Ann. Occup. Hyg., 2014, Vol. 58, No. 2, 206–216
doi:10.1093/annhyg/met054
Advance Access publication 9 October 2013

BOHS
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Total Inward Leakage Measurement of Particulates for N95 Filtering Facepiece Respirators—A Comparison Study

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Received 9 April 2013; revised 21 June 2013; revised version accepted 3 August 2013.

ABSTRACT

National Institute for Occupational Safety and Health (NIOSH) certified particulate respirators need to be properly fit tested before use to ensure workers' respiratory protection. However, the effectiveness of American National Standards Institute-/Occupational Safety and Health Administration (ANSI-/OSHA)-accepted fit tests for particulate respirators in predicting actual workplace protection provided to workers is lacking. NIOSH addressed this issue by evaluating the fit of half-mask particulate filtering respirators as a component of a program designed to add total inward leakage (TIL) requirements for all respirators to Title 42 Code of Federal Regulations Part 84. Specifically, NIOSH undertook a validation study to evaluate the reproducibility of the TIL test procedure between two laboratories. A PortaCount® was used to measure the TIL of five N95 model filtering facepiece respirators (FFRs) on test subjects in two different laboratories. Concurrently, filter efficiency for four of the five N95 FFR models was measured using laboratory aerosol as well as polydisperse NaCl aerosol employed for NIOSH particulate respirator certification. Results showed that two N95 models passed the TIL tests at a rate of ~80–85% and ~86–94% in the two laboratories, respectively. However, the TIL passing rate for the other three N95 models was 0–5.7% in both laboratories combined. Good agreement (≥83%) of the TIL data between the two laboratories was obtained. The three models that had relatively lower filter efficiency for laboratory aerosol as well as for NaCl aerosol showed relatively low TIL passing rates in both laboratories. Of the four models tested for penetration, one model with relatively higher efficiency showed a higher passing rate for TIL tests in both laboratories indicating that filter efficiency might influence TIL. Further studies are needed to better understand the implications of the data in the workplace.

KEYWORDS: aerosol; faceseal leakage; filter penetration; N95 filtering facepiece respirators; total inward leakage

INTRODUCTION

The use of appropriate respirators approved by the National Institute for Occupational Safety and Health (NIOSH) is one method for reducing occupational exposure to airborne particles if engineering and administrative controls are not sufficient. The major factors that determine the level of respiratory protection are the filter efficiency and respirator fit. For certification of particulate respirators, NIOSH requires a filter efficiency test but no test to assess faceseal leakage of particulates. Faceseal leakage created during respirator use is known to compromise respiratory protection. To address this issue, Occupational Safety and Health Administration (OSHA) requires a fit test of tight-fitting respirators prior to use in workplaces (OSHA, 1998a). Several studies have reported that fit testing largely improves the respiratory protection level of test subjects (Coffey *et al.*, 1999; Campbell *et al.*, 2001; Coffey *et al.*, 2004; Lawrence *et al.*, 2006). On the other hand, fit test–passed respirators in some studies have failed to provide expected level of protection (Duling *et al.*, 2007; Lee *et al.*, 2008). For respiratory protection, NIOSH has approved three classes (95, 99, and 100) of particulate filters with filter efficiencies of 95, 99, and 99.97%. All three classes of NIOSH-approved filtering facepieces have been assigned a protection factor (APF) of 10 (OSHA, 2006). An APF is defined as the minimum respiratory protection expected of a properly functioning respirator when used in a respiratory program. On the other hand, European standard has assigned APF values of 4, 10, and 20 to FFP1, FFP2, and FFP3 particulate filters, respectively, based on efficiency, hazard level, and occupational exposure limit (European Standard, 2005).

Evaluation of particulate respirators with either Bureau of Mines (BOM) or NIOSH approval has been reviewed (Campbell *et al.*, 2001; Spelce, 2009). BOM employed a 'coal dust test' as one of the methods for the evaluation of particulate respirators under Title 30 Code of Federal Regulations (CFR) Part 14 Schedule 21 (BOM, 1934). Three individuals donned respirators and did a regimen of moderate work and rest periods for 30 min in a room full of bituminous coal dust. After which, their forced nasal discharge, sputum, nasal cavities, and face were examined for black particulates. The coal dust test can be assumed to be equivalent to the total inward leakage (TIL) measurement comprised of filter penetration and leakage through the faceseal and other components including exhalation valves. Requirements were similar under Title 30 CFR Part 14 Schedule 21A in 1955 (BOM, 1955). By 1965 when Title 30 CFR Part 14 Schedule 21B was approved, coal dust was specified to be blown gently into the test subjects' face and the exercises were omitted (BOM, 1965). When the respirator certification requirements were incorporated into Title 30 CFR Part 11, the coal dust test was abolished (NIOSH and BOM, 1972). For Title 30 CFR Part 11 Schedule 21C, the BOM and NIOSH decided to use isoamyl acetate instead of coal dust to qualify the ability of all tight fitting and some loose fitting respirators to fit wearers (NIOSH and BOM, 1972). There was only one problem with this; isoamyl acetate is an organic vapor which is not removed by a dust, mist, fume, or high efficiency particulate filter. NIOSH dealt with this problem by testing particulate respirators modified to remove organic vapors. It was incorrectly assumed that a particulate respirator could be fitted with a vapor-removing element without changing its weight, resistance, or fitting characteristics and therefore be used as a surrogate for testing purposes.

When Title 42 CFR Part 84 was promulgated in 1995, this non-validated test of questionable effectiveness was also eliminated (NIOSH, 1995). In the preamble of Title 42 CFR Part 84, it is stated, 'The purpose of fit testing in the certification program has been to assure that respirators have generally good face fitting characteristics. However, at this time, NIOSH does not have studies that define the effectiveness of either the isoamyl acetate or American National Standards Institute-/Occupational Safety and Health Administration (ANSI-/OSHA)-accepted fit tests in predicting actual workplace protection provided to workers. NIOSH is presently conducting research for this purpose. …. NIOSH will address issues associated with face-fit efficacy in a separate module upon completion of the necessary research'.

In 2004, NIOSH developed a program concept for TIL performance requirements and test methods for personal protective equipment including all classes of respirators and protective garments (NIOSH, 2004). Subsequently, NIOSH evaluated half-mask particulate filtering respirators as a component of this program designed to add TIL requirements for all respirators to Title 42 CFR Part 84. Based on this

evaluation, NIOSH published a Notice of Proposed Rulemaking (NPRM) for TIL requirements for half-mask particulate filtering respirators (NIOSH, 2009). Subsequently, NIOSH held two public meetings to gain stakeholder input on the proposed rulemaking, and a NIOSH docket was opened for comments (NIOSH, 2010). Many of the comments concerned the reproducibility of the test procedure that had been developed and posted to the docket (NIOSH, 2008). Variability of the test procedure in different laboratories was one of the issues raised. As a result, NIOSH undertook this validation study to evaluate the reproducibility of the test procedure.

In this study, a PortaCount® Pro+ (Model 8038, TSI, Inc. Shoreview, MN; a condensation particle counter) was chosen as the method matching the requirements published in the TIL NPRM (NIOSH, 2009). The reason for choosing this method over other methods is discussed in the preamble of the NPRM. The condensation particle counting method has been widely used for quantitative fit testing because of its simplicity and portability. TIL was measured for test subjects in two laboratories (Laboratory 1 and Laboratory 2) located in the NIOSH facility. Five N95 filtering facepiece respirator (FFR) models were selected for the comparison of TIL tests in the two test laboratories. Concurrently, four of the five N95 models were also tested for filter efficiency against Laboratory 2 ambient aerosol. The comparison of the TIL results between the two test laboratories and the correlation of the TIL values to filter efficiency of the test respirators are discussed.

MATERIALS AND METHODS

Respirator selection

Five N95 FFR models were tested in the TIL protocol validation study (Table 1). The respirator models tested in the study include 3M (Model 8000), 3M (Model 9210), Kimberly–Clark (Model 170/174), Sperian–Willson (Model SAF-T-FIT, 10FL), and 3M (Model 8511), which were labeled as A, B, C, D, and E, respectively. Only one model (3M 8511) had an exhalation valve. Prior to this study, NIOSH conducted benchmark tests using several N95 model FFRs to measure TIL in 2005. From the test results, respirator models with wide range of TIL performances were selected for this study.

Test subjects

Thirty-five subjects were tested for TIL measurement with each of the five FFR models in both test laboratories. The NIOSH bivariate panel was used for placement of test subjects in specific face length by face width cells (Zhuang *et al.*, 2008). This study was approved by the NIOSH Human Subject Review Board, and all subjects gave written consent to participate.

Laboratory aerosol specifications for TIL testing

A minimum laboratory particle concentration of 1000 particles cm^{-3} was used during TIL testing. A particle generator (TSI Model 8026) was employed, as needed, to supplement laboratory particle concentration levels with NaCl aerosol. Ambient laboratory aerosol concentration (particles cm^{-3}) measured by the PortaCount in Laboratory 1 ranged between 1310 and 8740 (average 3010) and in Laboratory 2 ranged between 1370 and 10 100 (average 5410).

TIL testing

Subject testing

Test subjects were randomly directed for TIL testing in either Laboratory 1 or Laboratory 2 to start. The subjects subsequently travelled (~300 m) to Laboratory 2 or Laboratory 1, respectively, and were tested for TIL following the identical donning procedure. Different test operators administered the TIL testing in each of the two laboratories and each was an experienced fit tester. This study was double blind in the sense that the test operators in either laboratory did not know the results obtained by the other laboratory. All testing was performed in accordance with Standard Test Procedure RCT-APR-STP-0068 (posted under NIOSH Docket No. 36; NIOSH, 2007a), with few exceptions. These exceptions included increasing the minimum required particle count from the specified 500 particles cm^{-3} to 1000 particles cm^{-3} and operating the PortaCount with the N95 mode turned off to measure TIL as opposed to measuring only leakage through faceseal interface.

Subjects were trained using the manufacturer's user instructions on the proper donning and user seal-check procedures for each model. Subjects wore the FFR for a 5-min acclimatization period before the fit test. Each

Table 1. TIL for N95 FFR models measured on human subjects using a PortaCount Pro

Respirator	Number of subjects tested	Subjects passing TIL test (TIL ≤ 1) (%)	
		Laboratory 1	Laboratory 2
A	35	0	2.9
B	35	80.0	85.7
C	35	5.7	2.9
D	35	2.9	5.7
E	35	85.7	94.3

subject subsequently connected the PortaCount sample line to the connector on the respirator, donned the FFR, and made any necessary adjustments to the FFR until they felt they had achieved a good fit and could subsequently pass the user seal check without detecting a faceseal leak. Test administrators assured that the FFR was being properly donned by the test subject and provided whatever training was necessary to assure conformance to the user's instructions while respirator donning and adjustment was taking place. When ready, the subjects gave the test administrator an indication that she or he was ready to start the test. The drag/weight of the sample tubing and its effect on the FFR fit was minimized by the test subject holding the sample line with one hand away from the front of their chest. Subjects performed the eight exercises described in the standard OSHA fit test protocol (OSHA, 1998b). These eight exercises were performed in the following order: (i) normal breathing, (ii) deep breathing, (iii) turn head side to side (iv) move head up and down, (v) speak out loud (recitation of the 'rainbow' passage), (vi) reach for floor and ceiling, (vii) grimace, and (viii) normal breathing. A harmonic mean of the fit factors (FFs) measured for the eight exercises was determined by the PortaCount. At the end of the test, the subject removed the FFR and after a 5-min break redonned the same FFR for the next test. Three replicate tests were done in succession.

Two similar PortaCounts were used to measure the FF, the ratio of ambient aerosol concentration (C_{out}) to in-mask particle concentration (C_{in}) in the two test laboratories. A FitPro Fit Test software (TSI) was used to provide a fully automated fit test processing, data recording, and data storage during the testing. Test data, including test subject and respirator identifiers were downloaded into a pre-established database and were accessed after the test for analysis. Test data were also recorded manually for immediate review by project personnel.

TIL calculation

TIL was calculated from the FF obtained by the PortaCount based on the inverse relationship as shown below.

$$\mathrm{TIL} = \frac{100\%}{\mathrm{FF}}$$

To pass the test, NIOSH has proposed a TIL of ≤1% in any one of the three donnings of each FFR tested on each subject. A TIL value of ≤1% is equivalent to a FF value of ≥100 obtained for subjects performing the OSHA-prescribed exercises for passing the fit test. Further information on the criteria for passing the TIL test has been described (NIOSH, 2008).

Laboratory aerosol size distribution measurement

Two Scanning Mobility Particle Sizers (SMPS Model 3081, TSI) were used to measure the size distribution of particles in the 10–700 nm size range in the two laboratories. The SMPS was programed to scan the particle size distribution for 135 s, three times, every hour from 8:00 AM to 4:00 PM, Monday through Friday. From the SMPS scans, the average count median diameter (CMD) of laboratory aerosol was obtained.

Filter penetration

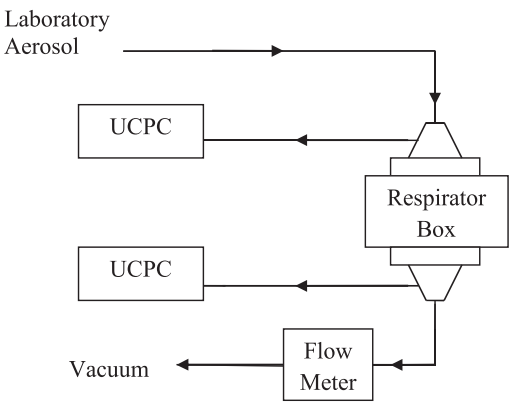
Only four N95 respirator models were tested because one model (3M 8511) was not available during the initial part of the study. Filter penetration was measured by two different methods: (i) a

particle-number-based method using ambient aerosol in the TIL test Laboratory 2, similar to the number-based PortaCount method used for TIL measurement and (ii) a particle mass-based method using polydisperse NaCl aerosols similar to the NIOSH particulate respirator certification method.

Particle-number-based penetration test

Instantaneous penetration against ambient Laboratory 2 aerosol was measured using a test set-up as shown in the schematics (Fig. 1). A Plexiglas box (20 × 20 × 10 cm) similar to the one described previously (Rengasamy *et al.*, 2008) was used to measure filter penetration with a respirator mounted on the bottom plate. A silicon sealant was used to seal the top and bottom plates to make the Plexiglas box airtight. The top and bottom holes of the plates were fixed to inlet and outlet tubes (2.0 cm diameter and 10 cm long). An aerosol sampling tube (0.5 cm diameter) was attached to the inlet and outlet close (2.5 cm) to the Plexiglas box. The sampling tubes were connected to two ultrafine condensation particle counters (UCPCs, TSI 2205) to measure the upstream and downstream aerosol concentrations. The bottom outlet was connected to a vacuum line through a mass flow meter. The desired flow rate was obtained by adjusting the vacuum.

Five samples from each model were tested in the morning (8:30–9:30 AM), stored, and then tested in the afternoon (2:30–3:30 PM), and the average penetration was obtained. Briefly, Laboratory 2 aerosol was passed through the respirator in the test box, and the particle number concentration upstream and downstream of the respirator was measured simultaneously after 1-min equilibration time at constant test flow rates of 30 and 85 l min^{-1}, representing moderate work rate and the NIOSH particulate respirator certification test flow rate, respectively. Percentage penetration was obtained from the ratio of the aerosol concentration downstream to upstream and multiplied by 100. From the penetration values, the filter efficiencies for the four models were assessed.



1 Schematic of the filtration test set-up used for measuring laboratory aerosol filter penetration.

Particle mass-based penetration test

Penetration was also measured using an Automated Filter Tester (TSI 8130) similar to the NIOSH particulate respirator certification method (NIOSH, 2007b). A Plexiglas test box (20 × 20 × 10 cm) was used to measure polydisperse NaCl aerosol penetration as described previously (Rengasamy *et al.*, 2008). The bottom plate was replaced by a plate mounted with an FFR tested previously for Laboratory 2 aerosol penetration. The Plexiglas box containing the respirator was placed in between the two filter chucks of the TSI 8130 and aligned to keep the top and bottom plate holes facing the upstream and downstream filter chucks, respectively. Penetration was measured under airtight conditions using the polydisperse NaCl aerosol (CMD; 75 ± 20 nm) generated by the TSI 8130. Initial penetration was measured for 1 min at 30 l min^{-1} as well as 85 l min^{-1} flow rates.

Data analysis

TIL pass/fail results were calculated. Agreement in TIL pass/fail results between the two laboratories were estimated using kappa statistics with STATA statistical software (College Station, TX). A kappa statistic is an estimate of the level of agreement of the results obtained between the two laboratories beyond that which could be expected by chance alone. A kappa statistic that is greater than zero but less than 0.40 is poor agreement, whereas a kappa between 0.40 and 0.75 is fair-to-good agreement, and a kappa >0.75 is excellent agreement (Fleiss, 1981).

RESULTS

TIL data

Table 1 shows the TIL data obtained for the different N95 models tested in Laboratory 1 and Laboratory

2. Of the five N95 models tested, models B and E passed the TIL test at higher percentage levels. Thirty-five human subjects tested with model B in Laboratory 1 as well as in Laboratory 2 passed 80 and 85.7% of tests, respectively. Similarly, model E FFRs showed 85.7 and 94.3% passing results in Laboratory 1 and Laboratory 2, respectively. However, the percentage of TIL passes for A, C, and D FFR models was small (0–5.7%) in the two test laboratories. The TIL data obtained for A, B, C, D, and E models showed 97, 83, 97, 97 and 91% agreement between the two laboratories, respectively.

Figure 2 shows the proportion of the 35 test subjects, according to their pass or fail status on the TIL test procedure in the two laboratories, for each of the five different N95 FFRs and corresponding kappa statistics. The proportion of subjects who showed agreement between the two laboratories (either passed or failed at both) was highest for models A, C, and D at 0.971. The proportion of subjects who showed agreement between the two laboratories (either passed or failed at both) was next highest for models B and E at 0.829 and 0.914, respectively.

Model A

Laboratory 1 \ Laboratory 2	Pass	Fail
Pass	0.000	0.000
Fail	0.029	0.971

Kappa = 0.00, p= 0.50

Model B

Laboratory 1 \ Laboratory 2	Pass	Fail
Pass	0.743	0.057
Fail	0.114	0.086

Kappa =0.40, p< 0.01

Model C

Laboratory 1 \ Laboratory 2	Pass	Fail
Pass	0.029	0.029
Fail	0.000	0.943

Kappa =0.65, p< 0.01

Model D

Laboratory 1 \ Laboratory 2	Pass	Fail
Pass	0.029	0.000
Fail	0.029	0.943

Kappa =0.65, p< 0.01

Model E

Laboratory 1 \ Laboratory 2	Pass	Fail
Pass	0.857	0.000
Fail	0.086	0.057

Kappa =0.53, p< 0.01

2 The proportion of 35 test subjects, according to their pass or fail status on the TIL test procedure in two laboratories, for five different N95 model filtering facepiece respirators and corresponding kappa statistics.

The kappa statistics for FFR models B, C, D, and E ranged from 0.40 to 0.65, indicating fair-to-good agreement between the two laboratories ($P < 0.01$ for all). The kappa statistic for FFR model A was zero, indicating that there was no evidence that the observed agreement was any different than would be expected by chance alone.

Laboratory aerosol size distribution

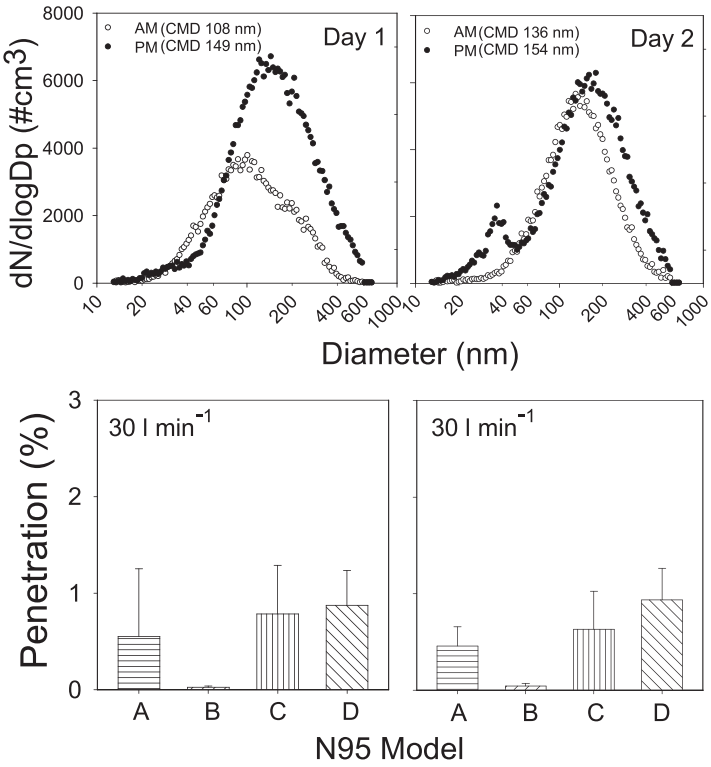
Figures 3 and 4, top panels show the size distribution of aerosol ranging from 20 to 700 nm obtained in Laboratory 2 on different days. In general, the CMD for ambient Laboratory 2 aerosol measured in the morning was smaller than the values obtained in the afternoon. On the other hand, on Day 5, the CMD for laboratory aerosol was larger (CMD 127.4 nm) in the morning than in the afternoon (CMD 86.6 nm; Fig. 5, top panel). Ambient aerosol size distribution for all test days showed CMD values of 82 ± 19 nm in Laboratory 1, and 131 ± 23 nm in Laboratory 2.

Filter penetration

Particle-number-based penetration measured against ambient Laboratory 2 aerosols on five different days at two different flow rates are shown in Figs 3–5 (bottom panels). Penetration values for model B were relatively lower than the penetrations for model A, C, and D. Similar results were obtained for polydisperse NaCl aerosols using a mass-based method at two different flow rates (Fig. 6). Based on the penetration values obtained in the tests, model B was considered as a relatively higher efficiency model than models A, C, and D.

DISCUSSION

In this study, 35 human subjects tested with five N95 model FFRs showed consistent TIL results in two different test laboratories. Respirator models that showed higher percentage of TIL pass in Laboratory 1 also had higher percentage of TIL pass in Laboratory 2. For example, N95 FFR models B and E showed

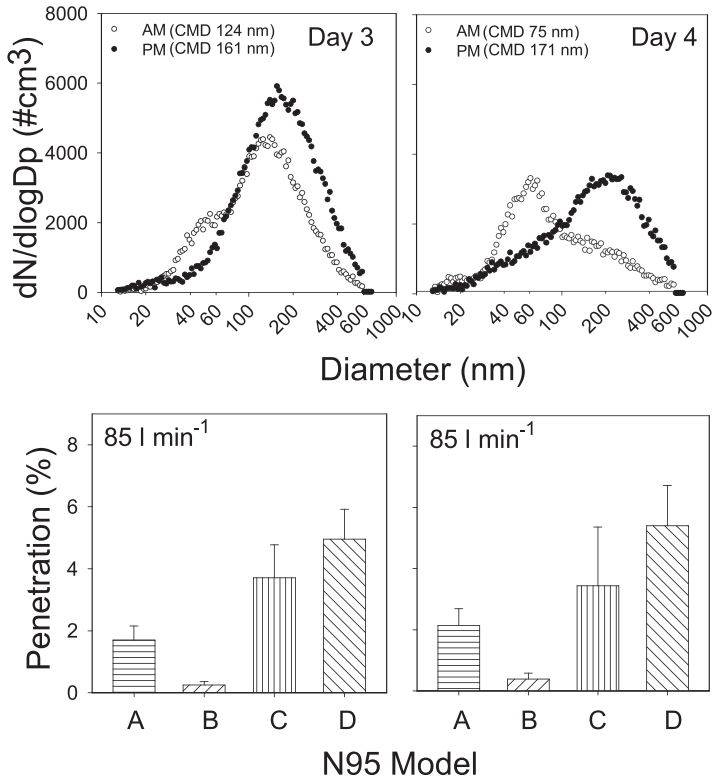


3 Laboratory aerosol size distribution obtained with a SMPS (top panels), and average penetration of morning (AM) and afternoon (PM) tests for four N95 model FFRs using two UCPCs at 30 l min^{-1} flow rate (bottom panels) on two different test days.

percentage of TIL passes ≥80% in both laboratories. On the other hand, models A, C, and D had a similar percentage (0–5.7%) of TIL passes in the two test laboratories. Moreover, TIL data measured for all five FFR models showed ≥83% agreement between the two laboratories. Incorporation of TIL as part of the respirator certification process may provide a better understanding on the level of protection expected in workplaces.

Filter efficiency appears to influence the TIL obtained for FFRs. The filtration efficiency for model B FFRs against TIL test laboratory aerosol as well as NaCl aerosol employed in the NIOSH particulate filter certification test were higher than the other three models. Both the filtration efficiency and the percentage of TIL passes were higher for model B than for models A, C, and D showing an association between filter efficiency and TIL passes. The results obtained in the study are consistent with the findings reported previously (Han and Lee, 2005). In that study, TIL values for Korean half-masks and three classes of FFRs with human subjects were measured. Among the three classes of FFRs, average TIL values for 'top class' (filter penetration < 1.0%) FFRs were 5.0%. However, the TIL values for FFRs certified with higher filter penetrations ('first class': <6.0% and 'second class': <20.0%) were ~2 times higher than the TIL values obtained for 'top class' FFRs. The results from these studies show that relatively higher efficiency FFRs produce lower TIL values.

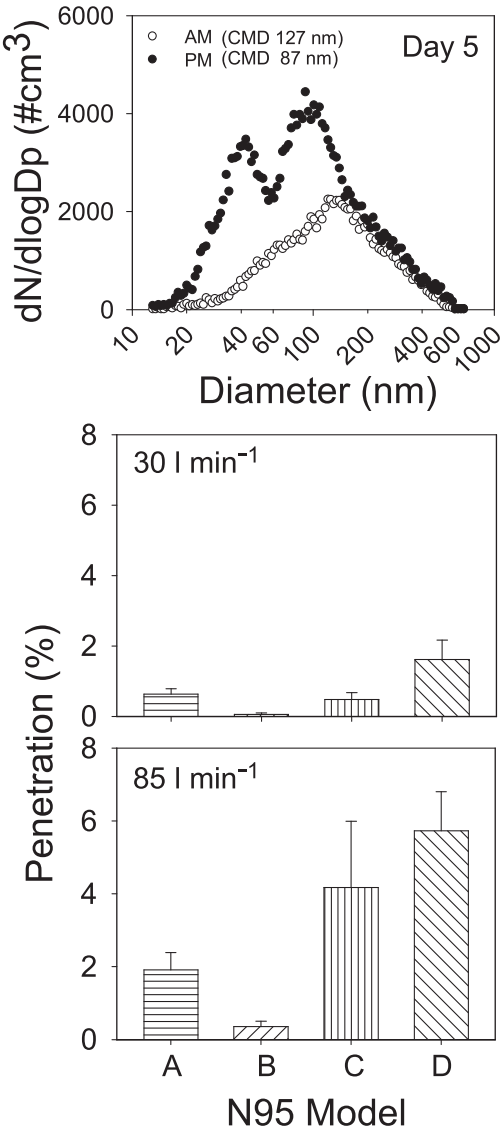
To better understand the influence of filter efficiency, TIL was measured under controlled conditions in our previous study (Rengasamy and Eimer, 2012a). Four N95 models were used to measure the TIL with a breathing manikin at different artificially introduced leaks and breathing minute volumes. Results showed that relatively higher efficiency N95 models also had lower TIL values for the different size particles indicating the filter efficiency dependence of TIL. Similar findings were obtained in another study which measured



4 Laboratory aerosol size distribution obtained with a SMPS (top panels), and average penetration of morning (AM) and afternoon (PM) tests for four N95 model FFRs using UCPCs at 85 l min^{-1} flow rate (bottom panels) on two different test days.

the protection factor (PF, an inverse function of TIL) of respirators (Liu *et al.*, 1993). These authors developed a theoretical expression for PF based on filter penetration, leakage, and flow rate and made a comparison with experimental results. Relatively less-penetrating 10-nm monodisperse NaCl particles were used to measure particle leakage using a manikin. Two relatively lower efficiency dust–mist respirators and one higher efficiency dust–mist–fume/radionuclide respirator were tested for penetration with controlled leak holes at three different steady flow rates. Their results showed that the higher efficiency respirator provided a higher PF value than the lower efficiency respirators. Overall, the filter efficiency dependence of TIL may be relevant to respiratory protection in real workplaces.

Filter penetration and faceseal leakage pathways contribute to the TIL, which is inversely related to respiratory protection (Han and Lee, 2005; Grinshpun *et al.*, 2009; Rengasamy and Eimer, 2012a). Grinshpun *et al.* (2009) showed that the number of particles passing through faceseal leakage far exceeded the number of particles that penetrate through the filter medium. Filter penetration is minimal or insignificant once leaks are introduced in the facemask. However, results obtained in our laboratory showed that filter penetration is critical to the TIL of different size particles (Rengasamy and Eimer, 2012a). In that study, four N95 model FFRs with and without electrostatic charge were tested for TIL using a breathing manikin under controlled leak conditions. The most penetrating particle size (MPPS) was ~45 nm for FFRs with charge and ~150 nm for the charge removed FFRs under sealed condition with no leaks. With increasing artificial leak sizes, TIL for different size particles increased, whereas the MPPS for the respective FFR groups remained the same. Results showed that faceseal leakage indiscriminately allowed all size particles to enter and exit the respirator, while filter penetration assigned the TIL for different size particles. This explains how the



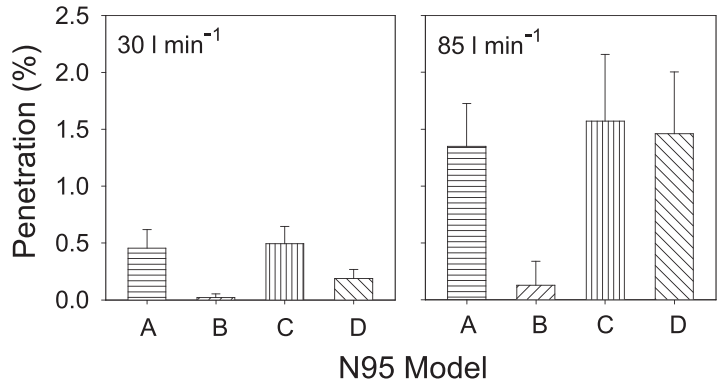
5 Laboratory aerosol size distribution obtained with a SMPS in the morning and afternoon (top panel) and average filter penetration values for four N95 model FFRs measured using two UCPCs (middle and bottom panels) on Day 5.

relatively higher efficiency (relatively lower penetration) N95 model B could produce lower TIL values than the relatively lower efficiency (higher penetration) models A, C, and D tested in the study.

The size distribution of laboratory aerosol may influence filter penetration of test respirators. The CMD of ambient aerosol in Laboratory 2 was smaller in the morning than in the afternoon on many days, while an opposite trend was observed on other days. However, the change in the size distribution of particles between morning and afternoon did not appear to affect the average penetration of N95 models measured by the number-based method as well as the mass-based method on different test days. One exception was that the penetration values measured by the particle-number-based UCPC method against laboratory aerosol were higher than the mass-based penetrations. This can partly be explained by the difference in the test methods (Biermann and Bergman, 1988; Rengasamy *et al.*, 2011; Rengasamy and Eimer, 2012b). The UCPC measures the particle numbers giving equal importance to the different size particles, whereas the light scatter intensity measured by the TSI 8130 photometer is dependent on the particle mass. The CMD of NaCl aerosol produced by the TSI 8130 is ~75 nm. However, the TSI 8130 photometer employed for measuring filter penetration is less sensitive to particles below 100 nm size which have no significant mass. Because of this, the penetration values measured for NIOSH-approved FFRs by the particle-number-based method are several-fold higher than the values obtained by the photometric method (Rengasamy *et al.*, 2011; Rengasamy and Eimer, 2012b).

LIMITATIONS

Limitations of the study include that the test subjects as well as the test operators are experienced in their role as they have participated in other fit test studies previously. These factors could have maximized the agreement in the results between the two laboratories. Only five N95 model FFRs were employed to measure the TIL, of which only four N95 models were tested for filter efficiency. The four models tested for filter efficiency in the study do not have exhalation valves. Additional FFR models with and without exhalation valves need to be tested for filter penetration and TIL to confirm the presence of an exhalation valve does not impact the relationship between filter penetration and TIL. A comparison of the mean or median TIL values for each subject in the two laboratories is desirable, but it is beyond the scope of the study. In this study, TIL was measured in two laboratories located in the same NIOSH facility. A more realistic reproducibility test should involve laboratories of two different research groups. Nevertheless, the TIL data for human subjects and the filter efficiency of respirators obtained in the study has a potential implication for respiratory protection in workplaces.



6 Polydisperse NaCl aerosol penetration for four N95 model FFRs was measured using a TSI 8130 Automated Filter Tester.

CONCLUSIONS

The data obtained for five N95 model FFRs tested with human subjects confirmed the reproducibility of the TIL test procedure in the two test laboratories. The TIL results for N95 models B and E passed ~80–85% of tests in Laboratory 1 and ~86–94% of tests in Laboratory 2. Furthermore, the percentage of TIL passes for the other three N95 models was relatively small (0–5.7%) in both test laboratories. A good agreement (≥83%) of the TIL data between the two laboratories was obtained. Of the four N95 models tested for filter penetration, the efficiency of one model was relatively higher than the other three models. The relatively higher efficiency model also showed higher TIL passing rates than the other three models. The data indicate that filter efficiency might influence the TIL for test subjects using N95 FFRs. Overall, the data suggest that TIL test may be reproducible between different laboratories, as long as each laboratory meets the test criteria.

ACKNOWLEDGEMENTS

The authors acknowledge NIOSH colleagues including William King, Jay Parker, and Christopher Coffey for their useful suggestions and critical review of the manuscript. This research work was supported by NIOSH funding.

DISCLAIMER

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REFERENCES

Biermann AH, Bergman W. (1988) Filter penetration measurements using a condensation nuclei counter and an aerosol photometer. J Aerosol Sci; 19: 471–83.

BOM. (1934) Title 30 CFR Part 14. Mineral Resources. Procedure for testing filter-Type dust, fume, and mist respirators for permissibility. Schedule 21, August 20, 1934.

BOM. (1955) Title 30 CFR Part 14. Mineral Resources. Revised test procedure for dust, fume, and mist respirators for permissibility. Schedule 21A, April 19, 1955.

BOM. (1965) Title 30 CFR Part 14. Mineral Resources. Filter-type dust, fume, and mist respirators, requirements investigation, testing, and certification. Schedule 21B, March 23, 1965.

Campbell DL, Coffey CC, Lenhart SW. (2001) Respiratory protection as a function of respirator fitting characteristics and fit-test accuracy. AIHAJ; 62: 36–44.

Coffey CC, Campbell DL, Zhuang Z. (1999) Simulated workplace performance of N95 respirators. Am Ind Hyg Assoc J; 60: 618–24.

Coffey CC, Lawrence RB, Campbell DL *et al.* (2004) Fitting characteristics of eighteen N95 filtering-facepiece respirators. J Occup Environ Hyg; 1: 262–71.

Duling MG, Lawrence RB, Slaven JE *et al.* (2007) Simulated workplace protection factors for half-facepiece respiratory protective devices. J Occup Environ Hyg; 4: 420–31.

European Standard. (2005) Respiratory protective devices - recommendations for selection, use, care and maintenance - guidance document. rue de Stassart, 36 B-1050 Brussels: European Committee for Standardization Management Centre.

Fleiss JL. (1981) Statistical methods for rates and proportions. 2nd ed. John Wiley & Sons, Inc., New York

Grinshpun SA, Haruta H, Eninger RM *et al.* (2009) Performance of an N95 filtering facepiece particulate respirator and a surgical mask during human breathing: two pathways for particle penetration. J Occup Environ Hyg; 6: 593–603.

Han DH, Lee J. (2005) Evaluation of particulate filtering respirators using inward leakage (IL) or total inward leakage (TIL) testing–Korean experience. Ann Occup Hyg; 49: 569–74.

Lawrence RB, Duling MG, Calvert CA *et al.* (2006) Comparison of performance of three different types of respiratory protection devices. J Occup Environ Hyg; 3: 465–74.

Lee SA, Grinshpun SA, Reponen T. (2008) Respiratory performance offered by N95 respirators and surgical masks: human subject evaluation with NaCl aerosol representing bacterial and viral particle size range. Ann Occup Hyg; 52: 177–85.

Liu BYH, Lee J-K, Mullins H, Danisch SG. (1993) Respirator leak detection by ultrafine rosols: a predictive model and experimental study. Aerosol Sci Tech; 19: 15–26.

NIOSH. (2004). Program concept for total inward leakage (TIL) performance requirements and test methods. Available at http://www.cdc.gov/niosh/npptl/standardsdev/til/.

NIOSH. (2007a) Procedure No. RCT-APR-STP-0068, Revision 0. Total inward leakage test for half-mask air-purifying particulate respirators.

NIOSH. (2007b) Procedure No. TEB-APR-STP-0059, Revision 2.0. Determination of particulate filter efficiency level for N95 series filters against solid particulates for non-powered, airpurifying respirators standard testing procedure (STP).

NIOSH. (2008) Total inward leakage requirements for half-mask air-purifying particulate respirators. NIOSH Docket Number 137. NIOSH draft statistical basis for TIL testing - determination of sample size and passing criteria for respirator fit test panels.

NIOSH. (1995) Title 42 CFR Part 84. Respiratory protective devices. Final Rules Notice; 60: 30335–98.

NIOSH. (2009) Total inward leakage requirements for respirators. Fed Reg; 74: 56141–51. http://www.gpo.gov/fdsys/pkg/FR-2009-10-30/pdf/E9-26008.pdf

NIOSH. (2010) Total inward leakage requirements for respirators. Vol. 75. pp. 20546–47. http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-137/0137-042010-FederalRegister.pdf

NIOSH, BOM. (1972) Title 30 CFR Part 11. Respiratory protective devices; tests for permissibility; fees.

OSHA. (1998a) Respiratory Protection. Title 29 CFR Part 1910.134 (f)(1).

OSHA. (1998b) Occupational safety and health standards. Fit testing procedures (Mandatory). Title 29 CFR Part 1910.134 Appendix A.

OSHA. (2006) Assigned protection factors: final rule. 29 CFR Parts 1910, 1915, 1926. Vol. 71. pp. 50121–92. Available at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=FEDERAL_REGISTER&p_id=18846.

Rengasamy S, Eimer BC. (2012a) Nanoparticle penetration through filter media and leakage through face seal interface of N95 filtering facepiece respirators. Ann Occup Hyg; 56: 568–80.

Rengasamy S, Eimer BC. (2012b) Nanoparticle filtration performance of NIOSH-certified particulate air-purifying filtering facepiece respirators: evaluation by light scattering photometric and particle number-based test methods. J Occup Environ Hyg; 9: 99–109.

Rengasamy S, King WP, Eimer BC *et al.* (2008) Filtration performance of NIOSH-approved N95 and P100 filtering facepiece respirators against 4 to 30 nanometer-size nanoparticles. J Occup Environ Hyg; 5: 556–64.

Rengasamy S, Miller A, Eimer BC. (2011) Evaluation of the filtration performance of NIOSH-approved N95 filtering facepiece respirators by photometric and number-based test methods. J Occup Environ Hyg; 8: 23–30.

Spelce DL. (2009) History of negative pressure particulate respirator certification. Navy and Marine Corps Public Health Center. Available at http://www.nmcphc.med.navy.mil/downloads. /IH/History%20of%20Particulate%20Respirator%20Certification%20Style%2015 June09.pdf>.

Zhuang Z, Groce D, Ahlers HW *et al.* (2008) Correlation between respirator fit and respirator fit test panel cells by respirator size. J Occup Environ Hyg; 5: 617–28.