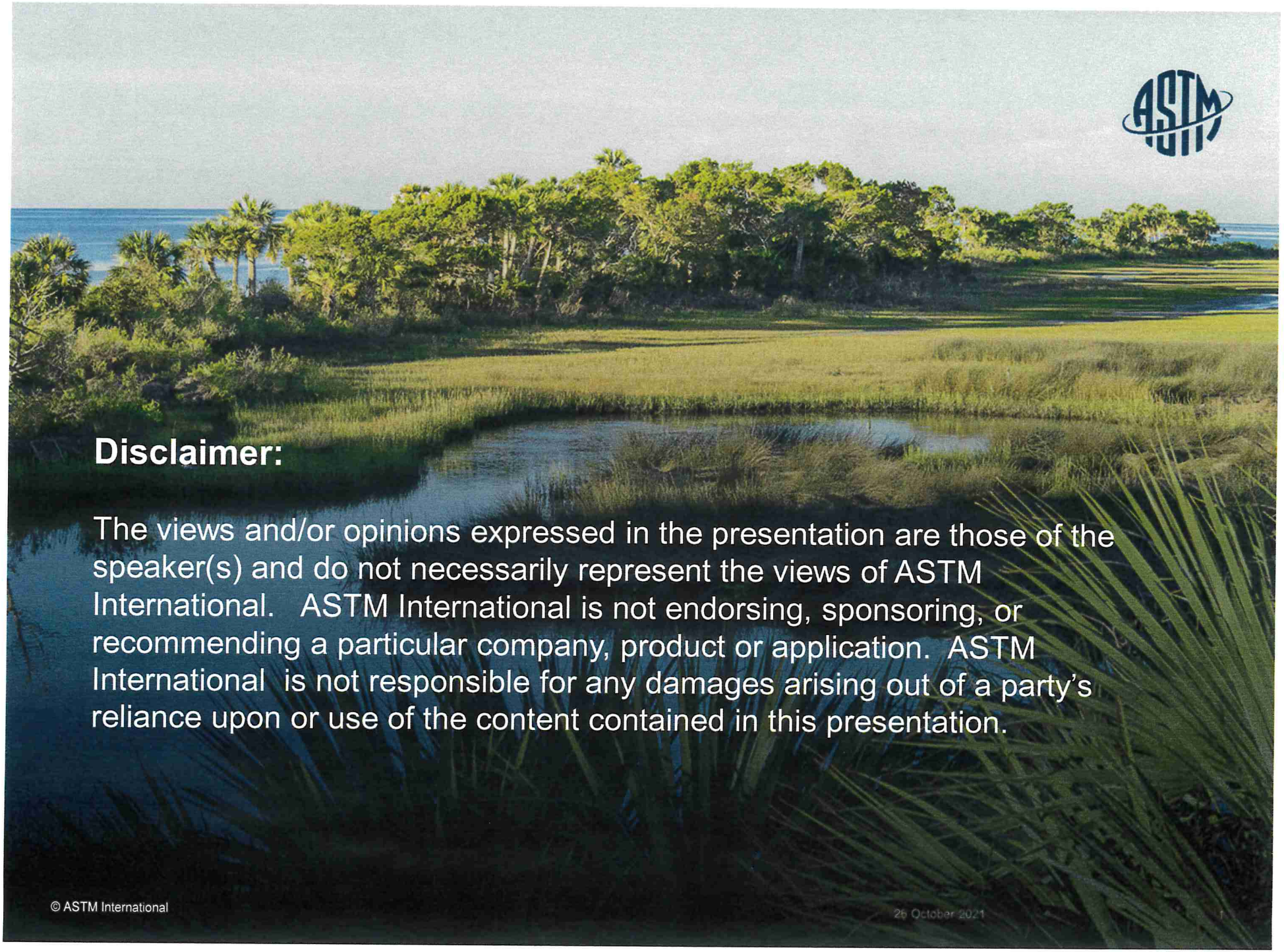

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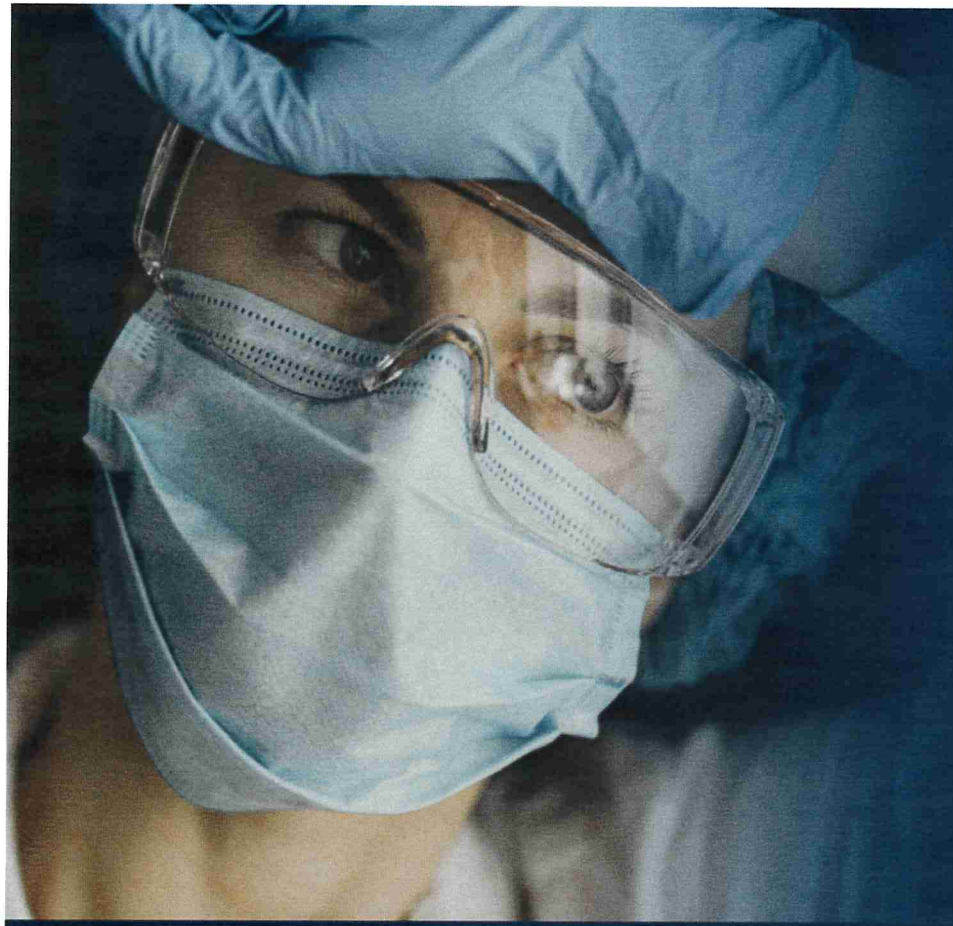

Positioning Respirators, Medical Face Masks, and Barrier Face Coverings for Meeting Regulatory Requirements Applied in the United States

Presentation to Jordan Stakeholders

Jeffrey O. Stull (ASTM PPE Consultant))

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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
    - R&D projects related to PPE materials, design, development, testing
    - 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

Learning Objectives

1. How different products work to capture expelled particulate and droplets
2. The degree to which face covering products provide protection to the wearer for the inhalation of potentially infectious particulates
3. The principal similarities and contrasts between respirators, medical masks, and face coverings
4. Different options for how products can be manufactured to meet U.S. standards and requirements and how related requirements can be applied locally for end users including healthcare and the general population
5. The utility of the new ASTM F3502 standard and changes being considered in its current revision

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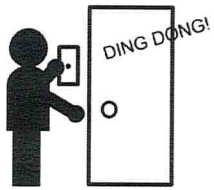
How PPE Affects Disease Transmission

Infectious Disease Transmission Modes

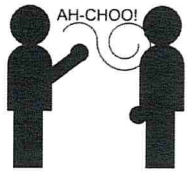
Transmission mode affects PPE selection

Indirect Contact



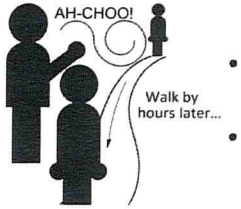
- Pathogen survives harsh environment
- Pick up pathogen from surface or air
- Eg Influenza, norovirus

Droplets



- Pathogens are in droplets, but do not survive long this way
- Eg: Ebola, *Bordetella pertussis*

Airborne



- Pathogens aerosolized and stay infective
- Eg: Influenza, Tuberculosis

Figure from: https://sitn.hms.harvard.edu/flash/special-edition-on-infectious-disease/2014/an-introduction-to-infectious-disease/

- ***Contact:*** use of gloves, other clothing and equipment to prevent transfer to body
- ***Droplet:*** need to prevent deposition of small droplets on personal surfaces (gloves, gowns, faceshields, masks)
- ***Airborne:*** additional forms of respiratory protection

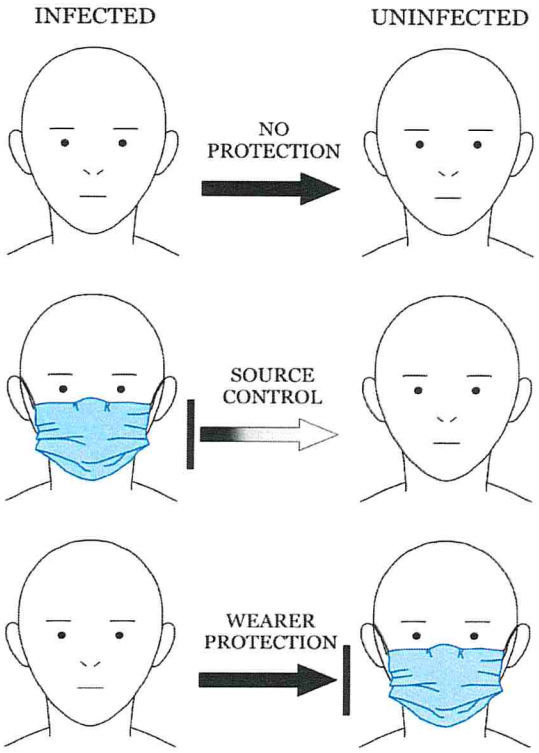
SARS-CoV-2 Transmission

The principal mode by which people are infected with SARS-CoV-2 (the virus that causes COVID-19) is through exposure to respiratory fluids carrying infectious virus. Exposure occurs in three principal ways:

1) inhalation of very fine respiratory droplets and aerosol particles,
2) deposition of respiratory droplets and particles on exposed mucous membranes in the mouth, nose, or eye by direct splashes and sprays, and
3) touching mucous membranes with hands that have been soiled either directly by virus-containing respiratory fluids or indirectly by touching surfaces with virus on them.

Source: Scientific Brief: SARS-CoV-2 Transmission, updated May 7, 2021 at https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html

Source Control versus Wearer Protection



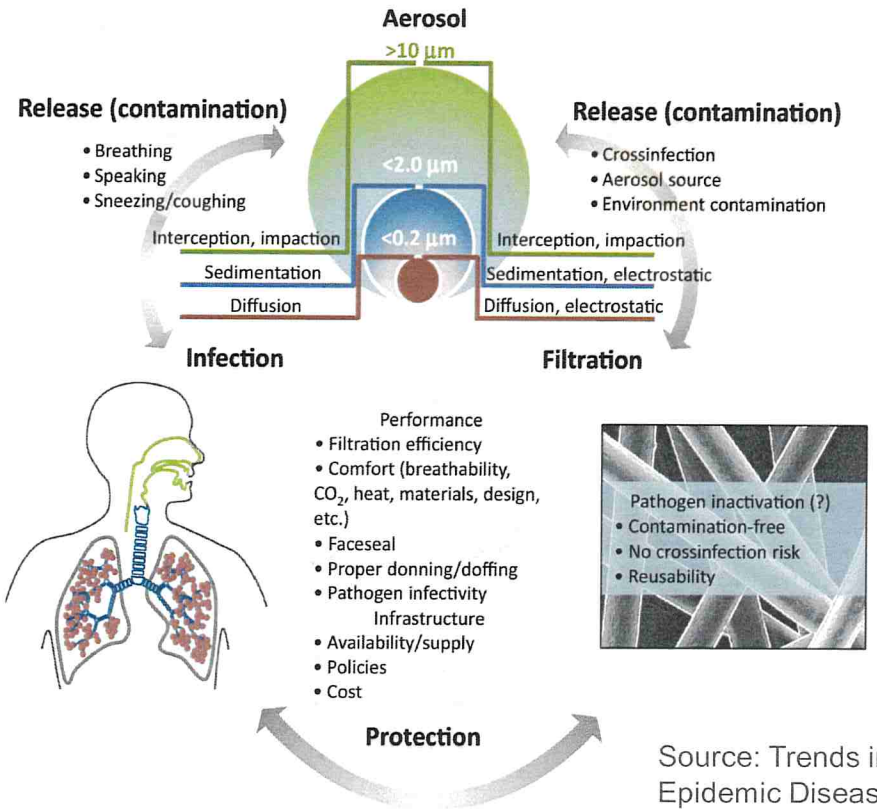
- In healthcare, historically "masks" used for infection control as a means for source control:
  - To prevent healthcare provider infection of patient
- Wearer protection for healthcare provider with known risks for exposure to infectious diseases
  - Principal examples: Tuberculosis, some forms of influenza, recent epidemics

Preventing Transmission by Source Control

Source: CDC (2021); https://www.cdc.gov/coronavirus/2019-ncov/your-health/effective-masks.html

- 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

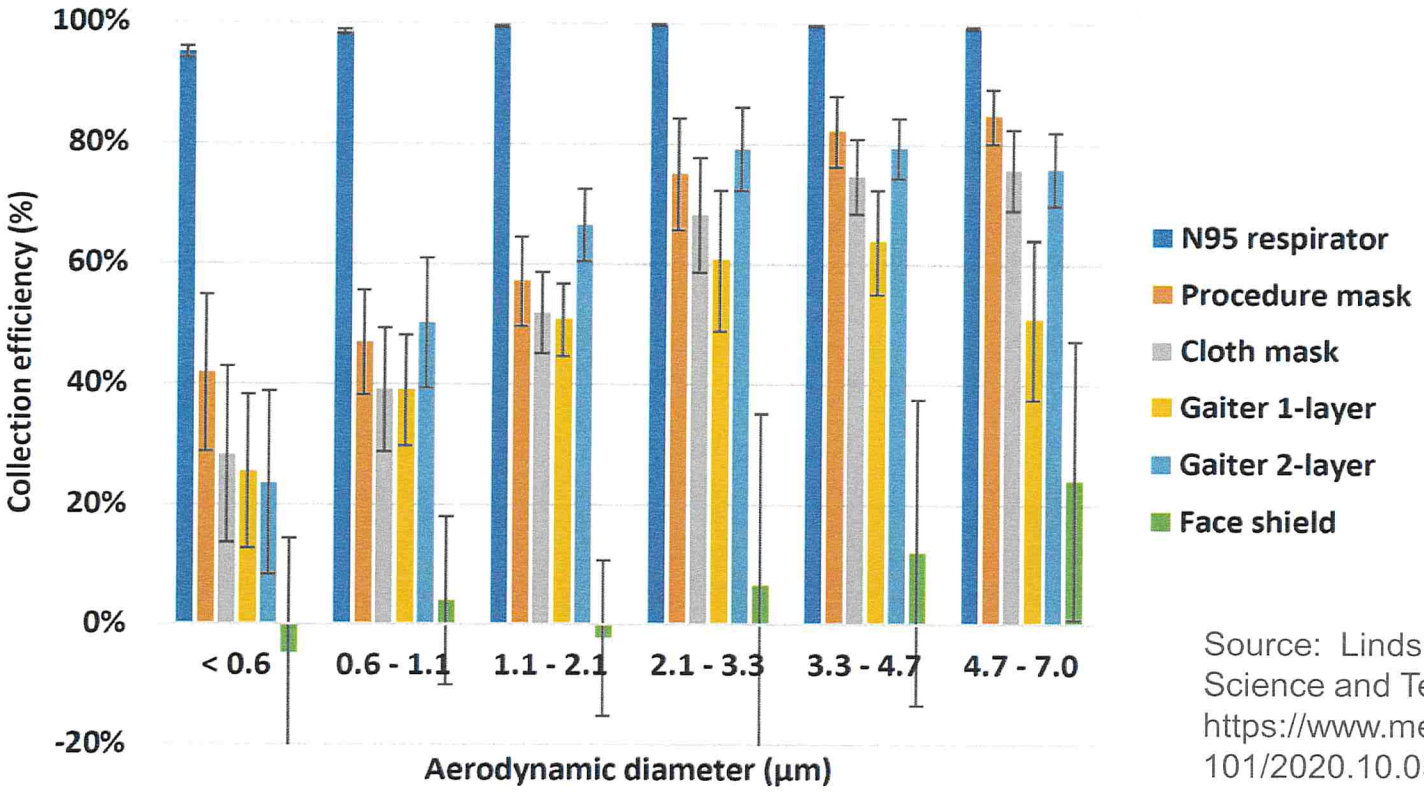
Preventing Transmission by Protection



- 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

Source: Trends in Biotechnology: Respiratory Protection against Pandemic and Epidemic Diseases; https://www.cell.com/trends/biotechnology/fulltext/S0167-7799(17)30133-6

Filtration Efficiency Differences



Source: Lindsley et al., Aerosol Science and Technology; https://www.medrxiv.org/content/10.1101/2020.10.05.20207241v1

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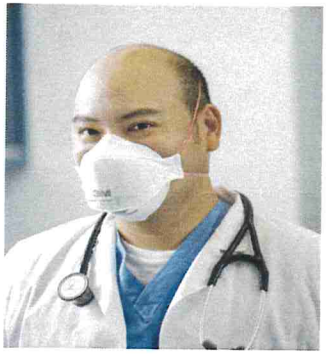
Differences between Respirators, Medical Face Masks, and Face Coverings

Respirators

- Respirators typically used in healthcare include:
  - Filtering facepiece respirators (disposable)
  - Elastomeric half facepiece air-purifying respirators or ***APR*** (reusable facepiece, disposable filters)
  - Powered air-purifying respirators ***PAPR*** (reusable blower, other components; disposable filters)
- Respirators offer varying degrees of protection from inhalation of contaminants



Filtering facepiece respirator

Elastomeric half facepiece APR

PAPR with hood

U.S. Filtering Facepiece Respirator Classifications

NIOSH RESPIRATOR FILTER CLASSES

NIOSH classifies the filtering media in respirators based on its resistance to oil and its particle filtering efficiency. The resistance to oil is designated as "N", "R", or "P". Particle filtering efficiency is designated "95", "99", or "99.97".

NOT RESISTANT TO OIL
N95, N99, N100
Filters at least 95%, 99%, or 99.97% of airborne particles

SOMEWHAT RESISTANT TO OIL
R95, R99, R100
Filters at least 95%, 99%, or 99.97% of airborne particles

STRONGLY RESISTANT TO OIL/OIL PROOF
P95, P99, P100
Filters at least 95%, 99%, or 99.97% of airborne particles

OILS
When products containing oil (like fuel, lubricating or hydraulic oils, solvents, paints, and pesticides) are sprayed or used in processes producing aerosols or droplets, the oil component may become airborne.

NIOSH Particulate Filter Classification

Respirator filters (such as disposable respirators and reusable respirator filters) must meet filtration standards from the National Institute for Occupational Safety and Health. The nine filtration classifications are shown in the chart below.

	FILTER EFFICIENCY		
	95 (≥95%)	99 (≥99%)	100 (≥99.97%)
OIL RESISTANCE			
N (Not resistant to oil)	N95	N99	N100
R (Resistant to oil; time-use limitations)	R95	R99	R100
P (Oil proof; time-use limitations)	P95	P99	P100

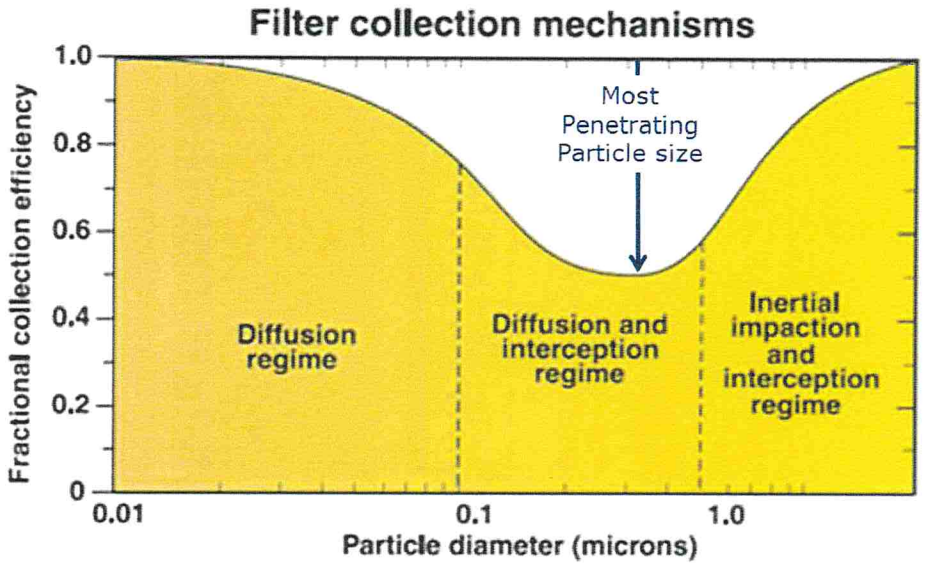
Key Filtering Facepiece Respirator Tests

- Filtration efficiency
- Airflow resistance for inhalation
- Airflow resistance for exhalation
- Exhalation valve leakage
- Total inward leakage*
- Carbon dioxide buildup*

Particle Filtration Efficiency Testing

Airflow Resistance Test Equipment

NIOSH Filtration Testing



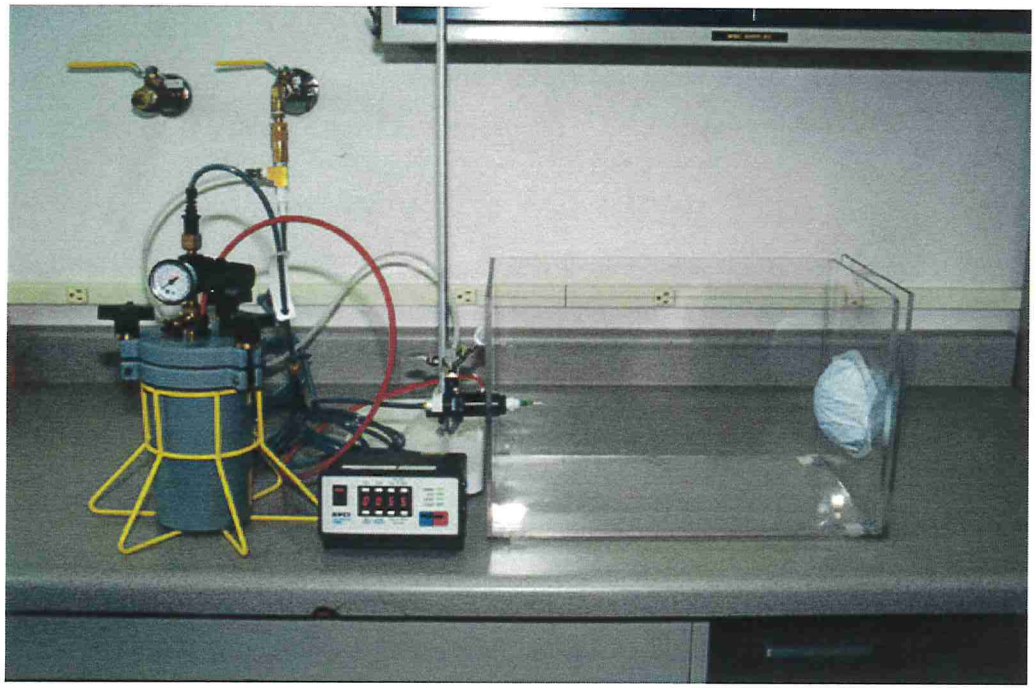
- Test method based on 42 CFR Part 84
  - Uses poly-disperse sodium chloride particles
  - Count medium diameter of 75 nm diameter
  - Mass median aerodynamic diameter of 0.3 µm
  - Airflow rate of 85 Liters/min
- Evaluates full product (not just material)
- Provides greater challenge than other filtration tests (much better at discriminating filtration performance)

Medical Face Masks (US ASTM F2100)

Understanding ASTM levels of protection is Key

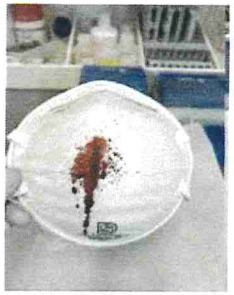
Characteristics	Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	Differential pressure, mm H20/cm2 (Breathability)	Bacterial filtration efficiency	Sub-micron particulates filtration efficient at 0.1 micron	Flame spread
ASTM F2100-11 Levels					
Level 1: low barrier protection General use for short procedures and exams that don't involve aerosols, spray or fluids	80 mm Hg	<4.0	≥95%	≥95%	Class1
Level 2: moderate barrier protection For low to moderate levels of aerosols, spray and/or fluids	120 mm Hg	<5.0	≥98%	≥98%	Class1
Level 3: maximum barrier protection For heavy levels of aerosols, spray and/or fluids	160 mm Hg	<5.0	≥98%	≥98%	Class1

Medical Face Masks as PPE (Fluid Resistance)



ASTM F1862 / ISO 22609 Test Apparatus

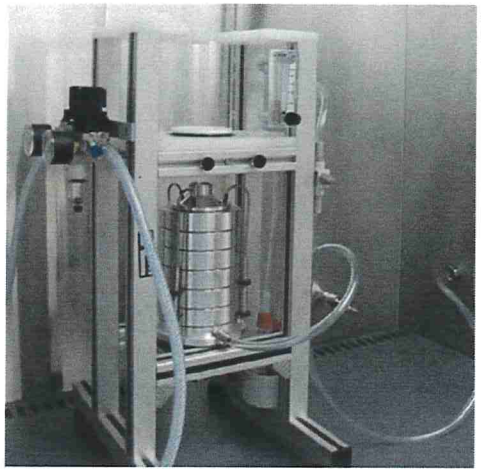
Blood Projection



Blood Strike Through

Other Key Performance Tests in US ASTM F2100

- Bacterial filtration efficiency
- Sub-micron particle filtration efficiency
  - Different than respirator test method
- Differential pressure
- Flammability
- Microbial cleanliness



Bacterial Filtration Efficiency Test Apparatus

16 CFR Part 1610 Flammability Test Apparatus

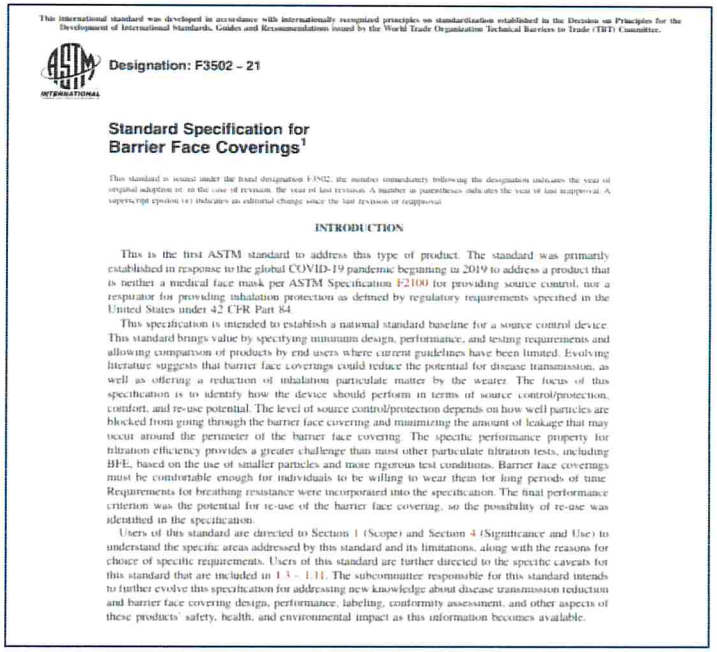
U.S. Surgical N95 Respirators

- N95 respirator that has been approved by NIOSH that is also subject to specific additional requirements normally applied to medical face masks
  - Fluid resistance
  - Flammability
  - Biocompatibility (cytotoxicity, skin irritation, sensitization)
- Joint approval process between U.S. NIOSH and U.S. FDA

Face Coverings

New ASTM F3502, Specification on Barrier Face Covering

- Purpose
  - Primary: SOURCE CONTROL
  - Secondary: Degree of inhalation protection to wearer
- Key attributes
  - Submicron filtration efficiency
  - Breathability
  - Leakage
- Conformity assessment
  - Key attribute testing by accredited laboratories; results available to buyer



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.

Designation: F3502 – 21

Standard Specification for Barrier Face Coverings[1]

This standard is issued under the fixed designation F3502; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

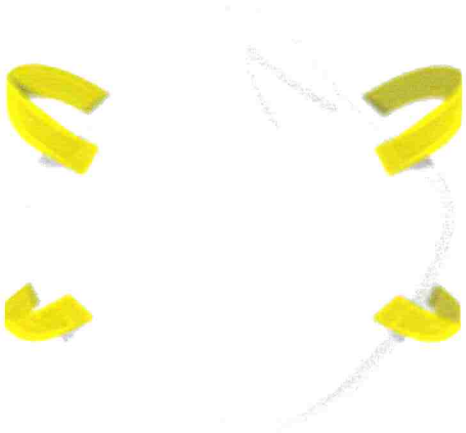
INTRODUCTION

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 potential. The level of source control/protection depends on how well particles are blocked from going through the barrier face covering and maximizing 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 of the barrier face covering, so the possibility of re-use was identified in the specification.

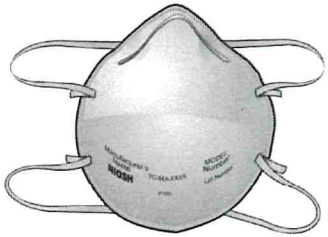
Users of this standard are directed to Section 1 (Scope) and Section 4 (Significance and Use) to understand the specific areas addressed by this standard and its limitations, along with the reasons for choice of specific requirements. Users of this standard are further directed to the specific caveats 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.

Varying Product Definitions



Respirators	Medical Face Masks	Barrier Face Coverings
Personal protective equipment (PPE) designed to protect the wearer from inhalation of hazardous atmospheres	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	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

Fit: Respirators vs. Masks vs. Face Coverings



OSHA-mandated fit testing

Fit not addressed

Optional

- ASTM F3407-2020, *Test Method for Respirator Fit Capability Conformance Test for Half-mask Air-purifying Particulate Respirators*
- Provides quantitative measurement of mask leakage using human subject panel

Application of Leakage Information

	Inward Leakage of Face Covering on Uninfected Receiver				
Outward Leakage of Face Covering From Infected Source	No Face Covering (100% Leakage)	80%	60%	40%	20%
No Face Covering (100% Leakage)	15 min	19 min	25 min	38 min	75 min
80%	19 min	23 min	31 min	47 min	94 min
60%	25 min	31 min	42 min	1 hr	2 hr
40%	38 min	47 min	1 hr	1.5 hr	3 hr
20%	75 min	94 min	2 hr	3 hr	6.25 hr

*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

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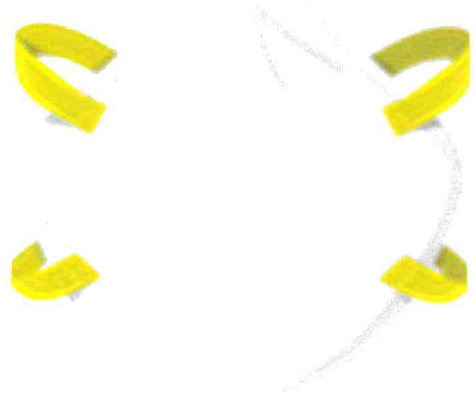
Regulatory Requirements for Respirators, Masks, and Face Coverings (Conformity Assessment)

Key Components of Conformity Assessment

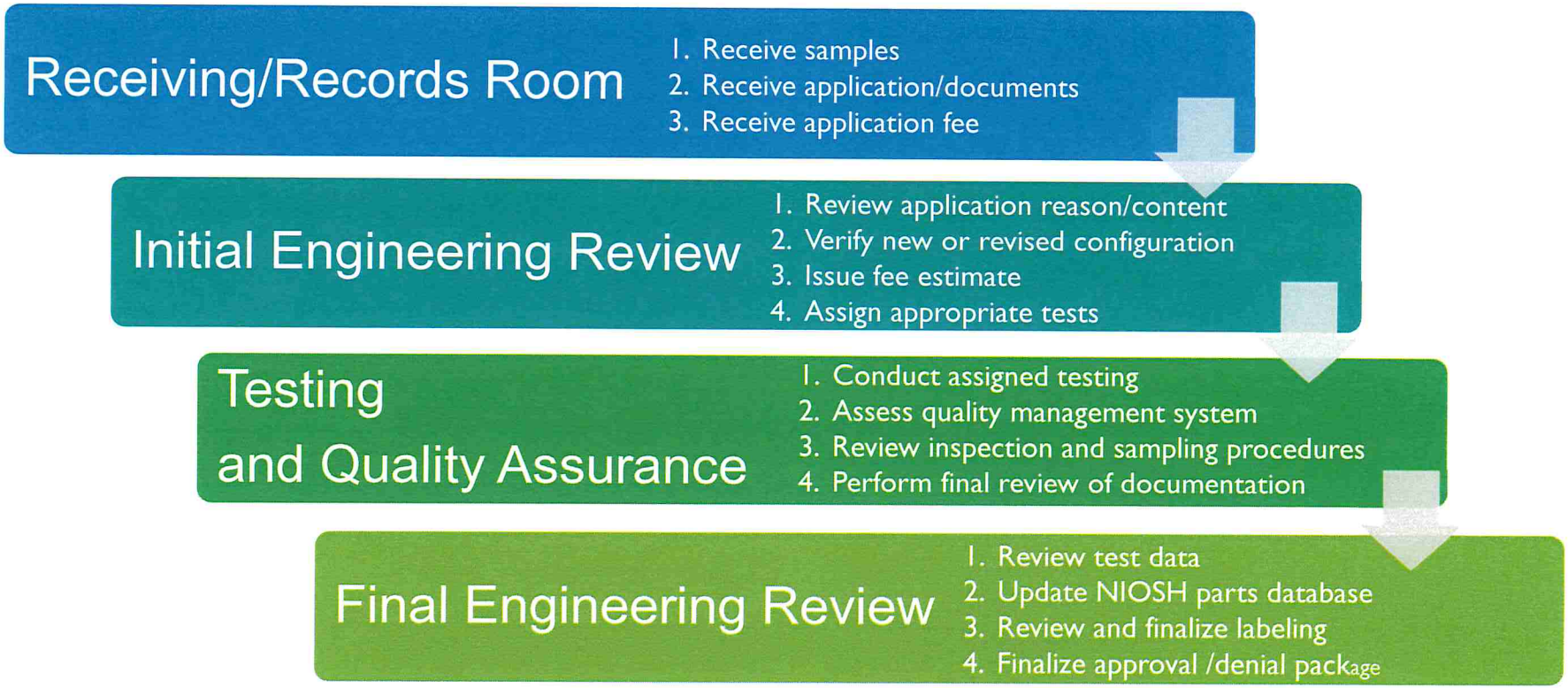
- Risk assessment to determine level needed
- Selection of suitable standard or set of requirements to be applied to product
- Identification of responsibility for carrying out testing and determining when testing is conducted
- Application of quality management system
- Requirements for product labeling
- Decision on who provides declaration of conformity
- Process to list products and conduct surveillance for continued conformity

U.S. Product Conformity Requirements

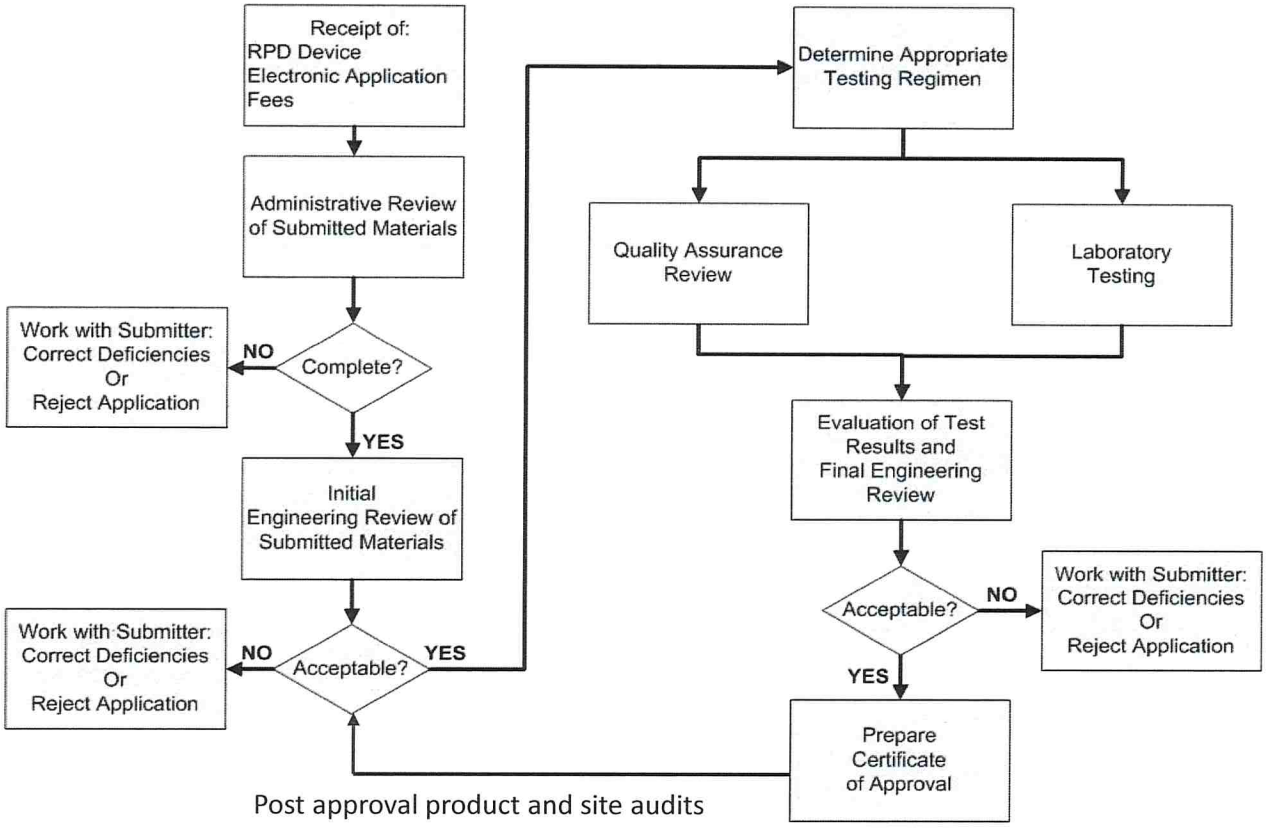


Respirators	Medical Face Masks	Face Coverings
Regulations set by NIOSH; NIOSH tests and approves all respirators; manufacturer must pass initial audit and is subject to future audits	Subject to FDA oversight as a "medical device"; suppliers must submit detailed technical information/test data for product to be "cleared"	While recently considered a "medical device", conformity assessment established by manufacturer declaration but required independent tests

U.S. NIOSH Approval Process for Respirators



Flow Chart for NIOSH Approval Process



Post approval product and site audits

Key Aspects for U.S. Respirator Approval

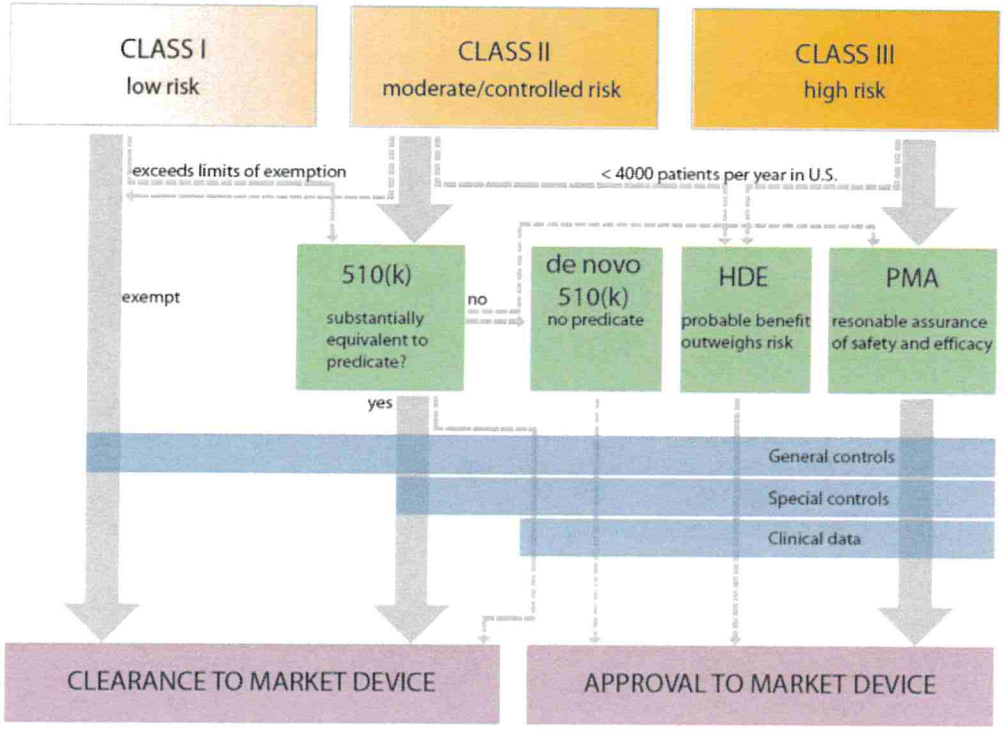
Required Parts of Application

- Detailed application form
- Engineering drawing(s)
- Proposed labeling/instructions
- Pre-submission test data
- Detailed product quality plan with inspection details
- Complete quality management system

Important Considerations

- NIOSH performs testing to confirm compliance
- NIOSH expects manufacturer to have operational QMS with records showing history that are verified by audit
- NIOSH conduct surveillance of product manufacturer while product is certified

U.S. FDA Medical Device Clearance Process



- Class I devices
  - Manufacturer meets general controls
- Class II devices (e.g., medical masks, gowns)
  - 510(k) submission
    - Demonstration of substantial equivalence to predicate product
    - Use of recognized standards
    - Manufacturer provision of safety and efficacy data
    - Good manufacturing practice

FDA Clearance of Medical Masks

Class II Devices Require 510(k)

- FDA provides guidance on requirements
- Manufacturer provides technical details, test data, and proposed labeling on product
- Manufacturer shows that product is substantially equivalent to existing cleared product

Important Considerations

- FDA recognizes specific ASTM F2100 for making mask claims
- Sampling requirements are extensive – AQL of 4%, e.g., of 32 specimens, only 3 can fail for primary tests
- Manufacturers must register each year and meet various "general controls"

Non-respirator/Non-mask Conformance

Variety of different conformity assessment practices are applied

- ASTM F3050 provides range of practices related to conformity assessment of PPE
  - Addresses who decides frequency of testing, qualification of testing laboratories, quality system requirements, who declares conformance
- Combination of practices used for products not subject to government regulations
  - Lowest level is self-declaration by manufacturer without requirements for laboratories, registered quality systems, or certification
  - Highest level is full third-party certification
  - Popular hybrid is manufacturer self-declaration supported by use of test data from accredited laboratories

Key Decisions for Instituting National Program

1. Decide on standard(s) to be applied
2. Determine how conformity assessment will be carried out
3. Identify laboratory capabilities to support both product qualification and manufacturing quality programs
4. Establish strategy to determine surveillance of in-country product and evaluate domestic or imported products
5. Create program to fully cover all stages of mask standardization, manufacturing, conformity assessment, and surveillance

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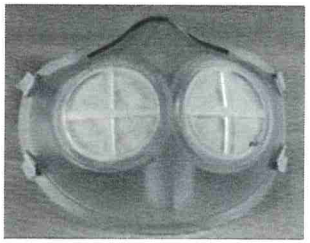
Explanation of ASTM F3502 Specification on Barrier Face Coverings

Design Requirements

Standard avoids being design-restrictive



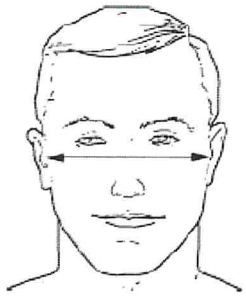
- Kept to a minimum to permit product type flexibility
  - Not be made of irritating or toxic materials
  - Not pose a flammability hazard
  - Cover at least nose and mouth
  - Fit snugly against the wearers face
  - Have a means of head retention
  - Not employ exhaust valves or open vents
  - Be permitted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

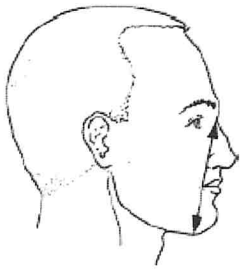
- Manufacturer required to conduct a “design analysis” to assess leakage around edges of BFCs on intended user population

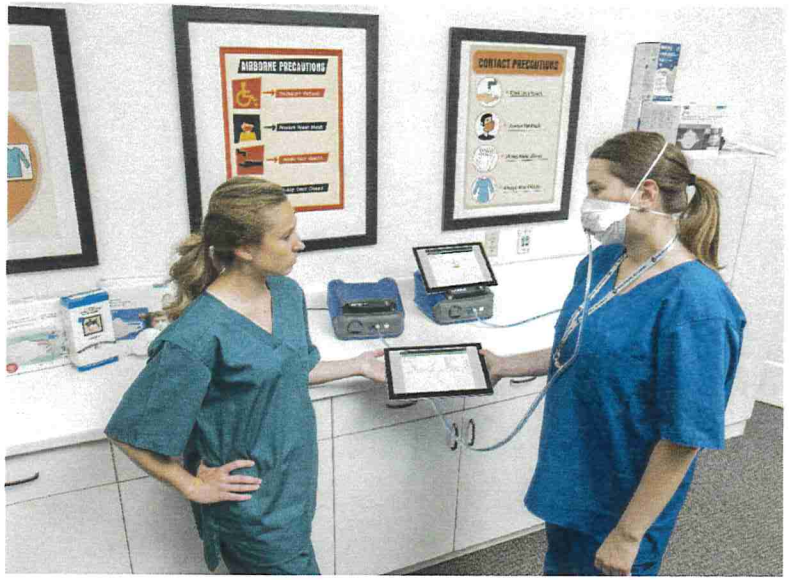
Optional Leakage Test

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







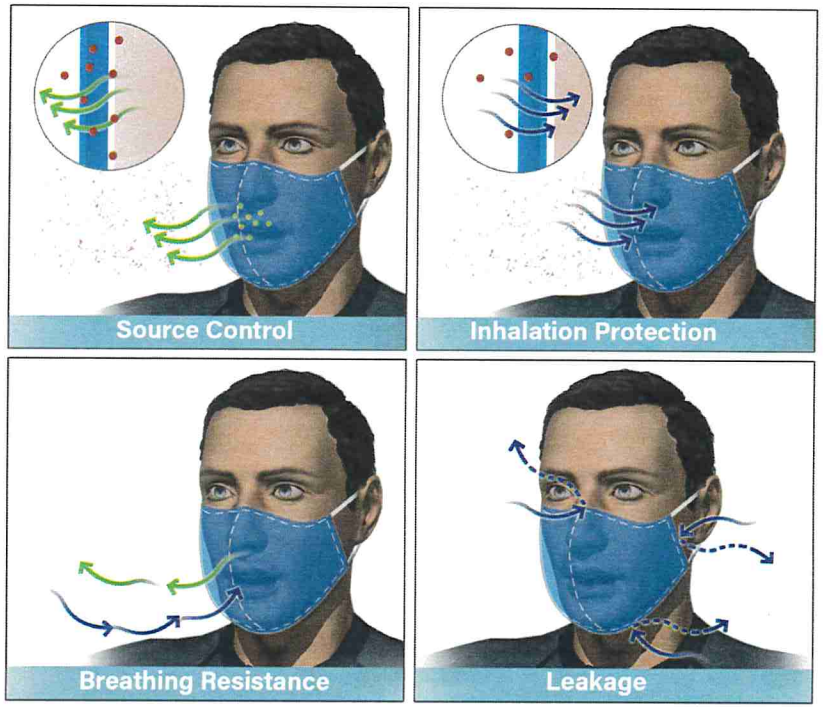
Performance Requirements

Assessment of key attributes

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



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

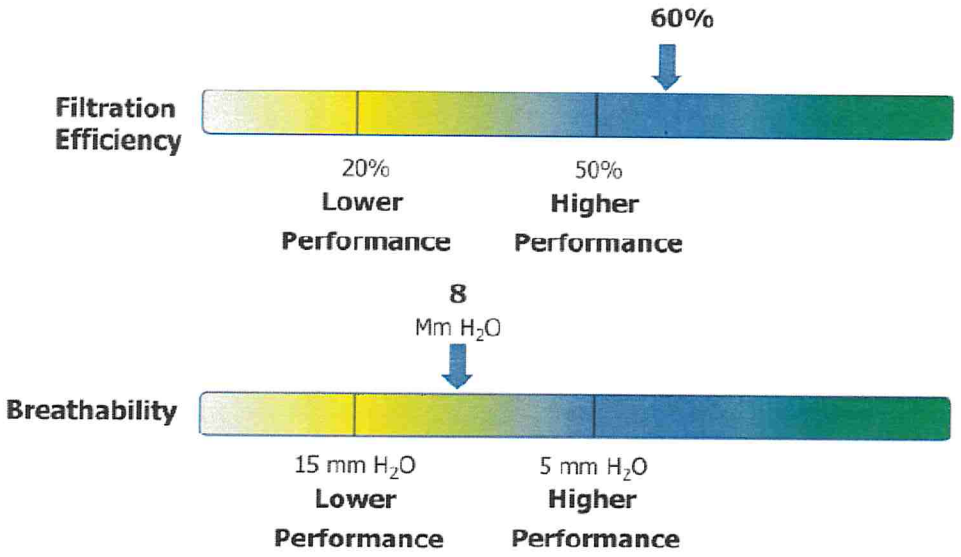
Common test platform, globally available

Performance Classification

Multiple Levels Allowing Tradeoffs

Property	Level 1	Level 2
Filtration efficiency	≥ 20%	≥ 50%
Airflow resistance	≤ 15 mm H_2O	≤ 5 mm H_2O

Each property is classified separately



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)

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			

Current CDC/NIOSH Website F3502 Postings

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

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

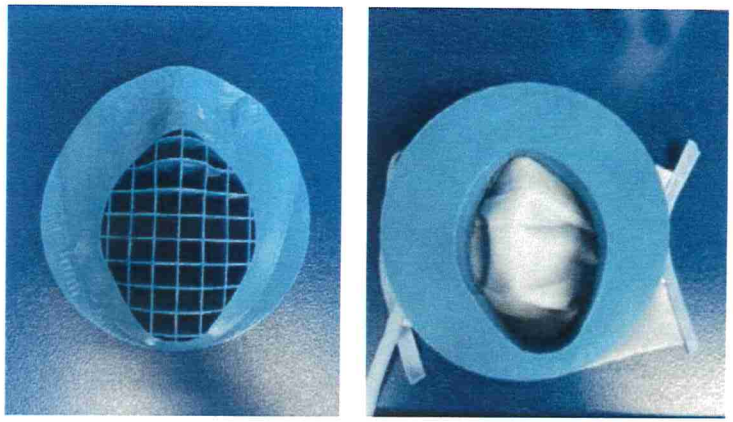
18 products have been listed through early October (the first four listings are shown)

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

Key Areas of Debate ASTM F3502

- More explicit details in test procedures to accommodate non-respirator-like products
- Possible use of standardized test fixture
- Mandatory application of quantitative leakage testing
- Establishment of true source control testing approach



Fixture used to support non-traditional face covering design

Simple changes like to be resolved early 2022; more complicated changes will require more time

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Questions?