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Permalink

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Journal

Annals of Work Exposures and Health, 65(5)

ISSN

2398-7308

Authors

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Publication Date

2021-06-12

DOI

10.1093/annweh/wxab008

Peer reviewed

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Annals of Work Exposures and Health, 2021, 1–10
doi: 10.1093/annweh/wxab008
Review

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Review

Standards for Surgical Respirators and Masks: Relevance for Protecting Healthcare Workers and the Public During Pandemics

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Submitted 2 October 2020; revised 2 November 2020; editorial decision 3 November 2020; revised version accepted 20 January 2021.

Abstract

National standards for surgical respirators and masks are written and enforced to protect healthcare workers from particles and microorganisms such as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). In addition to the ability to filter particles (e.g. filtration efficiency, FE), the standards address breathability (e.g. differential pressure), how well the mask seals to a worker's face (e.g. fit test), the level of protection from a fluid splash, and other factors. Standards used in the USA, European Union (EU), and China were compared with respect to testing methods and certification criteria. Although there are substantial similarities in standards for respirators, such as surgical N95, FFP2, and KN95 filtering facepiece respirators (FFRs), there are differences with respect to who performs that testing and fit-testing requirements that influence certification. There is greater variation in test methods between countries for surgical (USA) or medical (EU and China) masks than for FFRs. Surgical/medical masks can be certified to different levels of protection. The impact of the similarities and differences in testing methods and certification criteria on FFR and mask performance for protecting healthcare workers from SARS-CoV-2 are discussed, as well as the value of a new standard in the EU for testing fabrics for masks used by the public. Health and safety personnel in healthcare settings must understand the differences between standards so that they can select respirators and masks that provide appropriate protection for healthcare workers.

Keywords: COVID-19; healthcare workers; hospital; pandemic; respiratory protection

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What's important about this paper?

Coronavirus Disease 2019 (COVID-19) resulted in shortages of filtering facepiece respirators and medical/surgical masks for healthcare workers, leading many organizations and individuals to use new equipment, some of which had been evaluated under diverse, international testing methods and criteria. This paper reviews testing methods and standards for these devices from the USA, European Union, and China, so that users understand how the performance of equipment tested and certified according to the different standards compare. In addition, this paper discusses the relevance of different testing methods and standards for equipment used in healthcare settings and by the public, and strategies for research and outreach to improve usability and performance of equipment.

Introduction

The Coronavirus Disease 2019 (COVID-19) pandemic overwhelmed the global supply of personal protective equipment for healthcare workers, including respiratory protective devices, and led to the widespread use of face coverings among the public. Never have there been more eyes turned toward respirators, surgical masks, and cloth masks, and many saw a confusing array of jargon, testing methods, and performance standards. The first objective of this paper is to describe the testing methods and performance criteria in the USA, the European Union (EU), and China for the most commonly used type of respirators in healthcare settings—filtering facepiece respirators (FFRs), and surgical/medical masks. While other nations have performance criteria, we focus on these three regions owing to their large populations and influence on the marketplace. Testing methods and performance criteria were identified through iterative Internet searches for governmental policy documents and testing standards, and cross-referencing from identified documents. The second objective of this paper is to discuss the impact of the COVID-19 pandemic with respect to performance criteria for these devices, and research needs.

Owing to the variety of names used globally, some definitions are provided. A *respirator* is a piece of personal protective equipment that is designed to fit tightly to the face and prevent airborne contaminants from being inhaled by the wearer. Among the many types of respirators, FFRs feature a facepiece comprised entirely of the filter material, though they are available in many different designs. The phrase FFR, however, is a technical term predominantly used in the USA; healthcare workers often call these devices N95 masks, where N95 refers to the performance standard for the filter material specified by the National Institute for Occupational Safety and Health (NIOSH), the organization in the USA that certifies respiratory protective devices. In other countries, these devices may be called filtering half masks (EU EN 149+A1, 2009). A *surgical* or *medical mask*, in contrast, fits loosely over the face and is designed to prevent the emission of respiratory droplets and aerosols from the wearer (source control) and to prevent the exposure of droplets or spray onto the mouth or nose of the wearer (Brosseau *et al.* 2021; Garcia Godoy *et al.*, 2020). Herein, the phrases *FFR* and *surgical masks* will be used.

Testing methods

There are numerous testing methods used to evaluate the performance of FFRs and surgical masks. The focus of this summary is on tests most relevant to the ability of the devices to prevent the transmission of respiratory infectious disease and wearability, including filtration efficiency (FE), pressure differential, fluid barrier, and fit testing.

Filtration efficiency

FE is the proportion of particles that are intercepted by the filtration material. It is measured by challenging the material with particles of known size, carried at a known flow rate or velocity, and measuring the particle concentration upstream of the material, C_{up}, and downstream of the material, C_{down}. Particle penetration through the filter material, P_{filter}, is the ratio of the downstream concentration to the upstream concentration, multiplied by 100%. FE is the complement of particle penetration: FE = 100% – P_{filter}. A filter material through which 5% of particles penetrates (P_{filter} = 5%) has 95% FE. FE is influenced by multiple factors, including the filter material; size, shape, and charge of the challenge particles, airflow rate, temperature and humidity, loading, and other factors.

It is well known that the FE of filter material may vary for particles of different sizes and shapes. This is because filtration occurs through multiple physical processes—straining or sieving, inertial impaction, interception,

Table 1. Test methods for filtration efficiency.

	Filtering facepiece respirators				Surgical masks	
Standard	**TEB-APR-STP-0059 (NIOSH, 2019)**	**EU EN 13274-7**	**GB 2626-2006**	**ASTM F2299**	**ASTM F2101**	**EU EN 14683+C1**
Particle material	Sodium chloride	Sodium chloride	Sodium chloride	Latex spheres	*S. aureus* bacteria	*S. aureus* bacteria
Particle size	Polydisperse CMD = 0.075 ± 0.020 µm GSD ≤ 1.86	Polydisperse CMD = 0.06–0.1 µm GSD 2.0 to 3.0	Polydisperse CMD = 0.075 ± 0.020 µm GSD ≤ 1.86	Monodispersed in range 0.1–5 µm	Mean 3 ± 0.3 µm	Mean 3.0 µm
Particle charge	Neutralized	Not specified	Neutralized	Neutralized	Unneutralized	Unneutralized
Item tested	Entire facepiece	Entire facepiece	Entire facepiece	Material sample, 100 cm^2	Material sample, size unspecified	Material sample, at least 100 mm^2
Flow rate	85 l/min	95 l/min	85 l/min	28.3 l/min	28.3 l/min	28.3 l/min
Particle measurement	Particle count by light-scattering laser photometers	Particle count by light-scattering laser photometers	Particle count by light-scattering laser photometers	Particle count by light-scattering laser photometers	Colony Forming Units by the 6-stage sampler	Colony Forming Units by the 6-stage impactor

diffusion, gravitational settling, and electrostatic attraction (Hinds, 1999), and the efficiency of these processes varies by particle size. The particle size for which a filter material has the lowest FE is termed the *most penetrating particle size* (MPPS). Ideally, the MPPS is used to test filter performance, as the filter efficiency for all other particles will be better than that obtained with the MPPS. MPPS varies with filtration material and air velocity through the filter. Early studies reported MPPS for respirators of 0.3 µm, but more recent studies have shown that MPPS is in the 0.04–0.06 µm range (Rengasamy *et al.* 2012).

Table 1 summarizes common FE testing methods used in the USA, EU, and China for FFRs and surgical masks. All FE test methods for FFRs use sodium chloride particles with a count median diameter (CMD) of 0.075 µm [mass median aerodynamic diameter approximately 0.3 µm (Eninger *et al.* 2008)]. The FE test methods for surgical masks use larger particles and lower airflow rates than the test methods for FFRs. Filter material will generally show higher FE with larger particles than the MPPS, and with lower airflow rates (He *et al.*, 2013: Rengasamy *et al.*, 2013). The airflow rates, or face velocity, for testing are selected based on the expected upper end of flow rates by workers performing typical tasks. The airflow of 85 l/min was selected to represent a workers' inhalation at a high work rate. The airflow during rest or rapid walking will be between 10 and 40 l/min (Louhevaara *et al.* 1986).

Particles are charged neutralized in most tests for FFRs because such particles generally have a lower FE than charged particles (Eninger *et al.*, 2008). The ASTM F2299 method was recently altered to require charged neutralized particles for testing. A study completed prior to this change found that the ASTM F2299 method produced higher FE values than the NIOSH TEB-APR-STP-0059 method for the same filter materials (Rengasamy *et al.*, 2017; NIOSH, 2019). Of note, bacteria FE tests expose the *interior* of the mask to the particles, while tests used for FFRs expose the *exterior* of the filter to the particles. Furthermore, the bacterial nebulization method of ASTM F2101 may generate charged particles, which will increase measured FE.

Pressure differential

The pressure differential, or pressure drop, reflects how easy it is to breathe through the filter material. The pressure differential is generally determined by measuring the air pressure on both sides of the filter material while air flows at a known velocity through the filter material. The pressure differential is the difference between the two air pressures. A low-pressure differential means air easily passes through the filter material, making it easier

to breathe through. For a given experimental set-up, decreasing the air velocity will decrease the pressure differential and increasing the thickness of the filter material will increase the pressure differential. Table 2 summarizes methods used to measure pressure differential for filter materials.

The pressure differential is typically reported in the units of pascal (Pa) (1.0 Pa = 0.102 mmH_2O). Some pressure differential standards for surgical masks use the unit of Pa/cm^2, which has no physical meaning. These tests, however, specify the surface area of the mask material tested, so the values have been multiplied by the surface area tested to obtain a physically meaningful unit, Pa.

Fluid barrier

Fluid barrier tests evaluate how well the material prevents the penetration of liquid, such as might be splashed onto the device during healthcare activities. A primary test for the fluid barrier is ASTM F1862. ASTM F1862 is a qualitative test in which synthetic blood is projected onto the exterior of the mask at a specific pressure (80, 120, or 160 mmHg), and the interior of the mask is visually inspected for penetration (ASTM International, 2017b). The test seeks to represent the event of blood splatter exiting from a small arterial puncture.

Fit testing

Respirator fit testing is performed to determine how well the respirator fits the face of the wearer or the inward leakage of particles. In a quantitative fit test, the general approach is to measure the particle number concentration inside and outside of the respirator facepiece while the wearer performs a series of exercises; often sodium chloride or other particles are released outside the respirator to ensure that quantifiable particle concentrations penetrate the facepiece. The fit of the respirator is described by the fit factor, the ratio of the particle concentration outside the respirator to that inside the respirator facepiece. The fit test measures total inward leakage—the leakage of particulates through the face seal, valves, and gaskets, as well as penetration through the filter. Use of high-efficiency particulate filters, for example, N100 or P100 in the USA or KN100 in China, functionally eliminates penetration through the filters, so that the fit test measures leakage of particulates through the face seal, valves, and gaskets. Total inward leakage is calculated as 100% divided by the fit factor (Rengasamy *et al.*, 2014), but in the EU, the fit factor is adjusted by the duration of inhalation and exhalation to determine total inward leakage (EU EN 149+A1, 2009). In the USA, respirator

Table 2. Test methods for pressure differential.

	Respirators			Surgical masks	
Standard	NIOSH TEB-APR-STP-0007-508 & -0003-50[a]	EN 149+A1[b]	GB 2626-2006[c]	YY 0469-2011[d]	EN 14683+C1[e]
Item tested	Entire facepiece	Entire facepiece	Entire facepiece	Mask material, 4.9 cm^2	Mask material, 4.9 cm^2
Flow rate	85 l/min	30 or 95 l/min for Inhalation; 160 l/min for Exhalation	85 l/min	8 l/min	8 l/min
Air velocity[f]	9.4 cm/s	3.3, 10.6, or 17.8 cm/s	9.4 cm/s	27.2 cm/s	27.2 cm/s

[a] NIOSH, 2019a, 2019b.
[b] European Union EN149+A1, 2009.
[c] China National Standard GB 2626-2006, 2006.
[d] China National Pharmaceutical Industry Standard YY-0469-2011, 2011.
[e] European Union EN 13274-7, 2019.
[f] For respirators, air velocity is estimated based on the area of 150 cm^2.

fit testing is the responsibility of the employer (29 CFR 1910.134), and is not part of the respirator certification process. In the EU (EU EN 149+A1, 2009) and China (China National Standard GB 2626-2006, 2006), however, total inward leakage tests are required as part of the respirator certification process.

Product certification

Filtering facepiece respirators

The performance criteria for FFRs (e.g. filtering half masks) are shown in Table 3. In the USA, surgical N95 FFRs are required by the Food and Drug Administration (FDA) to undergo the same testing required for surgical masks—particle FE, bacteria FE, fluid penetration, pressure differential, and flammability (e.g. Table 4). Although these tests are reported by the manufacturer, the manufacturer may report results from the particle filtration and pressure differential tests performed by NIOSH as part of the respirator certification process to the FDA (NIOSH STP-0003, 2019; NIOSH STP-0007, 2019; NIOSH STP-0059, 2019). Fluid penetration testing is not required for certification of FFP1, FFP2, FFP3 filtering half masks in the EU, but is required in China (China National Standard GB 19083-2010, 2010) for devices worn in healthcare settings.

Respirator certification in the EU requires that 46 of 50 individual respirator fit-testing exercises (10 subjects × 5 exercises) have total inward leakage ≤25, 11, or 5% for FFP1, FFP2, and FFP3, respectively (EU EN 149+A1, 2009); and that at least 8 of 10 subjects have mean inward leakage ≤22, 8, and 2% for FFP1, FFP2, and FFP3, respectively (EU EN 149+A1, 2009; EU EN 13274-7, 2019). Similar criteria are used in China, where 46 of 50 individual respirator fit-testing exercises (10 subjects × 5 exercises) must have total inward leakage <13, 11, or 5% for KN90, KN95 and KN100 devices, respectively; and that at least 8 of 10 subjects have overall total inward leakage <10, 8, or 2% for KN90, KN95, and KN100 devices, respectively (China National Standard GB 2626-2006, 2006).

Surgical/medical masks

In the USA, surgical masks are cleared by the FDA through the premarket notification process (CFR 878.4040; 21CFR807.81; FDA, 2004, 2020). Manufacturers must submit data regarding particle FE, bacteria FE, fluid penetration, flammability, and pressure differential, but the FDA does not specify which test

Table 3. Selected performance criteria for filtering facepiece respirators.

	N95 FFR[a]	FFP1	FFP2	FFP3	KN95
Filtration efficiency testing method	NIOSH TEB-APR-STP-0059	EN 149+A1	EN 149+A1	EN 149+A1	GB 2626-2006 GB 19083-2010
Minimum filtration efficiency	≥95%	≥80%	≥94%	≥99%	≥95%
Maximum test challenge load	200 mg	Not specified	Not specified	Not specified	200 mg
Tested by	NIOSH	Manufacturer			Manufacturer
Number of respirators tested	20	9			20
Mean total inward leakage[a]	Not required	≤22%	≤8%	<2%	≤8%
Maximum pressure differential on inhalation	343 Pa	210 Pa at 95 l/min	240 Pa at 95 l/min, 70 Pa at 30 l/min	300 Pa at 95 l/min	350 Pa
Maximum pressure differential on exhalation	245 Pa	300 Pa at 160 l/min			250 Pa
Carbon dioxide	Not specified	<1% by volume			<1% by volume

[a] Observed for 8 of 10 subjects evaluated.

Table 4. ASTM criteria (F2100-19e1) for three barrier levels for surgical masks, as used in the USA.

Test method	Metric	Barrier level		
		1	2	3
ASTM F1862	Fluid resistance (mmHg)	80	120	160
ASTM F2299 or F2101	Filtration efficiency (%)	≥95	≥98	≥98
EU EN 14683:2019 Annex C	Pressure differential (Pa/cm^2) [Pa][a]	<50 [<245]	<60 [<294]	<60 [<294]

[a] Flow rate of 8 l/min. Pa calculated assuming 4.9 cm^2 material tested.

Table 5. Selected European Union criteria for three barrier levels for medical masks (EU EN 14683).

Metric	Type I	Type II	Type IIR
Fluid resistance (kPa)	Not required	Not required	≥16
Bacteria filtration efficiency (%)	≥95	≥98	≥98
Pressure differential (Pa/cm^2) [Pa]	<40 [196]	<40 [196]	<60 [294]

[a] Flow rate of 8 l/min. Pa calculated assuming 4.9 cm^2 material tested.

methods must be used. However, the FDA recommends ASTM 2299 for particulate FE, using 0.1 μm latex spheres that have not been charge-neutralized, but there is no specified flow rate. For bacteria FE, the FDA recommends ASTM F2101, Mil-M369454C, or the modified method of Greene and Vesley (1962). Once cleared by the FDA, surgical masks are often marketed based on their barrier performance level (e.g. 1, 2, or 3) as defined by ASTM International (Table 4).

The EU criteria also define three barrier levels for medical masks (EU EN 14683+C1, 2019), as shown in Table 5. The standards for testing and requirements for medical face masks (EU EN 14683+C1, 2019) are similar to the FDA requirements for surgical masks (Table 4). Only Type IIR requires splash protection/fluid resistance. Type II and IIR are intended to protect hospital staff from patients during surgical and other procedures. Type I are only for patients and the public during epidemics. The testing methods for BFE (Annex B) require preconditioning with 85% RH and 21°C for 4 h. The method is otherwise similar to ASTM F2101.

In China, the standard for surgical masks used in the pharmaceutical industry (China International Pharmaceutical Standard YY 0469-2011, 2011) provides for only one performance level. Performance requirements include, but are not limited to ≥95% bacterial FE (ASTM F2101), ≥30% particle FE (GB 2626-2006), no visible fluid penetration when synthetic blood is applied with 120 mmHg to the mask exterior, pressure differential ≤49 Pa, and noncombustible.

Discussion

Shortages of respirators and surgical masks during the COVID-19 pandemic have required many healthcare organizations to use new supply chains and products, which has led to confusion and concern about performance equivalence. One source of confusion is the use of various terms globally to refer to similar devices—for example, N95 FFRs and filtering half masks, or protective face masks. In addition, while testing methods and criteria for respirators are relatively similar (Tables 1–3), their performance in the field may vary. In particular, the ability of respirators to protect workers is dependent upon the quality of the respirator fit; FFRs may not fit a large segment of the population (Lee et al., 2008; Zhang *et al.*, 2020).

The 95% bacteria FE required for surgical masks (Tables 4 and 5) may lead some to consider that these devices offer protection to workers that are equivalent to respirators, since most respirators used in healthcare settings have filters with a FE of 95% (e.g. N95, FFP2, and KN95). Since filtration occurs through multiple physical processes, FE and the MPPS is influenced by the air velocity, particle size, particle charge, as well as charge of the filter material (Balazy *et al.*, 2006). FE tests for surgical masks and FFRs differ across many of these variables (Table 1). The size of the *Staphylococcus aureus* particles (3 μm) and the air velocity used to test bacteria FE mean that the bacteria FE tests are less stringent than the use of smaller sized NaCl particles to test respirators (Rengasamy *et al.*, 2017). Oberg and Brosseau (2008) tested nine surgical masks reported to have bacteria FE ≥95% and found filter efficiencies measured using the NIOSH NaCl respirator test methods to be much lower, for example, 10–90%. Because respiratory viruses are found in the air in particles with diameters <3.0 μm (Phan *et al*, 2020; Chia *et al.*, 2020), it is important for healthcare workers to have FFRs and masks capable of filtering particles in this size range with high efficiency. Another flaw arises from the ease with which particles can by-pass the filtration material of a surgical mask owing to the loose fit of the mask against the face (Oberg and Brosseau, 2008; Lee *et al.*, 2008). It is interesting

to note that a recent FDA Emergency Use Authorization (EUA) created a new term 'Authorized Surgical Masks' that they designate as PPE for healthcare personnel in healthcare settings, but the criteria for testing is not changed.

There is a need to improve the fit of FFRs. It is routine to find that FFRs fail to fit a substantial number of people (Lee *et al.*, 2008; Zhang *et al.*, 2020). It is difficult to find data about the quality of fit from manufacturers and distributors (Lofgren, 2018), and many peer-reviewed studies do not detail the models tested. As a result, employers must have multiple respirator models available and fit test workers with more than one model and more than one size per model. Fit testing of FFRs is required for respirator certification prior to sales in the EU and China, and the standards require testing of at least ten individuals (China National Standard GB 2626-2006, 2006; EU EN 149+A1, 2009), but it is not clear how well this requirement yields well-fitting FFRs (Foereland *et al.*, 2019). In the USA, there have been calls to require fit-testing as part of the NIOSH certification process and to generally improve the fit of FFRs (Lofgren, 2018). Toward that goal, a voluntary standard is under development that would incorporate respirator fit into conformity assessment (Coffey and Miller, 2019). Such a standard, along with improved face seal designs, may improve the effectiveness of FFRs.

The use of masks by the general public is now widely recommended as a COVID-19 control strategy. While the FE of cloth masks is highly variable (Rengasamy *et al.*, 2010; N95DECON et al., 2020), human experimental studies demonstrate that cloth masks can decrease the emission of respiratory droplets and epidemiologic studies demonstrate an impact of public mask-wearing on COVID-19 transmission (Davies *et al.*, 2013; Chu *et al.* 2020). Yet, there remains a need for further research about cloth mask performance as worn by the public as well as performance criteria. The European Committee on Standardization has proposed minimum requirements for face coverings used by the general public (CWA 17553, 2020), which includes FE testing with 3.0 μm particles (≥90% or ≥70% FE) and a pressure differential of less than 60 Pa/cm^2. This recommendation is consistent with the World Health Organization, which recommends a pressure differential of 100 Pa over the whole mask (WHO, 2020). Unfortunately, pressure differential and FE can work against one another. It is important to avoid cloth masks with pressure differentials high enough that the wearer finds the mask so uncomfortable as to wear it incorrectly, decreasing the effectiveness of the mask. Hopefully, this new guideline will enhance consumer decision making and improve the consistency of cloth mask performance. In general, cloth masks made of multiple layers of tightly woven fabric offer the best FE and should be worn tight to the face (N95DECON et al. 2020).

It should be a great concern to occupational hygienists, however, that surgical masks and cloth masks, rather than respirators, are widely used to protect workers from COVID-19 transmission in workplaces. In the US state of Utah, approximately 12% of confirmed COVID-19 cases were associated with workplace outbreaks: 58% of workplace outbreaks occurred in the manufacturing, construction and wholesale trade sectors and 73% of the affected workers identified as Hispanic or nonwhite (Bui *et al.*, 2020). Morally and ethically, workers—in particular, *essential* workers—should be provided with the safest working conditions possible. The hierarchy of controls recommends personal protective equipment as a last resort, but engineering controls to prevent aerosol transmissible diseases can take time to implement (Brosseau *et al.*, 2021). In the absence of other effective controls, workers should be provided with respirators rather than surgical masks or cloth masks given the role of respirable infectious aerosols in COVID-19 transmission (Brosseau *et al.*, 2021; Tang *et al.*, 2020). As indicated by the testing methods and performance criteria reviewed herein, cloth masks and surgical masks provide inferior protection relative to FFRs for bioaerosols.

Historically, surgical masks were designed to prevent the emission of respiratory droplets from the wearer (e.g. source control) while respirators were designed to prevent the inhalation of airborne contaminants by the wearer (e.g. receptor control; personal protection). These uses have morphed over time. Surgical masks, for example, as worn by health care workers protect them from droplets from patients but when worn by patients will control emissions (Siegel *et al.*, 2007). With respect to respirators, asymptomatic shedding of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by COVID-19 cases has led to questions about the performance of some respirators for source control. In particular, there is concern that the exhalation valves present on some FFRs (and all elastomeric respirators) may enable the release of SARS-CoV-2 from an infected wearer. Research is ongoing to quantify such emission (Ippolito *et al.*, 2020). There is a need to better characterize the effectiveness of respirators and surgical masks for these dual functions.

It is not clear that the current testing methods and criteria applied to respirators and surgical masks are appropriate for the use of these devices in healthcare settings. Herein, we have highlighted performance criteria most relevant to healthcare settings and which contrast

respirators and surgical masks, but standards may require other tests that are more relevant to industrial uses for the devices. For example, in the USA, NIOSH has developed alternate performance standards for a new class of powered air-purifying respirators (the PAPR100 class) that will undergo a sodium chloride aerosol test instead of the silica dust test, because it has been recognized that the devices are not subject to heavy dust loading in healthcare settings. The high airflow rate used for the NIOSH N95 test is extreme relative to the breathing rate of the person using a mask for source control, and, therefore, overestimates the pressure drop and underestimates the FE as actually worn. Fluid barrier performance may not be necessary for all healthcare activities, but is definitely important for surgical, wound, or emergency procedures that generate splashes and sprays of body fluids. In addition, the design of most FFRs is such that the majority of the filter material is held away from the nose and mouth, such that when splashed, the material is unlikely to penetrate to the facial mucous membranes before the wearer can safely egress to remove the device, even if the device is not fluid resistant.

The COVID-19 pandemic has highlighted a number of challenges related to testing and communication about respirators, surgical masks and cloth masks that should be addressed by the occupational hygiene and public health communities, some of which were discussed at an August 2020 workshop held by the National Academies of Sciences, *Current Issues in the Assessment of Respiratory Protective Devices: Non-Traditional Workers and Public Use*. The severe shortage of respirators has led to emergency guidelines issued by the CDC for extended use, re-use, and decontamination of respirators. Other issues previously discussed herein include the emission of respiratory aerosols through exhalation valves and the requirement of fit testing of respirators during the design, testing, and certification process. An area of public concern has been the measurement of carbon dioxide inside of masks and respirators, which is considered when certifying respirators in the EU and China, but not in the USA (Table 3). Another emerging issue is the design of standards for masks worn by the public for source control, especially in the setting of asymptomatic transmission. Given the similarity in performance standards between countries, consideration could be given for exchangeability of certification, the development of international standards, or the harmonization of standards as a long-term strategy to improve supply chains in emergencies, rather than addressing emergency requests.

Conclusions

Test methods and performance criteria for FFRs and surgical/medical masks are relatively similar among the USA, the EU and China but there are differences with respect to fit testing and whether or not independent laboratories perform the testing. The test methods for FFRs ensure that these devices provide better protection to the wearer than surgical/medical masks. The new EU guideline for evaluation of cloth masks worn by the general public is the start of a process to also develop parallel North American or international guidelines on cloth masks for source control. These guidelines should improve consumer knowledge and access to higher-performing products. The COVID-19 pandemic has highlighted the need for education about the performance and use of respirators and surgical masks beyond the community of occupational health professionals. There is also a need for additional research to improve FFR fit and the performance of surgical/medical masks as both source and receptor controls for infectious diseases.

Acknowledgements

We would like to thank Laura Kwong and Sylvia Smullin and other members of N95DECON.org for their contributions to early versions of the manuscript.

Funding

The authors received no funding for the preparation of the manuscript.

Conflict of interest

The author declares no conflict of interest.

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