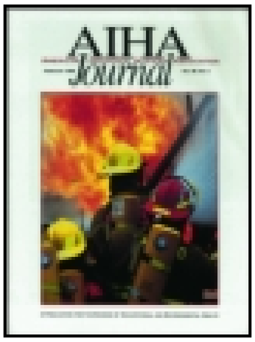

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Respiratory Protection as a Function of Respirator Fitting Characteristics and Fit-Test Accuracy

The fitting characteristics of particulate respirators are no longer assessed in the National Institute for Occupational Safety and Health respirator certification program. It is important for respirator program administrators to understand the implications of that change and the additional burden it may impose. To address that issue, a typical respirator fit-testing program is analyzed using a mathematical model that describes the effectiveness of a fit-testing program as a function of the fitting characteristics of the respirator and the accuracy of the fit-testing method. The model is used to estimate (1) the respirator assignment error, the percentage of respirator wearers mistakenly assigned an ill-fitting respirator; (2) the number of fit-test trials necessary to qualify a group of workers for respirator use; and (3) the number of workers who will fail the fit-test with any candidate respirator model and thereby fail to qualify for respirator use. Using data from previous studies, the model predicts respirator assignment errors ranging from 0 to 20%, depending on the fitting characteristics of the respirator models selected and the fit-testing method used. This analysis indicates that when respirators do not necessarily have good fitting characteristics, respirator program administrators should exercise increased care in the selection of respirator models and increased care in fit-testing. Also presented are ways to assess the fitting characteristics of candidate respirator models by monitoring the first-time fit-testing results. The model demonstrates that significant public health and economic benefits can result when only respirators having good fitting characteristics are purchased and respirators are assigned to workers using highly accurate fit-testing methods.

Keywords: assignment error, fit-testing, h-value, respirator

The National Institute for Occupational Safety and Health (NIOSH) certification requirements for particulate respirators were upgraded in 1995 with the new Part 84 regulations.[1] Although those new regulations substantially improved the requirements for particulate filters, the facepiece fitting characteristics of all particulate respirators became exempt from evaluation as a condition of NIOSH certification. This current situation increases the burden on respirator program administrators, since all respirator models will not necessarily have good fitting characteristics. Identifying respirators with good fitting characteristics is problematic, and fit-testing individual workers has become more critical. Given that fit-testing methods are not error free, it is important to explore how this current situation can affect the adequacy of a respirator program.

The most important, and most variable, attribute of any negative-pressure respirator is how well it seals to the face. The quality of face fits achieved by a group of respirator wearers is determined by two factors. First is the fitting characteristics of the respirator model. The term "fitting characteristics" is used here to refer to the ability of a particular respirator model to provide an adequate fit to a large percentage of the general population with its wide variety of face sizes and shapes. An "adequate fit" is one in which an individual consistently achieves a protection factor equal to, or greater than, the assigned protection factor (APF) for the respirator class.

The second factor is the accuracy of the fit-testing method used to verify that each respirator wearer has an adequately fitting respirator. Current fit-test methods are not error free, and their inherent errors can result in individuals being inappropriately assigned poor-fitting respirators for use in hazardous environments. The chance of an individual being assigned a poorly fitting respirator increases with increasing fit-testing error and decreases with improvements in the face-fitting characteristics of the respirator.

The purpose of this study was to quantify how the fitting characteristics of respirator models and fit-test accuracy interact in a typical fit-testing program to determine the level of protection provided to a population of workers. To that end, a model simulating a typical fit-testing program was constructed. The model was used to estimate, as a function of the two factors discussed above, the respirator assignment error, defined as the fraction of respirator wearers assigned an inadequately fitting respirator. Using data from previous studies as input for the model, this assignment error ranged from 0 to 20%, depending on the fitting characteristics of the individual respirator models and on the fit-testing method used.

The model also was used to estimate the number of fit-tests necessary to qualify a group of workers for respirator use and the number of workers who do not pass any fit-testing and thereby fail to qualify for respirator use. The model thereby demonstrates to respirator program administrators the importance of selecting respirators with good fitting characteristics and the importance of using accurate fit-testing methods.

A Respirator Fit-Testing Program Model

A model of a typical fit-testing program for negative-pressure respirators is depicted schematically in Figure 1. The model begins with a population of N people who are candidates for wearing respirator Model 1. The model assumes that each of the N individuals has selected an appropriate respirator size, will properly don the respirator, and will conduct the fit-check recommended by the manufacturer. The model conceptually divides N into two groups: those who will consistently achieve good fits during future use and those who will not. The size of each group depends on the fitting characteristics of respirator Model 1.

The parameter used to describe the fitting characteristics of a respirator is the fraction h of population N who will obtain an adequate fit when a respirator is selected, donned, and fit-checked according to its manufacturer's instructions before fit-testing. In this context an adequate fit is one resulting in a protection factor equal to or greater than the APF. In Figure 1 the number of candidate respirator wearers in the group having an inherently good fit is represented by N_g. By definition of h, $N_g = Nh_1$, where subscript 1 indicates the h-value for respirator Model 1. The number of candidate respirator wearers in the group having an inherently bad fit is thus $N_b = N(1\text{-}h_1)$. Fit-testing is conducted in an attempt to distinguish wearers in one group from wearers in the other.

The results of the first fit-tests are represented in the third row of Figure 1.

First Block

The first block on the left shows $N_{b,p1}$, which is the number of candidate respirator wearers with an inherently bad fit who pass the first fit-test, shown as $N_{b,p1} = N_b\beta$. Parameter β is the beta error of the fit-test, which is defined as the fraction of those wearers with an inadequate fit passing the fit-test erroneously.

Second Block

The second block represents the number of candidate wearers of poorly fitting respirators who fail the first fit-test, shown as $N_{b,f1} = N_b(1-\beta)$. This group has been identified correctly.

Third Block

The third block represents the number of candidate respirator wearers with an inherently good fit who pass the first fit-test, shown as $N_{g,p1} = N_g(1-\alpha)$. Parameter α is the alpha error of the fit-test and represents the fraction of wearers with an inherently good fit failing the fit-test in error.

Fourth Block

The fourth block represents the number of candidate wearers who inappropriately fail the first fit-test and is shown as $N_{g,f1} = N_g\alpha$.

Those passing the fit-test are qualified to wear respirator Model 1. Those failing the test are retrained in the proper respirator donning procedure and then tested a second time. The number passing and failing the second test are represented in the fourth row of Figure 1. The relationships used to compute these numbers and subsequent numbers throughout the fit-testing exercise also are shown in Figure 1.

After the second fit-test there will still be some people who have not passed. In this analysis it is assumed that these individuals will switch to a second respirator model and repeat the test process. The analysis for the second model is identical to that described for Model 1, except that the second respirator will have different fitting characteristics and therefore would have a different h-value, h_2. The values of α and β will be unchanged, since it is assumed the same fit-test is used throughout the exercise.

It also is assumed that those individuals who do not pass the fit-test with the second model will then switch to a third model and again repeat the fit-testing process. The third respirator model also has different fitting characteristics and therefore would have a different h-value, designated h_3.

The analysis ends after the third model is tested. Those who have not passed a fit-test with one of the three models are considered to have failed to qualify to use a negative-pressure respirator and should be assigned responsibilities not requiring a respirator, or use a respirator type not depending on a face seal (e.g., a loose-fitting, powered, air-purifying respirator).

Using the analytic model described above, it is possible to estimate several important characteristics of a fit-testing program as a function of h, α, and β.

The model is first used to estimate what is defined as assignment error, which is given by the following equation.

$$A_e = N_{b,p}/(N_{b,p} + N_{g,p})$$

where A_e= the fraction of the population of qualified respirator wearers with an inherently poor respirator fit who have mistakenly passed the fit-test and are assigned that respirator to wear in the workplace; $N_{b,p}$ = the number of respirator wearers with an inherently bad fit who have qualified for respirator use by passing a fit-test in error; $N_{g,p}$ = the total number of wearers with an inherently good fit who have qualified for respirator use by appropriately passing a fit-test. $N_{b,p} = N_{b,p1} + N_{b,p2} + N^2_{b,p1} + N^2_{b,p2} + N^3_{b,p1} + N^3_{b,p2}$, which is the sum of the underlined cells in Figure 1, and $N_{g,p} = N_{g,p1} + N_{g,p2} + N^2_{g,p1} + N^2_{g,p2} + N^3_{g,p1} + N^3_{g,p2}$,

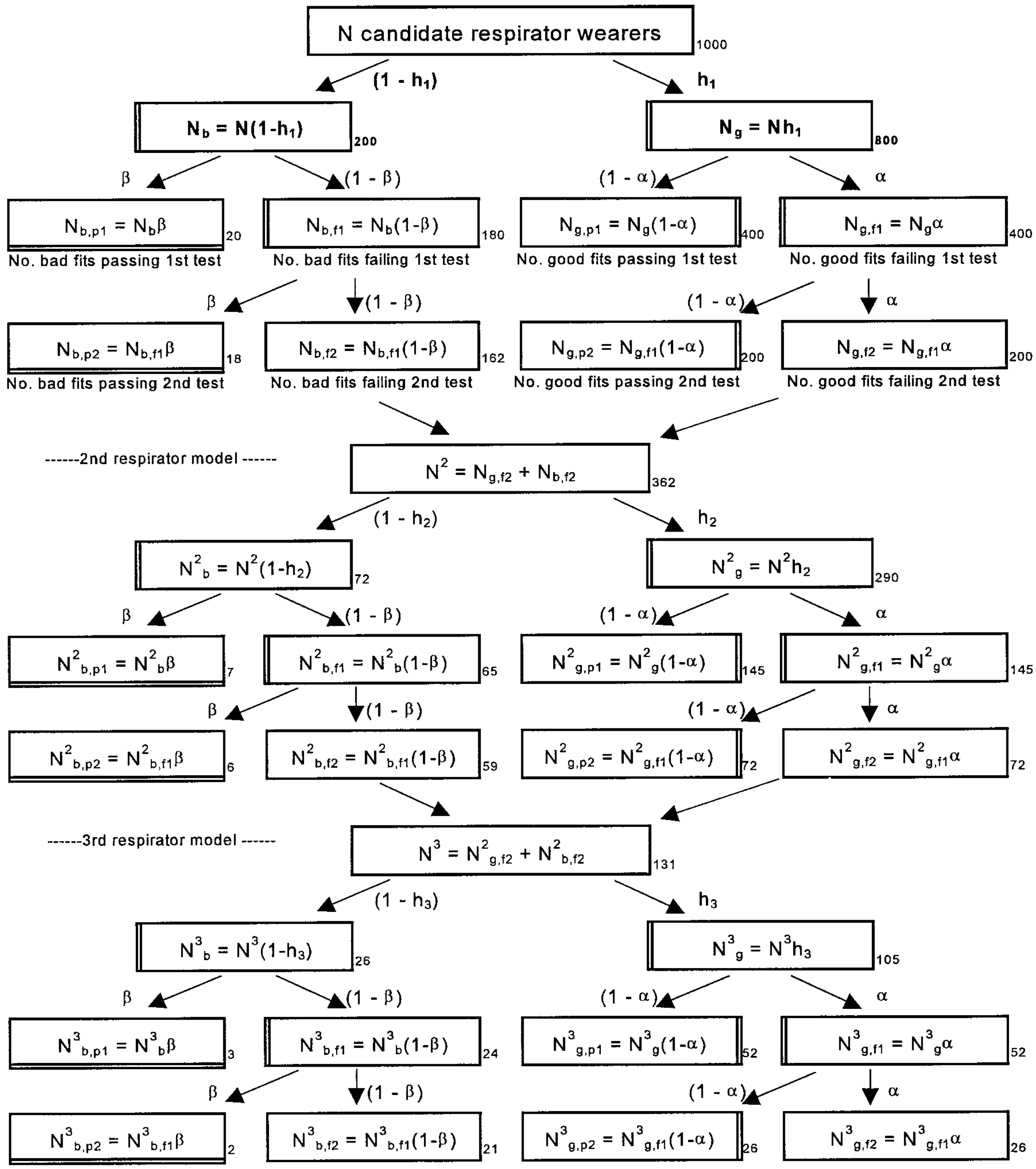

FIGURE 1. The flow of N candidate respirator wearers through a typical respirator fit-testing program. The proportion h has an inherently good fit with a particular respirator model whereas the proportion 1-h does not. Those failing the first fit-test are retrained in respirator donning and then fit-tested a second time. Those failing the second fit-test with the first model repeat the process with a second respirator model. Those failing with the second model try a third model. The alpha and beta error of the fit-test are represented by α and β, respectively. As an example, the number shown to the right of each cell is the number of workers in that cell for the case when N=1000, α=0.5, β=0.1, and h_1=h_2=h_3=0.8. The underlined cells are wearers assigned a poor-fitting respirator because of an error in the fit-test. In the example, the total of such workers is 20 + 18 + 7 + 6 + 3 + 2 = 56.

which is the sum of cells in Figure 1 with a double line on the right.

The model can be used to determine how the number of fit-tests necessary to qualify a given number of respirator wearers varies as a function of h, α, and β. Inspection of Figure 1 shows that the number of fit-tests per candidate respirator wearer is $N_{tests/c} = (N_b + N_g + N_{b,f1} + N_{g,f1} + N^2_b + N^2_g + N^2_{b,f1} + N^2_{g,f1} + N^3_b + N^3_g + N_{3b,f1} + N_{3g,f1})/N$, which is the sum of cells of Figure 1 with a double line on the left of the cell divided by N. However, the number of fit-tests per candidate respirator wearer, $N_{tests/c}$, is less useful than the number of fit-tests per qualified respirator wearer, $N_{tests/q}$, which is computed from $N_{tests/q} = N_{tests/c}\,[N/(N_{b,p} + N_{g,p})]$, where $(N_{b,p} + N_{g,p})$ is the total number of candidates who pass a fit-test.

The model can also be used to estimate how the number of workers failing to qualify for respirator use varies as a function of h, α, and β. The number who do not qualify to wear any of the three models is given by $N_{fq} = N^3_{b,f2} + N^3_{g,f2}$. The number who fail to qualify per qualified respirator wearer, $N_{fq/q}$, is given by $N_{fq/q} = N_{fq} [1/(N_{b,p} + N_{g,p})]$, where $N_{b,p}$ and $N_{g,p}$ are as defined above.

The respirator fit-testing program modeled here is only one of many possible fit-testing scenarios, some having more fitting trials and others having fewer. In general, the more fit-tests conducted with each model, the greater the risk of passing a fit-test in error. The approach used here can easily be modified to simulate other testing scenarios.

Input h-Values

To determine a realistic range of values for h, the authors followed the work of Hyatt, who established APF values in the mid-1970s using a quantitative fit-testing method.(2) (A brief history of fit-testing is provided in Appendix 1.) Every negative-pressure respirator model available in the United States at that time was evaluated on a panel of test subjects having a distribution of facial sizes approximating the general worker population. The respirator classes so studied included full-facepiece, half-facepiece, quarter-facepiece, single-use, and self-contained breathing apparatus. The APF values were established for each class so that every model in the class would provide protection factors equal to or greater than the APF for 95% of the test subjects. For example, all of the 8 then-available half-facepiece respirator models were found to provide 95% of the population with fit factors greater than 10 (without prior fit-testing to screen out subjects with poor fit). The APF was, therefore, set at 10. The performance of the other classes was similarly evaluated, and the APFs were established accordingly. Thus, the h-value was 0.95 or better for all respirator models available in the mid-1970s.

Hyatt reasoned that fit-tests on each individual worker were necessary to identify the 5% of wearers who would not achieve a protection factor at least equal to the APF and those few people with facial sizes not represented on the test panels. Thus, Hyatt's APF values depended first on respirators with good fitting characteristics (h ≥0.95) and second on fit-tests of each individual worker.

In a 1990 study of three models of elastomeric, half-facepiece respirators, h-values for 61 men and 60 women were measured.(3) The percentage of men obtaining protection factors of at least 10 were 84, 85, and 84% for the three models, or h-values of 0.84, 0.85, and 0.84. The h-values for the women were 0.89, 0.73, and 0.72.

To estimate the range of h-values of currently available respirators, the authors relied on a study of 21 models of N95 half-facepiece respirators certified under the revised certification regulations that do not include an assessment of fitting characteristics.(4,5) Twenty were filtering-facepiece respirators, whereas one was an unconventional elastomeric respirator. Each of the 21 models was evaluated by obtaining 100 measurements of simulated protection factors (4 replications on a panel of 25 subjects who had a distribution of facial sizes approximating that of the general population). The original data was used to compute h-values for each of the 21 models. The computed h-values are presented in Table I. For an APF of 10, h-values ranged from 0.99 to 0.44, with a median h-value of 0.83. Only 4 of the 21 models met Hyatt's criterion of an h-value of 0.95 or greater. The best-performing model provided a protection factor of 10 or greater in 99 of the 100 donnings (h= 0.99). The poorest performing model provided protection factors of 10 or greater in only 44 of the 100 donnings (h= 0.44).

TABLE I. Computed h-Values from Study of 21 N95 Half-Facepiece Respirators

Manufacturer/Model	h-value
Gerson/2735	0.99
3M/1860	0.98
3M/8210	0.96
Uvex/Pro-Tech N95	0.96
BBI/RX-2	0.93
Technol/PFR95 170-174	0.93
Moldex/2001/2002	0.90
Gerson/1730	0.91
Racal/Delta	0.85
MSA/Affinity Pro	0.84
Technol/PFR95110-114	0.83
Uvex/Pro-Tech N95-A	0.82
MSA/Affinity	0.78
Survivair/1930	0.76
Willson/N9510	0.68
San Huei/3810	0.66
Racal/Racal	0.59
Air Ace/9100	0.58
Alpha Pro Tech/MAS695	0.56
Moldex/2300N95	0.55
Willson/N9501	0.44

Since h-values are a function of APF value, the authors also computed the h-value corresponding to an APF of 5. For an APF of 5, h-values ranged from 1.0 to 0.71. The best model provided a protection factor of at least 5 in all of the 100 trials, whereas the poorest model provided a protection factor of at least 5 in 71% of the 100 trials. The median h-value was 0.95. Only 11 of the 21 models met Hyatt's criterion for an APF of 5.

The study of 21 N95 respirators was completed in 1997 and is not necessarily representative of respirators available in 2001, or any that will be marketed in the future. After their initial NIOSH certification, respirators frequently are modified throughout their market life. Although NIOSH reevaluates respirators to assure that they still meet the certification requirements, that evaluation does not include an assessment of the fitting characteristics, which may have changed.

As input for the model, the authors used a range of h-values from 0.95 to 0.45 to span the h-values described above. For this analysis, the laboratory tests (on which the h-values are determined) were considered to be a measure of workplace protection, although laboratory-measured protection factors may overestimate workplace protection factors (WPFs) and thus overestimate the workplace performance of a respirator. WPFs also may overestimate the real day-to-day protection provided by respirators because, by definition, measurements of WPFs are conducted in idealized respirator programs. Research to address these questions completely likely will not be completed in the near future. In the meantime, it is necessary to rely on the best available tools to assess respirator performance. If more refined methods become available to measure respirator performance, those methods also will be compatible with the model presented herein.

Input α- and β-Errors

The second and third parameters needed for this analysis are the α and β errors of the fit-tests. Beta errors of 5% (β = 0.05) are generally considered the goal for acceptable qualitative fit-testing methods. The authors used this value of β as a reference value in the simulations. Lower values of β also were used to see the effects

TABLE II. Respirator Assignment Error, A_e, the Percentage of Respirator Wearers Assigned an Inadequately Fitting Respirator

		$h = h_1 = h_2 = h_3$					
		0.95	0.85	0.75	0.65	0.55	0.45
Fit-Test Beta Error	0.05	0.68%	2.2%	4.2%	6.5%	9.6%	14%
(α=0.5)	0.10	1.3%	4.3%	7.8%	12%	17%	24%
	0.15	1.9%	6.1%	11%	17%	23%	31%
	0.20	2.5%	7.8%	14%	21%	28%	37%
	0.25	3.0%	9.3%	16%	24%	32%	42%

of fit-testing methods that were not up to that standard or fit-testing methods that were not conducted carefully. Alpha errors of 50% (α = 0.5) or less are generally considered adequate for respirator fit-testing, and this value was used in the following analysis. The authors also used lower and higher values of α to quantify whether the overall fit-testing program was sensitive to α error. A range of α- and β-errors have been reported for the fit-testing methods in common use.[6–10]

Given that the purpose of a fit-test is to assure that an individual will achieve a protection factor at least equal to the APF in the great majority of donnings throughout the work year, the single-donning approach of current fit-testing methods introduces uncertainty in the understanding of fit-testing errors. In the single-donning approach, the pass/fail level is increased by a factor of 10, seemingly to compensate for the use of a single donning when there is known to be a high degree of donning-to-donning variation. For example, when the APF is 10, the pass/fail level of the fit-test is set at 100. Although this approach introduces statistical uncertainty in both the α- and β-errors and substantially increases the α- error, the authors have not seen it analyzed in the literature. For the purpose of this analysis the α- and β-errors reported in the literature were used without regard to these uncertainties. On the other hand, these single-donning uncertainties do not apply to determining the h-value; h-values, by definition, must be determined by multiple donnings on a population of candidate respirator wearers.

RESULTS AND DISCUSSION

Tables II and III show the respirator assignment error, A_e, predicted by the model for a range of h-values and various combinations of α and β. The tables show that less than 1% of the population of respirator wearers will have an inappropriate respirator assigned to them (A_e <1%) when the respirator models have inherently good fitting characteristics (h $\geq$0.95) and when the fit-testing method is highly accurate (β $\leq$0.05). At the other extreme, it can be seen that without a highly accurate fit-test and without respirators with good fitting characteristics, the percentage of respirator wearers assigned inadequately fitting respirators can be quite high.

In general, the assignment error, A_e, increases as the quality of the fitting characteristics decrease (h decreases). Also, A_e increases when the reliability of the fit-test decreases (α and β increase). Although A_e increases as α increases, A_e is not as sensitive to the value of α as it is to the value of β. Overall, to minimize A_e, it is necessary for a respirator program to utilize (1) respirator models having good fitting characteristics (high h-values) and (2) highly accurate fit-testing methods (low α and β).

As a realistic example of the application of the model, consider the results of a study of 21 N95 half-facepiece respirators described earlier combined with the results of a recent study of the Bitrex™ qualitative fit-testing method (α= 41% and β= 9%).[4,10] For the poorest performing respirator in that study (h= 0.44) the model predicts a respirator assignment error of 20.8%. On the other hand, the model predicts that the four respirators with the best fitting characteristics (h $\geq$0.96) would have assignment errors of less than 1%.

Tables IV and V show the number of fit-tests necessary to qualify 100 respirator wearers when there is a range of h-values and various combinations of α and β. The number of fit-tests is a measure of the cost and disruption resulting from a respirator fit-testing program. From the tables it is clear that the cost of fit-testing is minimized with the use of (1) the most accurate fit-tests (low α) and (2) respirator models with good fitting characteristics (high h). Failure to incorporate both factors may significantly increase the number of tests needed.

Tables VI and VII show the number of workers who fail to qualify for respirator use under a range of h-values and various combinations of α and β and again demonstrate that a respirator must have good fitting characteristics and that the fit-test must be highly accurate. Failure to qualify may be a significant problem for both individual workers and employers. Not surprisingly, the number of workers failing to qualify is highly sensitive to h-value and to α error while being less sensitive to β error. There is a significant decrease in workers failing to qualify as β error increases when the respirator has poor fitting characteristics. This decrease results from the increased number of workers who pass the fit-test in error.

Overall, the above analysis supports the hypothesis that minimizing the health risk to respirator wearers requires (1) respirators with inherently good fitting characteristics and (2) highly accurate fit-testing methods. The analysis demonstrates that there also can

TABLE III. Respirator Assignment Error, A_e, the Percentage of Respirator Wearers Assigned an Inadequately Fitting Respirator

		$h = h_1 = h_2 = h_3$					
		0.95	0.85	0.75	0.65	0.55	0.45
Fit-Test Alpha Error	0.3	0.56%	1.9%	3.4%	5.5%	8.1%	12%
(β=0.05)	0.4	0.61%	2.0%	3.7%	5.9%	8.7%	12%
	0.5	0.68%	2.2%	4.2%	6.5%	9.6%	14%
	0.6	0.80%	2.6%	4.8%	7.6%	11%	16%
	0.7	1.0%	3.3%	6.0%	9.3%	14%	19%

TABLE IV. Number of Fit-Test Trials Per 100 Qualified Respirator Wearers

		h = h_1 = h_2 = h_3					
		0.95	0.85	0.75	0.65	0.55	0.45
Fit-Test Beta Error	0.05	212	240	275	318	373	447
(α=0.5)	0.10	211	234	262	296	337	389
	0.15	209	229	251	278	308	345
	0.20	207	223	241	262	285	311
	0.25	206	219	233	248	265	283

TABLE VI. Number of Workers Failing to Qualify for Respirator Use Per 100 Qualified Respirator Wearers

		h = h_1 = h_2 = h_3					
		0.95	0.85	0.75	0.65	0.55	0.45
Fit-Test Beta Error	0.05	2	4	8	12	19	29
(α=0.5)	0.10	2	4	6	10	14	21
	0.15	2	3	5	8	11	15
	0.20	2	3	4	6	8	11
	0.25	2	3	4	5	6	8

be economic and practical benefits as the number of fit-tests needed to qualify a group of workers is reduced.

Hoping to provide additional guidance to the practicing industrial hygienist, the authors explored the possibility of monitoring fit-test failure rates to assess the fitting characteristics of respirator models. However, they were unable to find a meaningful way to do that; it is not possible to determine what part of the fit-test failures is the result of a poor-fitting respirator and what part is the result of a high α-error of the fit-test. Tables VIII and IX show the failure rate for the initial respirator model after a first fit-test trial. That failure rate was calculated as $(N_{g,f1} + N_{b,f1})/N$, where is $N_{g,f1}$ is the number of subjects who failed the first fit-test trial because of the α-error in the fit-test, and where $N_{b,f1}$ is the number who appropriately fail because of inadequate fit. Tables VIII and IX show that the first-trial failure rate is quite sensitive to the α-error. Therefore, the authors see no meaningful way to obtain an indication of the respirator fitting characteristics (h-value) from the results of qualitative fit-testing.

A recent study of 211 subjects wearing half-mask respirators in the United Kingdom found a first-trial fit-test failure rate of 69% using the saccharin qualitative fit-test.[11] That is not necessarily an indication of poor fitting characteristics; it is possible that the seemingly high failure rate was simply the result of the high α-error that can be associated with this test. Tables VIII and IX show that even a respirator with good fitting characteristics (h $\geq$0.95) can have first-trial failure rates of 70% when the α-error is 0.7. Alpha errors that high have been reported for the saccharin fit-test.[6]

Also, a low first-trial failure rate is not necessarily a reliable indicator that a respirator model has good fitting characteristics; a low failure rate may simply reflect a high β-error. A high β-error can result from a fit-test that is not carefully and accurately performed.

Those who conduct quantitative fit-testing on a large population of workers, however, do have a more precise way to assess the fitting characteristics of a particular respirator. The h-value can be computed directly as the fraction of the first-trial protection factors that are above the APF of the respirator class. For all the reasons described above, a respirator with good fitting characteristics would have an h-value of 0.95 or above.

Although the accuracy of fit-testing methods as actually used in the workplace is unknown, it is generally believed that quantitative fit-testing in which facepiece leakage is measured is more accurate than qualitative fit-tests that rely on the subjective response of the wearer. In practice, quantitative fit-tests are typically used as a reference for the evaluation of qualitative fit-testing methods.[6–10] Previously, only qualitative fit-tests could be used for filtering facepiece-type respirators, one of the most popular respirator types. However, with the increased performance of filters required in all particulate respirators by NIOSH Part 84 regulations, filtering facepiece respirators now can be quantitatively fit-tested.[12] In addition, modern instruments have greatly simplified and quickened the procedures in quantitative fit-testing. Many vendors of fit-testing services offer both qualitative and quantitative tests at essentially the same cost. Thus, with the availability of modern test instruments and improved respirator filter performance, quantitative fit-testing has become an option not previously available.

RECOMMENDATIONS

For the public health and economic reasons described above, the authors make the obvious recommendation to first purchase only respirators with good fitting characteristics (h $\geq$0.95) and then carefully conduct fit-tests on individual workers. Beyond that, the following specific research recommendations also are suggested.

Continuing studies are necessary to measure and report the h-values for the large and ever-increasing number of available respirator models. As mentioned earlier, h-values can be determined by monitoring the first-donning protection factors measured in quantitative fit-testing programs. Administrators of large respirator programs already may be generating the data necessary to do this analysis. The authors encourage the sharing of such data with respirator users.

Research also is needed to measure the assignment errors of

TABLE V. Number of Fit-Test Trials Per 100 Qualified Respirator Wearers

		h = h_1 = h_2 = h_3					
		0.95	0.85	0.75	0.65	0.55	0.45
Fit-Test Alpha Error	0.3	153	177	207	244	293	358
(β=0.05)	0.4	178	203	235	275	326	394
	0.5	212	240	275	318	373	447
	0.6	264	296	335	383	444	525
	0.7	350	388	433	489	559	649

TABLE VII. Number of Workers Failing to Qualify for Respirator Use Per 100 Qualified Respirator Wearers

		h = h_1 = h_2 = h_3					
		0.95	0.85	0.75	0.65	0.55	0.45
Fit-Test Alpha Error	0.3	0	1	3	6	10	18
(β=0.05)	0.4	1	2	4	8	14	22
	0.5	2	4	8	12	19	29
	0.6	6	9	14	20	28	40
	0.7	15	20	26	34	45	58

TABLE VIII. Percentage of Workers Failing Initial Fit-Testing with First Candidate Respirator

		h =					
		0.95	0.85	0.75	0.65	0.55	0.45
Fit-Test Beta Error	0.05	52%	57%	61%	66%	70%	75%
(α=0.5)	0.10	52%	56%	60%	64%	68%	72%
	0.15	52%	55%	59%	62%	66%	69%
	0.20	52%	55%	58%	61%	64%	67%
	0.25	51%	54%	56%	59%	61%	64%

respirator fit-testing programs as actually used in the workplace. Other than the work presented here, the authors are not aware of other studies of the overall effectiveness of respirator fit-testing programs. Although studies of the accuracy of fit-testing methods have been published, studies of workplace fit-testing programs have not.[6–10] Assignment errors could be assessed in future research by conducting multiple-donning, quantitative fit-testing trials on a population of previously fit-tested respirator wearers and determining the fraction of that population not consistently achieving protection factors equal to, or greater than, the APF.

Also recommended is a statistical analysis of the current approach to fit-testing that uses a single respirator donning coupled with a "safety factor" of 10. Although it is a critical element in a fit-testing method, the authors have found no statistical analysis to justify this approach. Given the large donning-to-donning variation in protection factors, such analysis seems to be warranted.

There is a special group of respirator wearers who also need additional study. The above discussion concerns workers who have the advantage of some kind of fit-testing program. However, there are many workers who are not fit-tested at all, either because they are not covered by regulations that require fit-testing, not aware of such regulations, or because such regulations are not always followed.[13] For example, voluntary respirator use does not require fit-testing, and workers in agricultural workplaces are not covered by the Occupational Safety and Health Administration respiratory protection standard. Without the benefit of fit-tests, these workers depend entirely on the fitting characteristics of the respirator. The h-value is an estimate of the percentage of these workers who will achieve an adequate fit. If the h-value, for example, were 0.6, then only 60% of these respirator wearers would have an adequate fit even if the manufacturer's donning instructions were carefully followed. More research is needed to better understand the level of protection actually provided by respirators to this group of workers.

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TABLE IX. Percentage of Workers Failing Initial Fit-Testing Trial with First Candidate Respirator

		h =					
		0.95	0.85	0.75	0.65	0.55	0.45
Fit-Test Alpha Error	0.3	33%	40%	46%	53%	59%	66%
(β=0.05)	0.4	43%	48%	54%	59%	65%	70%
	0.5	52%	57%	61%	66%	70%	75%
	0.6	62%	65%	69%	72%	76%	79%
	0.7	71%	74%	76%	79%	81%	84%

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FIGURE A1. Coal dust deposition pattern on the faces of subjects after wearing half-facepiece respirators in the "coal dust tightness test" conducted by the former Bureau of Mines as part of its respirator certification program from 1934 until 1972. Only the center subject shows no leaks. The other two show leaks induced during a demonstration by a toothpick under the facepiece. Many facepieces submitted to the Bureau of Mines had to be redesigned before they could meet fitting requirements.[17]

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APPENDIX 1

History of Respirator Certification Regulations

For decades, concern over the importance of respirator facepiece fit motivated efforts to develop methods that would reliably indicate whether a respirator fit well or poorly. The following history of facepiece fit-testing methods and, in particular, their use as respirator certification requirements may be useful for clear understanding of the findings described in this article.

In 1911, German researchers reported studies in which two people entered a test chamber containing aerosolized industrial dusts (e.g., cotton, cement, slag, or rouge dust) mixed with bacterial spores.[14] However, only one wore a respirator. Both breathed through their noses, which were filled with cotton to filter out inhaled dust "without interfering too seriously with respiration." After each test, spores captured on the nose filters of each person were counted, and the difference was reported as the measure of a respirator's fit.

The Bureau of Mines (BOM) began issuing schedules or methods for testing respirators in 1919, but the first schedule for dust respirators was not issued until 1934.[15,16] In a 1937 article the BOM reported that "the difficulty of properly fitting the half-mask facepieces of mechanical-filter respirators to all types of faces has been brought out by the approval work on such respirators."[17] To address this concern, the BM added facepiece fit-testing to its respirator certification requirements.

One of the earliest fit-testing methods used at the BM was the "coal dust tightness test." This qualitative fit-test was used until 1972 and involved "three test subjects having full, average, and lean facial features."[18] After each person donned eye protection and a test respirator, a high concentration of fine coal dust was blown around the edges of each facepiece for 3 min. Figure A1 shows three subjects after this test. The requirements for a passing test were that "the following shall not show appreciably more black particulate matter than was observed before the test: the forced nasal discharge as shown on a white cloth; the sputum; and the nasal cavities, when examined with the aid of a speculum and illumination; and that part of the face covered by the facepiece of the respirator." A similar fit-test was used later by others for evaluating facepiece fits in a workplace. A worker blew his nose before donning a respirator, wore the respirator on the job, and blew his nose again after removing the respirator.[15] This test was said "to appeal to anyone's common sense and lifted respirator wearing out of the disciplinary regime into that of reason."

In 1959 the Atomic Energy Commission (AEC) Respirator Committee proposed specifications for evaluating how well respirators performed in purifying the air of radioactive contaminants.[19,20] Respirator performance was to be evaluated by a gas or particulate challenge. To pass, a respirator model had to adequately fit at least 95% of the *normal* adult population. Adequate fit for a half-facepiece respirator was face seal leakage of less than 1%. The 5% of wearers not achieving a fit were to be identified "by some measurable facial dimension." This facial dimension was not specified. In 1961 a report was published describing a quantitative method for evaluating facepiece fit that met the AEC Respirator Committee's specifications.[19] This method was the first that evaluated fit by simultaneously measuring the concentration of a challenge agent both outside and inside a facepiece while the test subject wore a respirator in an enclosure.

When the BOM published revised regulations for dust respirators (Schedule 21B) in 1965, facepiece fit-tests included the coal dust tightness test, a pressure tightness test, and an isoamyl acetate tightness test.[18] The pressure tightness test was essentially a positive-pressure, user seal check undergone by "15 to 20 persons having a wide variety of facial shapes and sizes." The isoamyl acetate tightness test was a qualitative fit-test. For half-facepiece dust respirators, this test required modifying the device by using organic vapor cartridges. Then 15 to 20 people wore the respirator while doing exercises in a chamber containing 100 ppm of isoamyl acetate. A respirator was considered to have failed if one or more wearers smelled isoamyl acetate.

Schedule 21B also included a new facepiece-fit requirement. Quantitative fit-testing using a challenge of 100 mg/m^3 of dioctyl phthalate (DOP) was required for respirators having high-efficiency filters.[2] Part of this test required each of three people to wear a respirator continuously for 2 hours. Three 15-min test periods inside the DOP chamber were alternated with two periods outside the chamber. The outside periods totaled 75 min during which the subjects "engaged in normal activities."[18]

In 1972, responsibility for testing and certifying respirators was transferred from the BOM to NIOSH, and respirator approvals were issued jointly by both agencies.[21] However, all facepiece fit-tests except the isoamyl acetate tests were omitted from the NIOSH requirements, and the number of test subjects involved was reduced to six or fewer.[22] A lack of specific criteria for the facial dimensions of test subjects remained a weakness of fit-testing requirements.

Soon after NIOSH began testing respirators, a contract was awarded to researchers at Los Alamos National Laboratories "to develop detailed anthropometric specifications to replace the vague and inadequate ones in the existing regulations."[22] A 16-member test panel was developed initially, but included only men, and the panel was later expanded to 25 to include women. Criteria for quantitative fit-testing using a 25-person test panel were developed by 1976. Borrowing from the AEC specifications, 24 of the 25 test subjects (95%) had to pass a quantitative fit-test for a respirator model to be acceptable. A test subject passed the quantitative fit-test when the face seal leakage was less than 10%.[23] (The AEC specification was 1%.) The 5% of wearers not achieving a fit were to be identified by "a stringent qualitative or quantitative fitting test or by anthropometric facial measurements."[2]

Although the Los Alamos research resulted in a promising solution to the fit-testing problem, isoamyl acetate fit-tests remain part of the NIOSH certification requirements, except that fit-tests for particulate respirators were omitted entirely from the updated certification requirements adopted in 1995.[1] A major reason for the omission was that a significant relationship had never been shown between any facepiece fit-test and the performance of a respirator in the workplace. NIOSH promised that it would "address issues associated with face-fit efficacy in a separate module (regulatory revision) upon completion of the necessary research."[1] Since 1995, NIOSH researchers have studied this issue, and fit-testing methods correlating with exposure have been validated.[24–26]

Given this long history of recognizing the importance of assessing fitting-characteristics as a requirement of certification and given the current absence of such requirements for the most popular respirator types certified in the United States, it is important to understand the added responsibility this places on respirator program administrators. To that end, it is useful to quantify how the fitting characteristics of individual respirator models affect the adequacy of respirator programs.