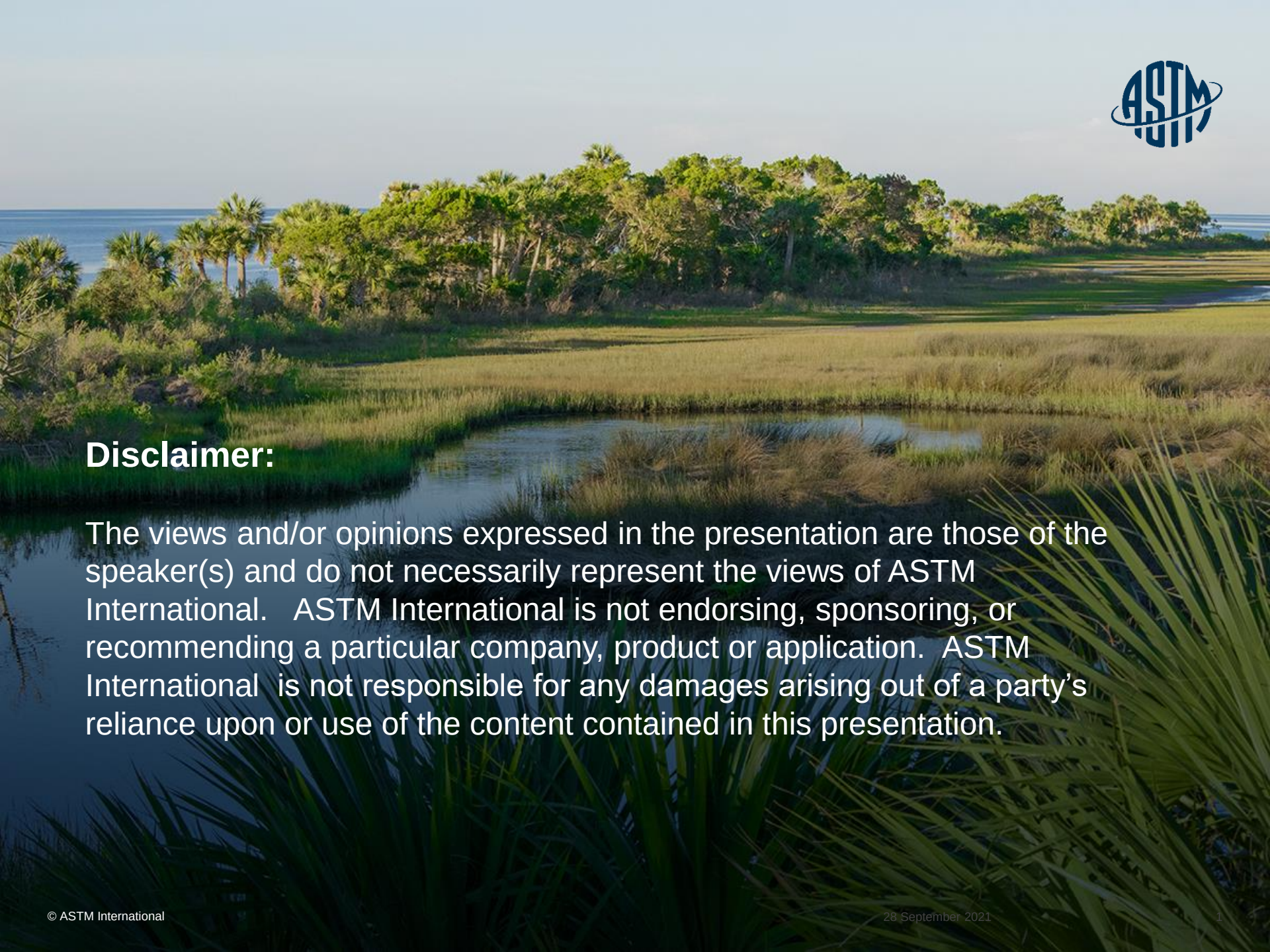

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# Standards and Their Application for the Production and Testing of Face Coverings and Related Products for Use against Infectious Diseases

**Presentation for Jordan Standards and Metrology Organization**

**Sponsored by ASTM International**

**Jeffrey O. Stull, MS ChE, MS Eng. Mgt.**

International Personnel Protection, Inc.™

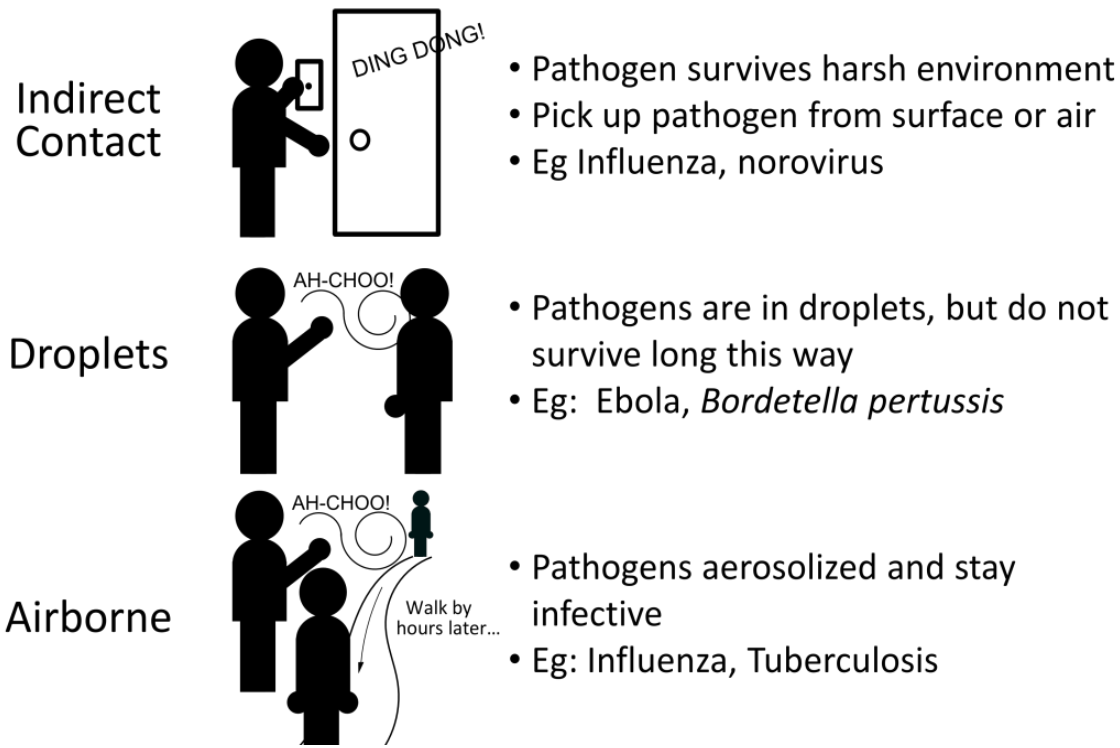
# Relevant Experience and Qualifications

- 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
  - Principal author for ASTM F1862 fluid resistance test/F2100 specification on medical face masks
  - 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 face covering products provide source capture or offer a degree of inhalation protection
2. Understand similarities and contrasts between respirators, medical face masks, and face coverings
3. Compare and contrast global standards related to these products
4. Know important differences for types of tests and requirements applied to these products

# Infectious Disease Transmission Modes




- Transmission mode affects PPE selection
  - 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

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

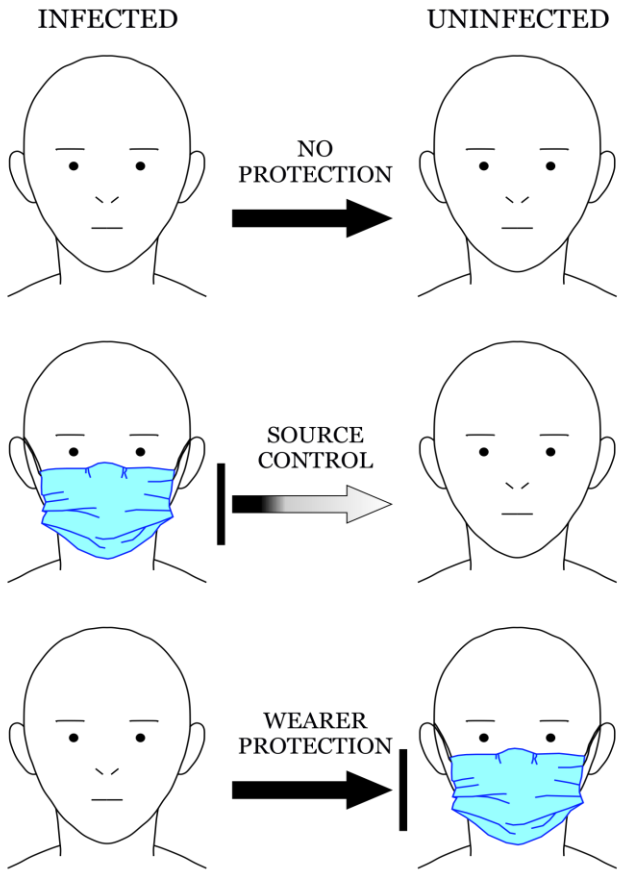
# SARS-CoV-2 Transmission

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



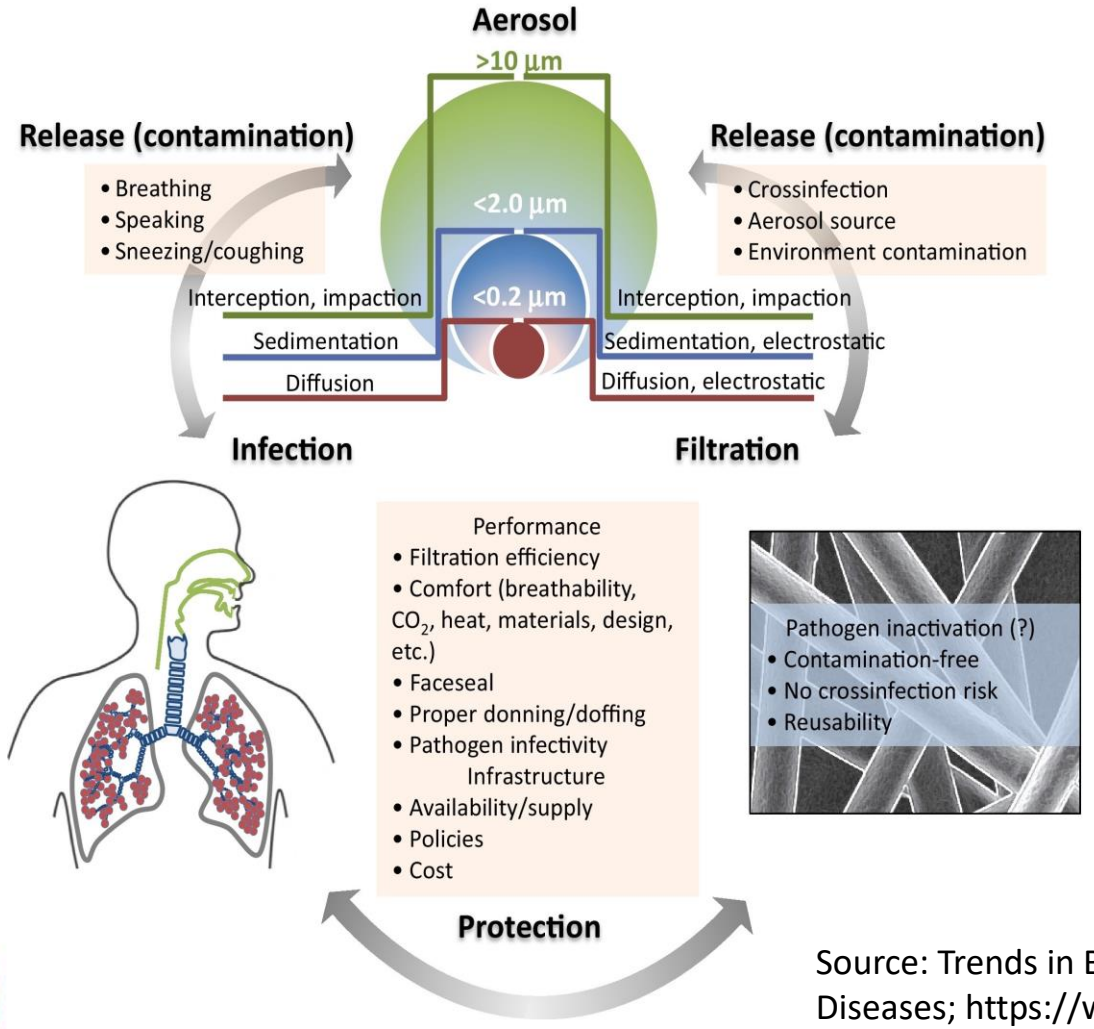

- In healthcare, historically “masks” used for infection control as a means for source control:
  - To prevent healthcare provider infection of patient
- Wearer protection for healthcare provider with known risks for exposure to infectious diseases
  - Principal examples: Tuberculosis, some forms of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

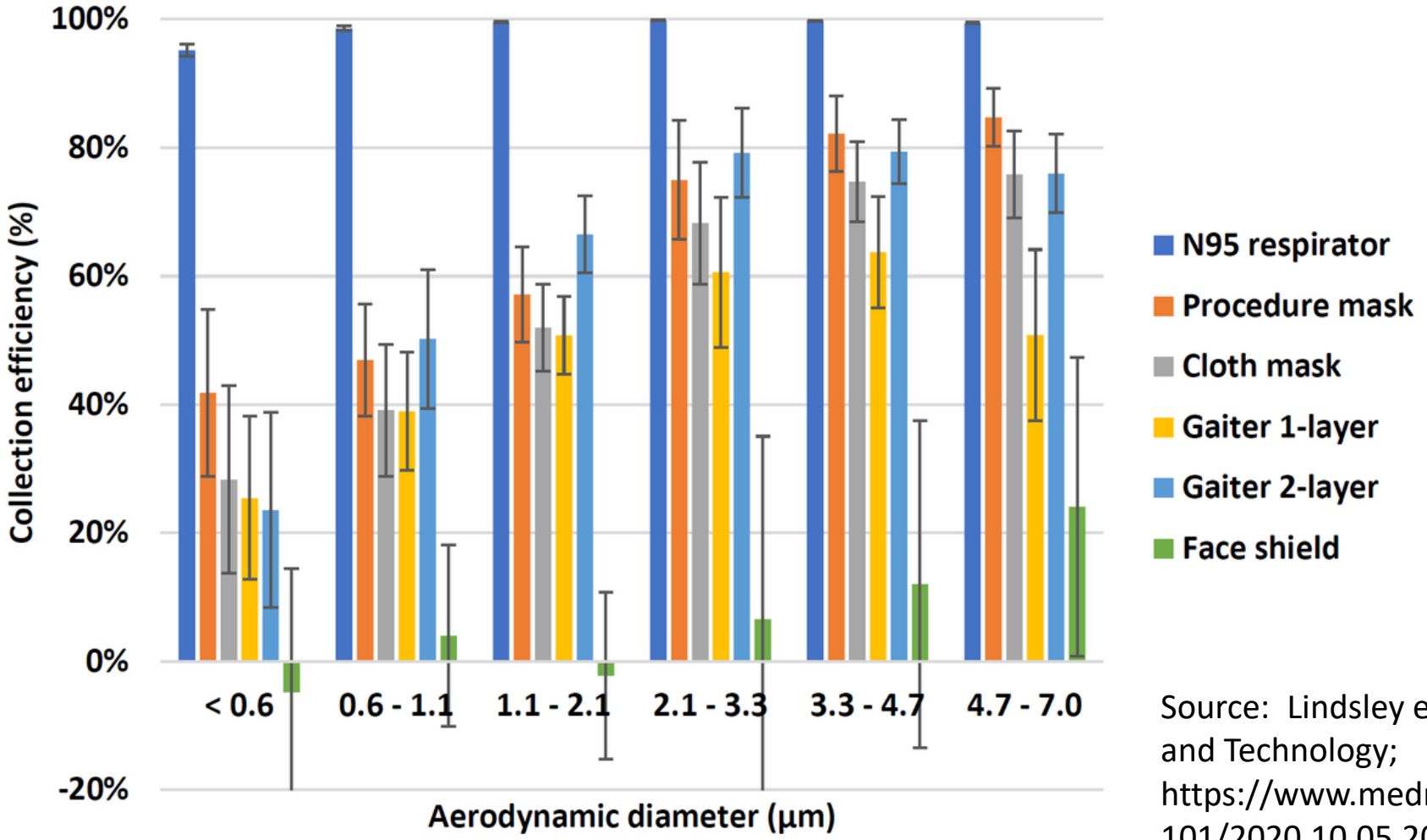
# Preventing Transmission by Protection




- Product prevents exposure to wearer by keeping infectious droplets or aerosols from being inhaled
- Effectiveness based on several factors
  - 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

# 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

# Assigned Protection Factor of Respirators

Filtering Facepiece Respirator (FFR)

APF = 10

Half Mask Air Purifying Respirator (APR)

APF = 10

Full Facepiece APR

APF = 50

Loose-Fitting Powered Air-Purifying Respirator (PAPR)

APF = 25*

Hooded PAPR

APF = 25*

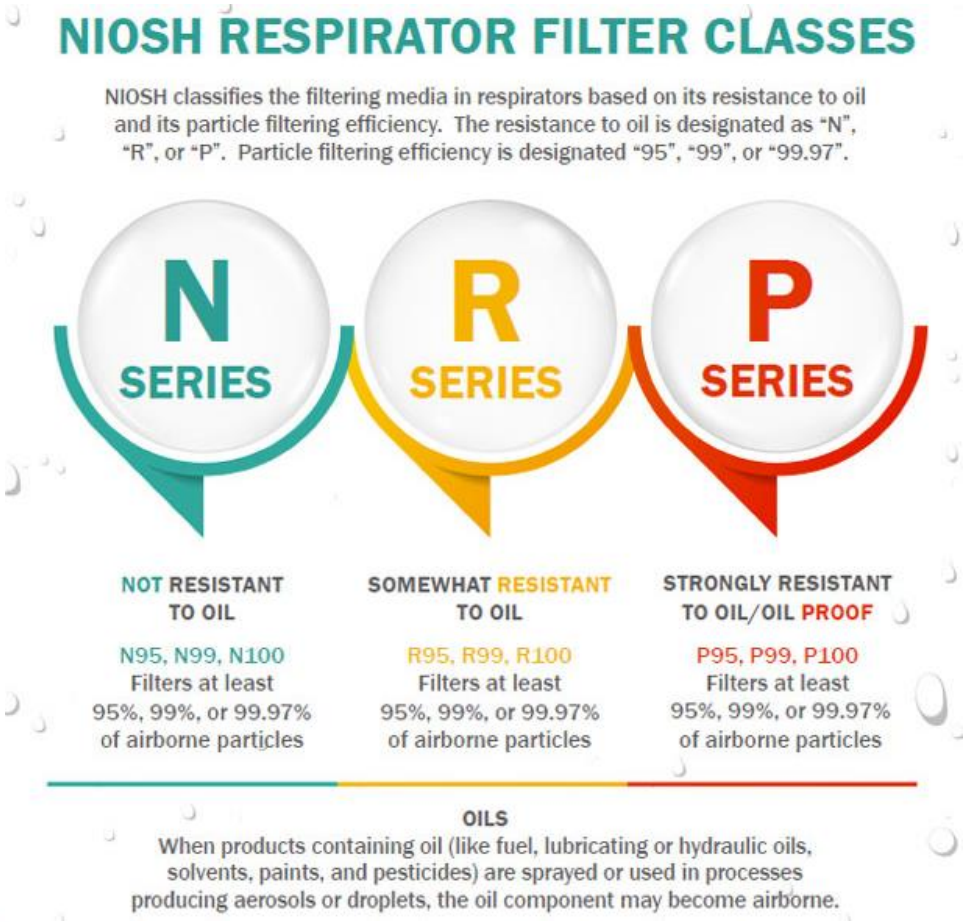
Self-Contained Breathing Apparatus (SCBA)

APF = 10,000

*In the United States, the Occupational Safety and Health Administration (OSHA) The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000.

Source: OSHA 3352-02 (2009), Assigned Protection Factors for the Revised Respiratory Protection Standard

# U.S. Filtering Facepiece Respirator Classifications




## 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 |

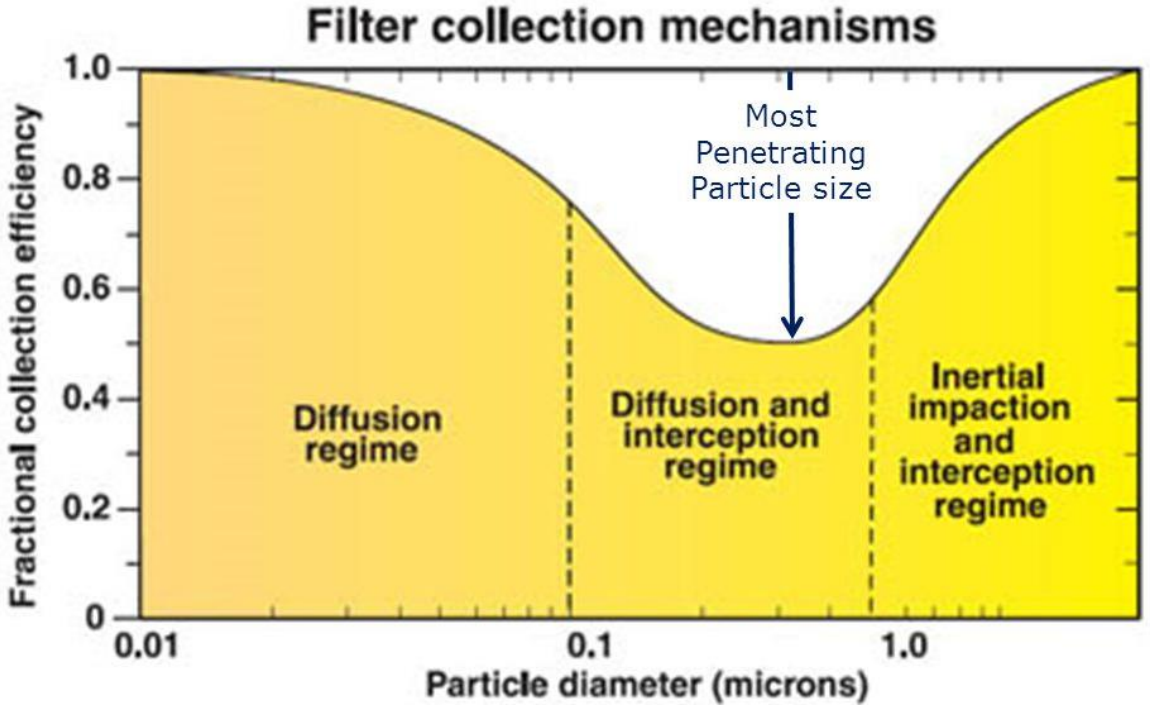
# Key Filtering Facepiece Respirator Tests

- 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)

# Comparison of US NIOSH N95 vs Europe FFP2

| Certification/ Class | USA N95 | Europe FFP2 |
|---|---|---|
| Standard | NIOSH-42C-FR84 | EN-149-2001 +A1:2009 |
| Filter performance | ≥ 95% | ≥ 94% |
| Test Agent | NaCl | NaCl and paraffin oil |
| Flow rate | 85 L/min | 95 L/min |
| Total inward leakage (TIL)[1] | N/A | ≤ 8% leakage (arithmetic mean) |
| Inhalation resistance | ≤ 343 Pa (at 85 L/min) | ≤ 70 Pa (at 30 L/min)<br>≤ 240 Pa (at 95 L/min)<br>≤ 500 Pa (clogging) |
| Exhalation resistance | ≤ 245 Pa (at 85 L/min) | ≤ 300 Pa (at 160 L/min) |
| Exhalation valve leakage requirement | Leak rate ≤ 30 mL/min at -245 Pa | N/A |
| $CO_2$ clearance requirement | N/A | ≤ 1% |

[1]In USA, Occupational Safety and Health Administration requires individuals wearing respirators to have quantitative fit test and achieve “fit factor” of at least 100.

# Global Standards on Respirators for Healthcare

- **N95** (United States NIOSH-42CFR84)
- **FFP2** (Europe EN 149-2001)
- **KN95** (China GB2626-2006)
- **P2** (Australia/New Zealand AS/NZA 1716:2012)
- **Korea 1st class** (Korea KMOEL - 2017-64)
- **DS** (Japan JMHLW-Notification 214, 2018)
- **PFF2** (Brazil ABNT/NBR 13698, 2011)

*While these respirators are often judged equivalent, there are differences in how testing is performed and how products are approved or certified*

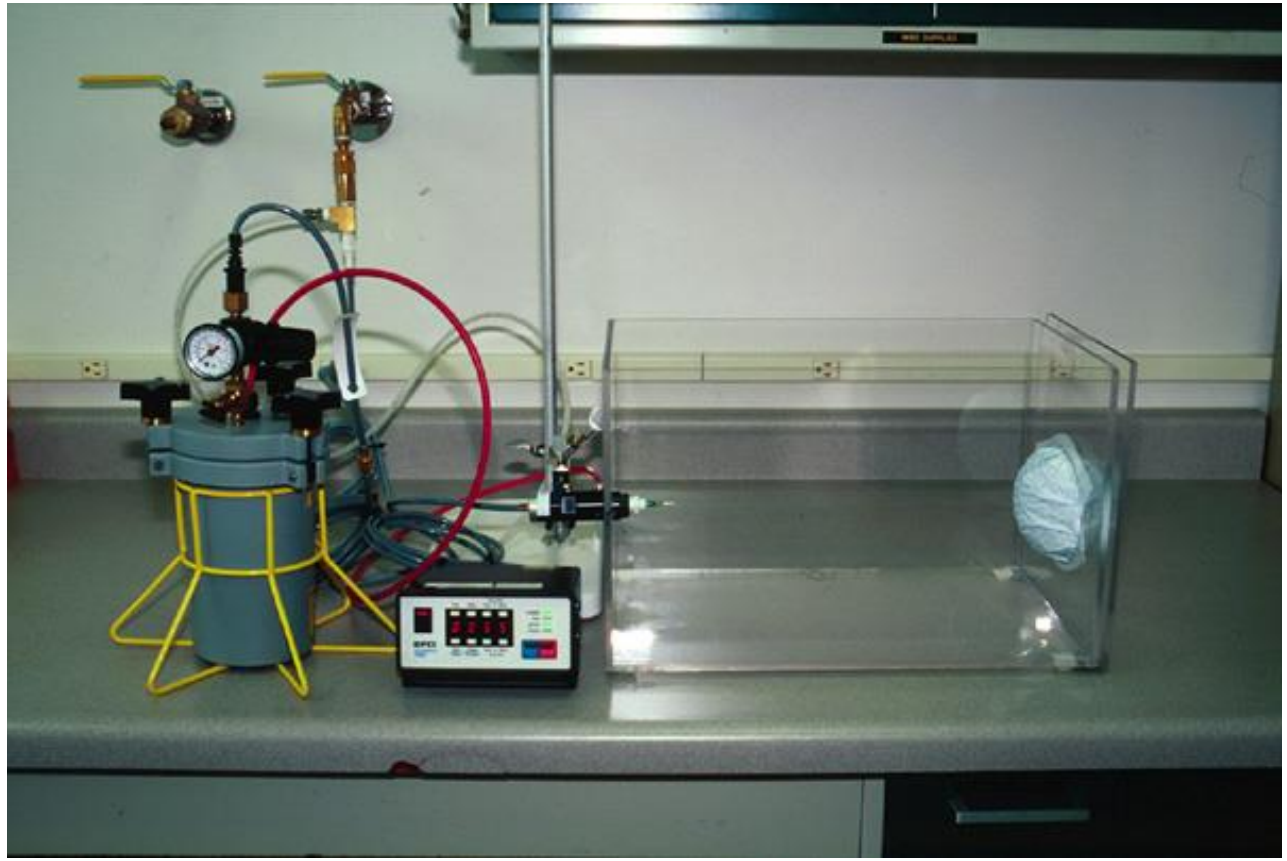
*During pandemic, there have multiple occasions of counterfeit products*

# Medical Face Masks (US ASTM F2100)

## Understanding ASTM levels of protection is Key

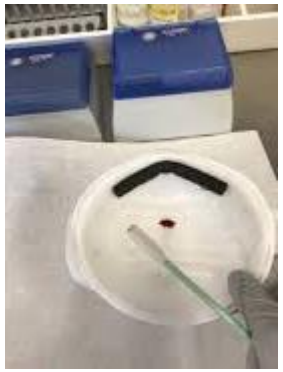
| Characteristics | Resistance to penetration by **synthetic blood,** minimum pressure in mm Hg for pass result | **Differential pressure,** mm H20/cm2 (Breathability) | **Bacterial** filtration efficiency | **Sub-micron particulates** filtration efficient at 0.1 micron | **Flame spread** |
|---|---|---|---|---|---|
| **ASTM F2100-11 Levels** | | | | | |
| 1 **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 |
| 2 **Level 2: moderate barrier protection** For low to moderate levels of aerosols, spray and/or fluids | 120 mm Hg | <5.0 | ≥98% | ≥98% | Class1 |
| 3 **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
  - Can be different than respirator test method
- Differential pressure
- Flammability
- Microbial cleanliness

Bacterial Filtration Efficiency Test Apparatus

16 CFR Part 1610 Flammability Test Apparatus

# US ASTM F2100 v EN 14683

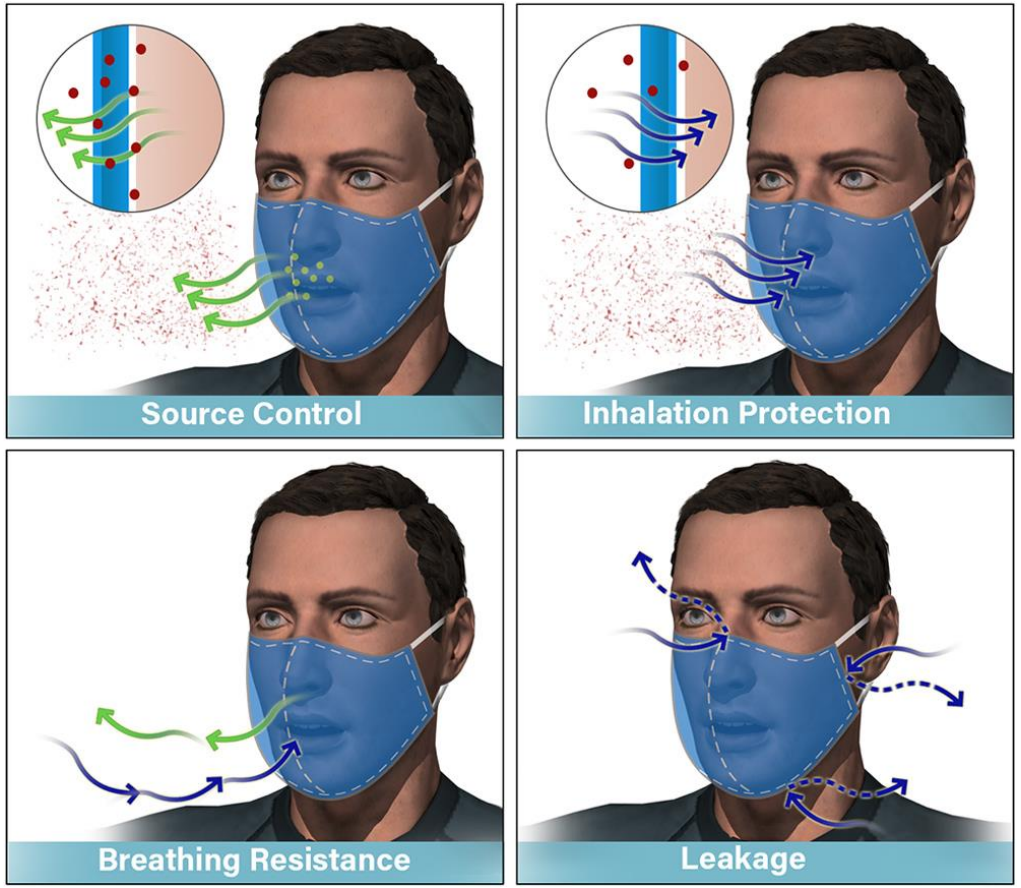
| Test | EN 14683 | | | ASTM F2100 | | |
|---|---|---|---|---|---|---|
| | Type I | Type II | Type IIR | Level 1 | Level 2 | Level 3 |
| Bacterial filtration efficiency, % | ≥95 | ≥98 | ≥98 | ≥95 | ≥98 | ≥98 |
| Differential pressure, mm $H_2O/cm^2$ Pa/$cm^2$ | <3.0 <29.4 | <3.0 <29.4 | <5.0 <49.0 | <4.0 <39.2 | <5.0 <49.0 | <5.0 <49.0 |
| Sub-micron particulate filtration efficiency at 0.1 micron, % | Not Required | Not Required | Not Required | ≥95 | ≥98 | ≥98 |
| Splash Resistance/ Synthetic Blood Resistance, mmHg Pass Result | Not Required | Not Required | 120 (16,0 kPa) | 80 | 120 | 160 |
| Flame Spread | Not Required | Not Required | Not Required | Class 1 | Class 1 | Class 1 |
| Microbial cleanliness (cfu/g) | ≤ 30 | ≤ 30 | ≤ 30 | Not Required | Not Required | Not Required |

# U.S. Surgical N95 Respirators

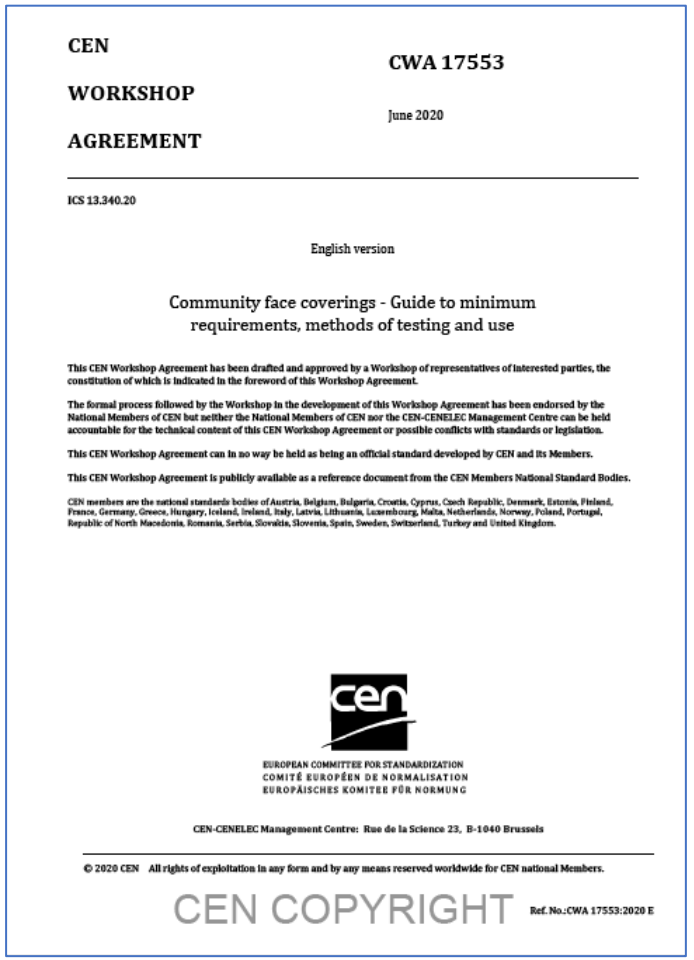
- N95 respirator that has been approved by NIOSH that is also subject to specific additional requirements normally applied to medical face masks
  - Fluid resistance
  - Flammability
  - Biocompatibility (cytotoxicity, skin irritation, sensitization)
- Joint approval process between U.S. NIOSH and U.S.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

# Face Coverings

- **ASTM F3502**, Specification for Barrier Face Coverings
  - 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

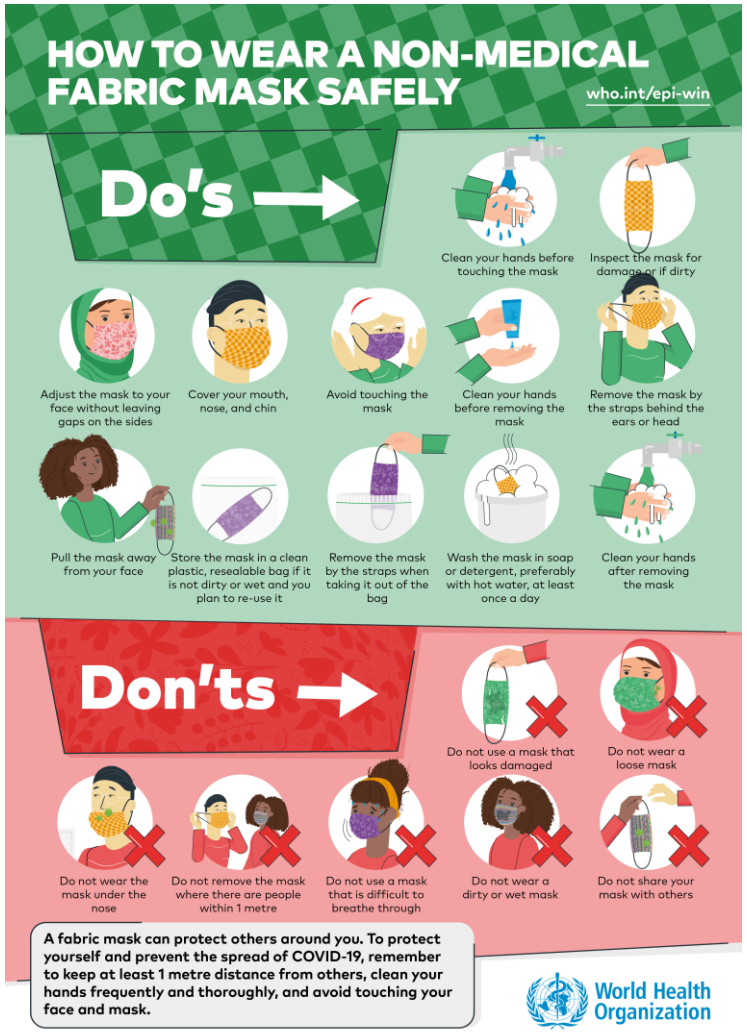


# Global Face Covering Standards


- Numerous standards or guides have been developed through-out the world
- Large differences in test methods and requirements
- Global harmonization not likely in short term

# Range of Face Covering Wearing Instructions




Nose Wire

Use Brace

Double Masking


Adjust Ear Loops

Don't use 2 disposable masks


Don't combine covering with KN95

# Varying Product Definitions

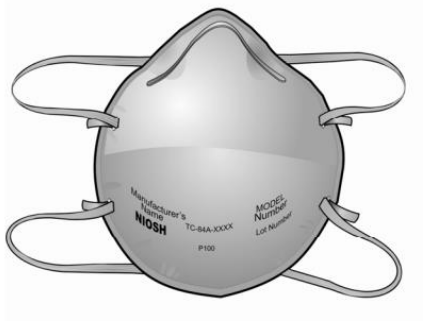
| Respirators | Medical Face Masks | Barrier Face Coverings |
|---|---|---|
| Personal protective equipment (PPE) designed to protect the wearer from inhalation of hazardous atmospheres | an item of protective clothing designed to protect portions of the wearer's face, including the mucous membrane areas 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 |

# Key Differences between Product Types

| | Face Mask (Cloth/Paper masks)** | Surgical Mask** | N95 Respirator** | Surgical N95 & N99 Respirators | |
|---|---|---|---|---|---|
| | Reusable or Disposable | Disposable | Disposable | Disposable** | Reusable |
| |  |  |  |  |  |
| **Is it a medical device?** | NO | YES | NO | YES | YES |
| **Purpose** | Prevents large particles expelled by you, the wearer, from reaching the environment. | Prevents large particles expelled by you, the wearer when you are ill, from reaching the environment.<br><br>To be used as a physical barrier to protect you from large droplets of blood or body fluids. | Reduces your exposure to very small airborne particles or contaminants.<br><br>May not protect against sprays and direct liquid splashes. | Provides the protection of both a surgical mask and N95 respirator.<br><br>To be used as a physical barrier from large droplets of blood or body fluids as well as very small particles (e.g. fine aerosolised droplets), such as those produced by coughing. | Provides the protection of both a surgical mask and N95 respirator.<br><br>To be used as a physical barrier from large droplets of blood or body fluids as well as very small particles (e.g. fine aerosolised droplets), such as those produced by coughing. |
| **Filtration efficiency** | Does not fit tightly | Bacterial filtration efficiency above 95% | Minimum 95% against particulate aerosols (of 0.3 micron in size) free of oil | Minimum 95% against particulate aerosols (of 0.3 micron in size) free of oil. | Minimum 95% against particulate aerosols (of 0.1 ~ 0.3 micron in size) free of oil. |
| **Fit** | Does not fit tightly | Does not fit tightly | Tight fit | Tight fit | Tight fit |

***Source: Health Sciences Authority of Singapore*

# 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

# Explanation of ASTM F3502 Specification on Barrier Face Coverings

# ASTM F3502 Scope

- Specification
- Mandatory performance-based requirements
- Primarily for source control (protect others) but also defines a level of inhalation protection (protect wearer)
- Includes requirements on
  - Design (limited)
  - Performance criteria with test methods
  - Labeling and user information
  - Minimum conformity assessment process

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 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 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.

**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 aerosols from the wearer's nose and mouth into the air; and (*2*) to potentially offer a degree of particulate filtration to reduce the amount of 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.

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

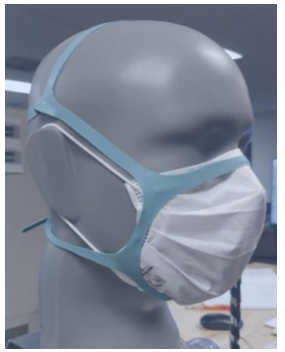
Current edition approved Feb. 15, 2021. Published February 2021. DOI: 10.1520/F3502-21.



Don't use 2 disposable masks

# ASTM F3502 Design Criteria

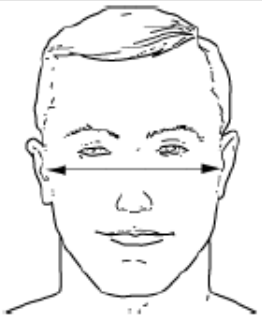
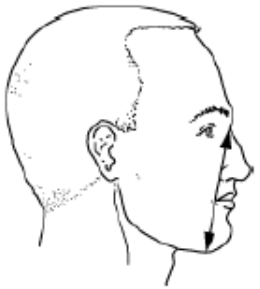
- Kept to a minimum to permit product type flexibility
  - Not be made of irritating or toxic materials
  - Not pose a flammability hazard
  - Cover at least nose and mouth
  - Fit snugly against the wearers face
  - Have a means of head retention
  - Not employ exhaust valves or open vents
  - Be permitted to be available in a universal or multiple sizes
- Manufacturer required to conduct a “design analysis” to assess leakage around edges of BFCs on intended user population



# ASTM F3502 Leakage Assessment

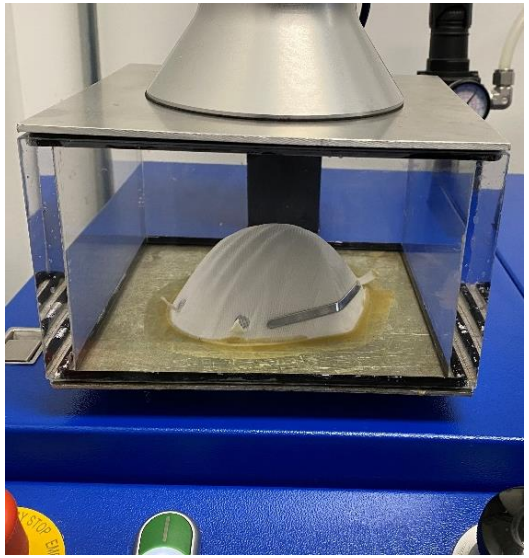
- Manufacturer must perform analysis to show that leakage around edges is minimal
- Modified form of ASTM F3407 can be performed to show leakage levels:
  - Smaller test subject panel
  - No specific passing criteria

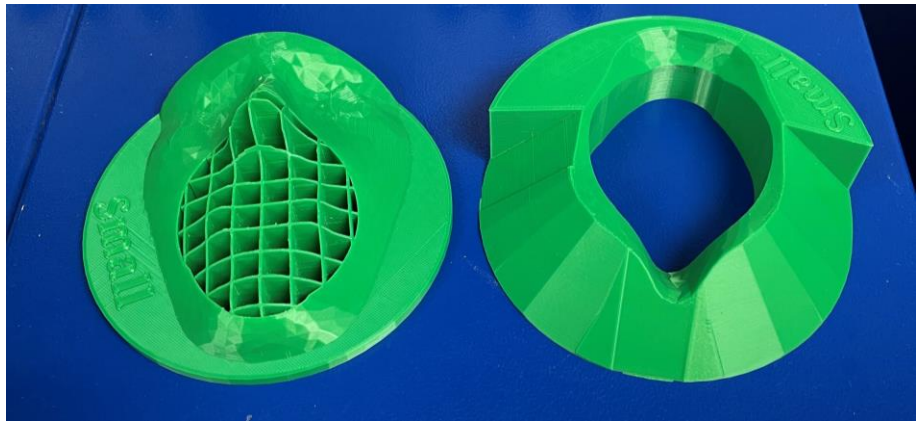
**TABLE X1.1 Measured Face Dimensions**

| 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 |  |

# ASTM F3502 Performance Criteria

- Sub-micron particulate filtration efficiency and airflow resistance are based on same NIOSH tests used to qualify N95 respirators
- Tests are performed on full products
  - Fixtures permitted to evaluate “flat” products
- Minimum level established
  - Filtration: ≥ 20%
  - Breathability: ≤ 15 mm $H_2O$





# ASTM F3502 Performance Classification

- Two separate classifications

| 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 $H_2O$ |

- Performance levels do not imply specific protection levels or applications

# ASTM F3502 Report

- Documentation of results/test information
- Provides
  - Manufacturer name
  - Product name or model number
  - Laboratory name/address
  - Laboratory accreditation info.
  - Specific test values
  - Laundering method & # cycles, if reusable
  - Other test documentation
  - Performance classifications

| 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 | | | | |

# ASTM F3502 Product Labeling

- 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)

**MEETS ASTM F3502, SPECIFICATION ON BARRIER FACE COVERINGS.**

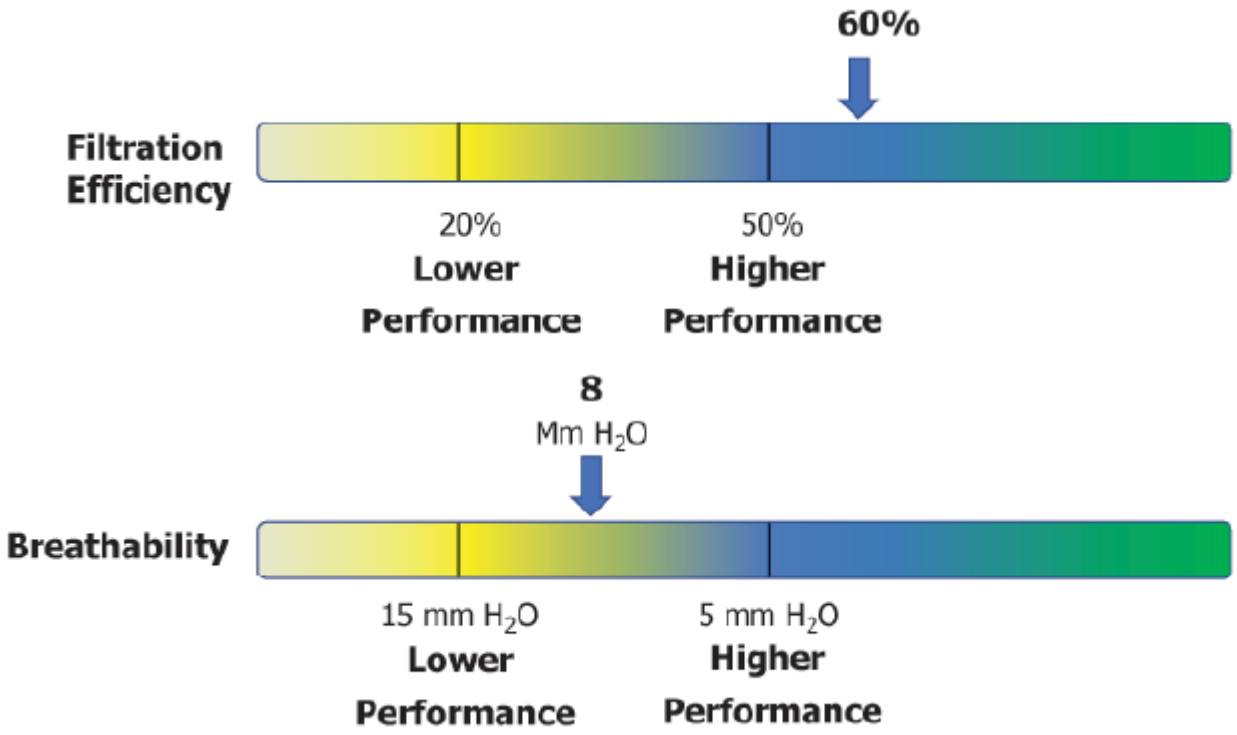
**THIS PRODUCT IS PRIMARILY INTENDED AS A MEANS OF SOURCE CONTROL FOR MINIMIZING THE PROJECTION OF THE EXPELLED MATERIALS FROM THE WEARER’S NOSE AND MOUTH.**

**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

# ASTM F3502 Rating Methods

- Suggested Scheme for Indicating Face Covering Performance



# ASTM F3502 User Instructions

- User instructions required for smallest saleable unit/package
- Content
  - Repeat of 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***

# ASTM F3502 Conformity Assessment

- Conformity assessment encompasses how a manufacturer product meets the ASTM F3502 standard
- Manufacturer self-declare conformance, set the frequency of testing, and address product quality (reference to ASTM F3050-17)
- Filtration efficiency and airflow resistance must be performed by laboratory accredited to ISO 17025
- Manufacturers are permitted to meet more rigorous requirements (e.g., 3rd party certification organization)

# Regulating Domestic Protection and the Import of Masks and Face Coverings (Perspectives from the U.S. and other countries)

Ask directly or place question into Chat Box

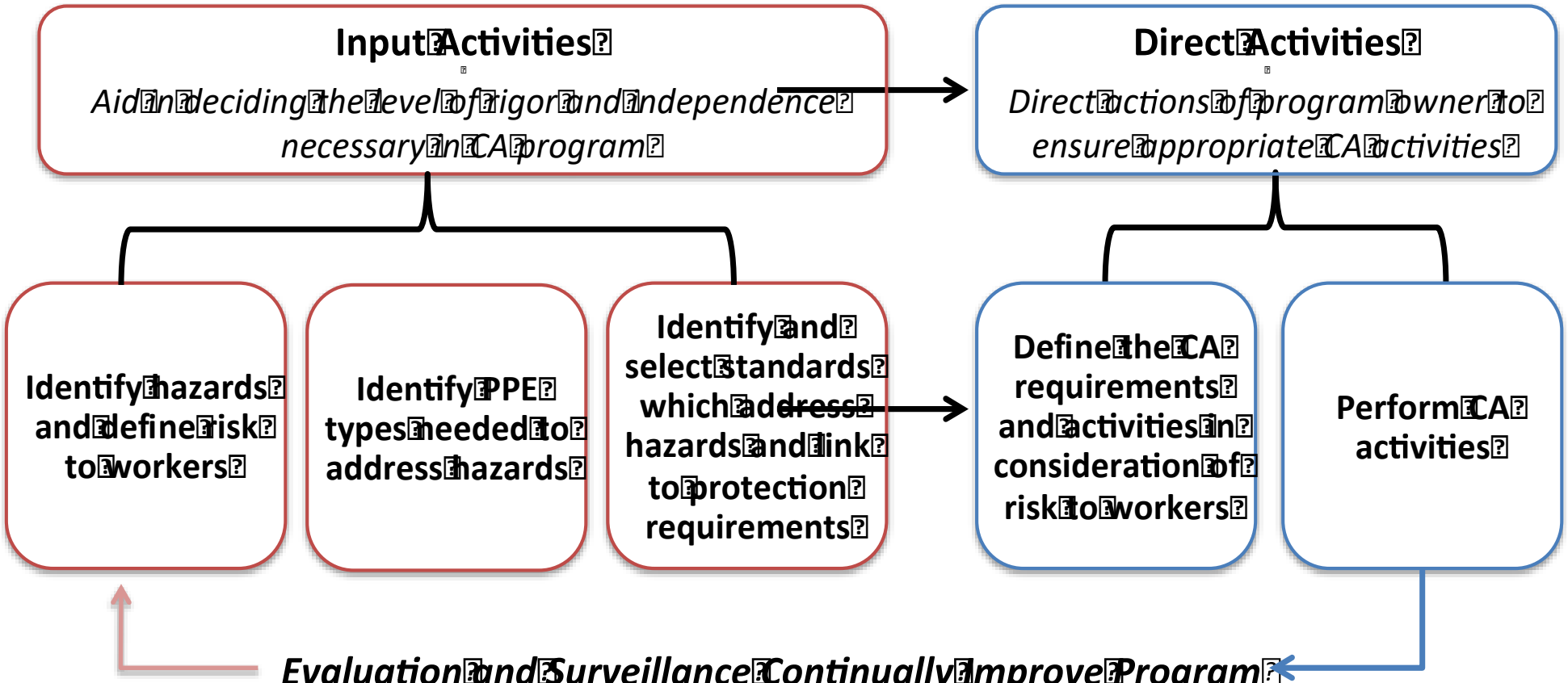
# Presentation Topics and Objectives

1. Understand the role and importance of conformity assessment
2. Compare and contrast different conformity assessment process
3. Use conformity assessment to ensure quality of domestic production
4. Use conformity assessment to aid in importing quality products

# Why Conformity Assessment?

- Provides a means for verifying that products (and services) meet a specific standard
  - Verifies manufacturer adherence to specific requirements
  - Establishes that required testing is performed by competent laboratories
  - Can ensure that product/service has continuing compliance to standard, through:
    - Institution of quality assurance requirements and audits
    - Follow on or periodic testing
    - Market surveillance activities
- Increasing risk (of product hazards or failure) warrants increased conformity assessment requirements

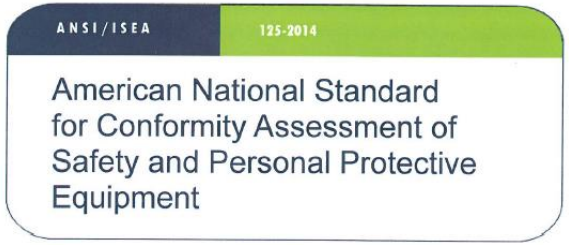
# Ideal Conformity Assessment Process

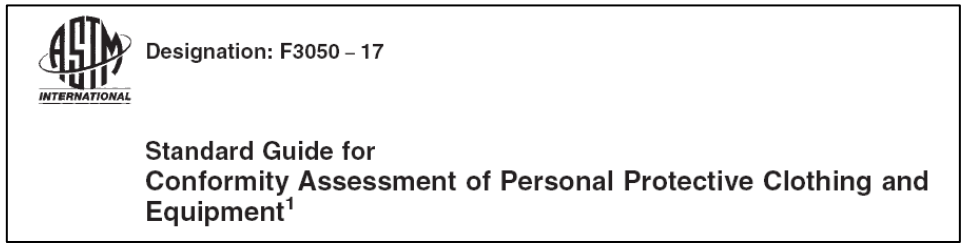


# Key Components of Conformity Assessment

- 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

# Current US PPE Conformity Assessment Standards




| Element | Level 1 | Level 2 | Level 3 | Model A | Model B | Model C | Model D |
|---|---|---|---|---|---|---|---|
| QMS | Supplier | ISO 9001 | 3rd party CO | Supplier | ISO 9001 | 3rd party CO | 3rd party CO |
| Test lab | Supplier | ISO 17025 | 3rd party CO | Supplier | ISO 17025 | 3rd party CO | By CO only |
| Retesting | Supplier | Supplier | 3rd party CO | Supplier | Supplier | 3rd party CO | 3rd party CO |
| Prod. Rev. | 5 yrs | 5 yrs | 3rd party CO | Supplier | Supplier | Annual; CO | Annual; CO |
| CAPA | Supplier | Supplier | Supplier | Supplier | Supplier | Supplier/CO | Supplier/CO |
| Recalls | Supplier | Supplier | Supplier | Supplier | Supplier | Supplier/CO | Supplier/CO |
| Cert. Org. | N/A | N/A | ISO 17065 | N/A | N/A | ISO 17065 | ISO 17025 |
| Declaration | Supplier | Supplier | 3rd party CO | Supplier | ISO 17050 | 3rd party CO | 3rd party CO |

QMS = quality management system; CAPA = corrective and preventative action; CO = certification organization

# U.S. NIOSH Approval Process for Respirators

**Receiving/Records Room**

1. Receive samples
2. Receive application/documents
3. Receive application fee

**Initial Engineering Review**

1. Review application reason/content
2. Verify new or revised Configuration
3. Issue fee estimate
4. Assign appropriate tests

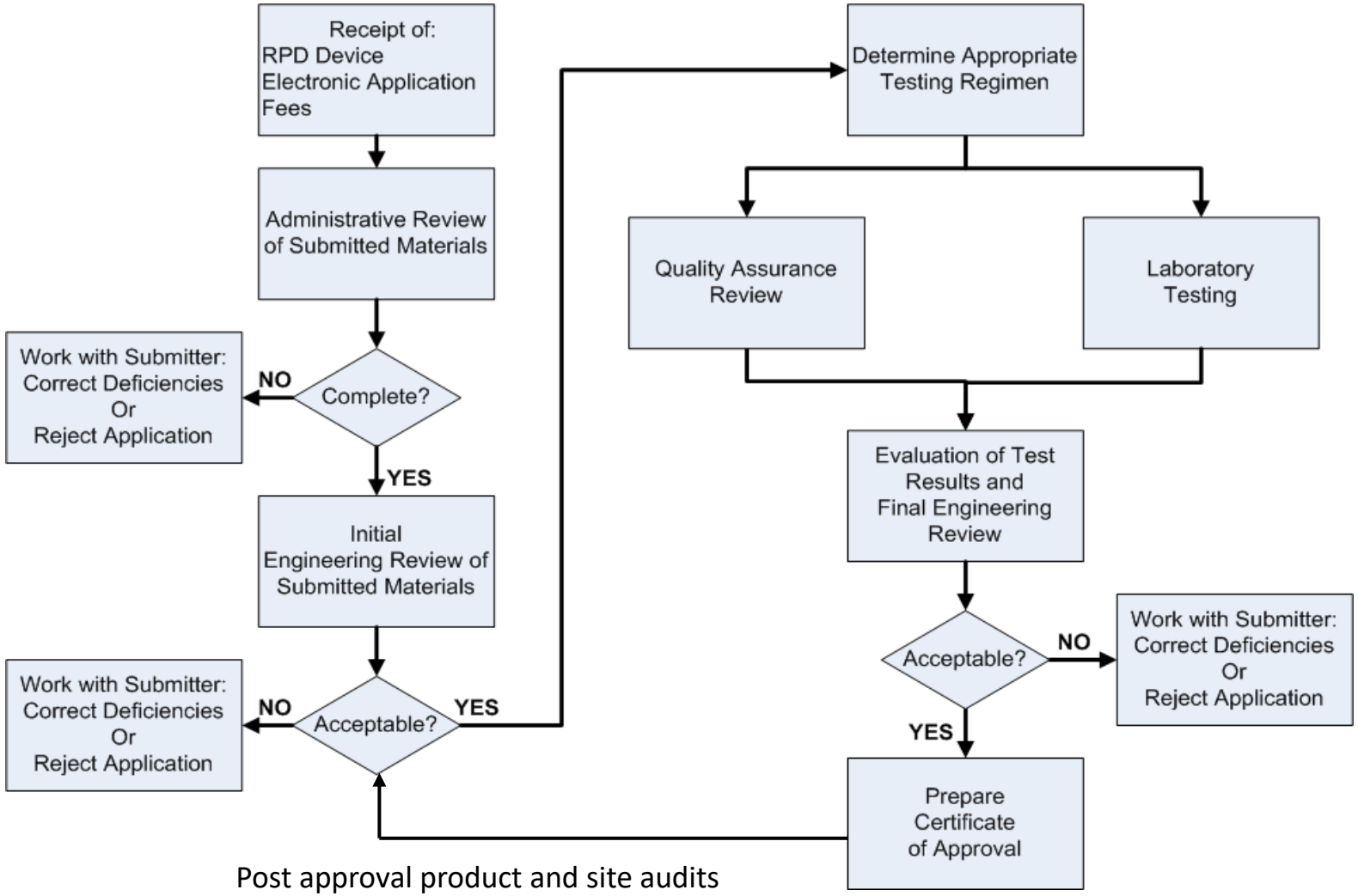
**Testing and Quality Assurance**

1. Conduct assigned testing
2. Assess quality management system
3. Review inspection and sample procedures
4. Perform final review of documentation

**Final Engineering Review**

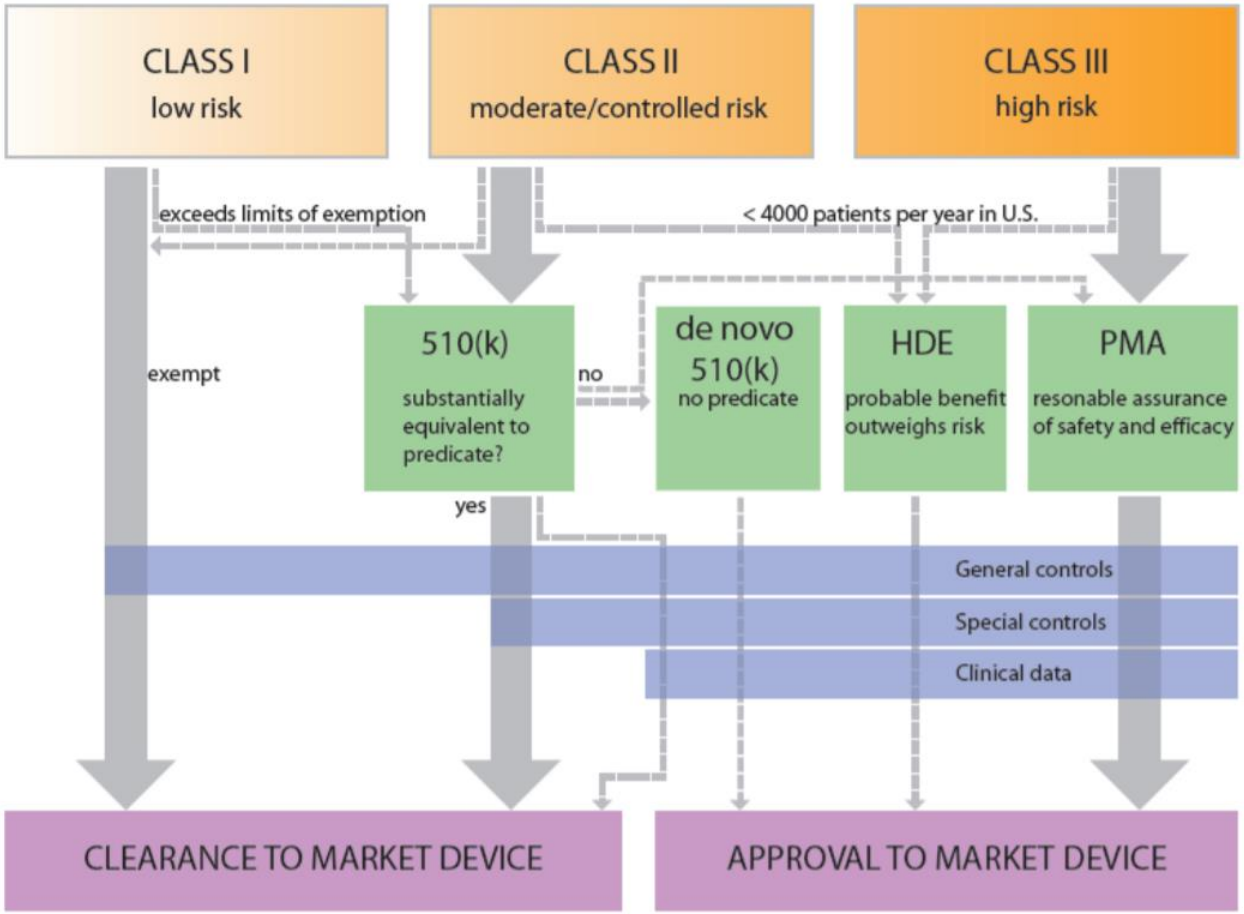
1. Review test data
2. Update NIOSH parts database
3. Review and finalize labeling
4. Finalize approval /denial package

# Flow Chart for NIOSH Approval Process



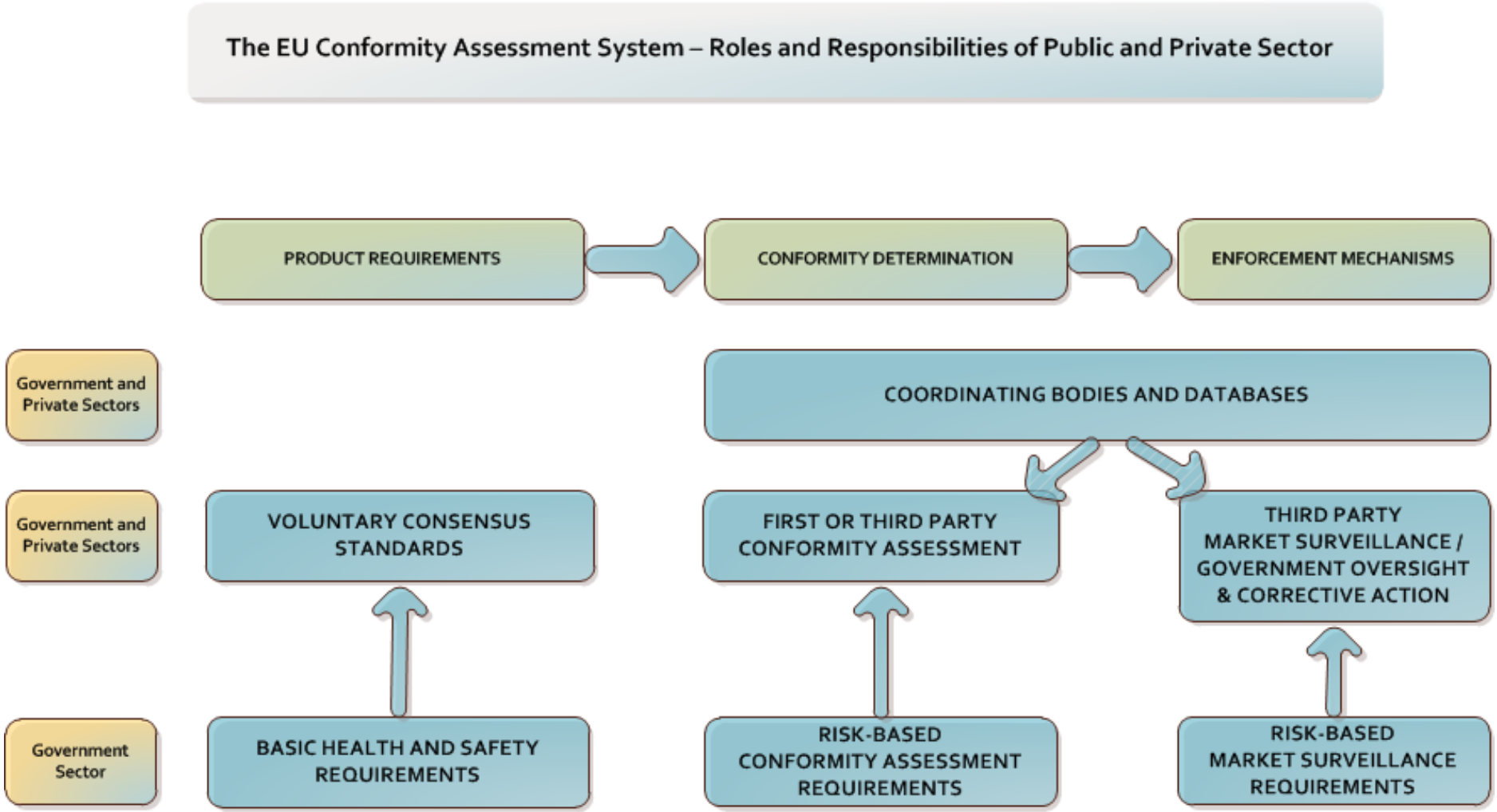

Post approval product and site audits

# U.S. FDA Medical Device Clearance Process



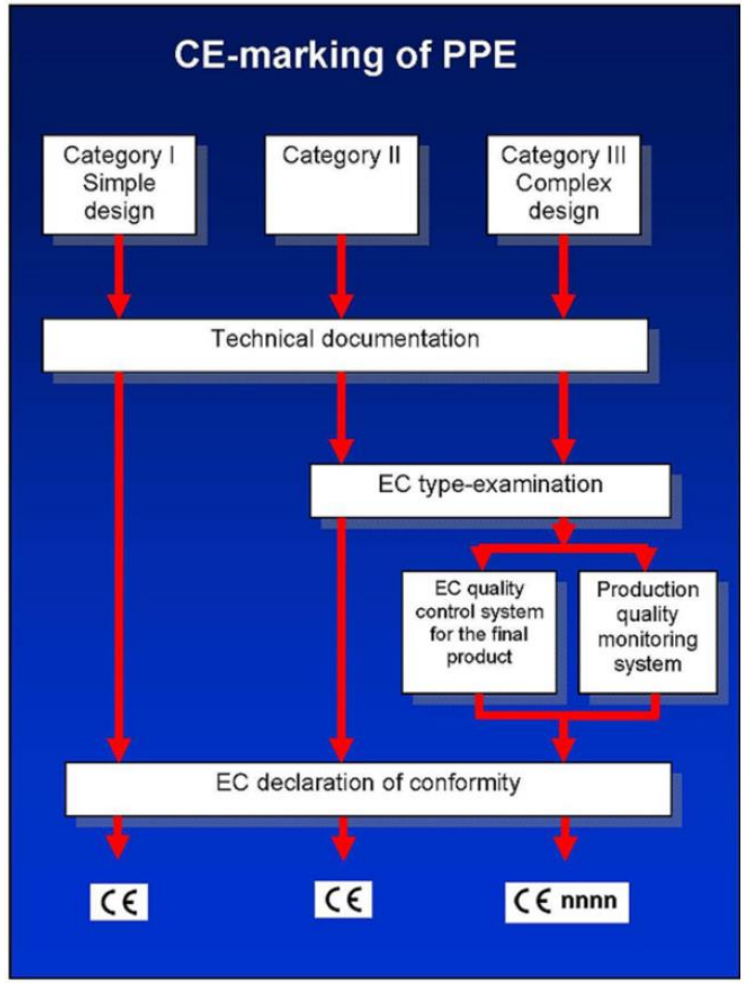

- Class I devices
  - Manufacturer meets general controls
- Class II devices (e.g., medical masks, gowns)
  - 510(k) submission
    - Demonstration of substantial equivalence to predicate product
    - Use of recognized standards
    - Manufacturer provision of safety and efficacy data
    - Good manufacturing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

# European Union Conformity Assessment System



# European Union Conformity Assessment Principles

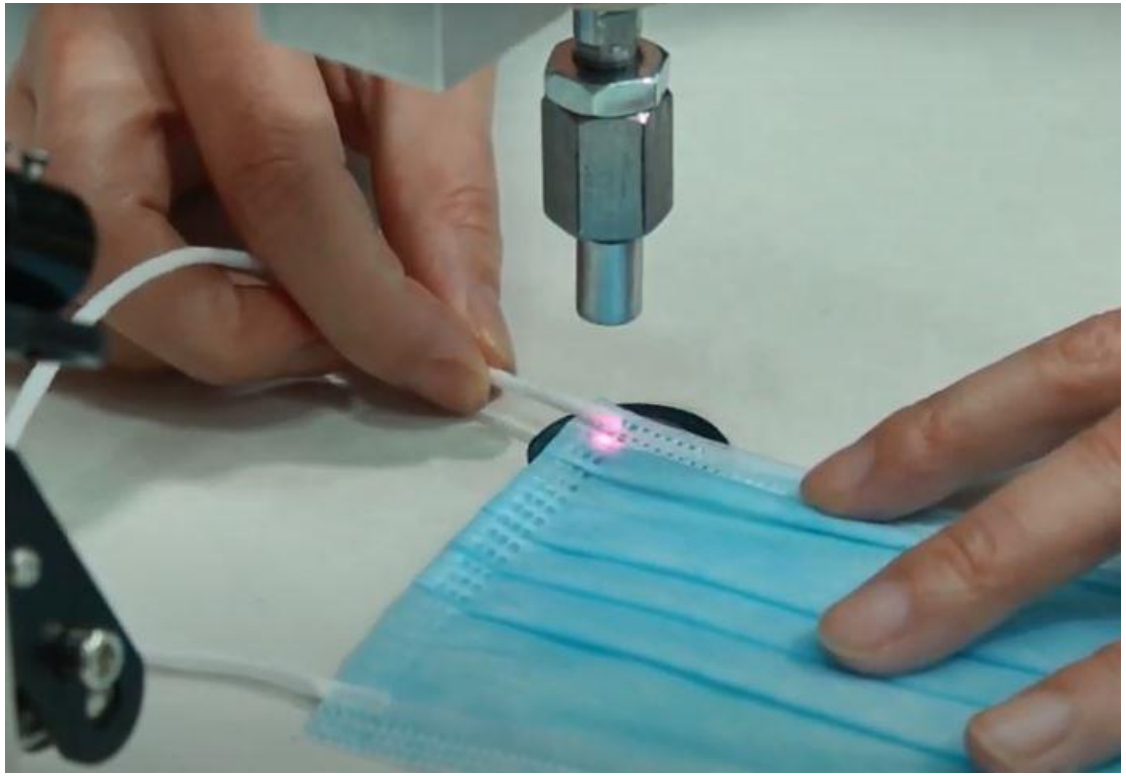
- Established by EU law (PPE Directive)
- Consistent with ISO CASCO standards
- Manufacturers are required to fulfill Basic Health and Safety Requirements before placing products on the market (voluntary consensus standards; not mandatory)
- Hazard-based conformity assessment procedures
- Post-market surveillance of PPE designed to protect against serious hazards; risk-based corrective actions
- Shared responsibilities – economic operators, private sector 3rd party bodies, government authorities, NGOs
- Transparency, collaboration, coordination



# Importance of Quality Management Systems

- Establishment of quality program essential to documenting quality
- For medical mask manufacturing
  - ISO 9001 registration of manufacturing with additional provisions specific to product
- For medical mask testing
  - Accreditation of laboratory to ISO 17025 for applicable test methods
- For medical mask certification
  - Accreditation of commercial certification bodies to ISO 17065 specific to products being certified
  - Government organizations may be exempt but should follow same practices specified in ISO 17065

# Establishment of Mask Manufacturing Capabilities



# Overall Inspection Scheme during Manufacturing

| Initial Inspections | In-process inspections | Final Inspections |
| --- | --- | --- |
| • Material quality<br>• Material testing | • Visual inspections<br>• Non-destructive tests | • Final checks before packaging<br>• Destructive testing |

# Classification of Defects and Attributes

| Classification | Description | Consequence | AQL |
|---|---|---|---|
| Critical | Product failure that results in condition immediately dangerous to life and health | Product recall | Full inspection |
| Major A | Product hazard that is likely to cause physical harm to end user and is not detectable by end user | Product recall or safety alert | 1.0% |
| Major B | Product hazard that causes reduced protection that is detectable by end user | Safety alert | 2.5% |
| Minor | Product hazard that reduces usability of product | No action | 4.0% |

- Application of Quality Standards
  - ISO 2859-1, Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
  - ANSI/ASQ Z1.4, similarly named

# Determination of Inspection Levels

| Lot or batch size | Special inspection levels | | | | General inspection levels | | |
|---|---|---|---|---|---|---|---|
| | S-1 | S-2 | S-3 | S-4 | I | II | III |
| 2 to 8 | A | A | A | A | A | A | B |
| 9 to 15 | A | A | A | A | A | B | C |
| 16 to 25 | A | A | B | B | B | C | D |
| 26 to 50 | A | B | B | C | C | D | E |
| 51 to 90 | B | B | C | C | C | E | F |
| 91 to 150 | B | B | C | D | D | F | G |
| 151 to 280 | B | C | D | E | E | G | H |
| 281 to 500 | B | C | D | E | F | H | J |
| 501 to 1200 | C | C | E | F | G | J | K |
| 1201 to 3200 | C | D | E | G | H | K | L |
| 3201 to 10000 | C | D | F | G | J | L | M |
| 10001 to 35000 | C | D | F | H | K | M | N |
| 35001 to 150000 | D | E | G | J | L | N | P |
| 150001 to 500000 | D | E | G | J | M | P | Q |
| 500001 and over | D | E | H | K | N | Q | R |

# Determination of Sampling Plans

| Sample size code letter | Sample size | Acceptance Quality Limits, *AQLs*, in Percent Nonconforming Items and Nonconformities per 100 Items (Normal Inspection) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 0.010 | | 0.015 | | 0.025 | | 0.040 | | 0.065 | | 0.10 | | 0.15 | | 0.25 | | 0.40 | | 0.65 | | 1.0 | | 1.5 | | 2.5 | | 4.0 | | 6.5 | | 10 | |
| | | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re |
| A | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | 0 | 1 | | |
| B | 3 | | | | | | | | | | | | | | | | | | | | | | | | | 0 | 1 | | | | |
| C | 5 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2 |
| D | 8 | | | | | | | | | | | | | | | | | | | | | | | 0 | 1 | | | 1 | 2 | 2 | 3 |
| E | 13 | | | | | | | | | | | | | | | | | | | | | 0 | 1 | | | 1 | 2 | 2 | 3 | 3 | 4 |
| F | 20 | | | | | | | | | | | | | | | | | | | 0 | 1 | | | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 6 |
| G | 32 | | | | | | | | | | | | | | | | | 0 | 1 | | | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 6 | 7 | 8 |
| H | 50 | | | | | | | | | | | | | | | 0 | 1 | | | | | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 6 | 7 | 8 |
| J | 80 | | | | | | | | | | | | | 0 | 1 | | | | | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 |
| K | 125 | | | | | | | | | | | 0 | 1 | | | | | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 14 | 15 |
| L | 200 | | | | | | | | | 0 | 1 | | | | | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 14 | 15 | 21 | 22 |
| M | 315 | | | | | | | 0 | 1 | | | | | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 14 | 15 | 21 | 22 | | |
| N | 500 | | | | | 0 | 1 | | | | | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 14 | 15 | 21 | 22 | | | | |
| P | 800 | | | 0 | 1 | | | | | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 14 | 15 | 21 | 22 | | | | | | |
| Q | 1250 | 0 | 1 | | | | | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 14 | 15 | 21 | 22 | | | | | | | | |
| R | 2000 | | | | | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 14 | 15 | 21 | 22 | | | | | | | | | | |

| Sample size code letter | Sample size | 15 | | 25 | | 40 | | 65 | | 100 | | 150 | | 250 | | 400 | | 650 | | 1000 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re | Ac | Re |
| A | 2 | | | | | | | | | | | | | | | | | | | | |
| B | 3 | | | | | | | | | | | | | | | | | | | | |
| C | 5 | 1 | 2 | 2 | 3 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 14 | 15 | 21 | 22 | 30 | 31 | 44 | 45 |
| D | 8 | 2 | 3 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 14 | 15 | 21 | 22 | 30 | 31 | 44 | 45 | | |
| E | 13 | 3 | 4 | 5 | 6 | 7 | 8 | 10 | 11 | 14 | 15 | 21 | 22 | 30 | 31 | 44 | 45 | | | | |
| F | 20 | 5 | 6 | 7 | 8 | 10 | 11 | 14 | 15 | 21 | 22 | | | | | | | | | | |
| G | 32 | 7 | 8 | 10 | 11 | 14 | 15 | 21 | 22 | | | | | | | | | | | | |
| H | 50 | 10 | 11 | 14 | 15 | 21 | 22 | | | | | | | | | | | | | | |
| J | 80 | 14 | 15 | 21 | 22 | | | | | | | | | | | | | | | | |
| K | 125 | 21 | 22 | | | | | | | | | | | | | | | | | | |
| L | 200 | | | | | | | | | | | | | | | | | | | | |
| M | 315 | | | | | | | | | | | | | | | | | | | | |
| N | 500 | | | | | | | | | | | | | | | | | | | | |
| P | 800 | | | | | | | | | | | | | | | | | | | | |
| Q | 1250 | | | | | | | | | | | | | | | | | | | | |
| R | 2000 | | | | | | | | | | | | | | | | | | | | |

↓ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 percent inspection.

↑ = Use the first sampling plan above the arrow.

Ac = Acceptance number.

Re = Rejection number.

# Key Decisions for Instituting National Program

1. Decide on a 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 imported product
5. Create program to fully cover all stages of mask standardization, manufacturing, conformity assessment, and surveillance

# Existing Jordan Standards

قاعدة فنية

هذه الوثيقة إلزامية التطبيق

**Technical Regulation**

*This document is mandatory*

معدات حماية الجهاز التنفسي ــ قناع نصفي بالترشيح للوقاية من الجزيئات ــ الاشتراطات و طرق الفحص وبطاقة البيان

*Respiratory protective devices - Filtering half masks to protect against particles - Requirement, testing and marking*

وافق مجلس إدارة مؤسسة المواصفات والمقاييس بجلسته رقم ٢٠١١/٣ المنعقدة بتاريخ ٢٠١١/٥/٣٠ على اعتماد المواصفة القياسية رقم ٢٠١١/١٩٤٣ كقاعدة فنية إلزامية التطبيق واعتبارها سارية المفعول من تاريخ ٢٠١١/٩/١٦ وذلك استناداً للصلاحيات المخولة له بموجب المادة (٨) فقرة (ب) من قانون المواصفات والمقاييس رقم ٢٠٠٠/٢٢.

مؤسسة المواصفات والمقاييس

المملكة الأردنية الهاشمية

قاعدة فنية

هذه الوثيقة إلزامية التطبيق

**Technical Regulation**

*This document is mandatory*

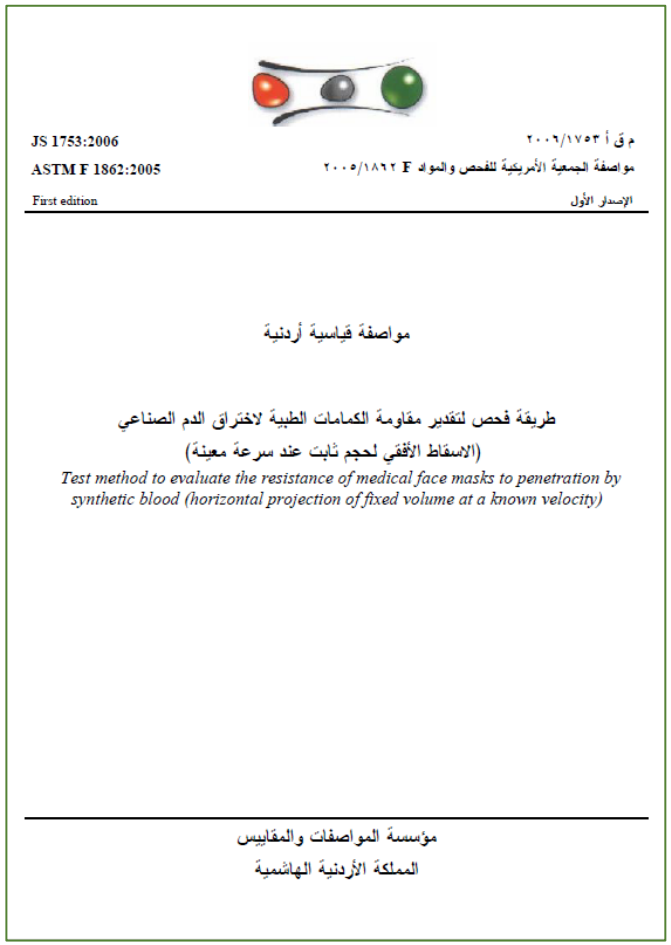
الكمامات الجراحية المستهلكة ــ الاشتراطات وطرق الفحص

*Disposable surgical masks — Requirements and test methods*

وافق مجلس إدارة مؤسسة المواصفات والمقاييس بجلسته رقم ٢٠٠٧/٦ المنعقدة بتاريخ ٢٠٠٧/٦/١٩ على اعتماد المواصفة القياسية رقم ٢٠٠٧/١٧٤٥ كقاعدة فنية إلزامية التطبيق واعتبارها سارية المفعول من تاريخ ٢٠٠٧/١٢/١٦ وذلك استناداً للصلاحيات المخولة له بموجب المادة (٨) فقرة (ب) من قانون المواصفات والمقاييس رقم ٢٠٠٠/٢٢.

مؤسسة المواصفات والمقاييس

المملكة الأردنية الهاشمية



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ASTM F 1862:2005 مواصفة الجمعية الأمريكية للفحص والمواد F ٢٠٠٥/١٨٦٢

First edition الإصدار الأول

مواصفة قياسية أردنية

طريقة فحص لتقدير مقاومة الكمامات الطبية لاختراق الدم الصناعي (الاسقاط الأفقي لحجم ثابت عند سرعة معينة)

*Test method to evaluate the resistance of medical face masks to penetration by synthetic blood (horizontal projection of fixed volume at a known velocity)*

مؤسسة المواصفات والمقاييس

المملكة الأردنية الهاشمية

# Questions?

Ask directly or place question into Chat Box