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### Simulated Workplace Performance of N95 Respirators

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# Simulated Workplace Performance of N95 Respirators

During July 1995 the National Institute for Occupational Safety and Health (NIOSH) began to certify nine new classes of particulate respirators. To determine the level of performance of these respirators, NIOSH researchers conducted a study to (1) measure the simulated workplace performance of 21 N95 respirator models, (2) determine whether fit-testing affected the performance, and (3) investigate the effect of varying fit-test pass/fail criteria on respirator performance. The performance of each respirator model was measured by conducting 100 total penetration tests. The performance of each respirator model was then estimated by determining the 95th percentile of the total penetration through the respirator (i.e., 95% of wearers of that respirator can expect to have a total penetration value below the 95th percentile penetration value). The 95th percentile of total penetrations for each respirator without fit-testing ranged from 6 to 88%. The 95th percentile of total penetrations for all the respirators combined was 33%, which exceeds the amount of total penetration (10%) normally expected of a half-mask respirator. When a surrogate fit test (1% criterion) was applied to the data, the 95th percentile of total penetrations for each respirator decreased to 1 to 16%. The 95th percentile of total penetrations for all the respirators combined was only 4%. Therefore, fit-testing of N95 respirators is necessary to ensure that the user receives the expected level of protection. The study also found that respirator performance was dependent on the value of the pass/fail criterion used in the surrogate fit-test.

**Keywords:** fit-test, N95 respirator, pass/fail criterion, total penetration

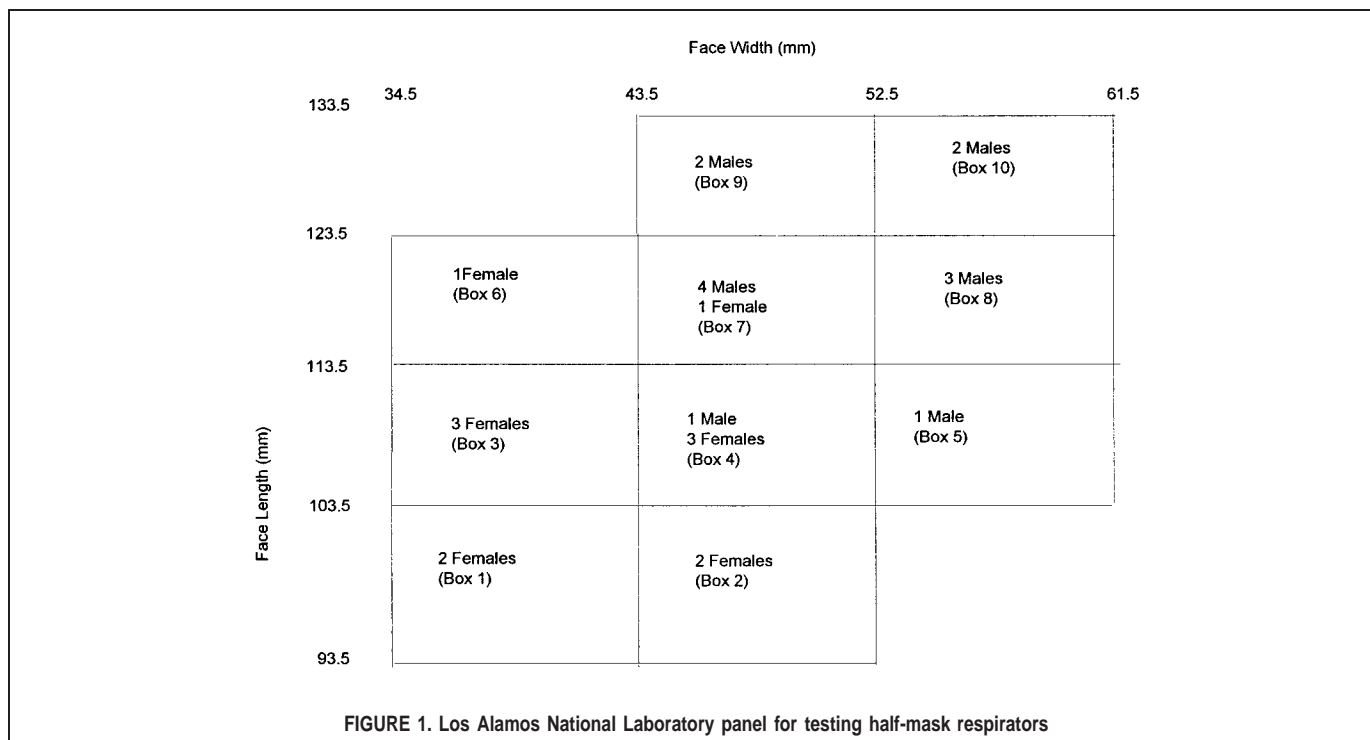
The ability to form a reliable seal (i.e., fit) is an important characteristic of any negative-pressure respirator, including filtering-facepiece respirators (disposables). It is so important that current regulations, standards, and recommendations addressing the use and selection of respirators require that individual users be fit-tested to determine the integrity of the respirator face seal as part of the selection process.<sup>(1-3)</sup> During a fit-test a series of exercises designed to stress the seal of the respirator is performed and inward leakage into the facepiece is determined. A fit-test is important for two reasons: (1) It can help ensure that each individual has an adequately fitting respirator (i.e., the respirator provides a minimum level of protection); and (2) it can be useful for training wearers in proper donning procedures.

There are two basic types of fit-tests. The first type of fit-test is the qualitative fit-test (QLFT), which relies on the wearer's subjective response to determine whether the face seal leaks. Four

QLFTs are in use today: (1) iso-amyl acetate (IAA), (2) irritant smoke, (3) saccharin, and (4) Bitrex<sup>®</sup>.<sup>(2,4)</sup> The IAA test is not appropriate for an N95 or any other particulate respirator, since the IAA vapor would penetrate the filter. The use of irritant smoke and saccharin are not recommended for use by the National Institute for Occupational Safety and Health (NIOSH) because of the associated health hazards.<sup>(5)</sup> The Bitrex test is similar to the saccharin test except that denatonium benzoate (Bitrex) is used as the challenge agent. Bitrex has a bitter unpleasant taste and is used as a taste-aversion agent in toxic household liquids to help prevent ingestion.<sup>(6)</sup>

The second type of fit-test is the quantitative fit-test (QNFT), which relies on instrumentation to quantify the amount of face seal leakage present. Available QNFT equipment measures either aerosol concentrations or pressure inside the respirator. The pressure method cannot be used with filtering-facepiece respirators, since the filtering area cannot be sealed. Aerosol methods

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typically use corn oil, sodium chloride, or ambient aerosols. The concentrations of the challenge aerosol in the facepiece,  $C_{in}$ , and outside the respirator,  $C_{out}$ , are determined. Then, a fit factor (a quantitative measure of the fit of a particular respirator facepiece to a particular individual) that is defined under the conditions of quantitative fit-testing as the ratio  $C_{out}/C_{in}$  can be calculated.<sup>(7)</sup>

In June 1995 NIOSH revised the certification regulations and transferred them from Title 30, *Code of Federal Regulations* (CFR) to Title 42 of CFR, Part 84 (42 CFR 84).<sup>(8,9)</sup> The 42 CFR 84 regulations provide for nine classifications of particulate respirators, that is, three filter efficiency levels (95, 99, and 99.97% referred to as 100%) each with three categories of resistance to degradation (N, R, and P with N the least resistant to degradation and P the most resistant). Therefore, an N95 filter or respirator is not resistant to degradation and has an efficiency between 95 and 99% when tested against the conditions of the 42 CFR 84 filter efficiency level determination tests.

Since the introduction of N95 respirators into the market place, NIOSH and the Occupational Safety and Health Administration (OSHA) have received many inquiries regarding the face-fitting characteristics of the new N95 respirators, especially the filtering-facepiece type. These inquiries raised the issues of how well these respirators fit and whether they need to be fit-tested. Therefore, the objectives of this study were to determine (1) the simulated workplace performance of N95 respirators, especially the filtering-facepiece type; (2) whether the simulated workplace performance of these respirators improved if a quantitative fit-test was used to eliminate wearers with poorly fitting respirators (i.e., whether N95 filtering facepiece respirators need to be fit-tested); and (3) the effect of varying pass/fail criteria for a quantitative fit-test on the performance of these respirators.

To evaluate the simulated workplace performance of N95 respirators, this study determined the total penetration (the combination of filter penetration and face seal leakage) of 21 models, each tested on a panel of 25 subjects. Four total penetration tests were performed on each subject/respirator combination and these

100 measurements were used to calculate a 95th percentile total penetration value for each respirator (i.e., 95% of wearers of that respirator can expect to have a total penetration value below the 95th percentile total penetration value). The first total penetration test was then used as a surrogate fit-test by subtracting out the filter penetration resulting in only face seal leakage. Those subjects having face seal leakage greater than a given criteria were removed from the data set. The remaining subjects were then used to determine a new 95th percentile of total penetration that reflects the performance of the respirator if fit-testing had been done prior to the total penetration testing.

## MATERIALS AND METHODS

### Subjects

A panel of 25 subjects consisting of 15 females and 10 males was used to measure the performance of each respirator model. Each subject was familiar with donning and wearing respirators. The subjects had facial sizes in accordance with the Los Alamos National Laboratory 25-member Respirator Panel for testing half-masks, as shown in Figure 1.<sup>(10)</sup>

### Respirators

One elastomeric respirator with replaceable filters, and 20 filtering-facepiece respirators were used in this study. The filtering-facepiece models were selected because they were representative of those models certified during the first year 42 CFR 84 was in effect. Nine of the filtering facepiece respirators were available in only one size. Three of the filtering facepiece models were available in two sizes, six models in three sizes, and two models in four sizes. Eight models were of the cup-shaped design, whereas the remaining filtering-facepiece respirators were of the folding type.

The one elastomeric respirator was selected for inclusion in this

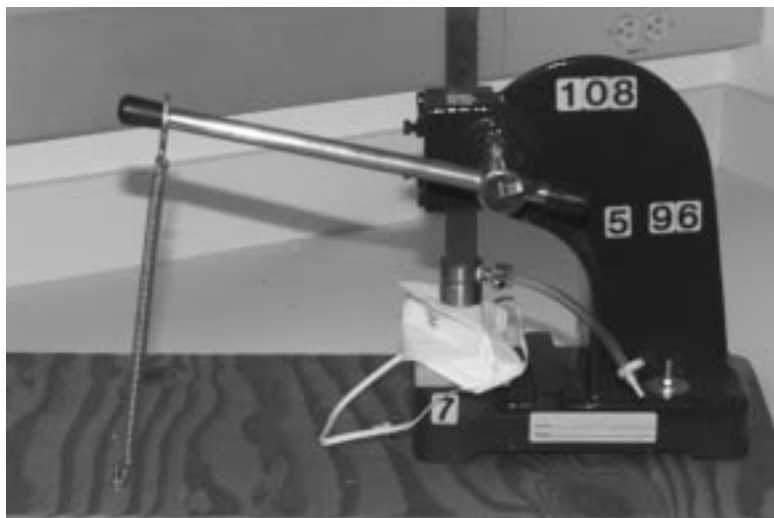


FIGURE 2. Side view of filter penetration tester with a N95 respirator

study because it was the first and only elastomeric respirator certified only with N95 filters during the first year after the promulgation of Part 84. For the total penetration testing, all of the respirators were probed approximately halfway between the nose and mouth using the TSI Fit Test Probe Kit (P/N 8025-N95, TSI Inc., St. Paul, Minn.).

It should be noted that the models tested in this study do not necessarily represent the models now available. Some of these 21 models are no longer manufactured and marketed in the version tested since they have either been modified by the manufacturers or replaced by newer versions. Many additional models are also now available.

#### Determination of Respirator Performance Without Fit-Testing

A TSI PortaCount Plus<sup>®</sup> Model 8020 was used to measure the performance (i.e., total penetration) of the respirators during a simulated workplace test conducted in a laboratory setting. The PortaCount Plus is a quantitative fit-test instrument that uses ambient particles as the challenge agent and counts the number inside and outside of the facepiece. The number inside is divided into the number outside and a fit factor is displayed.<sup>(11)</sup> The PortaCount Plus was chosen because it has been demonstrated, in a previous study, that the fit factors (the reciprocal of face seal leakage) obtained from this instrument during a simulated health-care workplace test have a high correlation with a wearer's actual exposure and are widely used for fit testing.<sup>(12)</sup> Prior to the start of a series of total penetration tests, the subject was given the manufacturer's donning and user seal check (also referred to as a pressure-tightness test or a negative/positive pressure check) instructions.

The respirators that were available in multiple sizes did not come with instructions on how to choose the appropriate size. Therefore, to provide the best performing respirator for each subject, each size was donned per the manufacturer's instructions and tested with the PortaCount Plus on the subject breathing normally for 80 sec. The size with the lowest total penetration (the reciprocal of the value obtained directly from the PortaCount Plus including face seal leakage and filter penetration) was then used during the total penetration testing.

The subject donned the respirator and conducted the user seal

check in accordance with the manufacturer's instructions. After the user seal check was successfully completed, the total penetration testing began. The subject performed the following exercises for approximately 80 sec each: (1) normal breathing, (2) deep breathing, (3) moving the head side to side, (4) moving the head up and down, (5) reading the rainbow passage out loud, and (6) normal breathing. These exercises are the same as those used in the correlation study with the PortaCount Plus.<sup>(12)</sup> A total penetration value was obtained from all six exercises. Total penetration is a measure of the protection received from a respirator and includes leakage from both filter penetration and around the face seal. After completing the first test, the subject removed the respirator and returned it to the test operator. The test operator then placed the respirator in its original configuration prior to donning it (e.g., loosening head straps, flattening nosepiece, etc.). The subject then donned and user seal-checked the same respirator again per the manufacturer's instructions. A second test, identical to the first, was conducted. This procedure was repeated two additional times for a total of four total penetration tests for each subject/respirator combination.

The resulting 100 total penetrations were used to calculate the 95th percentile of total penetration for each respirator model. This value will be referred as the 95th percentile without fit-testing. The 95th percentile was calculated using the geometric mean (GM) and the geometric standard deviation (GSD) as  $GM \times GSD^{1.645}$ .<sup>(13)</sup>

#### Measurement of Filter Penetration

For this study to use the first total penetration test as a surrogate fit-test, it was necessary to determine whether the proportion of the measured total penetration attributable to filter penetration was significant. This was accomplished by measuring the filter media efficiency (filter ratio) for ambient particles. The filter ratio was determined using the device shown in Figure 2.

The clamp seals a small area of the filtering facepiece so that the penetration of the ambient aerosols through the filter material can be determined with the PortaCount Plus. The filter ratio tester had a circular sealing edge with a diameter of 0.92 inch resulting

in 0.67 square inch of the respirator being used for the filter penetration measurement. This area was ascertained by measuring several types (both folding and cup-shaped) of N95 filtering facepiece respirators, finding a representative filter area (approximately 30 square inches), and determining the minute volume (10.3 L/min) and peak inspiratory flow rate (40 L/min) for a sedentary human.<sup>(14)</sup>

During human inspiration, the flow is not steady but approximately sinusoidal. Since the filter efficiency is a function of flow rate, a volume weighted average of the flow rate is appropriate for selecting a single flow rate to represent the cyclic flow. It can be shown that the volume weighted average flow is equal to  $\pi/4$  times the peak flow rate of 40 L/min. Therefore, a representative flow through a respirator is 31.4 L/min.

From the PortaCount Plus manual, the sampling rate is 0.7 L/min.<sup>(12)</sup> Therefore, the filter area over which the filter ratio is measured with the PortaCount Plus equals 0.67 square inch (0.7 L/min divided by 31.4 L/min times 30 square inches). Since the test area is circular, the diameter is equal to 0.92 inch (the square root of 4 times 0.67 square inch divided by  $\pi$ ).

The filter ratios of each model were measured from a number of samples to determine whether they were greater than 0.03%. The 0.03% value was chosen since, normally, high-efficiency filters (i.e., filter penetrations less than 0.03% when tested against a 0.3  $\mu\text{m}$  particle), which effectively stop all particles from passing through, are used on a respirator for fit-testing with the PortaCount Plus.

### Determination of Respirator Performance With Fit-Testing

To estimate the performance of N95 respirators when fit-testing is conducted prior to use (as required by various regulations and recommendations), the first of the four total penetration measurements was used as a surrogate fit-test.<sup>(1,2,4)</sup> Because a fit-test measures only face seal leakage, it was necessary to correct the measured penetrations (face seal leakage plus filter penetration) by subtracting out the filter penetration (the reciprocal of the filter ratio) determined for each respirator model immediately after the fourth total penetration test was completed. All subjects having a first donning face seal leakage greater than the pass/fail criterion were considered to have failed the fit-test and were removed from the data set. The total penetrations for donnings 2, 3, and 4 for the remaining subjects (those having a first donning face seal leakage less than the pass/fail criterion) were used to calculate a new 95th percentile of total penetration for each respirator model. Three different pass/fail criteria were used in this study: 1%, which is the value recommended by the American National Standards Institute (ANSI) and OSHA, 2% (twice the ANSI and OSHA values), and 10%, which is the level of protection half-mask respirators are expected to provide in the workplace.<sup>(1,2,4)</sup>

## RESULTS

### Respirator Performance Without Fit-Testing

Table I, column 2, summarizes the performance of the 21 respirators when fit-testing is not conducted (i.e., all 100 penetration tests were used to determine respirator performance). The 95th percentiles of total penetrations for each respirator ranged from 6 to 88%. The 95th percentile of total penetrations for all the respirators combined was 33%. Therefore, on average, respirator wearers could expect to have 95% of their total penetrations to be

TABLE I. Performance of N95 Respirators With and Without Fit-Testing

Respirator Model	Without Fit-Testing 95th Percentile of Total Penetration <sup>A</sup> (%)	With Fit-Testing (Pass/Fail Criterion of 1%)	
		Number of Persons Passing Fit-Test Out of 25	95th Percentile of Total Penetration <sup>A</sup> (%)
1	6	14	3
2	7	8	2
3	18	16	1
4	88	4	1
5	31	0	Not applicable
6	11	15	4
7	10	5	2
8	6	9	2
9	18	0	Not applicable
10	12	8	2
11	33	3	16
12	41	3	3
13	21	8	4
14	26	0	Not applicable
15	19	3	3
16	13	9	4
17	50	11	1
18	7	20	2
19	32	3	4
20	61	1	2
21	24	6	5
All	33	146 of 525	4

<sup>A</sup>Total penetration is the sum of filter penetration and face seal leakage, and, for example, a total penetration of 25% corresponds to an exposure equal to one-quarter of the exposure without a respirator. Ninety-five percent of wearers are expected to have total penetrations less than the stated value.

upwards of 33%. This is more than three times the level of performance (10%) normally expected of a half-mask respirator. These results indicate that a respirator wearer cannot reasonably expect to achieve the desired level of protection without fit-testing.

### Filter Penetration

The results of the trial ambient aerosol filter penetration tests are contained in Table II. At the beginning of the study it was thought that the ambient filter penetration of a respirator filter would not vary significantly during the day as long as the filters tested for total penetration during that day were from the same lot. Therefore, not every individual respirator filter was tested for filter penetration. Filter penetration was measured only for a random sample of filters from respirators tested during a given day. The sample size varied with the number of respirators tested in a day. For example, if five or six subjects tested a certain respirator in one day, then three filters were tested for penetration: the first respirator worn, a respirator worn around midday, and the last respirator worn. If three respirators were tested (two in the morning and one in the afternoon), then two filters were tested for penetration (the first one in the morning and the second one in the afternoon). However, as the study progressed, it became evident that there was a large variability in the filter penetration from respirators tested on the same day and between respirators tested on different days among the majority of the samples of the same respirator model. Therefore, at approximately halfway through the study, filter factors started to be taken on every respirator immediately after the fourth total penetration test.

**TABLE II. Filter Penetration of N95 Respirators**

Model	n	Filter Factors		Filter Penetration	
		Mean	Standard Deviation	Mean (%)	Standard Deviation (%)
1	11	3199	2987	0.05	0.04
2	25	544	282	0.24	0.13
3	25	1383	1095	0.14	0.12
4	12	75,882	100,536	0.01	0.01
5	25	449	246	0.33	0.24
6	25	5744	14,127	0.07	0.08
7	15	2794	8749	0.25	0.18
8	25	1445	1892	0.19	0.21
9	13	892	803	0.32	0.34
10	25	299	215	0.47	0.27
11	25	154	264	1.85	2.85
12	11	494	324	0.44	0.51
13	14	536	388	0.26	0.13
14	25	687	312	0.18	0.10
15	25	139	66	0.86	0.41
16	11	473	394	0.41	0.34
17	15	6914	7870	0.21	0.71
18	14	4350	3213	0.05	0.05
19	25	414	154	0.27	0.09
20	25	776	884	0.20	0.12
21	12	492	313	0.35	0.30

**Respirator Performance With Fit-Testing**

As can be seen from the data in Table II, only one of the models tested (Model 4) had a mean filter penetration less than the high-efficiency value of 0.03%. Therefore, it was necessary to subtract the mean filter penetration from the total penetration of the first test to use it as a surrogate fit-test. Table I, column 4, summarizes the performance of the 21 models when this surrogate fit-test was used to screen out poor fitting respirators. The criterion for a poor fitting respirator for this part of the study was one having a face seal leakage greater than 1% (the ANSI and OSHA value). The 95th percentile of total penetrations for each respirator ranged from 1 to 16%. Therefore, the 95th percentiles of total penetration with fit-testing were from 50 to 87% lower than the corresponding values without fit-testing, indicating an important increase in protection. For the five models with total penetrations less than 10% without fit-testing, using the first total penetration test as a surrogate fit-test increased the level of protection they provide to the wearer by 50 to 67%. The 95th percentile of total penetration with fit-testing for all of the respirators combined was 4%, which represented a reduction of about 88% from the 95th percentile of total penetration without fit-testing. Again, both of these increases are significant. Even for the five models having 95th percentiles of total penetration less than 10% without fit-testing, performing a fit-test has value. With fit-testing the total penetration decreased by a minimum of 50%. These results appear to indicate that a respirator wearer can reasonably expect to achieve the desired level of protection when quantitative fit-testing is conducted.

Respirator Model 11 was the only model not to have a 95th percentile of total penetration with fit-testing below 10%. This can probably be attributed to the fact that the filter penetration for this model had a GM total penetration two times greater than any other respirator and a large GSD. The large GM total penetration and GSD, along with only three of the subjects passing a surrogate fit-test (face seal leakage less than 1%), resulted in a large 95th

percentile of total penetration that may not be truly indicative of the level of protection the respirator actually provides.

The data in Table I also show that none of the 25 subjects passed the fit-test (i.e., had a first donning face seal leakage of 1% or less) with three of the respirator models. Therefore, the 95th percentile could not be computed for these models. In addition, Table I, column 3, shows a high fit-test failure rate for many models; 17 of the 21 respirator models had acceptable fits for less than half of the 25 panel members. In addition, only 146 of the 525 subjects for all 21 respirators (28%) passed the surrogate fit-test. It should be noted that continued product modifications by respirator manufacturers may affect the fitting characteristics of specific models. Therefore, the results of this study may not be indicative of the respirators currently on the market.

**Effect of Pass/Fail Criteria on Respirator Performance**

The surrogate fit-test procedure was repeated two additional times, one with a pass/fail criterion of 2% and the other with a criterion of 10%. As can be seen in Table III, doubling the pass/fail criterion from 1 to 2% resulted in a decrease in the level of protection for all of the respirators combined from 4 to 7%, a significant decrease. The 95th percentile of total penetration for the 21 respirators with a pass/fail criterion of 2% for the surrogate fit-tests ranged from 1 to 14%.

For models 3, 6, 8, and 13, the 95th percentile of total penetration was the same whether the 1 or 2% criterion was used. In addition, the 95th percentile of total penetration for Model 11 decreased from 16 to 14%. Again, this probably can be explained

**TABLE III. Effect of Pass/Fail Criteria on Performance of N95 Respirators**

Respirator Model	Pass/Fail Criterion of 2%		Pass/Fail Criterion of 10%	
	Number of Persons Passing Fit-Test Out of 25	95th Percentile of Total Penetration <sup>A</sup> (%)	Number of Persons Passing Fit-Test Out of 25	95th Percentile of Total Penetration <sup>A</sup> (%)
1	20	4	25	7
2	19	3	24	6
3	17	1	21	5
4	7	4	14	15
5	2	4	12	23
6	20	4	23	6
7	13	4	24	10
8	14	2	25	6
9	2	7	19	13
10	12	3	23	9
11	9	14	16	16
12	4	5	18	25
13	10	4	22	18
14	1	2	15	19
15	8	4	21	12
16	13	10	23	12
17	13	2	20	14
18	20	2	24	5
19	10	9	19	17
20	3	14	14	24
21	12	11	21	21
All	229 of 525	7	523 of 525	18

<sup>A</sup>Total penetration is the sum of filter penetration and face seal leakage, and, for example, a total penetration of 25% corresponds to an exposure equal to one-quarter of the exposure without a respirator; and 95% of wearers are expected to have total penetrations less than the stated value.

by the fact that nine persons passed the surrogate fit-test with the 2% criterion and only three persons passed with the 1% criterion. The additional five persons may have offset the large variability in the filter penetrations resulting in a smaller 95th percentile of total penetration. Since this respirator had a very large variability in its filter penetration, the total penetration value may not reflect the actual penetration. In addition, using a 2% criterion allowed a 95th percentile of total penetration to be computed for the three respirators in Table I for which a value could not be calculated using the 1% criterion. The total number of persons able to pass the surrogate fit-test was increased to 229 (43%) with the 2% criterion.

Table III also shows the 95th percentile of total penetrations when a criterion of 10% was used to screen out poor fitting respirators. The 95th percentile of total penetrations for all the respirators increased to 18%. The 95th percentile of total penetrations for each respirator ranged from 5 to 25%. Fifteen of the respirators had a 95th percentile of total penetrations in excess of 10%. Thus, it is reasonable to expect that the majority of the wearers would not achieve the expected level of protection in the workplace using this criterion. Using the criterion of 10% allowed 81% of the subjects to pass the surrogate fit-test. While increasing the number of wearers passing the fit-test may be desirable (the more people who can wear one type of respirator, the less complicated the respirator program needs to be), it must be balanced by the significant decrease in protection provided to each wearer.

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## DISCUSSION

The results of this study indicate that fit-testing is an essential element of a respirator program, the ability of N95 respirators to successfully fit a variety of face sizes and shapes varies considerably from model to model, and fit-testing appears to increase the protection provided by N95 respirators. Without fit-testing, the panel of test subjects received much less protection than expected of this class of respirators (i.e., exposure reduced to 10% of ambient concentration without a respirator). However, with the fit-testing method used in this study, the panel received significantly more protection than normally expected. Fit-testing ensures that the wearers can properly put on the respirator and greatly enhances the protection provided by the respirator as seen in the increase in the 95th percentiles of total penetration with fit-testing. Fit-testing screens out poor fitting respirators and helps to ensure that the respirator provides the highest protection possible. Without fit-testing, an individual may, day after day, unknowingly have a poor face seal with the associated increase in exposure.

In addition, the study looked at the effect of varying (from 1 to 10%) the pass/fail criterion used to screen out poor fitting respirators on the level of performance. The fit-test pass/fail level of 1% used in this study is typically recommended by respirator authorities. It is, however, based mostly on professional judgement. In general, it was seen in this study that as the level of the pass/fail criterion was raised from 1 to 10%, the level of performance of the N95 respirators decreased. Therefore, this study suggests that a pass/fail criterion greater than 10% is needed to ensure that N95 respirators provide the maximum protection in the workplace. However, because of the limited number of subjects, and the use of the PortaCount Plus to measure laboratory respirator performance with ambient aerosols whose relationship to workplace performance is unknown, this study should not be taken as a basis to adjust or justify the traditional pass/fail criterion of 1%.

The PortaCount Plus fit-test instrument used in this study uses the large number of very small particles (several thousands per

cubic centimeter) present in normal room atmospheres. The instrument measures the percentage of such particles that enter the respirator—either through face seal leakage or through filter penetration. Presently, the PortaCount Plus is used only with high-efficiency respirators that have negligible filter penetration to ensure any particles detected in the facepiece are due to face seal leakage. This study tested N95 respirators using the same procedure as for high-efficiency respirators. However, because N95 filters are not 100% efficient in removing ambient air particles, it was necessary to conduct two additional steps: measure filter penetration using the PortaCount Plus with a specially designed fixture and then subtract out the filter penetration. The techniques for quantitatively fit-testing N95 respirators used in this study are now only appropriate for research purposes. However, these techniques could easily become commercially available. The availability of such a fit-test system or similar fit-test systems could simplify fit-testing and would be a welcome option to many, especially those who already have the basic hardware for quantitative fit-testing.

In addition, TSI Inc. recently developed the N95-COMPANION<sup>™</sup> as an accessory to test N95 respirators with their PortaCount Plus. The N95-COMPANION removes the aerosol size range that is most penetrating to the respirator filter. Only the very small aerosol that does not significantly penetrate the filter remains. Thus, when using the N95-COMPANION, filter penetration is not a concern. Studies are needed to compare the N95-COMPANION with the method used in this study.

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## CONCLUSIONS

This study shows that not all of the certified N95 respirators provide the same level of performance. The 95th percentile of total penetrations for each respirator without fit-testing ranged from 6 to 88%. The 95th percentile of total penetrations for all the respirators combined was 33%, which exceeds by more than three times the level of performance (10%) normally expected of a half-mask respirator.

When a surrogate fit-test was applied to the data, the 95th percentile of total penetrations for each respirator decreased to 1 to 16%. The 95th percentile of total penetrations for all the respirators combined was only 4%, which is less than one-eighth of the value (33%) without fit-testing. In fact, only 4 of the 21 models successfully fit more than 50% of the test subjects when a pass/fail criterion of 1% was used. Thus, the study demonstrates the need for fit-testing to screen out those respirators that do not fit well and do not provide the necessary level of protection. The authors conclude that the expected level of protection (10% or less) is more than achieved for the vast majority of N95 respirators, but only when fit-testing is used to screen out poor face-fit respirators. This study also found that as the pass/fail criterion was made more stringent, the level of protection increased. Therefore, further research is needed to determine the appropriate pass/fail criterion for quantitative fit-tests and to improve the facepiece fit characteristics of N95 filtering-facepiece respirators.

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## REFERENCES

1. **American National Standards Institute (ANSI):** *American National Standard for Respiratory Protection* (ANSI Z88.2-1992). New York: ANSI, Inc., 1992.
2. **National Institute for Occupational Safety and Health (NIOSH):** *NIOSH Guide to Industrial Respiratory Protection* (DHHS [NIOSH] Publication No. 87-116). Cincinnati, OH: NIOSH, 1987.
3. **Colton, C.E., L.R. Birkner, and L.M. Brosseau (eds.):** *Respiratory Protection A Manual and Guideline*, 2nd ed. Fairfax, VA: American Industrial Hygiene Association, 1991. p. 81.
4. "Respiratory Protection; Final Rule," *Federal Register* 63:5 (8 January 1998), p. 1273.
5. **National Institute for Occupational Safety and Health (NIOSH):** *Comments of the National Institute for Occupational Safety and Health on the Occupational Safety and Health Administration Proposed Rule on Respiratory Protection, 29 CFR Parts 1910, 1915, and 1926* (Occupational Safety and Health Administration Docket No. H-049). 1995.
6. **Mullins, H.E., S.G. Danisch, and A.R. Johnston:** Development of a new qualitative fit test for fit testing respirators. *Am. Ind. Hyg. Assoc. J.* 56:1068-1073 (1995).
7. **American Industrial Hygiene Association Respiratory Protection Committee:** Respirator performance terminology [Letter to the Editor]. *Am. Ind. Hyg. Assoc. J.* (46)5:B22-24 (1985).
8. "Respiratory Protective Devices; Tests for Permissibility; Fees," *Code of Federal Regulations* Title 30, Part 11, 1991.
9. "Respiratory Protective Devices; Final Rules and Notice," *Federal Register* 60:110 (8 June 1995) pp. 30336-30398.
10. **Los Alamos Scientific Laboratory:** *Selection of Respirator Test Panels Representative of U.S. Adult Facial Sizes* (LA-5488), by A. Hack, E.C. Hyatt, B.J. Held, T.O. Moore, C.P. Richards, J.T. McConville. Los Alamos, NM: Los Alamos Scientific Laboratory, 1974.
11. **TSI Inc.:** *PortaCount Plus<sup>®</sup>M Manual* [Product manual]. St. Paul, MN: TSI Inc., 1994.
12. **Coffey C.C., D.L. Campbell, W.R. Myers, Z. Zhuang:** Comparison of six respirator fit-test methods with an actual measurement of exposure: Part II—Method comparison testing. *Am. Ind. Hyg. Assoc. J.* 59:862-870 (1998).
13. **Lenhart, S.W., and D.L. Campbell:** Assigned protection factors for two respirator types based upon workplace performance testing. *Ann. Occup. Hyg.* 28:173-182 (1984).
14. **Silverman L., G. Lee, T. Plotkin, L.A. Sawyers, and A.R. Yancey:** Airflow measurements on human subjects with and without respiratory resistance. *Arch. Ind. Hyg. Occup. Med.* 3:461-478 (1952).