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This study investigates two different methods (random effects model and 5th percentile) for determining the performance of three types of respiratory protective devices (elastomeric N95 respirators, N95 filtering-facepiece respirators, and surgical masks) during a simulated workplace test. This study recalculated the protection level of three types of respiratory protective devices using the random effects model, compared the two methods with each other and the APF of 10 for half-facepiece respirators, and determined the value of each of the fit test protocols in attaining the desired level of simulated workplace protection factor (SWPF). Twenty-five test subjects with varying face sizes tested 15 models of elastomeric N95 respirators, 15 models of N95 filtering-facepiece respirators, and 6 models of surgical masks. Simulated workplace testing was conducted using a TSI PORTACOUNT Plus model 8020 and consisted of a series of seven exercises. Six simulated workplace tests were performed with redonning of the respirator/mask occurring between each test. Each of the six tests produced an SWPF. To determine the level of protection provided by the respiratory protective devices, a 90% lower confidence limit for the simulated workplace protection factor ($SWPF_{LCL90\%}$) and the 5th percentile of simulated workplace protection factor were computed. The 5th percentile method values could be up to seven times higher than the $SWPF_{LCL90\%}$ values. Without fit testing, all half-facepiece N95 respirators had a 5th percentile of 4.6 and an $SWPF_{LCL90\%}$ value of 2.7. N95 filtering-facepiece respirators as a class had values of 3.3 and 2.0, respectively, whereas N95 elastomeric respirators had values of 7.3 and 4.6, respectively. Surgical masks did not provide any protection, with values of 1.2 and 1.4, respectively. Passing either the Bitrex, saccharin, or Companion fit test resulted in the respirators providing the expected level of protection with 5th percentiles greater than or equal to 10 except when passing the Bitrex test with N95 filtering-facepiece respirators, which resulted in a 5th percentile of only 7.9. No substantial difference was seen between the three fit tests. All of the $SWPF_{LCL90\%}$ values after passing a fit test were less than 10. The random model method provides a more conservative estimate of the protection provided by a respirator because it takes into account both between- and within-wearer variability.

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INTRODUCTION

The term "decontamination factor" was first introduced by the Bureau of Mines when they published the *Respirator Approval Schedule 21B* for dust, fume, and mist respirators. It was defined as "the ratio of the concentration of dust, fume, or mist present in the ambient air to the concentration of dust, fume, or mist within the facepiece while the respirator is being worn."[1,p.2] The Bureau of Mines Schedule 21B approval process for half-facepiece respirators required them to provide protection up to 10 times the appropriate American Conference of Governmental Industrial Hygienists (ACGIH®) threshold limit value (TLV®) (i.e., airborne concentration of chemical substances that represent conditions under which it is believed that nearly all workers can be repeatedly exposed day after day over a working lifetime without adverse health effects).[2] The Bureau of Mines based this protection factor on quantitative fit tests, using dioctyl phthalate, that were conducted on six male test subjects performing simulated work exercises.[1]

Over the last four decades, the concept of the protection factor has been adopted by various other agencies (e.g., the National Institute for Occupational Safety and Health, the Occupational Safety and Health Administration, etc.). Protection factor has been renamed respirator protection factor by this organization. The Bureau of Mines original definition, which included only dust, fume, and mist respirators, has been expanded to include other types of respiratory protection, such as supplied-air respirators and so on.

The respirator protection factor is the level of protection or performance based on the ratio of two measured variables, C_o (the concentration of a contaminant outside the respirator facepiece) and C_i (the concentration of a contaminant inside the respirator facepiece cavity).[3] Because there are a number of different situations where respirator protection factor can be used, specialized definitions have been developed to avoid confusion, including workplace protection factor (WPF), simulated workplace protection factor (SWPF), and assigned protection factor (APF). An WPF is a measure of the protection provided in the workplace by a properly functioning respirator when correctly worn and used. A SWPF is a surrogate measure of the workplace protection provided by a respirator usually measured in a laboratory simulation of a workplace setting. The definition of APF varies by organization.

The National Institute for Occupational Safety and Health (NIOSH) definition of APF is "the minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and trained users."[4,p.2] The Occupational Safety and Health Administration (OSHA) definition in Title 29 *Code of Federal Regulations* (CFR) 1910.134 is "the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section." The American National Standards Institute (ANSI) definition is "the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users."[5,p.2]

Any half-facepiece respirator (including filtering-facepiece or disposable) is given an APF of 10 in the recommended ANSI Z88.2 and OSHA (29 CFR 1910.134) standards.[5] The NIOSH Respirator Selection Logic assigns an APF of 10 to half-facepiece respirators equipped with the appropriate filter that will provide protection against the particles found in the workplace (including filtering-facepiece respirators if they are qualitatively or quantitatively fit tested on the individual worker).[4] Hyatt[6] stated that the APF value should be set so that 95% of all donnings will equal or exceed the APF.

More than three million American workers wear respirators.[7] Proper respirator selection using APFs is an important component of an effective respiratory protection program. Employers need accurate information on APFs to select appropriate respirators for employee use when engineering and work-practice controls are insufficient to maintain hazardous substances at safe levels in the workplace. Employers need to know that the respirators will provide the expected level of protection to workers when worn properly after fit testing.

A widely adopted method for determining the level of protection provided by a respirator during either a workplace or simulated workplace test is the 5th percentile method suggested by Lenhart and Campbell.[8] In this method, the WPF or SWPF values from all the wearers in a study are combined and a 5th percentile WPF or SWPF value is calculated. Recently, a different approach to determining the level of protection provided by a respirator has been suggested.[9] This new approach (random effects model) takes into account the within- and between-wearer variability and uses a confidence limit to determine the protection factor.

A study was recently completed that investigated the level of protection of three different types of respiratory protective devices (surgical masks, N95 filtering-facepiece respirators, and N95 elastomeric facepiece respirators) in which a panel of 25 subjects tested each of the respiratory protective devices during an SWPF test and three different fit tests. Surgical masks were included in the study because of the U.S. Department of Health and Human Services Pandemic Influenza Plan Supplement 4 Infection Control, which recommends the use of surgical masks as one of the basic infection control principles for preventing the spread of pandemic influenza in health care settings.[10] The 5th percentile method was used to determine the protection level of the three types of devices as a class and individual models within each class of device without regard to the results of the fit tests. The level of protection was then recalculated for the N95 filtering and elastomeric respirators using the SWPF values from only those subjects passing the fit tests.[11]

The purposes of this article are to (*a*) recalculate the protection level of three types of respiratory protective devices using the random effects model, (*b*) compare the two methods with each other and the APF of 10 for half-facepiece respirators, and (*c*) determine the value of each of the fit test procedures in attaining the desired level of SWPF.

MATERIALS AND METHODS

Test Subjects

Thirty-seven people (20 females and 17 males) ranging in age from 19 to 48 years participated in this study. Subjects were selected to provide a variety of facial sizes without regard to any particular facial size distribution. The subjects' lip and face lengths were measured; female test subjects had lip lengths ranging from 43 to 55 mm and face lengths ranging from 104 to 124 mm. Male subjects had lip lengths of 44 to 59 mm and face lengths of 112 to 135 mm.

Respirator Models

Fifteen models of N95 filtering-facepiece respirators, 15 models of N95 elastomeric half-facepiece respirators, and 6 surgical masks were tested. The N95 filtering-facepiece respirator models were randomly selected from more than 80 models that were commercially available at the time of

TABLE I. Respiratory Protective Devices Tested

Company	Model Number	Device Type	Description
3M	8511	N95 filtering-facepiece	Cup
3M	8515	N95 filtering-facepiece	Cup
3M	9210	N95 filtering-facepiece	Flat/folding
3M	9211	N95 filtering-facepiece	Flat/folding
Alpha Pro Tech	MAS695	N95 filtering-facepiece	Flat/folding
Aswan	M-12	N95 filtering-facepiece	Flat/folding
Draeger	Piccola without valve	N95 filtering-facepiece	Flat/folding
Gerson	1730	N95 filtering-facepiece	Cup
Gerson	2747	N95 filtering-facepiece	Cup
Gerson	3945	N95 filtering-facepiece	Cup
Makrite	910	N95 filtering-facepiece	Flat/folding
Moldex	2600/2601	N95 filtering-facepiece	Cup
MSA	FR200 affinity	N95 filtering-facepiece	Flat/folding
San M package	TN01	N95 filtering-facepiece	Flat/folding
Survivair	1913	N95 filtering-facepiece	Flat/folding
3M	7000	N95 elastomeric	Not applicable
AO safety	5 Star	N95 elastomeric	Not applicable
Lab safety	11291	N95 elastomeric	Not applicable
Moldex	8000	N95 elastomeric	Not applicable
MSA	Comfo classic	N95 elastomeric	Not applicable
MSA	Comfo elite	N95 elastomeric	Not applicable
North	7700	N95 elastomeric	Not applicable
Pro-tech	1490/1590	N95 elastomeric	Not applicable
Scott	66	N95 elastomeric	Not applicable
Sellstrom	2900	N95 elastomeric	Not applicable
Survivair	2000	N95 elastomeric	Not applicable
Survivair	7000	N95 elastomeric	Not applicable
Willson	1200	N95 elastomeric	Not applicable
Willson	6100	N95 elastomeric	Not applicable
Willson	6800	N95 elastomeric	Not applicable
3M	1818	Surgical mask	Flat/folding
3M	Aseptex 1800+	Surgical mask	Flat/folding
3M	Nexcare first aid	Surgical mask	Flat/folding
Johnson & Johnson	Surgine 4238	Surgical mask	Flat/folding
Medline	Prohibit series	Surgical mask	Cup
Tecnol	48237	Surgical mask	Flat/folding

the study and had not been previously tested as part of a NIOSH research study. The filtering-facepiece respirators were of two different configurations (cup and folding). The N95 elastomeric half-facepiece respirators were selected at random from the 56 models obtainable when the study started. The surgical masks were randomly selected to provide a variety of configurations, such as ear-loop, face shield, folding, and cup-shaped from the 160 models then available. Some of the models tested in this study may no longer be manufactured and marketed because manufacturers continually modify or replace respiratory protective devices with newer versions. Table I lists the respirator and surgical mask models tested.

Fit Testing and Simulated Workplace Testing

Summaries of the simulated workplace testing and fit tests are presented here. The fit tests are described in detail in Title 29, *Code of Federal Regulations*, 1910.134.

A panel of 25 subjects was selected from the 37 participants to test each respiratory protective device to provide the greatest feasible spectrum of facial sizes. Respiratory protective devices available in multiple sizes did not have instructions on how to choose an appropriate size. Test subjects were given a device based on their face and lip length measurements as recommended by the Los Alamos National Laboratory.[12]

Respiratory protective device performance was determined using an SWPF test (the concentration of the ambient particles measured outside the respiratory protective device divided by the concentration inside). Total penetration (i.e., filter penetration and face-seal leakage) was determined during six trials (i.e., replicates) using the PORTACOUNT Plus (TSI, St. Paul, Minn.). The fit tests used were Bitrex (denatonium benzoate) Solution Aerosol Qualitative Fit Test, Saccharin Solution Aerosol, and Ambient Aerosol Condensation Nuclei Counter Quantitative Fit Testing Protocols.

Each of the three fit tests was performed once with a given subject/respiratory protective device combination. A subject wore the same respiratory protective device during each of the six SWPF trials and all three fit tests. To complete the required testing regime for each respirator, two visits by each subject were necessary. The first visit consisted of the Bitrex Solution Aerosol Qualitative Fit Test and Ambient Aerosol Condensation Nuclei Counter Quantitative Fit Testing Protocol fit tests and the first three replicates of the SWPF test.

The second visit consisted of the Saccharin Solution Aerosol Protocol fit test and the remaining three replicates of the SWPF test. Every subject tested each N95 respirator model in exactly this same order. Between each SWPF trial and fit test of a particular respirator, the subject removed the respirator, gave it to the test operator who returned the respirator to its original configuration (e.g., loosening head straps, straightening the nosepiece, etc.). The subject then redonned the respirator for the next test. Surgical masks were not fit tested.

Because smokers exhale particles for at least 30 min, test subjects who smoked were asked to refrain. The PORTA-COUNT Plus detects exhaled particles and interprets the cause as face-seal leakage, producing erroneous results. All subjects abstained from eating, chewing gum, and drinking (except for plain water) for at least 15 min before testing. These restrictions ensured that the subjects would be able to detect the qualitative fit testing agents at the lowest possible concentration. The order in which the subjects tested the 36 respiratory protective devices was randomized.

Fit Tests

The three fit tests used in this study were two qualitative (Bitrex Solution Aerosol Qualitative Fit Test and Saccharin Solution Aerosol Protocols) and one quantitative (Ambient Aerosol Condensation Nuclei Counter Quantitative Fit Testing Protocol). All fit testing was conducted in accordance with protocols from the OSHA respiratory protection standard, including the number, type, and duration of the exercises, and the performance of a user seal check in accordance with the manufacturers' instructions.

Bitrex (Denatonium Benzoate) Solution Aerosol Qualitative Fit Test Protocol

The Bitrex test uses a person's ability to taste a bitter solution to determine whether a respirator fits properly. Each subject was given a taste-threshold screening test prior to each fit test to ensure that he or she could taste Bitrex at the specified concentration. All subjects reported tasting the Bitrex during each screening test. After the screening test, the subject left the laboratory, drank water, and rinsed his or her lips and mouth. The subject then donned the respirator and the Bitrex fit test was conducted. If a subject tasted Bitrex at any time, the test was considered a failure; otherwise, the subject passed the test.

Saccharin Solution Aerosol Protocol

The saccharin test uses a person's ability to taste a sweet solution to determine whether a respirator fits properly. As with the Bitrex test, test subjects were given a taste-threshold screening test to ensure that they could taste saccharin aerosol at the specified concentration. After the screening test, the subject drank water and rinsed his or her lips and mouth. The subject then donned the respirator and the saccharin fit test was conducted. If a subject tasted saccharin at any time, the test was considered a failure; otherwise, the subject passed the test.

Ambient Aerosol Condensation Nuclei Counter Quantitative Fit Testing Protocol (Companion Fit Test)

TSI developed the N95-Companion accessory to the POR-TACOUNT Plus specifically for fit testing N95 filtering-facepiece respirators. Because the OSHA regulation 1910.134 does not preclude the use of the N95-Companion as part of the Ambient Aerosol Condensation Nuclei Counter Quantitative Fit Testing Protocol, it was used in this study. The N95-Companion is an aerosol preconditioner that selects particles in a specific size range (approximately 0.03 μm to 0.06 μm, which do not penetrate the N95 filter media) and passes them on to the PORTACOUNT Plus. Particles that are not in this range are discarded. The PORTACOUNT Plus then generates a fit factor as the ratio of the number of particles outside the mask to the number inside the mask. A TSI model 8026 particle generator was used to generate a sodium chloride aerosol to ensure the ambient aerosol concentration in the appropriate size was at least 70 particles/cc (the minimum level needed to conduct the test). For a subject to be considered as having passed the Companion fit test, the subject had to have a fit factor $\geq$100 with a particular respirator model.

SWPF Testing

The SWPF test results were used to determine the level of protection provided without a fit test being performed and to determine the effect of passing each of the fit tests. An SWPF is a measure of the protection received by an individual from a respirator and considers both filter penetration and face seal leakage. The PORTACOUNT Plus was used for the SWPF test because during a simulated health care workplace test, it predicted the wearer's actual exposure from facepiece leakage with a high correlation (coefficient of determination r^2 of 0.78), and of the six SWPF methods investigated it was the one closest to a fit test.[13] It should be noted that this study did not

determine the correlation between the wearer's actual exposure due to total inward leakage and the PORTACOUNT fit factors.

An SWPF test consisted of a test subject performing the following seven exercises for 1 min each: (1) normal breathing, (2) deep breathing, (3) moving head side to side, (4) moving head up and down, (5) reading the rainbow passage out loud, (6) bending at the waist, and (7) normal breathing. The seven individual exercise SWPF values were computed in the same manner as the N95-Companion fit test fit factors—by dividing the number of particles outside the facepiece by the number counted inside. The particle generator was not used. The harmonic mean of the individual exercise SWPF values from each test (overall SWPF) was computed using Eq. 1. The overall SWPF was the value used in subsequent analyses.

$$\text{Overall SWPF} = \frac{7}{\frac{1}{\text{SWPF}_1} + \frac{1}{\text{SWPF}_2} + \cdots + \frac{1}{\text{SWPF}_6} + \frac{1}{\text{SWPF}_7}} \quad \textbf{(1)}$$

where SWPF_x = the SWPF for exercise.

Before starting an SWPF test, a subject donned the respirator and performed a user-seal check, per the respirator manufacturer's instructions. After the respirator was donned, SWPF testing began. After completing the first SWPF test, a subject removed the respirator and gave it to the test operator. The test operator returned the respirator to its original configuration (e.g., loosening head straps, flattening the nosepiece) to ensure that the respirator wearer would not have to readjust the respirator between donnings. The subject then donned and user-seal-checked the same respirator again and performed another SWPF test. This procedure was repeated four additional times for a total of six SWPF tests for each subject and respirator combination.

DATA ANALYSIS

5th Percentile SWPF Values

The performance of the respiratory protective devices was measured using the 5th percentile and geometric mean (GM) SWPF values. The 5th percentile SWPF was computed from the formula $\text{GM}/\text{GSD}^{1.645}$ where GSD = geometric standard deviation.[7] The GM and 5th percentile SWPF for each device was calculated from the 150 overall SWPF values (six SWPF replicates times 25 subjects) without regard to any fit test result. This value represents the level of protection of the respiratory protective device "without fit testing." Separate GM and 5th percentile SWPF values were then calculated for only those subjects passing a fit-test while wearing an N95 filtering-facepiece or elastomeric respirator.

Random Effects Method

Nicas and Neuhaus[9] have proposed a different method for computing the level of protection afforded by a respirator. Their method takes into account the within/between-wearer variability components. This is done because the presence of between-wearer variability in the average level of respiratory protection impacts APF calculation. The method uses a normal random effects model for log transformed penetration values. To use this model, we first converted each overall SWPF value into a total penetration value by taking its reciprocal. The six penetration values for all subjects result in a lognormal distribution with a geometric standard deviation value, GSD_W, where the subscript W denotes within-wearer variability. All subject/respirator combinations in each of the two data sets (without and after passing a fit test) have distributions with the same GSD_W, although their variances differ.

Each subject/respirator combination has a unique geometric mean total penetration value, which also signifies that each subject has a unique arithmetic mean total penetration value, P, or the penetration value averaged across all donnings with a particular respirator. The mean penetration values among different wearers are lognormally distributed.

This lognormal distribution has a geometric standard deviation GSD_B where the subscript B signifies between-wearer variability. The arithmetic mean of the P distribution is denoted μ_P, which is the grand mean of all the individual wearer values. When the lognormal P distributions of all wearers are aggregated, the resulting total (marginal) distribution of P is lognormal. The total P distribution has arithmetic mean μ_P (the same arithmetic mean as the P distribution).

For each type of transformed P value in the study, we estimated the within-subject variance ($\hat{\sigma}_w^2$), the between-subject variance ($\hat{\sigma}_B^2$), and the population mean value (μ_ι) using Proc Mixed in SAS (SAS Institute, Cary, N.C.). Using these values, the estimate of κ_1, the 95% percentile of the lognormal between-wearer distribution, was made by inserting the parameter estimates into the appropriate equation presented by Nicas and Neuhaus.[9]

However, because $\hat{\kappa}_\ell$ is only a point estimate of the true population value, a one-sided lower confidence limit ($\text{SWPF}_{\text{LCL90\%}}$) was used to determine the APF.

The percentage of subjects having their SWPF values below a target APF ($\text{Sub}_{\text{fractotal}}$) was calculated using parameters μ_P, GSD_B, and GSD_W to determine the GM and GSD of the total (marginal) P distribution. The GM and GSD for the 95th percentile penetration values were then used to calculate the percentage of subjects having more than 5% of their p-values greater than the specified value (Percentage 95% Dist.), for example, 0.1 or APF < 10. This calculation reveals not only the number of subjects whose overall SWPF values were below the target, but also how many had more than 5% of individual donnings below the target.

RESULTS

The tables list the 5th percentile, $\text{SWPF}_{\text{LCL90\%}}$, subfractotal and percentage 95% distribution values. Table II summarizes the level of protection without fit testing provided by all 36 half-facepiece respiratory protective devices. For the filtering-facepiece respirators, the 5th percentile SWPF values ranged from a low of 1.1 (protection factor of 1.0 indicates the respirator provides no protection) to 13.2. The $\text{SWPF}_{\text{LCL90\%}}$ values ranged 1.2 to 6.7. When all the filtering-facepiece

TABLE II. Level of Protection Without Fit Testing

Type/Model Number	5th Percentile	SWPF$_{LCL90\%}$	Target APF = 10		Target APF = 5		Target APF = 3	
			Sub$_{fractotal}$ (%)[A]	Percentage 95% Dist.[B]	Sub$_{fractotal}$ (%)	Percentage 95% Dist.	Sub$_{fractotal}$ (%)	Percentage 95% Dist.
Half-facepieces[C]	4.6	2.7	9	20	3	7	1	7
Filtering-facepieces								
All	3.3	2.0	14	31	5	13	2	13
3M 8511	12.8	6.7	1	6	0	0	0	0
3M 8515	6.9	3.2	5	37	1	3	0	3
3M 9210	13.2	6.1	1	5	0	0	0	0
3M 9211	6.7	2.8	5	26	1	5	0	5
Alpha Pro Tech MAS695	1.1	1.2	95	100	78	100	56	100
Aswan M-12	4.1	2.8	55	88	14	57	2	57
Draeger Piccola without valve	3.0	1.9	37	98	13	71	5	71
Gerson 1730	9.8	5.6	4	20	0	1	0	1
Gerson 2747	3.6	2.0	14	83	5	32	2	32
Gerson 3945	11.8	5.7	2	8	0	0	0	0
Makrite 910	6.8	3.9	11	53	1	7	0	7
Moldex 2600/2601	4.6	2.2	10	58	3	16	1	16
MSA FR200 affinity	2.3	1.6	43	98	19	80	8	80
San M package TN01	3.4	1.8	13	69	4	27	2	27
Survivair 1913	9.9	5.7	3	14	0	1	0	1
Elastomeric facepieces								
All	7.3	4.6	4	11	1	2	0	2
3M 7000	25.3	8.8	0	0	0	0	0	0
AO Safety 5 Star	3.8	2.0	7	51	2	13	1	13
Lab Safety 11291	7.3	4.5	5	32	1	2	0	2
Moldex 8000	9.1	5.3	5	28	0	1	0	1
MSA comfo classic	10.9	6.7	3	15	0	0	0	0
MSA comfo elite	8.1	4.8	7	34	1	3	0	0
North 7700	19.0	12.8	0	0	0	0	0	3
Pro-tech 1490/1590	20.8	12.6	0	0	0	0	0	0
Scott 66	5.3	2.4	7	46	2	10	1	10
Sellstrom 2900	4.7	2.2	10	58	3	17	1	17
Survivair 2000	23.4	12.6	0	0	0	0	0	0
Survivair 7000	25.3	3.4	3	18	1	3	0	3
Willson 1200	9.8	6.9	4	10	0	1	0	1
Willson 6100	7.0	3.6	7	33	1	6	0	6
Willson 6800	11.5	6.3	2	9	0	0	0	0
Surgical masks								
All	1.2	1.4	99	100	92	99	72	99
3M 1818	1.9	1.5	93	100	67	100	38	100
3M aseptex 1800+	1.9	1.7	100	100	100	100	100	100
3M Nexcare first aid	1.6	1.6	100	100	93	100	68	100
Johnson and Johnson Surgine 4238	1.3	1.5	100	100	91	100	65	100
Medline prohibit series	1.3	1.8	100	100	100	100	100	100
Tecnol 48237	1.0	1.4	100	100	96	100	81	100

[A] The percentage of subjects having their SWPF values below a target APF.
[B] The percentage of subjects having more than 5% of their SWPF values less than the specified value.
[C] All filtering-facepiece and elastomeric facepiece models combined.

TABLE III. Levels of Protection After Passing Bitrex Test

Type/Model Number (n)	5th Percentile SWPF	SWPF$_{LCL90\%}$	Target APF = 10 Sub$_{fractotal}$ (%)	Target APF = 10 Percentage 95% Dist.	Target APF = 5 Sub$_{fractotal}$ (%)	Target APF = 5 Percentage 95% Dist.	Target APF = 3 Sub$_{fractotal}$ (%)	Target APF = 3 Percentage 95% Dist.
All half-facepieces (161)	10.1	5.3	3	8	0	1	0	1
All filtering (42)	7.9	3.4	4	15	1	3	0	3
Elastomerics								
All (119)	11.1	6.2	2	6	0	1	0	1
3M 7000 (11)	22.9	5.7	0	1	0	0	0	0
Pro-Tech 1490/1590 (10)	24.6	14.1	0	0	0	0	0	0
North 7700 (11)	15.1	12.5	0	0	0	0	0	0
Moldex 8000 (11)	10.9	5.8	3	13	0	0	0	0
Sellstrom 2900 (10)	7.8	3.2	5	25	1	4	0	4
Survivair 7000 (10)	15.1	7.4	1	3	0	0	0	0

respirator data was combined, the 5th percentile SWPF was 3.3, whereas the SWPF$_{LCL90\%}$ was 2.0.

Using a target level APF equal to 10 (which is the normally accepted expected level of protection for all half-facepiece respirators regardless of facepiece type), combining the filtering-facepiece and elastomeric respirator data resulted in 9% of the aggregated SWPF values being less than 10 (Table II). One in five (20%) wearers had a SWPF distribution such that more than five % of their SWPF values would be less than 10. There was only one filtering-facepiece respirator that met both criteria at the target APF of 10, the 3M 9210. Only 1% of the aggregate SWPF values were below 10, and only 5% (one person) had more than 5% of their total SWPF values less than 10.

For the elastomeric facepiece models, the 5th percentile SWPF values ranged from a low of 3.8 to 25.3. SWPF$_{LCL90\%}$ values ranged from 2.0 to 12.8. When all the elastomeric facepiece respirator data was combined, the 5th percentile SWPF was 7.3, whereas the SWPF$_{LCL90\%}$ was 4.6. For the surgical mask models, the 5th percentile SWPF values were very low (ranging from 1.0 to 1.9). The SWPF$_{LCL90\%}$ values were also low, ranging from 1.4 to 1.8. When all the surgical mask data was combined, the 5th percentile SWPF was 1.2, whereas the SWPF$_{LCL90\%}$ was 1.4.

Elastomeric facepiece respirators performed somewhat better as a group than did the filtering-facepiece respirators. They provided a level of protection approximately 60% better than the filtering-facepiece respirator class (Table II). In addition, there were four elastomeric models having 5% or less of their wearers having more than 5% SWPF values less than 10. Using the 5th percentile method, 7 out of the 15 elastomeric respirators had a 5th percentile of 10 or more (4 had one of 20 or greater), whereas filtering-facepieces had only three models with values higher than 10 (the highest was only 13.2). Two elastomeric respirator models were below 5%, whereas seven of the filtering facepiece models had values below 5%. Three elastomeric facepiece models had SWPF$_{LCL90\%}$ values equal to or greater than 10, whereas no filtering-

facepiece models did. There were also four filtering-facepiece models with SWPF$_{LCL90\%}$ values less than 2. There were no elastomeric models having SWPF$_{LCL90\%}$ values less than 2. The SWPF$_{LCL90\%}$ value for elastomeric respirators as a class was more than twice that for filtering-facepiece respirators. This data suggests that elastomeric respirators may have better-fitting characteristics (i.e., provide a higher level of protection without fit testing) than filtering-facepiece respirators. It also indicates that there is a wide discrepancy between models even in the same type of respiratory protective device.

Surgical masks performed very poorly (Table II). The best performing model had only 7% of the SWPF values equal to or greater than 10. All models had 100% of their wearers having at least 5% of their SWPF values less than 10.

Table III contains the level of protection for the half-facepiece respirators for those subjects passing the Bitrex fit test. Because none of the 15 different filtering-facepiece respirator models had at least 10 subjects passing the Bitrex fit test, the level of protection after passing the Bitrex fit test was calculated only on the filtering-facepiece class as a whole (i.e., the data from all subjects passing the Bitrex test were combined without regard to the model passed). Nine of the 15 individual elastomeric facepiece models had fewer than 10 subjects passing the Bitrex fit test, so the level of protection after passing the Bitrex test was computed for only six models of elastomeric facepiece respirators. Combining both the elastomeric and filtering-facepiece models resulted in a 5th percentile SWPF value of 10.1 and a SWPF$_{LCL90\%}$ of 5.3. The values for all filtering-facepiece respirators combined were 7.9 and 3.4, respectively. For all the elastomeric facepiece models combined, the values were 11.1 and 6.2, respectively. At least 10 people passed the Bitrex test with 6 out of the 15 elastomeric models. For these six models, the 5th percentile SWPF values ranged from 7.8 to 24.6, whereas the SWPF$_{LCL90\%}$ values ranges from 3.2 to 14.1.

Table IV contains the level of protection for the half-facepiece respirators for those subjects passing the saccharin

TABLE IV. Levels of Protection After Passing a Saccharin Fit Test

Type/Model Number (n)	5th Percentile SWPF	$\text{SWPF}_{\text{LCL90\%}}$	Target APF = 10		Target APF = 5		Target APF = 3	
			$\text{Sub}_{\text{fractotal}}$ (%)	Percentage 95% Dist.	$\text{Sub}_{\text{fractotal}}$ (%)	Percentage 95% Dist.	$\text{Sub}_{\text{fractotal}}$ (%)	Percentage 95% Dist.
All half-facepieces (172)	11.5	5.5	2	6	0	1	0	0
All filtering (43)	11.0	2.5	4	27	1	5	0	5
Elastomerics								
All (129)	11.7	5.6	1	6	0	1	0	1
3M 7000 (13)	50.0	18.3	0	0	0	0	0	0
Survivair 2000 (14)	31.1	16.9	0	0	0	0	0	0
Pro-Tech 1490/1590 (12)	30.7	20.3	0	0	0	0	0	0
North 7700 (13)	18.1	11.2	0	1	0	0	0	0
Willson 6800 (12)	11.9	5.7	1	7	0	0	0	0
MSA comfo classic (10)	12.0	7.8	2	7	0	0	0	0

fit test. Combining both the elastomeric and filtering-facepiece models resulted in a 5th percentile SWPF value of 11.5 and a $\text{SWPF}_{\text{LCL90\%}}$ of 5.5. The values for all filtering-facepiece respirators combined were 11.0 and 2.5, respectively. For all the elastomeric facepiece models combined, the values were 11.7 and 5.6, respectively. No filtering-facepiece models had at least 10 subjects passing the saccharin test. At least 10 people

passed the saccharin test with 6 out of the 15 elastomeric models (not all the same subjects as for the Bitrex test). For these 6 models, the 5th percentile SWPF values ranged from 11.7 to 50.0 whereas the $\text{SWPF}_{\text{LCL90\%}}$ values ranged from 5.7 to 20.3.

Table V contains the level of protection for the half-facepiece respirators for those subjects passing the Companion

TABLE V. Levels of Protection After Passing a Companion Test

Type/Model Number (n)	5th Percentile SWPF	$\text{SWPF}_{\text{LCL90\%}}$	Target APF = 10		Target APF = 5		Target APF = 3	
			$\text{Sub}_{\text{fractotal}}$ (%)	Percentage 95% Dist.	$\text{Sub}_{\text{fractotal}}$ (%)	Percentage 95% Dist.	$\text{Sub}_{\text{fractotal}}$ (%)	Percentage 95% Dist.
All half-facepieces (309)	14.5	8.8	1	3	0	0	0	0
Filtering								
All (82)	20.5	14.2	0	0	0	0	0	0
3M 8515 (13)	26.1	15.8	0	0	0	0	0	0
3M 9210 (11)	34.6	7.1	0	2	0	0	0	0
Gerson 1730 (11)	24.5	18.2	0	0	0	0	0	0
Gerson 3945 (15)	24.8	17.5	0	0	0	0	0	0
Moldex 2600/2601 (10)	21.4	12.5	0	0	0	0	0	0
Elastomerics								
All (227)	13.0	7.6	1	4	0	0	0	0
3M 7000 (15)	50.7	20.9	0	0	0	0	0	0
AO safety 5 star (11)	17.8	7.4	0	2	0	0	0	0
Lab safety 11291 (19)	15.8	10.1	0	1	0	0	0	0
Moldex 8000 (12)	14.0	8.4	1	4	0	0	0	0
MSA comfo classic (14)	15.4	10.7	0	1	0	0	0	0
North 7700 (22)	22.3	16.4	0	0	0	0	0	0
Pro-tech 1490/1590 (17)	26.0	16.6	0	0	0	0	0	0
Scott 66 (13)	27.9	16.5	0	0	0	0	0	0
Sellstrom 2900 (14)	18.5	11.5	0	1	0	0	0	0
Survivair 2000 (21)	30.7	17.4	0	0	0	0	0	0
Survivair 7000 (17)	13.8	7.0	1	4	0	0	0	0
Willson 1200 (13)	10.2	7.0	3	7	0	0	0	0
Willson 6100 (13)	15.1	9.6	1	2	0	0	0	0
Willson 6800 (21)	10.8	5.7	2	10	0	1	0	1

fit test. Combining both the elastomeric and filtering-facepiece models resulted in a 5th percentile SWPF value of 14.5 and a $SWPF_{LCL90\%}$ of 8.8. The values for all filtering-facepiece respirators combined were 20.5 and 14.2, respectively. For all the elastomeric facepiece models combined, the values were 13.0 and 7.6, respectively. Five filtering-facepiece models had at least 10 subjects passing the Companion test. For these five models, the 5th percentile SWPF values ranged from 21.4 to 34.6, and the $SWPF_{LCL90\%}$ values ranged from 7.1 to 18.2. Fourteen out of the 15 elastomeric models had at least 10 people passing the Companion test. For these models, the 5th percentile SWPF values ranged from 10.2 to 50.7, whereas the $SWPF_{LCL90\%}$ values ranged from 5.7 to 20.9, respectively.

DISCUSSION

Level of Protection Afforded by the Different Types of Respiratory Protective Devices

NIOSH defines the APF as the minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and trained users. Historically this percentage has been 95%. Hence, Lenhart and Campbell[8] selected the 5th percentile method for determining the APF of a respirator. Ninety-five percent of all the protection factors would be equal to or greater than the 5th percentile value. The 5th percentile SWPF method aggregates SWPF values across all wearers. It does not take into account either between- or within-wearer variability. The random effects model method does take into account both of these sources of variability. This results in the $SWPF_{LCL90\%}$ values being generally lower in Tables II through V. The exceptions are the very low values near 1, which indicates that the respiratory protection device did not provide any protection for the surgical masks and the MAS 695 filtering-facepiece respirator in Table II.

Our data demonstrate that using the random effects model and lower confidence limit method provides substantially more conservative values for the level of protection provided by a respirator than the 5th percentile method. For filtering-facepiece respirators as a class, the level of protection calculated by the random effects model and lower confidence limit method was 59% of the value obtained by using the 5th percentile. For the 14 different filtering-facepiece models (one was not included because both methods gave values of approximately 1, the lowest achievable value), the random effects model provided values ranging from 42% to 70% of the corresponding 5th percentile values. For elastomeric facepiece respirators as a class, the random effects model value was 63% of the 5th percentile value. For the different models, the values of the random effects model ranged from 13% to 70% of the 5th percentile values.

By aggregating all SWPF values across all wearers, the 5th percentile method may allow a substantial number of wearers to have more than 5% of their SWPFs below the APF value.[9] To determine whether this was correct, both the percentage of SWPFs lower than a target APF and the percentage of wearers having more than 5% of their SWPF values less than the target APF were computed. The target values chosen were 10, 5, and 3. Ten was selected because it is the APF usually assigned to half-facepiece respirators. Five was selected due to its being the APF previously recommended by NIOSH for a single-use dust respirator not quantitatively fit tested. After computing the results for a target APF of 5, there were still a large number of filtering-facepiece respirators and some elastomeric respirators that did not meet the criteria. A new target value of 3 was chosen to see if these poor performing respirators could meet this minimum criterion.

The majority of the half-facepiece respirators did not meet the criteria at the target APF of 10. Using 5 as the target APF, all half-facepiece respirators combined met the 5% value for the aggregate SWPF values (Table II). Reducing the target APF value to 5 increased the number of filtering-facepiece models meeting the 5% criterion from 5 to 11. As a class, the filtering-facepieces still had 13% of wearers having 5% of their SWPF values less than 5. There were eight models of filtering-facepieces that had more than 5% of their wearers with 5th percentiles less than 5. All subjects wearing the Alpha Pro-Tech MAS 695 are projected to have SWPF values less than 5 based on our analysis.

Elastomeric respirators performed better. As a class, they met both criteria. Only 1% of all SWPF values were less than 5 and only 2% of the wearers had 5th percentiles less than 5. All models had less than 5% of the SWPF values less than 5. Four models had more than 5% of the wearers with 5th percentiles less than 5, the highest being 17%. This data supports the idea that elastomeric respirators have better fitting characteristics. Reducing the target value to 5 made no difference with the surgical masks (Table II).

Because there were a number of individual respirator models (both filtering and elastomeric) that did not pass both criteria even when using a target value of 5, the calculations were redone with a target APF value of 3 to determine if additional respirators could meet this minimum criterion. Lowering the target APF value did not have much of an effect (Table II). There were still two filtering-facepiece models that did not meet both criteria. Fifty-six percent of the SWPF values for the Alpha Pro-Tech MAS 695 and 8% for the MSA Affinity FR200 still exceeded 3. Eight of the filtering-facepiece models had a large portion of the wearers with 5th percentiles less than 3. The Draeger Piccola without valve had 71%, the MSA Affinity FR200 had 80%, and 100% of the wearers of the Alpha Pro-Tech MAS 695 had 5th percentiles less than 3. No surgical mask models met either of the criteria when a target APF value of 3 was used. This may be partly due to the filter material of surgical masks having a high penetration of room air particles than when combined with the face-seal leakage would result in high total penetration and low SWPF values.

Effect of Fit Testing on Level of Protection

Because the respirators did not have adequate fitting characteristics to provide the expected level of protection without fit testing, the calculations were redone only on those subjects

passing each of the three fit tests (Tables III through V). Only models having at least 10 of 25 subjects passing the given fit test were included in this analysis. It was felt that having less than 10 subjects would not provide an accurate estimate of the between-wearer variability. Without an accurate estimate of the between-wearer variability, the $SWPF_{LCL90\%}$ method would not provide meaningful results. The effect of having an accurate estimate of the variability can be seen in Table III. Respirator models having large variability result in lower $SWPF_{LCL90\%}$ values. For example, after passing the Bitrex test, both the North 7700 and Survivair 7000 had the same 5th percentile value (15.1). The North 7700 had a $SWPF_{LCL90\%}$ value of 12.5 using a target APF of 10. The Survivair 7000 had a $SWPF_{LCL90\%}$ value of 7.4. The difference in $SWPF_{LCL90\%}$ values is due to the North 7700 having a within-wearer GSD of 1.38 and a between-wearer GSD of 1.33. The Survivair 7000 had within- and between-wearer GSDs of 2.03 and 1.41, respectively.

When the data from all half-facepiece respirators passing the Bitrex fit test were combined, half-facepiece respirators as a class met the expected APF of 10 using the 5th percentile method (Table III). The $SWPF_{LCL90\%}$ value was only approximately half of the 5th percentile at 5.3. Three percent (135 of 4500) of all half-facepiece respirator SWPF values were less than 10, whereas 8% of the wearers had 5th percentiles less than 10. Filtering facepieces as a class did not meet the expected level of protection using either the 5th percentile (7.9) method or random effects model (3.4). Even though only 4% of the SWPF values for the filtering-facepiece models were less than 10, 15% of the wearers had 5th percentiles less than 10. All filtering-facepiece models had fewer than 10 subjects passing the Bitrex resulting in their exclusion from Table III.

Using the 5th percentile, elastomerics as a class did provide the expected level of protection (11.1). When the random effects model was used, elastomerics as a class provided less protection than expected (6.2). Elastomerics as a class had 2% of SWPF values less than 10, but 6% of the wearers had 5th percentiles less than 10. Six individual elastomeric models had 10 or more subjects passing the Bitrex. Of these, one (Sellstrom 2900) had a 5th percentile of only 7.8 with 25% of the wearers having a 5th percentile less than 10. Having a 5th percentile greater than 10 does not guarantee every donning for each wearer of that model adequate protection. The Moldex 8000 elastomeric facepiece respirators had a 5th percentile SWPF of 10.8; however, 13% of the individual wearers had 5th percentiles less than 10.

Lowering the target APF to 5 resulted in the half-facepiece respirator class having only 1% of the total number of SWPFs lower than 5. For filtering facepieces, using a target APF of 5 resulted in 3% of the wearers having 5th percentiles less than 5. For half-facepiece respirators lowering the target APF to 3 had no effect. The data in Table III indicate that passing a Bitrex test does not guarantee the respirator worn will provide the expected level of protection (i.e., APF of 10) regardless of the method (i.e., 5th percentile or random effects model) used to calculate the protection. This result is consistent with those

obtained by McKay and Davies.[14] The data also indicate that filtering-facepiece and elastomeric respirators as classes do not provide substantially different levels of protection.

The results for the subjects passing the saccharin test were similar to those passing the Bitrex test. After passing the saccharin test (Table IV), the percentage of filtering-facepiece wearers having 5th percentile values less than 10 (27%) was higher than after passing the Bitrex test (15%). Six percent of the wearers of half-facepiece and elastomeric facepiece respirators as a class had 5th percentiles less than 10. When the target APF value was lowered to 5, there were no SWPF values lower than the target APF and only 1% of the wearers had a 5th percentile lower than 5.

The Companion fit test had the highest pass rate and level of protection of the three fit tests (Table V). After passing the Companion fit test, all half-facepiece respirators, along with elastomeric facepiece and filtering-facepiece types, as a class, met both criteria. For all half-facepiece respirators, only 1% of the SWPF values were less than 10, whereas only 3% of the wearers had a 5th percentile value less than 10. Passing a Companion fit test with a filtering-facepiece respirator would provide the expected level of protection of 10 for all wearers (no wearers had a 5th percentile less than 10 after passing the Companion test (Table V)).

As with both the Bitrex and saccharin tests, there appears to be only a slight difference in the level of protection provided by filtering-facepiece respirators as compared with elastomeric facepiece respirators. With the Bitrex and saccharin tests, filtering-facepiece respirators as a class provided slightly less protection than the elastomeric facepiece respirators, whereas with the Companion the opposite was true. The data indicate that there is no substantial difference in the level of protection provided by a respirator after passing the Companion fit test as compared with passing one of the qualitative fit tests. This finding supports the implicit assumption behind both 29 CFR 1910.134 and ANSI Z88.10 fit test standards that one can use any of the listed fit tests whether qualitative or quantitative and obtain comparable results. The reasons why the Companion fit test has a higher pass rate than the other two fit tests are worthy of investigation. The data indicate that fit testing is a necessary component of a complete respiratory protection program. Without fit testing, half-facepiece respirators will not provide the expected level of protection.

LIMITATIONS

The limitations of this study can be summarized as:

■ The levels of protection afforded by the respiratory protective devices in this study may not be representative of those that could be achieved in the actual workplace. The seven SWPF exercise regime may not be representative of all actual workplace movements. Therefore, the results obtained in this study provide the relative performance of each respirator model compared with the others under the given study conditions only. The performance data

cannot be viewed as the protection that all wearers in all workplace applications will receive. The estimated level of protection provided to a particular individual can be altered by changes in facial characteristics, weight gain or loss, and so on.[15] Recent workplace protection factor studies indicate that half-facepiece negative-pressure air-purifying respirators do provide a level of protection greater than the APF. In a steel foundry, P100 half-facepiece respirators had workplace protection factors ranging from 513–230,000 with a GSD of 17.8.[16] A workplace study in a fiber glass boat manufacturing facility measuring styrene found workplace protection factors of half-facepiece respirators with organic vapor cartridges and dust and mist filters ranging from 11 to 248.[17]

- The subjects may not have worn the size of respirator that provided the highest level of protection. The subjects were given the size as determined by the LANL study.[6]
- The subjects participating in this study may not be representative of all respirator wearers, who may have a different facial size distribution than that of the subjects in this study. The subjects in the study may not have been as ethnically diverse as the population of actual respirator wearers.
- The devices tested may not be representative of all models available when the study commenced. Because only a subpopulation of available models were tested, these models may not have included ones that would have provided better or worse protection.

CONCLUSIONS

The data indicate that surgical masks perform much more poorly than either elastomeric or filtering-facepiece N95 respirators. Surgical masks may not provide the expected level of protection of a half-facepiece respirator. Half-facepiece N95 respirators tested in this study as a group provided a level of protection less than the APF of 10 for half-facepiece respirators with a 5th percentile SWPF value of 4.6 without fit testing computed by combining all 4500 SWPF values. Fit characteristics vary widely within each respirator type (filtering-facepiece and elastomeric). Using the 5th percentile method without fit testing, the filtering-facepiece respirator models had protection levels ranging from none to slightly above the APF of 10. Elastomeric facepiece model protection levels ranged from slightly less than half of the expected APF level to two and half times the expected level. Lowering the APF to 5 for filtering-facepiece respirators would not assure all wearers receive that level of protection.

These data demonstrate the need for a standardized test in the respirator certification regulations (Title 42 *Code of Federal Regulations* Part 84) to ensure that all certified respirators have the ability to provide the expected level of protection to 95% of wearers. Fit testing is extremely important in the context of a complete respiratory protection program to assure the wearer is issued a respirator that provides an adequate level of protection. After passing a fit test, the wearer has a higher probability of receiving the expected level of protection. Under

the conditions of the study, subjects passing a fit test did not necessarily obtain the target APF of 10 from the respirator. Further research is needed to investigate why this occurred. Research is also needed to determine why the Companion fit test has a pass rate so much greater than the qualitative tests.

For the past 20 years, the 5th percentile method has been used to determine APFs. This method aggregates the data that could lead to more than 5% of the wearers having 5th percentile values less than 10. This could lead to wearers, who are relying on their respirator to provide an APF of 10, being overexposed. Instead, setting APFs using the random effects model could lower the possibility of a given wearer being overexposed because it takes into account within- and between-wearer variability.

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