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A Research-Grade N95 Respirator Particle Filtration Efficiency Measurement Procedure

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Summary

This report describes the instruments, supporting equipment, and test methods used in the development of the NRC Metrology research-grade N95 respirator Particle Filtration Efficiency Measurement System (PFEMS). The report also presents data acquired to validate the performance of the system in terms of range, repeatability, intermediate precision, and linearity.

This system was designed to quantify number-based filtration efficiency as well as pressure drop across a respirator or other filter media. Two essential quantities are reported: 1) particle number filtration efficiency (η), and 2) pressure drop (ΔP), often referred to as resistance. These two reported quantities are traceable to the SI.

The NRC Metrology PFEMS is based on the NIOSH TEB-APR-STP-0059 protocol, with modifications to use research-grade condensation particle counters (CPCs) and scanning mobility particle sizers (SMPSs) to measure initial number filtration efficiency and other performance characteristics of candidate N95 respirators or filter media. The system is adaptable for ASTM F2299/F2100 testing. The key characteristics of the system are presented in the table below.

Key Characteristics of the NRC Metrology PFEMS	
Specification	**Characteristics**
Limitations on respirator geometry	None
Number filtration efficiency, η (%)	Two CPCs
Mass filtration efficiency (%)	Two SMPSs
Pressure Drop (Resistance) (Pa)	Two barometric pressure gauges
Size dependent filtration efficiency (%)	Two SMPSs
Aerosol source	Nebulized 2% NaCl (by mass) in deionized water or spherical latex beads
Aerosol size distribution	75 ± 30 nm count median diameter (CMD); Geometric standard deviation (GSD) < 1.86; based on mobility diameter for NaCl
Aerosol flow rate	Variable, up to 85 ± 4 slpm
Face velocity	Variable, up to 75 ± 4 cm/s

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List of Abbreviations

Abbreviation	Description
CMD	Count Median Diameter
CPC	Condensation Particle Counter
GSD	Geometric Standard Deviation
HEPA filter	High Efficiency Particulate Air filter
lpm	litres per minute
MFC	Mass Flow Controller
MMAD	Mass Median Aerodynamic Diameter
N95 respirator	facepiece product that filters at least 95% of airborne particles
NIOSH	National Institute of Occupational Safety and Health
PHAC	Public Health Agency of Canada
PPE	Personal Protective Equipment
RH	Relative Humidity
sccm	standard cubic centimetres per minute
SI	International System of Units
slpm	standard litres per minute
SMPS	Scanning Mobility Particle Sizer

List of Symbols

Symbol	Description	Units
η	Particle number filtration efficiency	%
ΔP	pressure drop	Pa
$C_{\#,i}$	Particle concentration as measured by the CPC i	#/cm³
$C_{\#,i}^{Zero}$	Particle concentration of filtered air	#/cm³
$C_{\#,i}^{0}$	Particle concentration adjusted to STP (T°= 293 K, P°=101.325 kPa)	#/cm³
$C_{\#,i}^{Blank}$	Particle concentration in the absence of filtration	#/cm³

1 Background

1.1 SARS-CoV-2 pandemic and need for N95 respirator testing

The SARS-CoV-2 pandemic has caused a dramatic increase in demand for personal protective equipment (PPE), notably including the N95 respirators used to protect medical personnel, first responders, and other frontline workers from the inhalation of airborne droplets, small droplet residues, or other aerosol particles that may contain pathogens. At the same time, the pandemic has disrupted the manufacture and distribution of such equipment by established sources. This has compelled users to consider alternative sources of supply: expired stock that would in normal circumstances be discarded, newly-established manufacturing facilities with no prior history or certifications for the production of such respirators, or foreign suppliers whose products may be certified according to the similar but non-equivalent standards from other jurisdictions. Several countries have also reported counterfeit and sub-standard products being sold. There is an urgent need for performance evaluation of these N95 respirators to identify the products and suppliers that can meet the needs of Canada, from both filtration efficiency and resistance (pressure drop) perspectives.

The N95 designation is used for particulate filtering facepiece respirators that filter at least 95% of airborne particles in accordance with the US National Institute for Occupational Safety and Health (NIOSH) standard testing procedures (NIOSH, 2016). At the onset of the SARS-CoV-2 pandemic outbreak in March 2020, Canada had limited capacity to manufacture, test, or certify N95 respirators. Previously, respirators used in Canada were obtained from foreign suppliers whose products were already certified according to NIOSH standards in the US, and no NIOSH-compliant testing was performed in Canada. Anticipating the need to test products both from newly established domestic manufacturers as well as from suppliers adhering to different certification and testing standards, the National Research Council of Canada (NRC) Metrology Research Centre has developed and validated a research-grade system for particle filtration efficiency and resistance performance-testing of N95 respirators.

This report describes the instruments, supporting equipment, and test methods used as well as the lessons learned in the development of the NRC Metrology research-grade N95 respirator Particle Filtration Efficiency Measurement System (PFEMS). This system is designed to quantify number-based filtration efficiency as well as pressure drop across a respirator or other filter media. The mass-based filtration efficiency can also be inferred with this system, the demonstration of which is beyond the scope of this document.

1.2 Aerosolized viruses and respirator filtration

The airborne transmission of disease may occur when particles are produced from the respiratory tract lining fluid by various routes. In order of increasing particle emission rates, these include normal respiratory activities (breathing and talking), symptomatic respiratory activities (coughing and sneezing), and aerosol-generating medical procedures such as intubation (Jones and Brosseau 2015; Tellier et al. 2019). By number, the majority of emitted particles have diameters < 1 micrometre (µm) (Bake et al. 2019; Papineni and Rosenthal 1997; Morawska et al. 2008), although sneezing, coughing, and medical procedures may also generate larger droplets (Gralton et al. 2011). After emission, respiratory droplets dry rapidly to reach

about 30% of their initial diameter (Redrow et al. 2011). Here, the term “droplet” is used to refer to respiratory particles before drying and the term “particle” is used to refer to respiratory particles after drying. Some medical sources use the term “droplet nuclei” for dried respiratory particles (World Health Organization, 2020).

Patients infected with various diseases have been shown to generate infectious airborne particles from all of the aforementioned activities (breath, speech, coughing, sneezing) (Fennelly et al. 2004; Lloyd-Smith et al. 2005; Cowling et al. 2013; Jones and Brosseau 2015; Yan et al. 2018; Leung et al. 2020). The pathogen may be of a size comparable to the emitted particles, as is the case for many micrometer-sized bacterial pathogens, or much smaller (on the order of 0.1 µm in diameter) in the case of many viruses including influenza viruses and coronaviruses. For example, the SARS-CoV-1 (the virus that caused the 2003-2004 SARS outbreak) is 0.078 µm in diameter (Goldsmith et al. 2004). SARS-CoV-2 has a similar molecular mass to SARS-CoV-1 and therefore will have a similar diameter. Since the diameter of such coronaviruses is smaller than the typical diameter of respiratory particles, infectious particles should be viewed as bioaerosols of lipids, water, proteins, and potentially viruses and bacteria (with typical sizes less than 1 µm as noted above).

All of these particles are within the range that an N95 respirator is expected to efficiently remove. Although the N95 specification was designed for manufacturing and construction industries, the fundamental science of particle filtration is not significantly different between industrial and infectious particles (Radonovich et al. 2009; Kulkarni, Baron, and Willeke, 2011).

1.3 Current state of knowledge on most relevant testing procedures

Airborne nanoparticles may be captured during their passage through a filter when they come into contact with the filter by diffusion, inertial impaction, or interception. Interception occurs when a particle following gas-flow streamlines comes within one particle radius of the filtration medium. These three processes may be viewed in terms of a nanoparticle’s size; the path of smaller particles is significantly affected by their interaction with gas molecules, thus more subject to a random walk, and therefore undergoing diffusion, whereas larger particles are well described by viewing the air as a continuous fluid where impaction and interception are more important. Therefore, diffusion mainly applies to the smallest particles (diameters below ~0.1 µm) and impaction and interception to larger particles (diameters above ~1 µm) (Kulkarni, Baron, and Willeke, 2011). Between these size ranges (0.15 - 0.5 µm), particles are generally captured by a mixture of these mechanisms, but with lower efficiency, as they do not efficiently undergo either process. Electrostatic forces, resulting either from the use of electrostatically charged materials or from the accumulated deposition of naturally charged particles, can greatly enhance efficiency in this range (Wang, 2001).

Infectious aerosol particles can span a very wide range of sizes, such that all of the above processes come into play during their filtration (Gralton et al. 2011). Importantly, the efficiency with which a given pathogen (such as SARS-CoV-2) is filtered does not depend only on the diameter of the pathogen itself, but also on the amount of additional material (e.g. lipids, water, and proteins) also present in the respiratory droplet.

In order to address a wide range of infectious aerosols, respirator performance is best evaluated using test particles of a size which is most likely to be transmitted through a filter material. In the NIOSH TEB-APR-

STP-0059-508 N95 standard, this concept is addressed by the use of sodium chloride (NaCl) particles with a count median mobility diameter (CMD) of 0.075 ± 0.020 µm and a lognormal size distribution with geometric standard deviation (GSD) < 1.86. The approach documented by the NIOSH N95 standard was modified by NRC Metrology (see Section 3.1) for the express purpose of providing reliable testing for healthcare workers using state-of-the-art aerosol instrumentation.

Counterintuitively, the same population of NaCl particles can be described by the 0.075 ± 0.020 µm CMD specified by the NIOSH protocol and by the 0.3 µm mass median aerodynamic diameter (MMAD) specified by the US 42 CFR 84 regulation. For the same size distribution of NaCl aerosol, the MMAD is larger than the CMD primarily because the MMAD represents single-particle-mass-weighted particle counts, whereas the CMD represents only particle counts. However, the MMAD is also larger because it reflects the aerodynamic diameter (the diameter of a particle with settling velocity equivalent to a volume-equivalent sphere with a density of 1000 kg m^{-3}), which is connected to inertia and therefore particle density, in contrast to the mobility diameter (the diameter of a particle with migration velocity equal to that of a volume-equivalent sphere). Conversion between CMD and MMAD can be accomplished using the mathematical definitions of mobility diameter, aerodynamic diameter, MMAD, and CMD given by Hinds (1999). It is necessary to take into account the density of NaCl (2160 kg m^{-3}), the experimentally determined 1.1-fold enhancement in aerodynamic drag force experienced by laboratory-generated NaCl particles (the so-called shape factor; Zieger et al., 2018), and the fact that nanoparticles do not experience a continuum drag force but rather “slip” between air molecules (this “Cunningham slip correction” was calculated using the data of Kim et al., 2005). The result is that when observed with an electron microscope, these NaCl particles would have a median physical diameter of 0.071 µm, but the majority of their mass would deposit on to the lungs with a pattern similar to 0.3 µm water droplets.

It should be noted that the flexibility of the NRC PFEMS facilitates alternative testing procedures such as ASTM F2299/F2100, which can readily be implemented with minimal changes to the system. Demonstration of the NRC PFEMS for ASTM F2299/F2100-equivalent testing will be presented in a future publication.

2 Method

2.1 Overview

The method described below is used to provide the two essential reported quantities: 1) particle number filtration efficiency (η), and 2) pressure drop (ΔP), often referred to as resistance. These two reported quantities are traceable to the SI (International System of Units). To reliably obtain these quantities, the particle size distribution, particle number concentration, flow rate, pressure, temperature, and relative humidity are continuously monitored.

The protocol employed by the NRC Metrology PFEMS measures the number fraction of airborne NaCl particles with CMD 0.075 ± 0.020 µm that are transmitted by a given N95 respirator, using a pair of condensation particle counter (CPC) instruments. A particle entering a CPC is exposed to supersaturated vapour (butanol or water, depending on the model of the CPC), resulting in condensation of the vapour onto the nanoparticle. This condensation grows the particle to a diameter sufficiently large (> 1 µm) to be easily counted by laser light scattering recorded by a photodetector in an optical chamber. The number of particles K_i counted in a time duration t (minutes) at a flow rate of Q_i (sccm) gives the number concentration (particles per cubic centimetre) measured by CPC i:

$$C_i = \frac{K_i}{tQ_i} \qquad \text{(Equation 1)}$$

Zero conditions for each CPC ($C_{\#,1}^{Zero}$ and $C_{\#,2}^{Zero}$) are defined as the particle number concentration when sampling HEPA-filtered air at the inlet of the sampling system to remove all background particles and with the line from the nebulizer closed (see Figure 1). Reference CPC conditions ($C_{\#,1}^{Blank}$ and $C_{\#,2}^{Blank}$) were defined by running the system with no respirator in place, in order to quantify particle transmission losses in the system (between the upstream CPC1 and downstream CPC2 relative to the candidate N95 respirator under test). The reference conditions also serve to ensure that the two CPC calibrations are consistent, and to normalize for any systematic differences in K_i or Q_i. The final filtration efficiency is then calculated from the CPC measurements as

$$\eta = \left(1 - \left(\frac{C_{\#,2} - C_{\#,2}^{Zero}}{C_{\#,1} - C_{\#,1}^{Zero}}\right)\left(\frac{C_{\#,1}^{Blank}}{C_{\#,2}^{Blank}}\right)\left(\frac{T_2}{P_2}\right)\left(\frac{P_1}{T_1}\right)\right) \times 100 \qquad \text{(Equation 2)}$$

If the number concentrations in Equation 2 are replaced with mass concentrations, then a mass-based filtration efficiency can be derived. This option is further discussed in Section 3.1 and will be addressed in future work.

2.2 Apparatus

Figure 1 is a graphical representation of the NRC Metrology PFEMS used to test the number-based filtration efficiency of candidate N95 respirators.

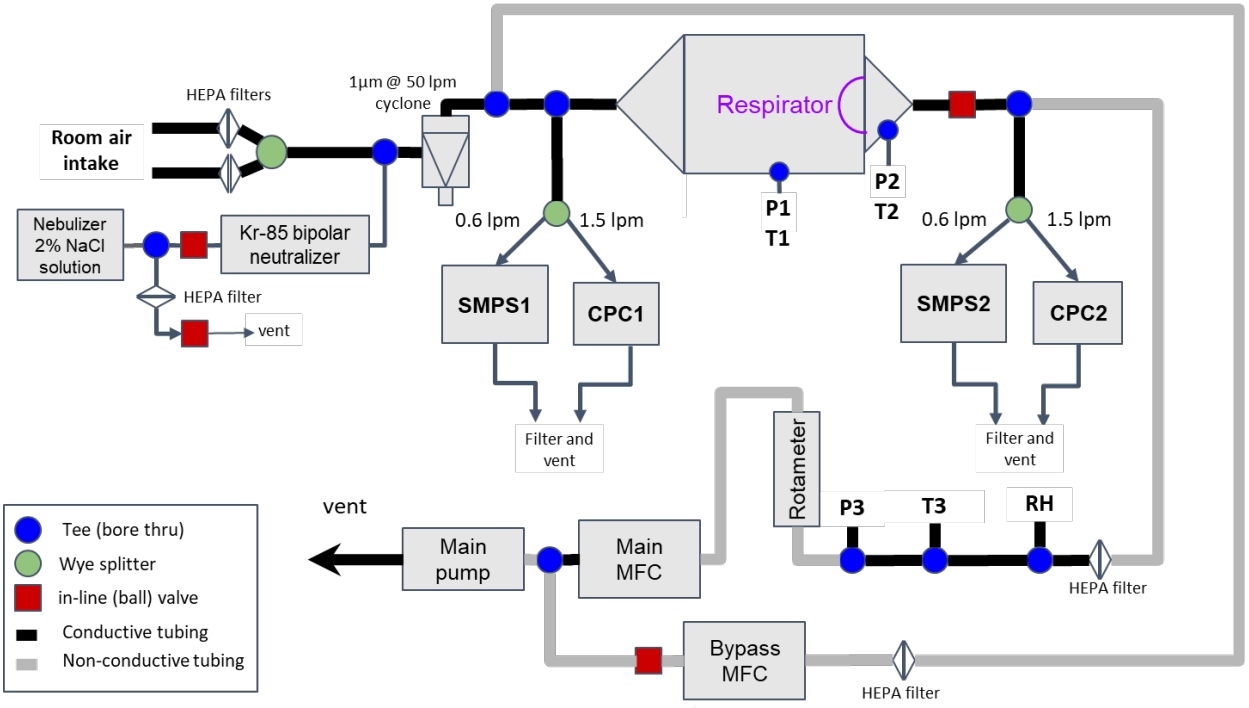

Figure 1. Schematic of the apparatus used for N95 respirator particle number-based filtration efficiency testing.

2.2.1 Aerosol flow path

The aerosol flow is driven by the main pump which draws filtered air through the testing system. The aerosol generation takes place in the nebulizer. For zero-particle testing, filtered room air is sampled through the parallel path. The nebulizer generates an aerosol of air and NaCl particles from a solution of 2% by mass NaCl in deionized water, and with a flow rate of approximately 2 lpm. The generated aerosol is passed through a Krypton-85 bipolar charger (also known as a neutralizer) to impart a Boltzmann distribution of electric charge to the particles, resulting in equilibrium (Kulkarni, Willeke, and Baron, 2011). Excess generated aerosol is vented to the room through a HEPA filter. The upper “zero air intake” branch is used for dilution of the generated aerosol and also to satisfy the flow rate requirements of 85 ± 4 lpm. The temperature and relative humidity of the zero air intake is maintained at 25 ± 5 °C and 30 ± 20% RH, respectively.

After the aerosol is at charge equilibrium, it passes through a cyclone which is used to remove large (> 1 µm) particles, preventing contamination of the instruments, and ensuring full mixing of the NaCl aerosol stream with the dilution air stream. From there, the upstream particle number concentration is measured with a CPC (CPC1) and the particle mobility size distribution is monitored with a Scanning Mobility Particle Sizer (SMPS) (SMPS1). The particle size distribution is monitored to ensure that the CMD is within

0.075 ± 0.030 µm and the GSD does not exceed 1.86. The aerosol is then pulled through the N95 respirator testing chamber and through the respirator under test, which is to be prepared as described in the next section. The pressure is measured with barometers upstream and downstream of the N95 respirator (P_1 and P_2, respectively), allowing the pressure drop through the respirator to be calculated as $\Delta P = P_2 - P_1$.

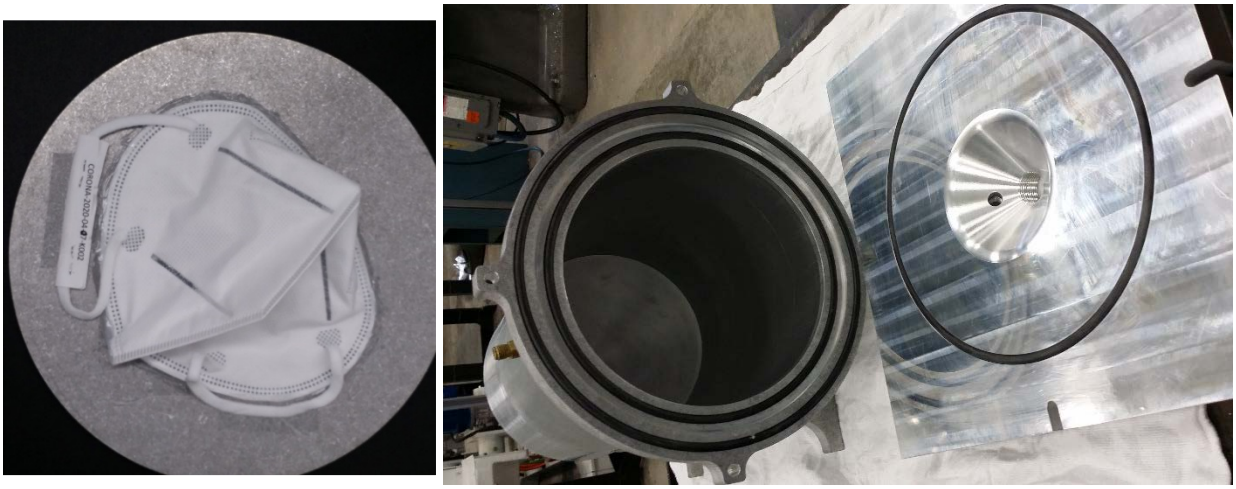

Figure 2. N95 respirator mounting and testing chamber. (Left: N95 respirator glued on a disc with a 90 mm diameter hole in the middle. Right: respirator-testing chamber, open.)
The chamber starts with a 10 cm long expansion cone from a ½ inch Swagelok to the 17 cm diameter X 16.5 long cylinder leading to the N95 respirator under test. There is another cone behind the N95 respirator where the aerosol is being evacuated. The chamber is equipped with quick release clamps which reduces the time needed to change the discs with glued N95 respirators.

Downstream of the N95 respirator, measurements are taken using a second CPC (CPC2) and SMPS (SMPS2). The two SMPS systems, upstream and downstream of the N95 respirator, provide data to estimate the mass-based and size-resolved filtration efficiency of the candidate N95 respirator. The system may also be operated without the two SMPSs (which are an addition to the NIOSH procedure) provided the aerosol size upstream of the N95 respirator is known.

With the exception of the two SMPSs, all instrument readings are recorded by a data acquisition system at a rate of 1 Hz. The SMPSs are set to perform a scan every 120 s, and this data is also recorded by a data acquisition system.

The approximate filtration efficiency of the N95 respirator is given by:

$$\eta = 1 - \frac{C_{\#,2}}{C_{\#,1}} \qquad \text{(Equation 3)}$$

The aerosol is then filtered before its relative humidity is measured by a hygrometer (RH), temperature by a thermocouple readout (T_3), and pressure by a barometer (P_3). The air flow then goes through a rotameter where the volumetric flow rate is measured. A mass flow controller adjusted to 82.9 slpm controls the flow rate just before the pump, with the balance of the target 85 slpm flow through the respirator being drawn by the downstream instruments, CPC2 (1.5 slpm) and SMPS2 (0.6 slpm).

2.3 Testing Method

The candidate N95 respirators are first labelled with the lot and sample numbers to assist in tracking and record keeping. The elastic retaining straps are cut off to simplify handling and to avoid reduction of effective filtering cross-section, and the periphery of the candidate N95 respirator is mounted to a circular aluminum plate with hot-melt adhesive. Care is taken to ensure that the adhesive provides an airtight seal around the entire periphery of the candidate N95 respirator, to avoid leakage during testing. Once mounted to their plates, the candidate N95 respirators may be conditioned in an environmental chamber at a temperature of 38 °C ± 2.5 °C and a relative humidity of 85 % ± 5 % for a period of 25 ± 1 hours. Upon removal from the chamber the respirators are sealed into airtight plastic bags and immediately transferred for testing. After a final visual inspection to check for tears, cuts, or other damage, each sample in turn is tested within 10 hours after removal from the environmental chamber. The N95 respirators may also be tested without prior environmental conditioning.

The plate holding the respirator is mounted in the test chamber, with the outer face of the N95 respirator facing the incident air stream, and the aft wall of the chamber is clamped against the plate, sealing its edges with O-rings on both sides of the metal plate holder. The mounting plate for the respirator has a 90 mm diameter hole centred in a 200 mm diameter disc. The main pump is turned on and, after a period of time (typically within one to two minutes) to allow flow rates and particle number concentrations to stabilize, pressures, temperatures, humidity, particle number concentrations (from the CPCs) and particle size distributions (from the SMPSs) are logged continuously for 5 minutes. During this time the upstream particle number concentration must be below $3x10^5$ particles/cm^3 (the maximum acceptable concentration for the upstream CPC currently in use) while the downstream concentration must be above $5x10^2$ particles/cm^3 (the minimum acceptable concentration for the specific downstream CPC currently in use; see Figure 3). Any necessary adjustments to the output flow from the nebulizer to maintain the desired aerosol number concentration level are carried out before the start of the test.

The background concentration readings of the CPCs (typically ca. 10 particles/cm^3) are checked at the start and end of each day's measurements by collecting 5 minutes of data with no aerosol flow (nebulizer valve closed). "Blank" measurements, using a mounting plate without a candidate N95 respirator, provide particle number concentrations at the upper limit of the range, which can be used to normalize for particle losses in the system as well as for minor calibration differences between the two CPCs. Blank measurements are performed at the start and end of the day, and after every 8-10 candidate N95 respirators (approximately every 1-2 hours) in between. An additional daily test run with a reference N95 respirator of known performance serves as a process-control check. In combination, the zero, blank, and reference N95 respirator serve as daily method verification of the measurement system.

Throughput with this process is around 7-8 candidate N95 respirators per hour, excluding the time spent on method verification and additional blank and zero checks (and excluding the time for mounting and conditioning the respirators). With practiced operators, the interval for respirator changeover and stabilization of the count rates after restarting the main pump is around 2 minutes between runs.

2.4 Analysis Method

The filtration efficiency is calculated with the following four-step procedure. The first step, after importing the data, is to average the particle concentration between specific start and stop time for a given test run. The start and stop times are recorded manually while performing the experiment, along with the temperature and the pressure in the sampling line. The second step is to correct for background concentration readings from both CPCs, at the initial measuring step. The third step is to correct the CPC concentrations to standard temperature and pressure (T°= 293.15 K and P°=101.325 kPa). The particle number concentration, corrected for background and for temperature and pressure, is expressed as

$$C_{\#,i}^{0} = \left(C_{\#,i} - C_{\#,i}^{Zero}\right)\frac{T_i}{\mathrm{T}^\circ}\frac{\mathrm{P}^\circ}{P_i} \qquad \text{(Equation 4)}$$

Finally, the last step is to calculate the filtration efficiency using the following formula

$$\eta = \left(1 - \frac{C_{\#,2}^{0}}{C_{\#,1}^{0}}\frac{C_{\#,1}^{Blank}}{C_{\#,2}^{Blank}}\right) \times 100 \qquad \text{(Equation 5)}$$

The $C_{\#,i}^{Blank}$ is the particle number concentration, of CPCi, measured when there is no respirator inside the testing chamber.

Since the measured particle concentrations during zero tests are negligible, and since the CPCs are in very good agreement during blank tests, and since temperatures and pressures upstream and downstream of the respirators are close to standard condition, the approximate filtration efficiency determined from the manually recorded values is normally within 5% of the final reported values. These manually recorded values are therefore used during quality assurance.

3 Validation of the method

3.1 Differences between the NRC Metrology PFEMS and NIOSH TEB-APR-STP-0059-508

Normally, N95 respirators used in Canada are tested and certified according to NIOSH TEB-APR-STP-0059 protocol (hereafter referred to as the NIOSH protocol). The NIOSH protocol is itself based on the US 42 CFR 84 regulation. NRC Metrology adapted the NIOSH protocol while developing its testing procedure for three reasons. First, the NIOSH protocol involves very high particle concentrations in order to represent the clouds of dust to which miners and industrial workers are exposed; healthcare workers are not exposed to comparable doses even during aerosol-generating procedures. Second, the NIOSH protocol specifies the use of a photometer detector to infer mass concentration, which is less accurate than the CPCs used here to measure number concentration here (although the SMPSs used here can also be used to determine mass concentrations). Third, the NIOSH protocol specifies other extremely precise details, including the manufacturer and model number of the instruments (in particular the TSI 8130A) and supplies to be used in the tests.

The modifications made by NRC Metrology therefore represent a substantial increase in capital cost but also in accuracy. The modifications adopted include:

- The filtration efficiency reported by the NRC Metrology PFEMS is expressed as a particle **number** concentration filtration efficiency, whereas the NIOSH protocol requires a **mass** concentration filtration efficiency. Number concentrations can be specified with lower uncertainty than mass concentrations. There is no experimental evidence available on whether particle number or mass correlate more closely with the risk of infection of respiratory particles, although it is known that more massive particles are less likely to penetrate deep into the lungs.
- Research-grade Scanning Mobility Particle Sizers (SMPSs) were utilized to ensure that the particles generated are within the prescribed size range, instead of using calibrated filter paper. This is a direct measure of size, instead of an inferred value. The SMPSs also have the advantage of being able to provide mass concentration estimates.
- Neither the mass flux of the aerosol nor the test duration in terms of mass loading is reported. This information is not essential, since the NRC Metrology PFEMS was not developed to measure the high dust concentrations to which industrial workers are exposed. However, the NRC Metrology PFEMS does provide enough information to estimate the mass flux (by combining the CPC and SMPS data with the measured flow rate). The test duration is typically 5 minutes, which can be extended as necessary.
- Relaxed constraints on the particle size (CMD of 0.075 ± 0.030 µm rather than 0.075 ± 0.020 µm) and ambient humidity (30 ± 20% RH rather than 30 ± 10% RH) are used.
- The NRC Metrology PFEMS was developed to measure the initial filtration efficiency, the most relevant measurand for frontline workers potentially being exposed to virus-laden aerosol particles.

The details which are consistent between the NRC Metrology and NIOSH protocols are:

- Candidate N95 respirators are preconditioned in an environmental chamber for 25 ± 1 hours at a relative humidity of 85 ± 5 % and a temperature of 38 ± 2.5 °C.
- The air flow through the respirator is maintained at 85 lpm.
- The aerosol used is a 2% by mass solution of NaCl in deionized water.

3.2 Traceability and Process Control

3.2.1 Calibrations

Four CPCs were used in the NRC Metrology PFEMS. One with an independent laboratory calibration certificate was used to calibrate the other CPCs in the NRC Metrology laboratory over the full range of concentrations in which single-count mode for the CPC is applicable. In Figure 3, the response of three CPCs as a function of the response of a fourth in-calibration CPC is presented. This shows that the response of all four CPCs is linear, with exception of the TSI 3025A CPC, whose response is linear above $6x10^2$ #/cm^3.

A zero (particle-free, no N95 respirator) and a blank (no N95 respirator with particles in the flow) test is performed before and after every measurement cycle. The ratio of the responses obtained during a blank measurement from the two CPCs used to determine filtration efficiency as well as the zero measurements are used to correct the measured concentration. The NRC Metrology analysis requires that the relative responses of the two CPCs is similar at the concentrations used to measure the blanks and the N95 respirator.

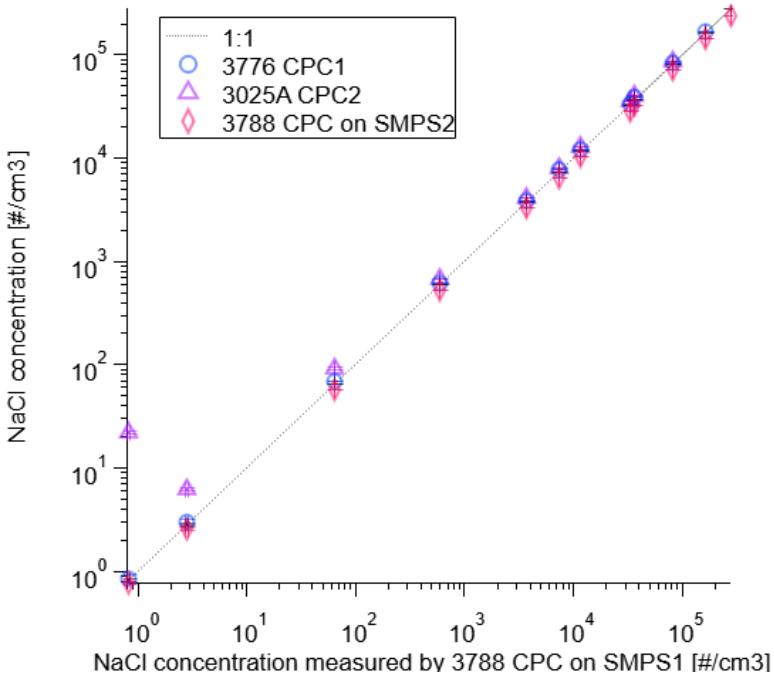

Figure 3: Linearity of CPC response as a function of an in-calibration TSI 3788 CPC.

During the initial evaluation of the NRC Metrology PFEMS, it was verified that the relative responses between the in-calibration CPC 3788 and the other CPCs were constant over the range of concentrations to be measured.

3.2.2 Data and Analysis Quality Assurance

Quality control of the data involves:

- Ensuring that the difference between the initial estimate (Equation 2) and final calculated filtration efficiency (Equation 3) is less than approximately 5%. The cause of larger deviations (e.g. due to a respirator with a higher pressure drop) should be ascertained.
- Ensuring that all pressure drops are positive and confirm any outliers using the real time automatically logged data.
- Inspecting time series of all measurands to ensure that the system was stable during each five minute measurement point.
- Inspecting SMPS size distributions upstream of the N95 respirator to ensure that the NaCl aerosol particle size distribution is within the desired specifications.

Graphs or tables of all quality control steps are recorded and archived.

3.3 Method Validation

A series of experiments were performed in order to conduct a method validation for the NRC Metrology PFEMS.

3.3.1 Demonstration of Range

Candidate N95 respirators were measured with number filtration efficiencies from 65% to 99.5%, as shown in Figure 4. This is not the absolute limit of the range, which is known from the zero and blank measurements to cover 0% to 100%, but it is a demonstration of the range determined for a number of candidate N95 respirators.

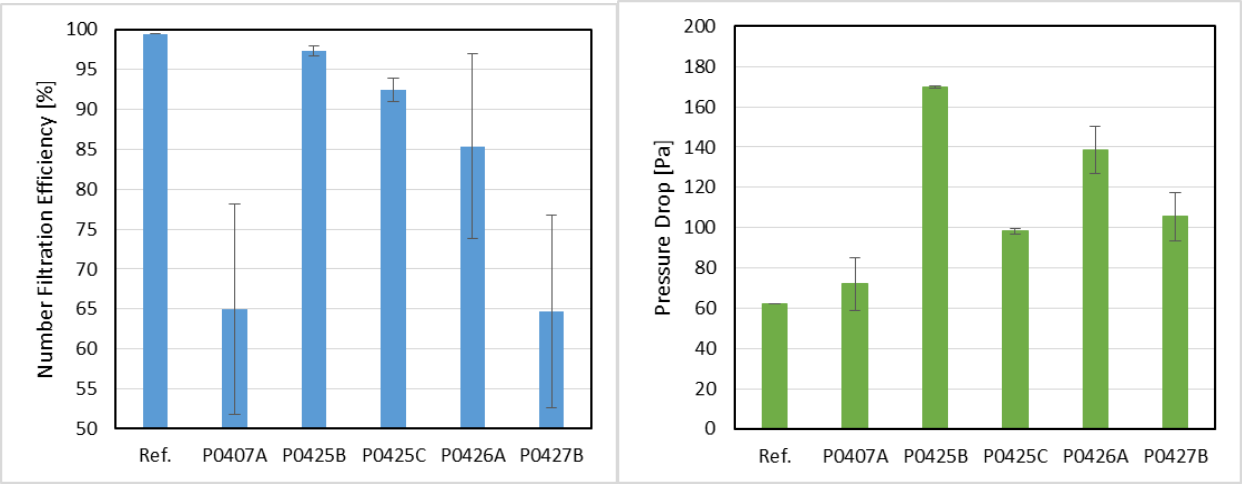

Figure 4: Illustration of the range of the NRC Metrology PFEMS, covering filtration efficiencies from under 65% to over 99% and pressure drop from 60 to 170 Pa, for 1 certified and 26 candidate N95 respirators from 5 different lots.

3.3.2 Repeatability

An experiment was performed to assess the repeatability of the NRC Metrology PFEMS. A single certified N95 respirator was inserted into the respirator-testing chamber, tested for 5 minutes, and removed from the respirator-testing chamber. The respirator remained glued to the same mounting plate for the repeatability test. This was repeated ten times at the same test conditions. The results are shown in Table 1 below.

Table 1: Repeatability determined for the NRC Metrology PFEMS.

N95 Respirator ID	Pressure drop, ΔP [Pa]	Number-based Filtration Efficiency, η [%] (mean)	Number-based Filtration Efficiency, η [%] (uncertainty, k=2)
R007_1	66.7	99.59	0.01
R007_2	73.1	99.19	0.16
R007_3	70.7	99.60	0.02
R007_4	58.5	99.58	0.01
R007_5	68.8	99.57	0.01
R007_6	69.8	99.55	0.01
R007_7	68.0	99.57	0.01
R007_8	83.6	99.59	0.02
R007_9	66.7	99.54	0.01
R007_10	66.8	99.50	0.02
Mean	**69.4**	**99.57**	

It should be noted that the respirator-to-respirator variability is expected to be larger than the low uncertainty found with this repeatability measurement. The day-to-day variability was not evaluated during this test. This repeatability test demonstrates the reliability of respirator loading and unloading procedures and overall system variability over the series of ten 5-minute test runs.

3.3.3 Intermediate Precision

An experiment was performed to assess the intermediate precision of the NRC Metrology PFEMS. This experiment involved the testing of fifteen different certified N95 respirators of the same model type and from the same lot. The respirators were certified N95 3M Aura 9210, and they were tested for 15 minutes per respirator. The results were that the mean pressure drop was 76 Pa, and the filtration efficiency was 99.45 ± 0.13% (k=2).

Table 2: Intermediate precision determined for the NRC Metrology PFEMS.

N95 Respirator ID	Pressure drop, ΔP [Pa]	Number-based Filtration Efficiency, η [%] (mean)	Number-based Filtration Efficiency, η [%] (uncertainty, k=2)
R001	69.9	99.48	0.01
R002	71.4	99.43	0.01
R003	72.9	99.56	0.01
R004	72.6	99.56	0.01
R005	73.5	99.47	0.01
R006	70.8	99.26	0.02
R007	72.1	99.41	0.02
R009	69.3	99.26	0.02
R010	76.9	99.63	0.01
R011	72.1	99.57	0.01
R012	69.0	99.34	0.02
R013	74.7	99.59	0.01
R014	73.6	99.30	0.02
R019	69.7	99.35	0.02
R020	71.6	99.52	0.01
Mean	**73.0**	**99.50**	

3.3.4 Linearity

To assess the linearity of the NRC Metrology PFEMS, a series of experiments were conducted on a single certified N95 respirator. It was initially tested while in new condition. Subsequently, the performance of the respirator was intentionally degraded by punching holes in it with a 1.5 mm diameter metal punch. 10, 20, and 30 evenly spaced holes were made in the respirator, with testing occurring after each group of 10 holes. The results shown in Figure 5 illustrate that the NRC Metrology PFEMS has remarkable linearity over the range from 85% number filtration efficiency to greater than 99%. Filtration efficiencies below 85% were not measured, as such efficiencies are already lower than the target efficiency of 95%. However, a similar linearity below 85% can be predicted since the blank condition corresponds to an efficiency of 0% and since the CPCs were demonstrated to be linear across a wide range (Figure 3).

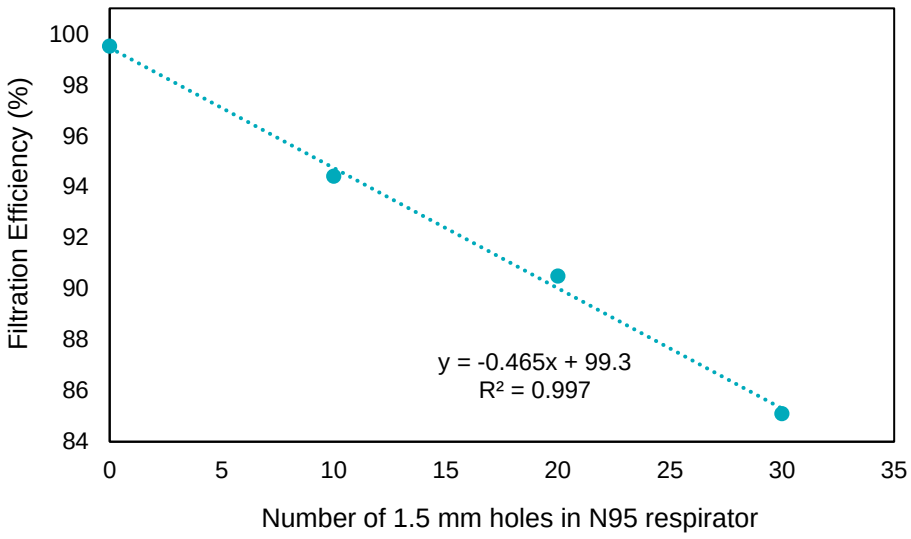

Figure 5: Demonstration of linearity for the NRC Metrology PFEMS

3.3.5 Duration of N95 respirator Testing Time

The duration of N95 respirator testing time was assessed by comparing the first 5, 10 and 15 minute real-time data from 15 minute respirator testing runs. This was conducted for fourteen certified N95 3M Aura 9210 N95 respirators. The results shown in Figure 6 illustrate that there is no significant difference between sampling for 5 minutes compared to 10 or 15 minutes.

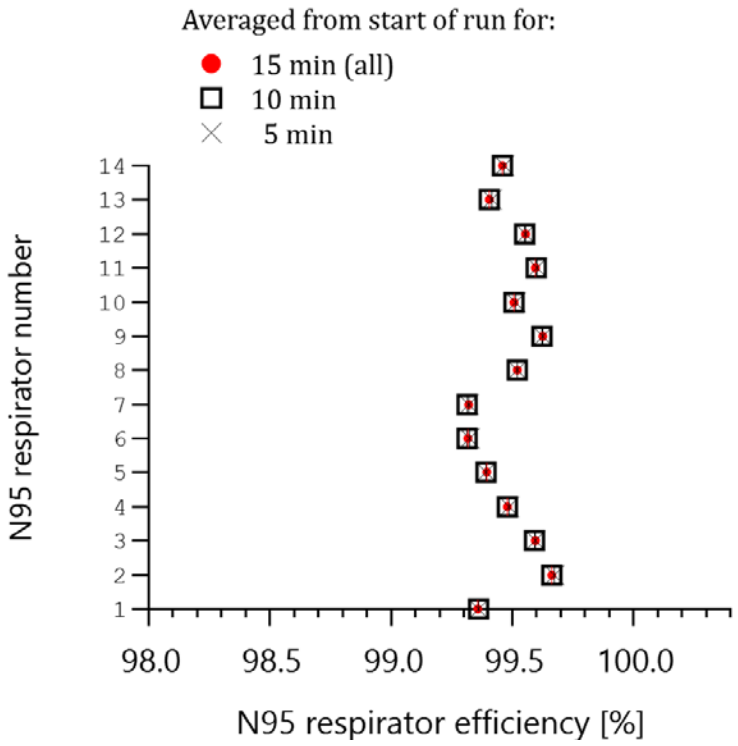

Figure 6: Demonstration of the influence of respirator testing time on the filtration efficiency for the NRC Metrology PFEMS

3.4 Method Verification

Method verification is conducted daily. Three whole-system measurements are performed every measurement day: a zero-particle test, a blank test (no N95 respirator) and a reference N95 respirator test. The zero and blank measurements serve a purpose similar to a zero-and-span check, covering the 0% to 100% of full-scale range for the filtration efficiency.

- The zero-particle test serves to check for leaks in the system and to assess any initial bias for the CPCs and SMPSs. It is performed using HEPA-filtered air at the inlet of the system at the beginning of the day and at the end of the day. Typically the values on the CPCs should be < 10 #/cm^3. If this value is > 20 #/cm^3, the experiment should be paused and the source of the leak investigated.
- The blank-test test serves to provide data for normalizing CPC1 and CPC2 as well as SMPS1 and SMPS2. It is performed using the nebulized NaCl aerosol and a mounting plate with a 90 mm diameter hole, but without a respirator affixed to it. It is performed at the beginning of the day and at the end of the day, and approximately every 1.5 hours during measurement periods. This normalization is required, as there is some loss of particles between the upstream and downstream sampling ports, as the particles pass through the measurement chamber for the respirators.
- The reference N95 respirator test is performed as a whole-system repeatability check with an accepted certified N95 respirator. It is performed at the beginning of the measurement day, with a reference N95 respirator glued to a mounting plate with a 90 mm diameter hole.

3.5 Size-resolved efficiency

The SMPS measurements provided by the NRC Metrology PFEMS allows size-resolved filtration efficiencies to be calculated, providing insight into the mechanisms of particle capture. This is possible by applying Equation 2 to each size bin recorded by the two SMPSs, rather than to the total number.

As shown in Figure 7, an example using data for two different respirators, the performance of respirator B is excellent at all sizes, whereas the performance of respirator A is substantially reduced at larger sizes. This suggests that filter B is less effective in capturing particles through impaction or interception mechanisms which are related to particle inertia (Section 1.3).

The horizontal dashed lines in Figure 7 show the filtration efficiencies calculated from the CPC data for the same respirators using Equation 2, for context. The two independent measurements show good consistency. Note that the blank measurement conditions were used to derive a single calibration factor for SMPS2 transferred from SMPS1. The alternative is to calculate a calibration factor for each size bin in the SMPS data. This alternative may introduce substantial uncertainty, since the counts in a given SMPS size bin are affected by multiple charge and diffusion corrections (among other factors).

Although CPC-based total number efficiencies are preferentially reported due to their greater accuracy, size-resolved filtration efficiencies provide insight into the mechanism by which a respirator filters particles. Horizontal dashed lines in (A) and (B) represent the filtration efficiencies derived from the CPCs (Equation 2), which are in good agreement with the SMPS data.

The SMPS data may also be used to provide mass-based filtration efficiencies. This application is beyond the scope of the present document.

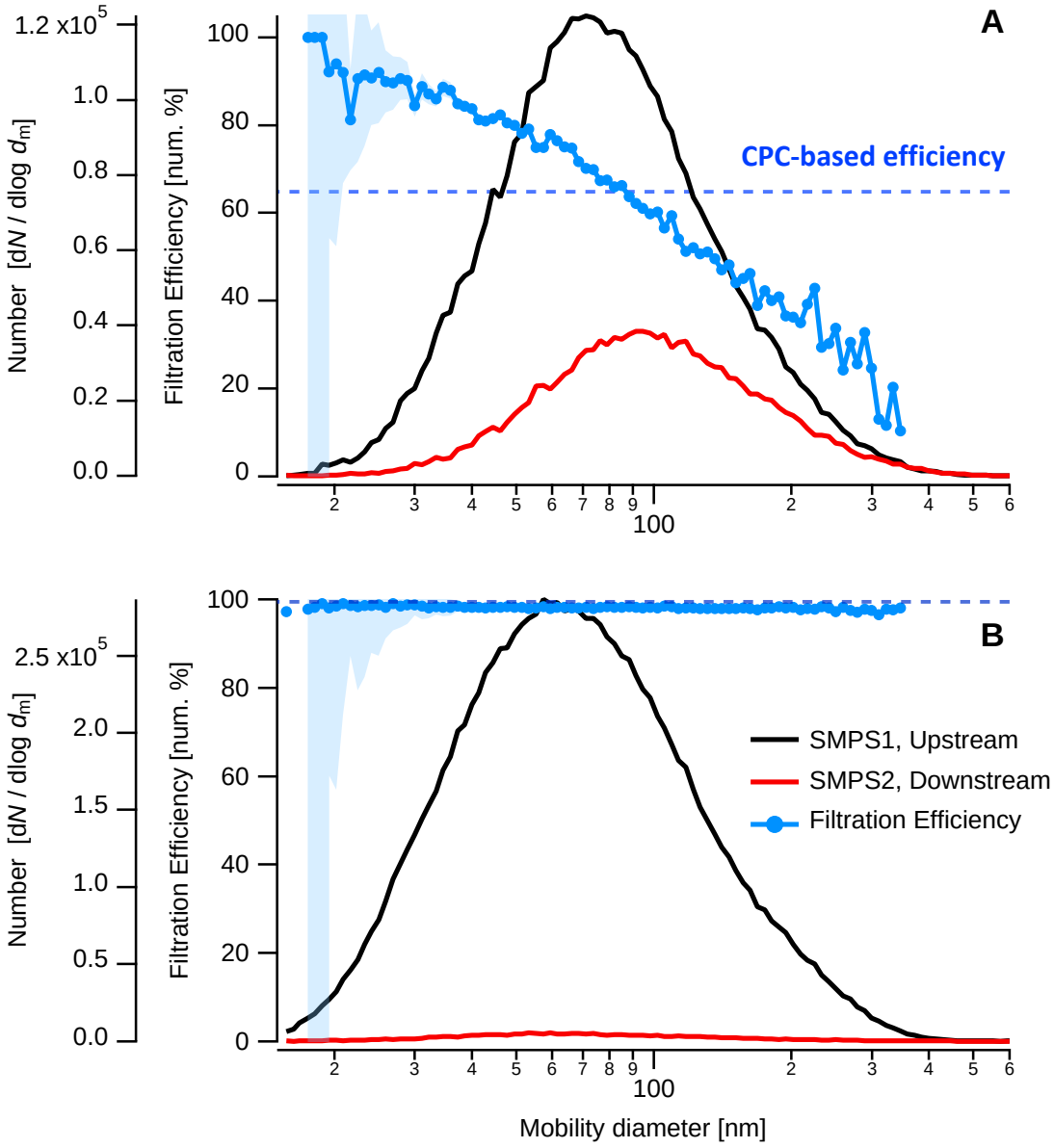

Figure 7: Illustration of size-resolved filtration efficiencies obtained from the SMPS data for two representative respirator samples.

4 Conclusions

NRC Metrology has developed a system for measuring the aerosol particle filtration efficiency of respirator using components available in many aerosol research laboratories. The performance of this system was validated through the determination of the range, linearity, respirator testing duration, repeatability, and intermediate precision of the apparatus. The NRC Metrology PFEMS has been demonstrated to be a capable performer for measuring the number filtration efficiency of candidate N95 respirators.

The measurement system described in this document provides insights to aerosol research laboratories on the apparatus developed at NRC Metrology and, importantly, demonstrates that all the method validation required to confidently measure filtration efficiency were performed, and the daily method verification to ensure the NRC Metrology PFEMS is operating optimally are being performed.

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