th>Breathability (mm H2O)</th>
<th>Leakage Ratio²</th>
<th>Workplace Performance/Workplace Performance Plus Rating²</th>
</tr>
</thead>
<tbody>
<tr>
<td>3M</td>
<td>Advanced Filtering Face Mask AFFM</td>
<td>Single</td>
<td>99% - Level 2</td>
<td>13 mm – Level 1</td>
<td>73</td>
<td>Workplace Performance Plus</td>
</tr>
<tr>
<td>Contact: Linda Eichinger</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aries</td>
<td>Aries Barrier Face Covering</td>
<td>Single</td>
<td>83% - Level 2</td>
<td>5 mm – Level 2</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Contact: Jane Foreman</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impulse Fashion, Inc.</td>
<td>Hope Mask</td>
<td>Reusable</td>
<td>22% - Level 1</td>
<td>12 mm – Level 1</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Contact: Donald Roberts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buckeye Mask Company</td>
<td>PFM-153081</td>
<td>Reusable</td>
<td>24% - Level 1</td>
<td>5 mm – Level 2</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Contact: Carla Macdlin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

24 products have been listed through early 2022 (the first four listings are shown)
Proposed Revisions to ASTM F3502

• Changes to introduction
• Use of the term aerosol to refer to particles and droplets
• Clarification of product performance for both source control and inhalation protection
• Restriction of claims for anti-viral or anti-microbial performance
• Better definition for using of non-toxic or irritating materials
• Procedures to address logos and embellishments
• Updates to conformity assessment requirements
• Provision of sample declaration form