Classifications and Testing Requirements for general purpose face-coverings

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Masks and Respirators - relevant standards and requirements

My today's content will be around Masks:

- Not: Respirators (N95)
- Not: Surgical or Medical masks
- **General Purpose face-coverings**

Understanding the Difference

	Surgical Mask	N95 Respirator
Testing and Approval	Cleared by the U.S. Food and Drug Administration (FDA)	Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84
Intended Use and Purpose	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Reduces wearer's exposure to particles including small particle aerosols and large droplets (only non-oil aerosols).
Face Seal Fit	Loose-fitting	Tight-fitting
Fit Testing Requirement	No	Yes
User Seal Check Requirement	No	Yes. Required each time the respirator is donned (put on)
Filtration	Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Filters out at least 95% of airborne particles including large and small particles
Leakage	Leakage occurs around the edge of the mask when user inhales	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales
Use Limitations	Disposable. Discard after each patient encounter.	Ideally should be discarded after each patient encounter and after aerosol-generating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.

CDC NIOSH Centers for Disease Control and Prevention National Institute for Occupational Safety and Health

Why separate requirements for general purpose masks?

International standards for protective masks:

- Most – if not all – are focused on occupational health settings
- Focus: keep people safe at work
- Little to no formal standards and requirements exist for general purpose masks
- Voluntary guidance documents: AFNOR, CE, BSI, DND, NEN, …

Based on this comparison, it is reasonable to consider China KN95, AS/NZ P2, Korea 1st Class, and Japan DS FFRs as "equivalent" to US NIOSH N95 and European FFP2 respirators, for filtering non-oil-based particles such as those resulting from wildfires, PM 2.5 air pollution, volcanic eruptions, or bioaerosols (e.g. viruses). However, prior to selecting a respirator, users should consult their local respiratory protection regulations and requirements or check with their local public health authorities for selection guidance.

Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-2006)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS (Japan JMHLW-Notification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A	Depressurization to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurization to 0 Pa ≥ 15 sec
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1,470 Pa
CO_2 clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%

*Japan JMHLW-Notification 214 requires an Inward Leakage test rather than a TIL test.

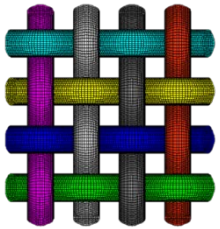
General purpose/general public face coverings

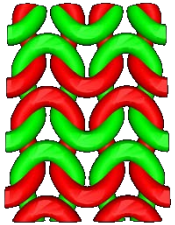
- Voluntary draft: https://www.aatcc.org/testing/emerging/
  - Basic design and guidance, very basic construction suggestions,

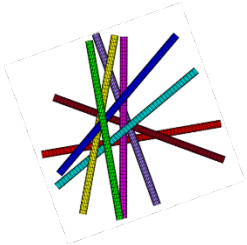
Particle Filtration		
Filtration efficiency	ASTM F2299 (or technical equivalent)	Face covering shall demonstrate a particle filtration efficiency of >70% with maximum 3-micron particle size at a face velocity of 10.4 cm/s. Testing shall be performed on “as-received” samples and after claimed number of washes.
Breathing Resistance - Air permeability		
Air permeability	EN 14683 (Annex C)	Using 8 L/min air flow, with standard diameter of 25 mm. Should exhibit a maximum of 36.7 Pa/cm^2.
	ASTM D737	Using a standard 125 Pa pressure drop. Use the standard 38.3 cm^2 test area. Should exhibit a minimum of a minimum of 37.5 ft^3/min/ft^2
	ISO 9237	Using a standard 100 Pa pressure differential. Should exhibit a minimum of 0.91 L/min/cm^2 (or 15 cm/s).

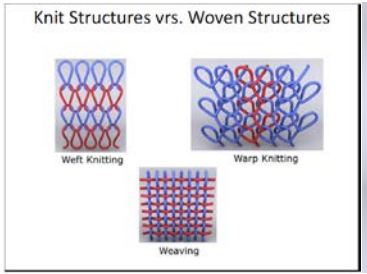
Masks - relevant standards and requirements

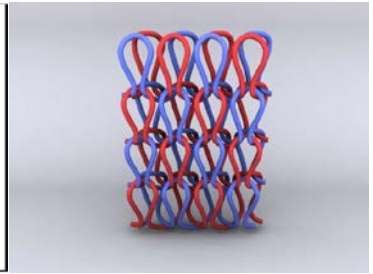
- **Non-Medical masks – general purpose/general public:**
  - One cloth does not equal another
  - Huge variation, no clear and easy guidance possible for structure
  - Efficiency should be measured, it cannot (yet) be predicted

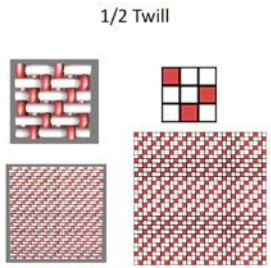












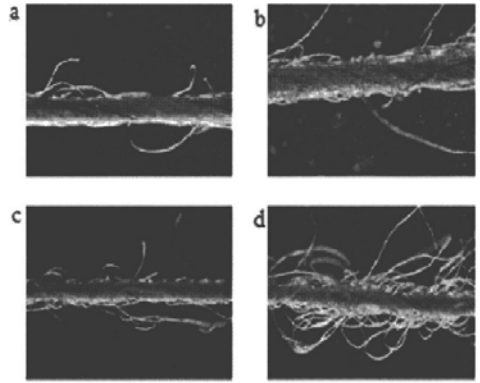
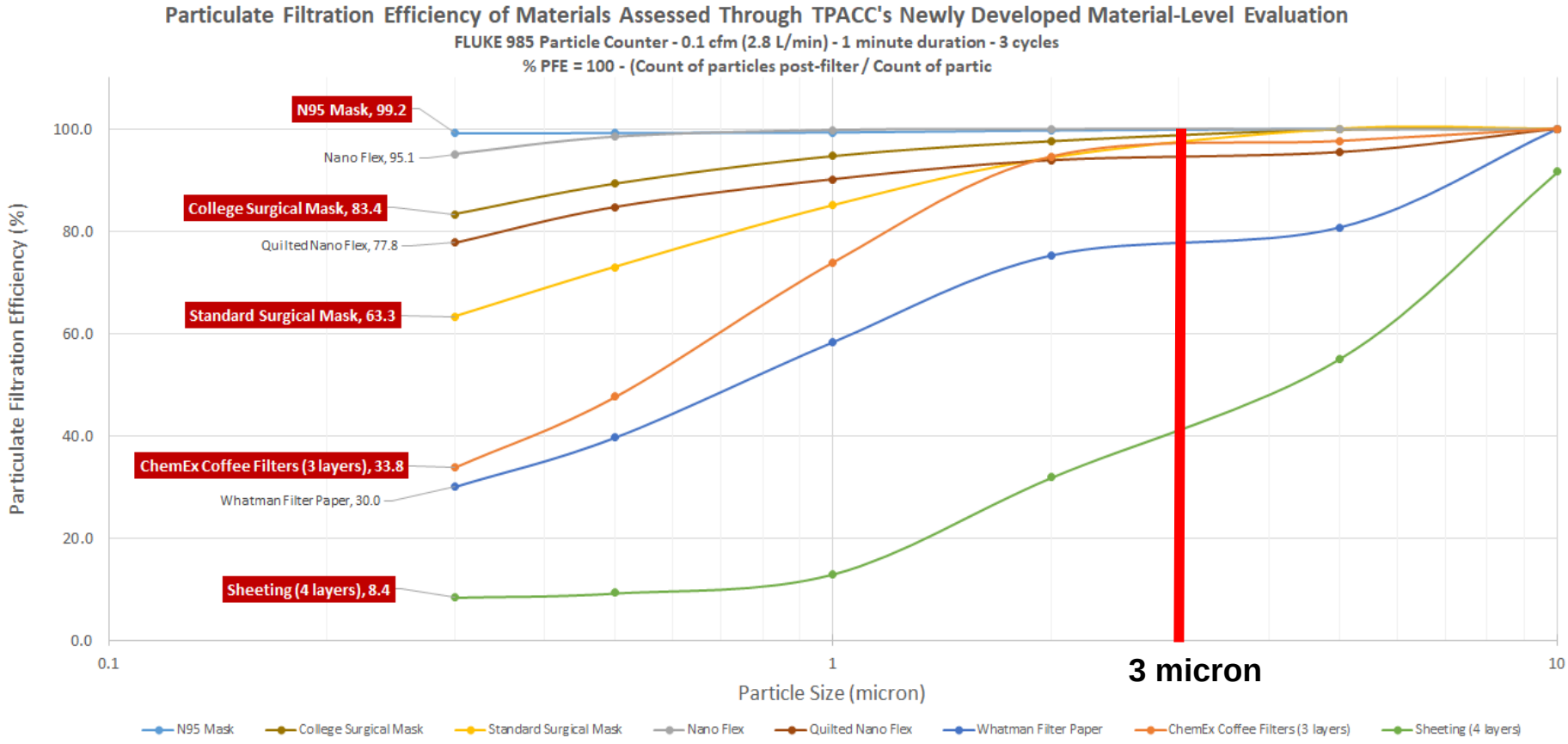
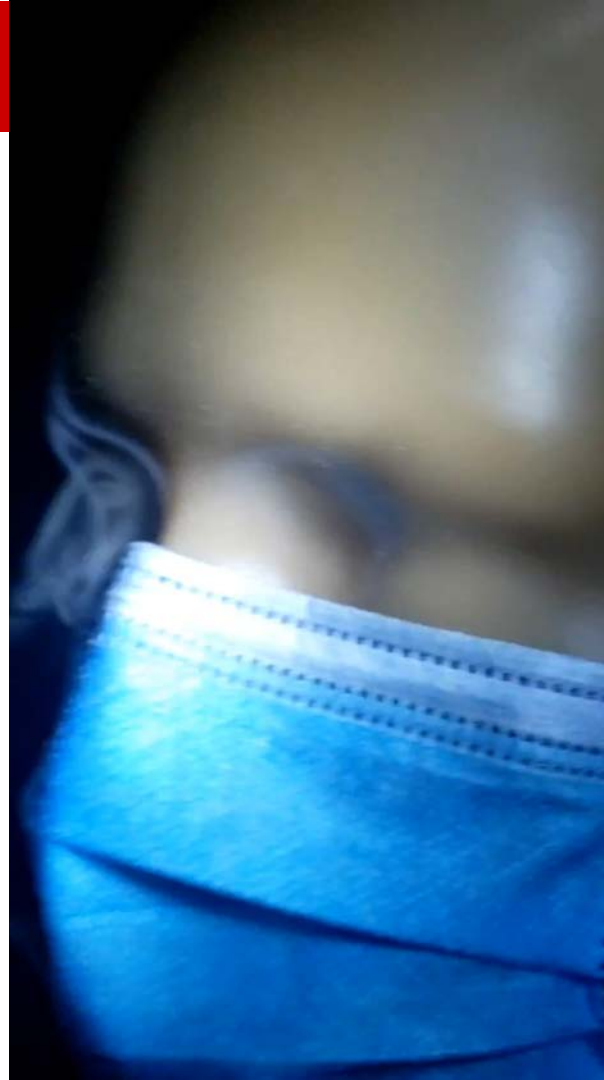


Fig. 8. Images of different spun yarns (a) ring, (b) rotor, (c) air-jet, and (d) OE friction
Ghosh et al., Journal of Applied Polymer Science, 2008, Vol. 108, 3233–3238.


Particulate Filtration Efficiency of Materials Assessed Through TPACC's Newly Developed Material-Level Evaluation
FLUKE 985 Particle Counter - 0.1 cfm (2.8 L/min) - 1 minute duration - 3 cycles
% PFE = 100 - (Count of particles post-filter / Count of partic
N95 Mask, 99.2
Nano Flex, 95.1
College Surgical Mask, 83.4
Quilted Nano Flex, 77.8
Standard Surgical Mask, 63.3
ChemEx Coffee Filters (3 layers), 33.8
Whatman Filter Paper, 30.0
Sheeting (4 layers), 8.4
Particulate Filtration Efficiency (%)
100.0
80.0
60.0
40.0
20.0
0.0
0.1
1
10
3 micron
Particle Size (micron)
N95 Mask
College Surgical Mask
Standard Surgical Mask
Nano Flex
Quilted Nano Flex
Whatman Filter Paper
ChemEx Coffee Filters (3 layers)
Sheeting (4 layers)

Protection and reduction inward and outward – general reminders

- PPE: Protection is not only about the fabric used, but all about the final product and its personal fit
- For masks: filtration fabric + good fit to the face
- Air will follow the path of least resistance
  - If you feel air escape, that is where most of it is going
  - If your glasses fog up, your protection is low (inward and outward)
  - The smaller the particles (aerosols) the better they follow the air flow



General purpose/general public/community face coverings:

- Basic idea: these face-coverings are **NOT PPE**, but will help reduce the aerosol-exposure of the wearer somewhat, and may reduce spread from the wearer in case of infectious diseases
  - Minimal effective level: Unknown, i.e.: 20% may still be a significant reduction that contributes to improved public health outcomes, where it would be insufficient for PPE (occupational).
  - If 10 million people are exposed, the mask may now avoid exposing 2 million people, with 0.2% mortality rate it suggests 4,000 lives were saved!
- **“Not PPE” does not mean “not effective”**
  - **The objective of community masks is public health improvement, not individual protection in hazardous environments**

Thanks for your attention

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