

Surgical Mask Particle Filtration Efficiency (PFE): The Standard Needs to be Updated

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The particle filtration efficiency (PFE) of surgical (procedure) masks is a key differentiator of its classification and therefore, its use by healthcare workers.

Surgical masks are regulated by the Food and Drug Administration (FDA). The FDA Guidance document has adopted a number of ASTM standards for establishing the criteria for the classification of masks.

ASTM F2299 is recommended for the measurement of PFE with minor modifications.

Both ASTM F2299 and the FDA Guidance Document fail however to establish standard test procedures and therefore, it is possible to attain diverging results. This creates a major problem in one's ability to be able to relate the measured performance across different masks on the market.

In this paper, we outline the deficiencies of these test methods and discuss the challenges that need to be addressed by FDA and other regulatory agencies.

Citation

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Introduction

During the COVID-19 coronavirus crisis, the shortage of personal protective equipment (PPE) has been severe, and continues to date especially regarding the availability of N95 and surgical masks. A great deal of effort has gone into the development of new forms of filter media used in masks.

There are various types of masks available on the market. The N95 or the N99 are the most well known as are surgical masks... these are quite different.

N95 respirators are considered as personal protective equipment that are used to protect the wearer from airborne particles and from liquid contaminating in the case of surgical masks. The N95 and N99 respirators are regulated by the Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) and Occupational Safety and Health Administration (OSHA), and must adhere to the strict performance guideline established by these organizations.

An **N95 respirator** is a respiratory protective device designed to achieve a **close facial fit** and very efficient filtration of airborne particles if fitted properly.

Surgical N95 Respirators are commonly used in healthcare settings and are a subset of N95 Filtering Facepiece Respirators (FFRs), often referred to as N95s.

The similarities among surgical masks and surgical N95s are that they are tested for fluid resistance, filtration efficiency (particulate filtration efficiency and bacterial filtration efficiency), flammability and biocompatibility.

The N95 fitted masks may have a higher pressure drop than surgical masks. Therefore, CDC recommends that people with chronic respiratory, cardiac, or other medical conditions that make breathing difficult should check with their health care provider before using an N95 respirator because the N95 respirator can make it more difficult for the wearer to breathe. Some models have an exhalation valve that can make breathing out easier and help reduce heat build-up. These should not be used when sterile conditions are needed, because the exhalation valve does not provide filtration, and therefore the exhaled air presents a danger of exposure to all those who are in the vicinity of the wearer of an N95 mask with a valve.

Also, N95 respirators are not designed for children or people with facial hair. Because a proper fit cannot be achieved on children and people with facial hair, and consequently, the N95 respirator may not provide full protection.

The single-use, disposable respiratory protective devices used and worn by health care personnel during procedures to protect both the patient and health care personnel from the transfer of microorganisms, body fluids, and particulate material. These surgical N95 respirators are class II devices regulated by the FDA, under 21 CFR 878.4040, and CDC NIOSH under 42 CFR Part 84.

N95s respirators regulated under product code MSH are intended to prevent specific diseases or infections, or filtering surgical smoke or plumes.

N95 Respirator filters must meet stringent certification tests (42 CFR Part 84) established by NIOSH. The NIOSH tests use what are considered “worst case” parameters, including¹ :

1. A sodium chloride (for N-series filters) or a dioctyl phthalate oil (for R- and P-series filters) test aerosol with a mass median aerodynamic diameter particle of ~ **0.3 µm**, which is in the **MPPS-range** for most filters
2. Airflow rate of **85 L/min**, which represents a moderately-high work rate
3. Conditioning at **85% relative humidity** and **38°C** for 24 hours prior to testing
4. An initial breathing resistance (resistance to airflow) not exceeding **35 mm water column (~343 Pa)** height pressure and initial exhalation resistance not exceeding **25 mm water column (~245 Pa)** height pressure
5. A **charge-neutralized** aerosol
6. **Aerosol loading** conducted to a minimum of **200 mg**, which represents a **very high workplace exposure**
7. The filter **efficiency cannot fall below the certification class level** at any time during the NIOSH certification tests

A **surgical mask** is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. These are often referred to as face masks, although not all face masks are regulated as surgical masks. Unlike the N95 respirators, the edges of the surgical mask are not designed to form a good seal around the nose and mouth.

Collectively, there are a number of standards that apply to surgical masks. These are shown below in Table 1.

ASTM F2299/F2299M-03(2017)	Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
ASTM F2101-19	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
ASTM F2100-19	Standard Specification for Performance of Materials Used in Medical Face Masks
ASTM F1862/F1862M-17	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
ASTM F1494-14	Standard Terminology Relating to Protective Clothing
ASTM F3387-19	Standard Practice for Respiratory Protection
FDA Guidelines	FDA Guidance Document ²

Table 1. Various Standards and Guidelines for Surgical Masks

Surgical masks are classified as Levels 1 to 3. See table 2 below

		Level 1	Level 2	Level 3
Barrier testing	BFE% ASTM F2101, EN 14683	≥ 95	≥ 98	
	PFE% ASTM F2299	≥ 95	≥ 98	
	Synthetic Blood ASTM F1862, ISO 22609	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg
Physical Testing	Differential Pressure EN 14683	<5.0 mmH ₂ O/cm ²	<6.0 mmH ₂ O/cm ²	
Safety Testing	Flammability 16 CFR Part 1610	Class 1 (≥3.5 seconds)		
	Microbial Cleanliness ISO 11737-1	Not Required		
	Biocompatibility ISO 10993	510 K Guidance recommends testing to ISO 10993		
Sampling: ANSI/ASQC Z1.4 ISO 2859-1		· AQL 4% for BFE, PFE, Delta P · 32 masks for Synthetic Blood (Pass= ≥29 passing, Fail= ≤28 passing) · 14 masks for Flammability		

Table 2. ASTM F2100-19 Standard Specification For Performance Of Materials Used In Medical Face Masks

These standards have been used for many years. The PFE Standard Test Protocols are inadequate in that it is possible to attain different classifications depending on how the test is performed. This is described fully below.

Particle Filtration Efficiency (PFE) for Surgical Masks

The ASTM F2299 (reapproved in 2017) establishes the procedures for the measurement of the initial efficiency of materials used in medical facemasks (surgical masks) by using monodispersed latex spheres.

The test method recommends utilizing a light scattering particle counter to measure particles in the size range of **0.1 to 5.0** micron and the airflow test velocity of **0.5 to 25 cm/s**.

The test procedure measures filtration efficiency by comparing the particle count feed stream (upstream) to that in the filtrate (downstream). It is further recommended that the particles are **charge neutralized**.

The challenge with this test method lies in the fact that the specimen size is not specified and that the face velocity is not fixed.

The face velocity is defined as:

$$V = \frac{Q}{A}$$

where V is the face velocity $\left(\frac{cm}{s}\right)$, Q is the flow rate $\left(\frac{cm^3}{s}\right)$ and A is the area (cm^2)

.

The NIOSH Standard Test Protocol for N95 respirators specifies the flow rate (85 L/min) for the device to be tested. The only avenue for a manufacturer of the device to impact the face velocity is to use a larger mask. For molded masks, there is a limit to which this can be accomplished. Some recent patents show that the mask surface is being pleated to increase the surface area. The testing facility however, has no control over the test procedure and therefore, the test results are reproducible and repeatable (provided that the equipment is calibrated and the **TEB-APR-STP-0057-0058** is followed correctly). Further, NIOSH uses a specific instrument (TSI 8130 or TSI 8130A). The procedures and testing modes (**42 CFR PART 84**) are well documents and easy to follow. Note that regardless of the size of the filter or the mask, the flow rate is fixed.

For a fixed flow rate, the size of the mask (or sample used) impact the face velocity – see figure 1 below.

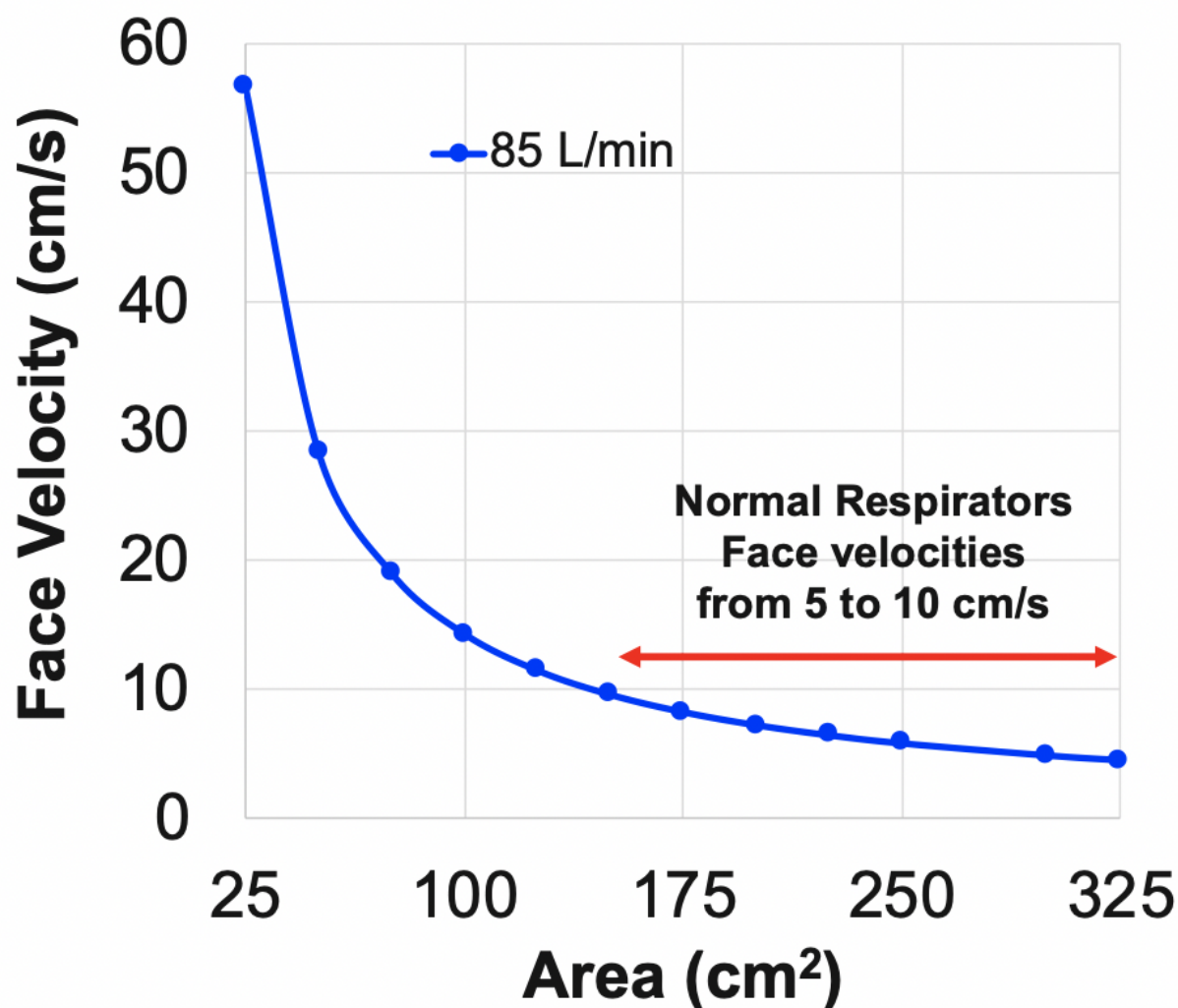


Figure 1. Face velocity as a function of surface area at 85 L/min.

Due to COVID-19, there have been many attempts to create 3D printed masks with filter inserts. Most such filters are small and therefore, the face velocities will be incredibly high with the consequence of very high pressure drops and lower efficiencies even when using the current N95 filters used in respirators.

For a given sample size, the flow rate has a profound impact on the face velocity which in turn impacts particle capture efficiency and pressure drop. In Figures 2 and 3, we show the pressure drop and the efficiency for a classical N95 meltblown filter. Most masks fall in the range of 7.5 to 10 cm/s at 85 L/min. Note that the particle efficiency (at ~ 0.3 microns measured on TSI 8130) drops quickly with face velocity and the pressure drop increases rapidly.

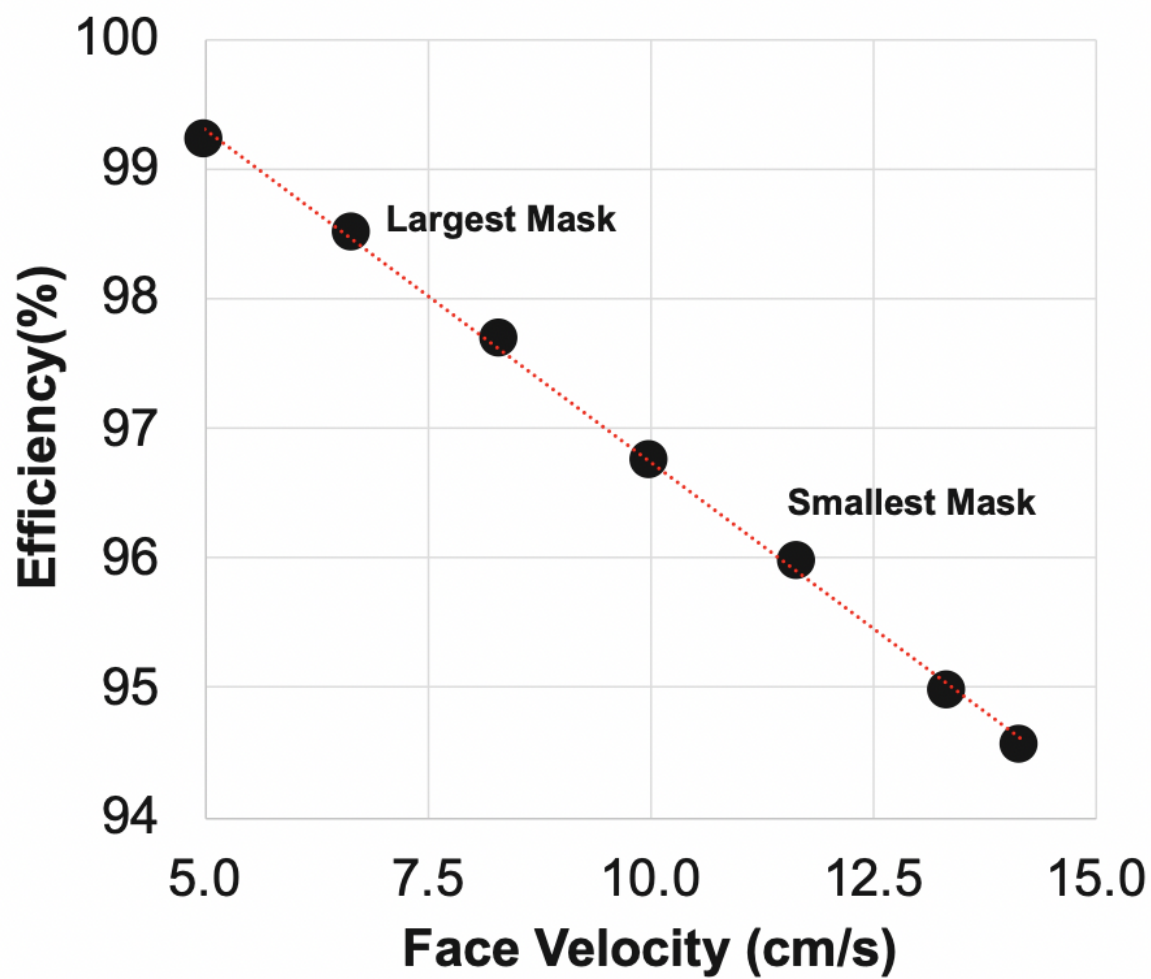


Figure 2. Efficiency as a function of face velocity.

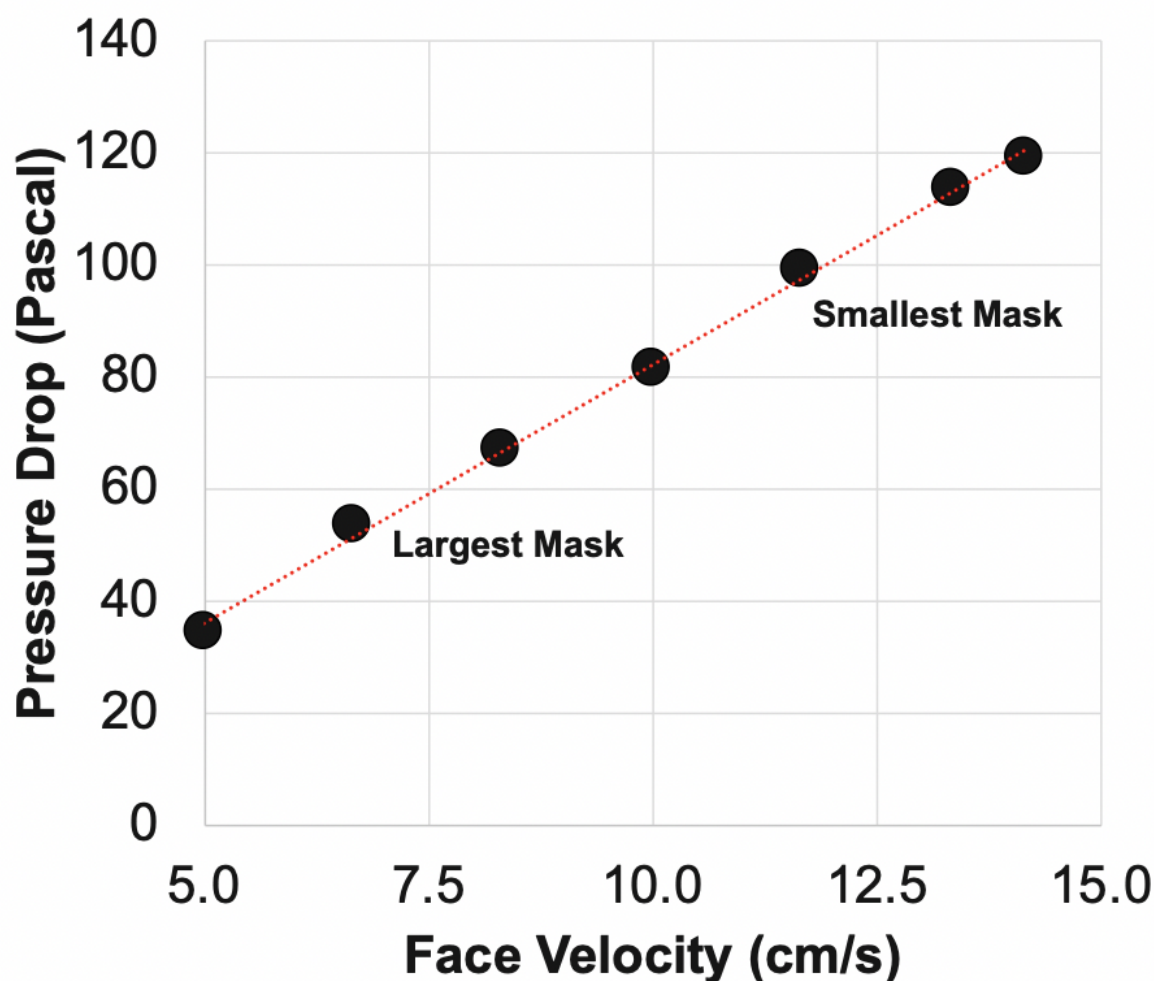


Figure 3. Pressure drop as a function of face velocity.

This is precisely the problem with the ASTM F2299. The face velocity is not fixed and more importantly, the sample size of the flow rates are not specified.

Let us examine two sample size - 50 cm² and 100 cm². Per ASTM, the face velocity can be in the range of 0.5 to 25 cm/s. The flow rates for each sample size are specified in table 3 below.

Face Velocity (cm/s)	Flow Rate (L/min) 50 cm ² Sample	Flow Rate (L/min) 100 cm ² Sample
0.5	1.5	3.0
1.0	3.0	6.0
3.0	9.0	18.0
5.0	15.0	30.0
10.0	30.0	60.0
15.0	45.0	90.0
20.0	60.0	120.0
25.0	75.0	150.0

Table 3. Flow rates for different sample size.

The consequence of this is that the lower flow rates make the samples appear more efficient and the filter will show naturally, a lower pressure drop.

The example below in Figure 4 clearly makes the point that at high flow rates, the filter's efficiency is below 95% but at 30 L/min, it has an efficiency of 99%.

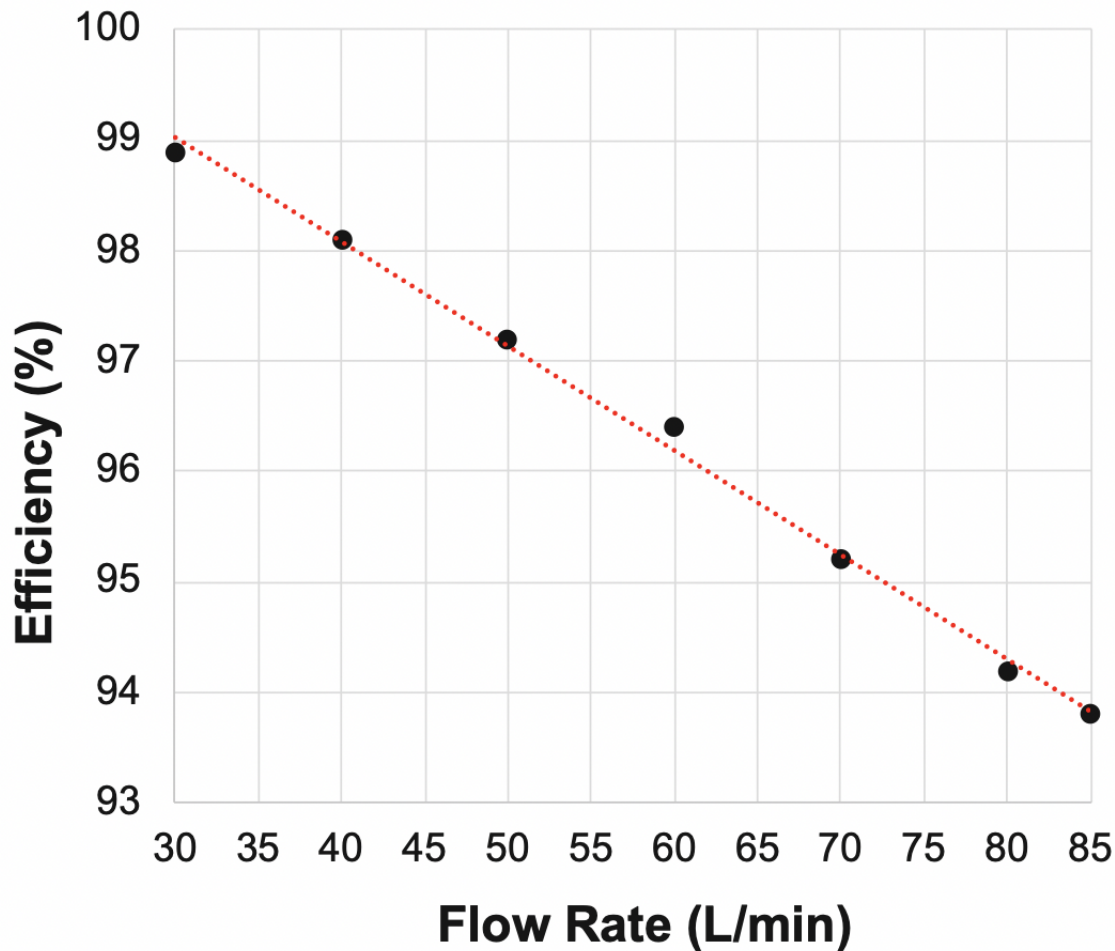


Figure 4. Efficiency as a function of flow rate.

The other challenge is that particle size matters very greatly. The filter behavior at 0.1 micron is not the same as 0.3 or 3 or 5 microns. NISOH “fixes” the particle size since TSI 8130 has a mass mean diameter of ~0.26 micron which is in the range of the most penetrating particle size (MPPS).

The FDA guidance Document however, “fixes” the particle size at 0.1 micron. However, FDA recommends the use of un-neutralized latex particles, but falls short of specifying the flow rate and the sample size. ASTM F2100 also specifies a particle size of 0.1 microns and refers back to F2299 for the test procedure.

Nelson Labs is a certified lab that has performed pre-certification for both surgical masks and N95 respirators for many years. They use a challenge particle size of 0.1µm. Nelson labs uses an optical laser based particle counter and operates at a flow rate of 1 cubic foot per minute (CFM) or 28.3 liters per minute (LPM). The sample size is set at 91.5 cm². This translates to a face velocity of 5.2

cm/s. They specify that they use un-neutralized particles per FDA guidelines³.

Below, we summarize the variance observed in Table 4.

(PFE) ASTM F2299		(PFE) Nelson Labs
Particle Charge	Neutralized	Un-neutralized
Particle Size (mm)	0.1 to 5	0.1
Flow Rate (L/min)	Not specified	Not specified
Face Velocity (cm/s)	0.5 to 25	Not specified
Test area (cm ²)	Not specified	Not specified

Table 4. Summary of the variance in PFE test protocol.

It is our opinion that Nelson Labs is following the spirit of the FDA guidelines and the ASTM protocols to derive at a reasonable test protocol.

The challenge is that other laboratories use charge neutralized particles at a face velocity of more than 10 cm/s. What may be a Class 3 under one testing scenario, becomes a class 1 under another. PFE measure at 5.2 cm/s with unneutralized particles will be significantly different from the PFE measured by using neutralized particles at over 10 cm/s. This creates a clear discrepancy in terms of what has been approved by one method versus another.

CDC clearly states (the highlights are ours) that⁴:

“Manufacturers of surgical masks.... must demonstrate that their product is at least as good as a mask already on the market to obtain “clearance” for marketing.

Manufacturers may choose from filter tests using

a biological organism aerosol at an airflow of 28 L/min (bacterial filtration efficiency)

or

*an aerosol of 0.1 µm latex spheres and a velocity ranging from **0.5 to 25 cm/sec** (particulate filtration efficiency). It is important to note that the FDA specifies that the latex sphere aerosol **must not be charge-neutralized***

.... allowing the manufacturer to select from a range of air velocity means that the test results can be easily manipulated. In general, particles are collected with higher efficiency at lower velocity through a filter.

Both of these aspects yield a test that is not necessarily “worst case” for a surgical mask filter .

*Because the performance parameters for surgical masks are less stringent than those required for filters used in NIOSH-certified respirators, the fiber diameters, porosity, and filter thicknesses found in surgical masks are designed with significantly lower levels of particle collection efficiencies at their **MPPS** .”*

What we propose is to use the same method as used by NIOSH where the measurement is made at MPPS (or close to it as is the case with TSI 8130) or establish a fixed face velocity that is meaningful and a sample size that is large enough to provide a representative average of the performance. For example, 100 cm² would be fine while 10 cm² would not be since the results would be a function of the mass uniformity of the material and its microstructure and not the macrostructure used in masks. We also recommend that the Bacteria efficiency test be dropped since there are no standard pieces of equipment readily available for performing the test. In addition, it would be very welcoming to include some measure of the fit for the surgical mask especially given that today, there are a number of other designs that are quite different from the traditional/classical 3-ply pleated surgical mask.

We have started to use a TSI 3160 with monodisperse latex particles where we have the option to turn on or off the neutralizer. The sample size is fixed at 100 cm², and we use 32 L/min to achieve a face velocity similar to Nelson Labs at 5.2 cm/s. This way, the results are comparable and not a function of how the tests are performed and comparisons amongst various products would be consistent and fair.

Conclusion

There is an urgency in ensuring that there is a well-defined standard protocol for the measurement of the performance of surgical masks. The current procedures can be misused and do not easily allow comparisons to be made from one laboratory to another.

Statement of Conflict of Interest

The author has no financial or commercial interest in any of the material presented in this report, and claim no intellectual priority or rights. This information is offered entirely in the public interest, without restriction or limitation.

Footnotes

¹ <<https://blogs.cdc.gov/niosh-science-blog/2009/10/14/n95/>>

² <<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-masks-premarket-notification-510k-submissions>>

³ <<https://www.nelsonlabs.com/testing/particle-filtration-efficiency-pfe/>>

⁴ <<https://blogs.cdc.gov/niosh-science-blog/2009/10/14/n95/>>

Relevant Links

Links to FDA, CDC, and NIH advice on the reuse of N95 respirators

US FDA advice on N95 Respirators and Surgical Masks (Face Masks)
<<https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks>>

Pre-print of article: Assessment of N95 respirator decontamination and re-use for SARS-CoV-2
<<https://www.medrxiv.org/content/10.1101/2020.04.11.20062018v1>>

CDC infographic on N95 respirators versus surgical masks
<<https://www.cdc.gov/niosh/npptl/pdfs/UnderstandDifferenceInfographic-508.pdf>>

FDA Guidance
<<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-masks-premarket-notification-510k-submissions>>

Appendix A to §1910.134—Fit Testing Procedures (Mandatory)
<<https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA>>

References

1. Gray Nicholas. Ozone Disinfection. In: Percival Steven L., Yates Marylynn V., Williams David W., Chalmers Rachel M., Gray Nicholas F.. *Microbiology of Waterborne Diseases: Microbiological Aspects and Risks*. Academic Press; 2014:599-615. [DOI](#)