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# Errors Associated with Three Methods of Assessing Respirator Fit

**Christopher C. Coffey,[1] Robert B. Lawrence,[1] Ziqing Zhuang,[2] Matthew G. Duling,[1] and Donald L. Campbell[2]**

[1]Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Division of Respiratory Disease Studies, Morgantown, West Virginia
[2]Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, Pennsylvania

*Three fit test methods (Bitrex, saccharin, and TSI Porta-Count Plus with the N95-Companion) were evaluated for their ability to identify wearers of respirators that do not provide adequate protection during a simulated workplace test. Thirty models of NIOSH-certified N95 half-facepiece respirators (15 filtering-facepiece models and 15 elastomeric models) were tested by a panel of 25 subjects using each of the three fit testing methods. Fit testing results were compared to 5th percentiles of simulated workplace protection factors. Alpha errors (the chance of failing a fit test in error) for all 30 respirators were 71% for the Bitrex method, 68% for the saccharin method, and 40% for the Companion method. Beta errors (the chance of passing a fit test in error) for all 30 respirator models combined were 8% for the Bitrex method, 8% for the saccharin method, and 9% for the Companion method. The three fit test methods had different error rates when assessed with filtering facepieces and when assessed with elastomeric respirators. For example, beta errors for the three fit test methods assessed with the 15 filtering facepiece respirators were ≤5% but ranged from 14% to 21% when assessed with the 15 elastomeric respirators. To predict what happens in a realistic fit testing program, the data were also used to estimate the alpha and beta errors for a simulated respiratory protection program in which a wearer is given up to three trials with one respirator model to pass a fit test before moving onto another model. A subject passing with any of the three methods was considered to have passed the fit test program. The alpha and beta errors for the fit testing in this simulated respiratory protection program were 29% and 19%, respectively. Thus, it is estimated, under the conditions of the simulation, that roughly one in three respirator wearers receiving the expected reduction in exposure (with a particular model) will fail to pass (with that particular model), and that roughly one in five wearers receiving less reduction in exposure than expected will pass the fit testing program in error.*

**Keywords** error rates, fit test methods, N95 half-facepiece respirators, simulated respiratory protection program

Address correspondence to: Christopher C. Coffey, Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Division of Respiratory Disease Studies, 1095 Willowdale Road, Morgantown, WV 26505; e-mail: ccoffey@cdc.gov.

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Over three million American workers are required to wear respirators. Of the 282,000 establishments using respirators for required purposes, at least 225,100 of them use tight-fitting respirators that require fit testing.[1] The level of protection provided these workers depends on the inherent fitting properties of respirator models and on the accuracy of fit test methods.[2] The most important, and most variable, attribute of any negative-pressure respirator is how well it seals to the face. The quality of the face fit greatly affects the level of protection received by the respirator wearer and is influenced by two factors. First is the ability of a particular respirator model to provide an adequate fit to a large percentage (≥95%) of the general population with a wide variety of face sizes and shapes. The second factor is the accuracy of the fit test method used to identify those respirator wearers without an adequately fitting respirator. An "adequately fitting" respirator model is one that consistently provides a level of protection in the workplace equal to, or greater than, the assigned protection factor (APF) for that respirator

Previous studies have demonstrated that the current fit test methods are not error free.[3] Janssen et al.[4] examined (a) the comparability of the controlled negative pressure and

particle counting quantitative fit tests and the bitter aerosol qualitative fit test, and (b) the effect of the reference method on the apparent performance of a fit test method under evaluation. The methods were evaluated using the American National Standards Institute (ANSI) Z88.10 recommended standard criteria. None of the test methods met the ANSI sensitivity criterion of 0.95 or greater when compared with either of the other two methods. They also found that results varied depending on which fit test was used as the reference method, and the three fit tests use different criteria to identify inadequately fitting respirators.

Coffey et al.[5] determined the error rates for five fit testing methods (Bitrex, ambient aerosol condensation nuclei counter using the TSI PortaCount Plus [TSI Inc., St. Paul, Minn.], saccharin, modified ambient aerosol condensation nuclei counter using the TSI PortaCount Plus with the N95-Companion, and generated aerosol using corn oil) using 18 models of National Institute for Occupational Safety and Health (NIOSH)-certified, N95 filtering-facepiece respirators. Fit testing results were compared to 5th percentiles of simulated workplace protection factors. Beta errors (the chance of passing a fit test in error) ranged from 3% to 11%. Alpha errors (the chance of failing a fit test in error) ranged from 51% to 84%.

The errors inherent in fit test methods can result in individuals being inappropriately assigned inadequately fitting respirators for use in hazardous environments. The chance of an individual being assigned an inadequately fitting respirator becomes greater with increasing fit testing errors and decreases with improvements in the face-fitting characteristics of the respirator.[2] The accuracy of fit test methods is critical in assuring adequate protection for these workers. The purpose of this report is to describe a study of error rates associated with three of the fit test methods performed in accordance in the Occupational Safety and Health Administration (OSHA) standard, 29 CFR 1910.134, when used with N95 half-facepiece respirators. Two are qualitative fit tests (saccharin and Bitrex) and one is a quantitative fit test (TSI PortaCount Plus with the N95-companion). These three fit test methods are the only ones that are applicable to both filtering-facepiece N95 respirators and elastomeric half-facepiece N95 respirators. Both filtering-facepiece and elastomeric respirators were included in this study to determine the effect of facepiece type on error rates of the fit test methods. The results of this study are the "worst case" errors that can occur when a respiratory protection program neglects proper selection and training.

## MATERIALS AND METHODS

### Subjects

A total of 38 individuals (20 females and 18 males) participated in this study. The age of the panel members ranged from 19 to 48 years. Panel members were selected to provide a variety of facial sizes without regard to any particular facial size distribution. Female subjects had lip lengths ranging from 43 to 55 mm and face lengths ranging from 94 to 124 mm. Male subjects had lip lengths of 44 to 59 mm and face lengths of 112 to 135 mm. A panel of 25 subjects (one subject from each of the cells in Figure 1) tested each respirator model. Test subjects who were smokers refrained from smoking for at least 30 min before the tests because smokers exhale particles for at least 30 min after smoking a cigarette or cigar. The PortaCount Plus with the N95-Companion would detect these exhaled particles and interpret them as being caused by faceseal leakage. The time between the cessation of smoking and the test reduced the concentration of exhaled particles to a level that should have not caused erroneous results. To ensure that the subjects would be able to detect the qualitative fit testing agents at the lowest possible concentration, all subjects abstained from eating, chewing gum, and drinking (except for plain water) for at least 15 min before testing. In order to obtain the wide variety of fits needed for this study, including ones barely above and below the pass/fail level, the subjects were not given any training on the proper way to don and wear the respirators.

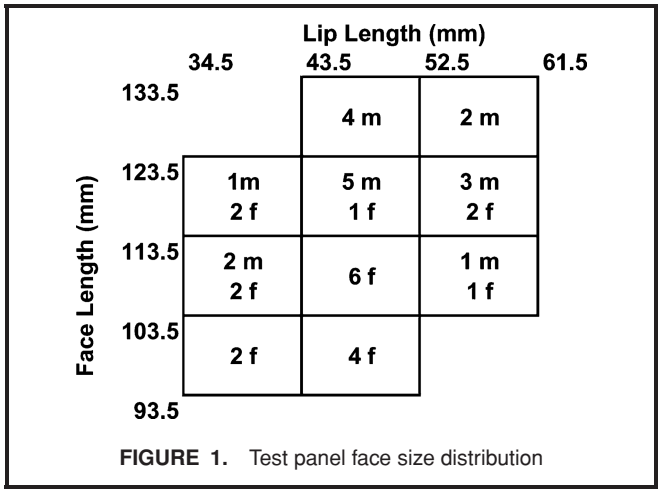


**FIGURE 1.** Test panel face size distribution

### Respirators

Thirty models of NIOSH-certified N95 respirators were used in this study and are listed in Table I. These models were selected at random from those commercially available at the beginning of the study and purchased from safety equipment supply companies. For respirators available in multiple sizes, test subjects were given the size consistent with recommendations of the Los Alamos National Laboratory based on individual face and lip length measurements, since no other guidance was provided by the manufacturers.[6] This method of facepiece size selection is not performed in the context of a respiratory protection program. Using this method for facepiece size selection without training the subjects allowed this range of fits to be obtained.

### Fit Testing

All fit testing was conducted in accordance with the protocol contained in 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. Only a summary of the fit

**TABLE I. List of Respirators Tested**

| Manufacturer | Description | Facepiece Size(s) | Facepiece | Style |
|---|---|---|---|---|
| 3M | 8511 | OSFA | Filtering | Cup |
| 3M | 8515 | OSFA | Filtering | Cup |
| 3M | 9210 | OSFA | Filtering | Cup |
| 3M | 9211 | OSFA | Filtering | Cup |
| 3M | 7000 with 7N11 filter | Small/medium, medium/marge | Elastomeric | NA[B] |
| AlphaProtech | 695 | OSFA | Filtering | Folding |
| AO Safety | 5Star with 9500R filter | Small/medium/large | Elastomeric | NA |
| Aswan | M-12 | OSFA | Filtering | Cup |
| Draeger | Piccola | OSFA | Filtering | Folding |
| Gerson | 1730 | OSFA | Filtering | Cup |
| Gerson | 2747 | OSFA | Filtering | Cup |
| Gerson | 3945 | OSFA | Filtering | Folding |
| Lab Safety | 11291 with 30638 filter | Small/medium/large | Elastomeric | NA |
| Makrite | 910-N95 | OSFA | Filtering | Cup |
| Moldex-Metrics | 2600 | Small, medium/large | Filtering | Cup |
| Moldex-Metrics | 8000 with 8910 filter | Small/medium/large | Elastomeric | NA |
| MSA | AffinityFR200 | OSFA | Elastomeric | NA |
| MSA | Comfo Elite | Small/medium/large | Elastomeric | NA |
| MSA | COMFO with 816291 filter | Small/medium/large | Elastomeric | NA |
| North | 7700-30 with 7506N95 filter | Small/medium/large | Elastomeric | NA |
| Pro-Tech | 1590 with F200 filter | Small/medium/large | Elastomeric | NA |
| San-M | TN01 | Small, medium/large | Filtering | Folding |
| Scott | 66 | Small/medium/large | Elastomeric | NA |
| Sellstrom | Econ-Air | Small/medium/large | Elastomeric | NA |
| Survivair | 1913 | Small/medium/large | Filtering | Folding |
| Survivair | 2000 with 1060 filter | Small/medium/large | Elastomeric | NA |
| Survivair | 7000 with 7860 filter | Small/medium/large | Elastomeric | NA |
| Willson | 1200with GN95 | Small/medium/large | Elastomeric | NA |
| Willson | 6100 | Small/medium/large | Elastomeric | NA |
| Willson | 6800 | Small/medium, medium/large | Elastomeric | NA |

*Note*: [A]OSFA = one size fits all. [B]NA = not applicable.

test methods is presented here, since they are described in detail elsewhere. Between donnings of a particular respirator, the subject removed the respirator and gave it to the test operator, who returned the respirator to its original configuration (e.g., loosening head straps, straightening the nose clip, etc.).

### *Bitrex (Denatonium Benzoate) Solution Aerosol Fit Test*

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 to ensure that he or she could taste Bitrex at the specified concentration. All subjects reported tasting the Bitrex during each screening test before 10 squeezes were applied. After the screening test, a subject left the laboratory, drank water, and rinsed his or her lips and mouth. The subject returned to the laboratory, donned the respirator, and the Bitrex fit test was conducted using 10 squeezes of the fit test solution initially and 5 squeezes every 30 sec to maintain the concentration. If the person did not taste Bitrex the test was considered a pass. If a subject tasted Bitrex at any time the test was considered a failure.

### *Saccharin Solution Aerosol Fit Test*

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 at the specified concentration. All subjects reported tasting the saccharin during each screening test before 10 squeezes were applied. After the screening test, a subject left the laboratory, drank water, and rinsed his or her lips and mouth. The subject returned to the laboratory, donned the respirator, and the saccharin fit test was conducted using 10 squeezes of the fit test solution initially and 5 squeezes every 30 sec to maintain the concentration. If the person did not taste saccharin the test was considered a pass. If a subject tasted saccharin at any time the test was considered a failure.

### *Ambient Aerosol Condensation Nuclei Counter Fit Test with the N95-Companion Method*

TSI developed the N95-Companion accessory to the PortaCount Plus specifically for fit testing N95 filtering-facepiece respirators. The N95-Companion is an aerosol preconditioner that selects particles in the size range of approximately 0.03 to 0.06 micrometer and passes them on to the PortaCount Plus for counting. The maximum penetration of particles in this size range through N95 filter media is 0.3%. Particles that are outside the selected range are discarded. Allowing only particles of 0.03 to 0.06 micrometer to pass through to the PortaCount Plus ensures that almost 100% of the particles counted inside the facepiece are due to faceseal leakage. The PortaCount Plus then computes an individual exercise fit factor (i.e., the number of particles outside the mask divided by the number inside the mask in the selected range). A TSI model 8026 particle generator was used to generate a sodium chloride aerosol and set to ensure that the ambient aerosol contained at least 100 particles/cc in the appropriate size range. The computation of the overall fit factor (i.e., harmonic mean fit factor for all the exercises performed during a fit test) for the Companion method was performed as prescribed by OSHA (i.e., the grimace exercise fit factor was not used in the overall fit factor calculation). The Companion method was used in this study for testing both the filtering-facepiece and elastomeric respirators. In practice, the Companion method is not normally used for fit testing N95 elastomeric respirators. Instead, the N95 filters are replaced with 100 series filters and the fit testing done using only the PortaCount Plus.

## Simulated Workplace Protection Factor (SWPF) Testing

The results of the fit tests were compared to SWPF test values. An SWPF is a measure of the protection received by an individual from a respirator; it considers both filter penetration and faceseal leakage. The SWPF testing in this study used the PortaCount Plus to determine whether an acceptable level of protection was obtained. This SWPF test was selected because PortaCount Plus fit factors have been demonstrated to have a high correlation (coefficient of determination [$r^2$] of 0.78) with a measurement of a wearer's actual exposure in a simulated health care workplace test.[7] This $r^2$ value is comparable to the continuous high-flow, deep-probe (CHD) method's $r^2$ value of 0.81, which was the highest in the previous study.[7] The CHD method was not used as the SWPF test since it requires a chamber, uses corn oil, and has a longer duration than an ambient aerosol test (30 min compared with 12 min). The SWPF values were computed in the same way as the Companion method fit factors. Individual exercise SWPF values were calculated by dividing the number of particles outside the facepiece by the number counted inside. The harmonic mean of the individual exercise SWPF values from each test was computed and used as the SWPF value compared to the fit test results.

Before starting an SWPF test, a subject donned the respirator per the respirator manufacturer's instructions, which include performing a user seal check. After the respirator was donned, SWPF testing began. After completing the first 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 nosepiece). This procedure was repeated four additional times, for a total of six SWPF tests for each subject and respirator combination.

## Sampling Configurations

For the Companion fit tests and the SWPF tests of the filtering-facepiece respirators, a sampling probe was inserted into each respirator using a TSI Fit-Test Probe Kit (P/N 8025-N95) (Figure 2). For the elastomeric facepiece respirators, sampling adaptors were used when commercially available (Figure 3). This allowed fit testing of the respirators without the installation of a probe through the facepiece. In the instances where sampling adapters were not available, the facepiece was


(a) (b)

**FIGURE 2.** Filtering-facepiece respirator with probe (a) Outside (b) Inside

(a) (b)

**FIGURE 3.** Probed elastomeric respirator (a) Inside with sampling line (b) Close-up of outside of probe

probed halfway between the nose and the mouth. In all cases, the probe's inlet was flush with the inside of the respirator.

## Exercise Regimes

For the three fit tests, subjects performed the exercises contained in the OSHA regulations for the particular fit test method. The SWPF test exercises were: normal breathing, deep breathing, moving head side-to-side, moving head up and down, reading the rainbow passage aloud (an articulation exercise including all the normal sounds of spoken English that forces use of a variety of facial configurations to stress the respirator to face seal), bending, and normal breathing. These exercises were used in the previous NIOSH SWPF study.[7] The in-facepiece sampling for each exercise in the Companion fit test and SWPF test lasted 1 minute, except for grimacing, which lasted 15 sec.

## Statistical Analysis

### *5th Percentile Simulated Workplace Protection Factor*

The six SWPF tests for each subject and respirator combination were used to calculate the 5th percentile SWPF value (95% of the SWPF values for a given subject/respirator combination would be greater than or equal to this number). The 5th percentile SWPF was calculated using the geometric mean (GM) and the geometric standard deviation (GSD) as $GM/GSD^{1.645}$.[8]

### *Alpha and Beta Errors*

To determine if a fit test adequately screened out poorly fitting N95 filtering-facepiece respirators, a statistical approach, similar to that used in biomedical applications, was used.[9] Alpha ($\alpha$) and beta ($\beta$) errors for each method were computed using the fit test results and the 5th percentile SWPFs calculated for each subject and respirator combination. If the 5th percentile SWPF was $\geq$10, the respirator was considered to have provided adequate protection.[10–14] The number of subject/respirator combinations in each of four categories was determined: false passes (A)–subjects passing a fit test but having a 5th percentile SWPF $<$10; true passes (B)–subjects passing a fit test and having a 5th percentile SWPF $\geq$10; true failures (C)–subjects failing a fit test and having a 5th percentile SWPF $<$10; and false failures (D)–subjects failing a fit test but having a 5th percentile SWPF $\geq$10.

The $\alpha$ error (referred to as a false negative) is the fraction of subjects having a respirator that provided adequate protection (as defined by the 5th percentile SWPF) but failed the fit test (i.e., a false conclusion of inadequate protection). It is calculated by dividing the number of false failures (D) by the total number of failures (B+D). The $\beta$ error (referred to as a false positive) is the fraction of subjects having a respirator that provided inadequate protection but passed the fit test (i.e., a false conclusion of adequate protection). It is calculated by dividing the number of false passes (A) by the total number of passes (A+C). The $\beta$ error is more important than the $\alpha$ error because it may lead to overexposure of a respirator wearer. The $\alpha$ error is important because of the burden it places on respirator users and programs; a high $\alpha$ error results in the unnecessary retesting of wearers who already have an adequately fitting respirator. The $\alpha$ and $\beta$ errors for each fit test method were computed for all 30 respirators combined and for the two types of half-facepiece respirators (i.e., filtering-facepiece and elastomeric respirators). The 95% confidence interval was calculated for each $\alpha$ and $\beta$ error using the binominal distribution.

### *Simulated Respiratory Program Error*

A simulated respirator fit test program assignment error was calculated. For the simulated respirator fit test program assignment error, it was assumed that a wearer was given up to three trials to pass a fit test with a particular respirator, before trying another respirator model. Each of the three fit test methods were used to represent the result of one trial with a particular wearer/respirator combination (i.e., the Bitrex result

was trial one, the saccharin result was trial two, etc.). This could be done since the fit test error rates for the three fit test methods were similar. Those subjects passing any of the three methods were considered to have passed the simulated fit test program. The $\alpha$ and $\beta$ errors for this simulated respirator fit test program were then computed.

### *Pooled Analysis*

The three fit test methods had been evaluated in a previous study with 18 filtering-facepiece respirators.[15] Using data from both studies (for a total of 48 respirator models), a pooled analysis was conducted. This increased the numbers of observations for each fit test method, resulting in a more accurate estimate of the $\alpha$ and $\beta$ errors.

## RESULTS

Table II presents the error rate results based on 2-by-2 contingency table analysis for the three fit test methods and the simulated fit test program. For all respirators combined, the three fit test methods had approximately the same $\beta$ error (8–9%). The two qualitative tests had approximately the same $\alpha$ error (68% and 71%), substantially higher than the quantitative Companion test $\alpha$ error (40%). When the error rates are computed for each of the two facepiece types, the same pattern among the three fit test methods was found; elastomeric facepiece respirators had consistently lower $\alpha$ errors than the filtering-facepiece respirators, whereas the reverse was true for the $\beta$ errors.

The simulated fit test program $\beta$ error rates tend to be substantially higher than those for the fit test methods for all 30 models and 15 filtering facepiece models, whereas the $\alpha$ errors tend to be lower (Table II). When only the elastomeric data was used, the simulated fit-test program $\beta$ error was slightly lower than those for the fit test methods. The $\alpha$ error was lower than for the Bitrex and saccharin fit test methods but higher than for the Companion methods. The 95 percent confidence intervals for both errors overlap except for those for the simulated fit test program and the fit test methods when all 30 models are considered. For the 15 elastomeric respirators, the difference between the $\beta$ errors for the simulated respirator fit test program and the fit test methods were not as large. The difference between the lowest fit test method $\beta$ and the simulated fit test program $\beta$ error was 1% for the elastomeric respirators as compared with 11% for all 30 models combined and 7% for the 15 filtering-facepiece respirators. The $\alpha$ errors for fit test methods using the elastomeric respirators was lower than for the filtering-facepiece respirators; the $\beta$ errors for fit test methods, using filtering-facepiece respirators, were significantly lower than the $\beta$ fit test method errors using elastomeric facepieces indicating that the fit test method $\alpha$ and $\beta$ errors may depend on respirator type. For the simulated fit test program the errors were approximately the same for both respirator types.

**TABLE II. 2 × 2 Contingency Table Values for Current Study Only**

| Method | Total Tests | Number of False Passes (A) | Number of True Passes (B) | Number of True Failures (C) | Number of False Failures (D) | $\alpha$ Error[A] [D/(B+D)] (%) | $\alpha$ Error 95% CI[C] (% ) | $\beta$ Error[B] [A/(A+C)] (%) | $\beta$ Error 95% CI[C] (% ) |
|---|---|---|---|---|---|---|---|---|---|
| All 30 models | | | | | | | | | |
| Bitrex | 746[D] | 23 | 138 | 251 | 334 | 71 | 66–77 | 8 | 5–12 |
| Saccharin | 746[D] | 23 | 149 | 251 | 323 | 68 | 64–73 | 8 | 5–12 |
| Companion | 746[D] | 25 | 284 | 249 | 188 | 40 | 35–44 | 9 | 6–13 |
| Simulated fit test program | 746[D] | 52 | 334 | 222 | 138 | 29 | 25–34 | 19 | 15–24 |
| 15 Filtering facepiece models | | | | | | | | | |
| Bitrex | 374[E] | 10 | 32 | 172 | 160 | 83 | 77–88 | 5 | 3–10 |
| Saccharin | 374[E] | 6 | 37 | 176 | 155 | 81 | 74–86 | 3 | 1–7 |
| Companion | 374[E] | 6 | 76 | 176 | 116 | 60 | 53–67 | 3 | 1–7 |
| Simulated fit test program | 374[E] | 18 | 99 | 164 | 93 | 48 | 41–56 | 10 | 6–15 |
| 15 Elastomeric facepiece models | | | | | | | | | |
| Bitrex | 372[F] | 13 | 106 | 79 | 174 | 62 | 56–68 | 14 | 8–20 |
| Saccharin | 372[F] | 17 | 112 | 75 | 168 | 60 | 54–66 | 19 | 11–28 |
| Companion | 372[F] | 19 | 208 | 73 | 72 | 26 | 21–31 | 21 | 13–30 |
| Simulated fit test program | 372[F] | 34 | 58 | 235 | 45 | 44 | 34–54 | 13 | 9–17 |

[A] Failing in error.
[B] Passing in error.
[C] CI = confidence interval.
[D] Total tests do not equal 750 because one subject did not test four of the respirator models.
[E] Total tests do not equal 375 because one subject did not test one respirator model.
[F] Total tests do not equal 375 because one subject did not test three respirator models.

**TABLE III. 2 × 2 Contingency Table Values for Pooled Analysis**

| Method | Total Tests[A] | Number of False Passes (A) | Number of True Passes (B) | Number of True Failures (C) | Number of False Failures (D) | $\alpha$ Error [D/(B+D)][B] (%) | $\alpha$ Error 95% CI[C] (% ) | $\beta$ Error [A/(A+C)][D] (%) | $\beta$ Error 95% CI[E] (% ) |
|---|---|---|---|---|---|---|---|---|---|
| All 48 Models | | | | | | | | | |
| Bitrex | 1220 | 44 | 272 | 428 | 476 | 64 | 60–67 | 9 | 7–12 |
| Saccharin | 970 | 34 | 193 | 363 | 380 | 66 | 62–70 | 9 | 6–12 |
| Companion | 1220 | 42 | 404 | 430 | 344 | 46 | 42–50 | 9 | 7–12 |
| 33 Filtering face-piece models | | | | | | | | | |
| Bitrex | 848 | 31 | 166 | 349 | 302 | 65 | 60–69 | 8 | 6–11 |
| Saccharin | 598 | 17 | 81 | 288 | 212 | 72 | 764–77 | 6 | 3–9 |
| Companion | 848 | 23 | 196 | 357 | 272 | 58 | 54–63 | 6 | 4– 9 |

*Note:* Combined fit test data from current study and Coffey et al.[8]

[A]Total tests for the saccharin test do not equal those of the Bitrex and Companion because not all 33 models from Coffey et al.[8] were tested using the saccharin test due to NIOSH policy then in effect. The total tests for all 48 models do not equal 1200 because one model was repeated with the 25-subject panel and one subject did not test four respirator models.

[B]Failing in error.

[C]CI = confidence interval.

[D]Passing in error.

The $\alpha$ and $\beta$ error analysis was conducted using all SWPF 5th percentile values. The ANSI Z88.10 standard states: "Reference method fit factors with one (1) standard deviation of the required fit should be excluded."[4] The error analysis was repeated by excluding all the SWPF 5th percentile values within one standard deviation (1.1) of the SWPF pass/fail level of 10. The standard deviation for the SWPF method was approximated by having a SWPF near 10 and making multiple measurements during a single mask donning to determine the PortaCount Plus system reproducibility. Eliminating the SWPF 5th percentile values near 10 did not change the results substantially. The $\alpha$ error was reduced by approximately 2% and the $\beta$ error by about 1%, which did not change whether or not the fit test methods met the criteria.

Table III contains the results based on the pooled analysis for the three fit test methods using 48 respirator models (33 filtering-facepiece models and 15 elastomeric models) from this study and a previous study.[15] Based on the pooled results from the two studies, all three fit test methods had the same $\beta$ error (9%) with all 48 respirator models. The $\beta$ errors for the 30 combined respirators in the current study were 8% (Bitrex and saccharin methods) and 9% Companion method). Adding the 18 filtering-facepiece models from the previous study to the 15 models in this study increased the $\beta$ errors 3% for all three fit test methods (see Tables II and III). The additional 18 models lowered the $\alpha$ errors. The Bitrex method had the largest decrease and the Companion the smallest (2%).

## DISCUSSION

The American National Standards Institute (ANSI) has recommended values for the $\alpha$ and $\beta$ errors to use when comparing a new fit test method to a currently ANSI accepted quantitative fit test. The ANSI recommended values are $\leq$50% for the $\alpha$ error and $\leq$5% for the $\beta$ error.[4] These values are $\leq$50% for the $\alpha$ error and $\leq$5% for the $\beta$ error. These values are given for comparison purposes only. They may not be adequate to ensure each wearer passing a given fit test is provided an adequately fitting respirator. In this study, no fit test method met this ANSI recommended criteria for both errors. The Companion method, using all 30 models combined and elastomeric facepieces, met the $\alpha$ error criterion. All three fit test methods met the $\beta$ error criterion using only the filtering-facepieces.

Two general results of this study were somewhat unexpected. First, there was a substantial difference between the error rates of elastomeric respirators and filtering-facepiece respirators. Second, there was a difference between the error rates with the 15 filtering-facepiece models determined in this study that had not been tested in previous NIOSH studies and the error rates previously tested for 18 other filtering-facepiece models in the same laboratory with similar protocols.[15] Both the $\alpha$ and $\beta$ errors of the three fit test methods, with the 15 models of filtering-facepieces measured in this study, were different from those reported previously for 18 different models of filtering-facepieces. In this study of 15 models, the $\beta$ errors ranged from 3% to 5% whereas they ranged from 9% to 11% in the previous study.[15] The $\alpha$ errors ranged from 60% to 85% in this study; they ranged from 51% to 57% in the previous study. Some of the differences between the two studies may be attributed to the same panel of subjects not wearing each of the 33 respirators.

Both of these findings suggest that the fit test method errors may be quite sensitive to the characteristics of the respirator models used to assess those errors. One of the characteristics that may be quite significant is the difference in the surface area of filter media between the different respirator models. Many filters used with elastomeric facepiece

respirators tend to have a smaller surface area than filtering facepieces. This difference in area will result in very different face velocities for different brands and thus a difference in filter penetration. It is important that this possibility and the affect of different panels on fit test method errors be explored in future research.

It is not sufficient to reduce just the $\beta$ error; the $\alpha$ error also needs to be as low as possible. High $\alpha$ errors lead to unnecessary retesting due to properly fitting respirators being rejected. This retesting may cause a poorly fitting respirator to be erroneously (due to high $\beta$ errors) assigned to a wearer, because most programs do not disqualify a person from wearing a respirator after failing a fit test the first time. Efforts are needed to optimize the value of a fit test and minimize fit testing error rates. One way is to better train respirator wearers so that their donnings are more consistent. A second way is to develop a multidonning quantitative fit test for filtering-facepiece respirators and to determine the appropriate pass/fail level of the test. If a quantitative fit test method utilizing a number of respirator donnings in an attempt to substantially reduce fit test method errors was developed, the total time to conduct a fit test could not be significantly longer than current fit test methods. This would keep the personnel costs of a fit testing program approximately the same as or lower than the current methods (e.g., the time each respirator wearer is away from the job, the number of fit tests each operator can conduct in a given time frame, etc.). If the $\alpha$ error of the proposed fit test method is less than current methods, the need for retesting will be reduced and the total time required for fit testing programs can be reduced.

Two other fit test methods used in prior NIOSH research were not used in the current study.[5] The generated aerosol method was not used for two reasons: (1) it uses corn oil, and N95 filters are only certified for oil-free workplace aerosols; and (2) it measures total penetration (i.e., faceseal leakage and filter penetration) rather than just faceseal leakage, as do the other methods. The ambient aerosol method, modified for filter penetration, was not used because it is a research method that is not included in the OSHA regulations.[3] The $\beta$ errors in the previous study with filtering facepiece respirators were 3% for the generated aerosol method and 4% for the ambient aerosol method. If these two methods using elastomeric facepieces equipped with P100 filters had been included in the current study, the $\beta$ errors for the methods using the elastomeric facepieces might have been lower (possibly in the range of 3–4%), which would be similar to the values obtained with the filtering-facepiece respirators reported in the current and previous studies.[5]

## CONCLUSIONS

Given that fit testing is an essential and critical element of respiratory protection programs, the excessive errors of the three fit test methods used in the current study can inadvertently lead to less reduction in exposure than expected from the respirator class for respirator wearers. The significance of the errors in current fit test methods is best appreciated by recognizing that, in a typical fit test program, a worker has more than one chance to pass a fit test. Such repeat fit testing trials have the effect of increasing the $\beta$ error and decreasing the $\alpha$ error for the fit testing program. By simulating a program in which an employee has three trials to pass a fit test, the data suggests the probability that a worker would mistakenly pass a fit test with an inadequate fitting respirator could be as high as 1 in 5.

These findings also suggest that the errors of fit test methods may be sensitive to the characteristics of the respirator models used to assess those errors and, therefore, that fit test accuracy may vary from one respirator model to another. Further study is needed to answer why elastomeric respirators provided different fit test method errors than filtering-facepiece respirators, to develop a method with lower $\alpha$ and $\beta$ errors, and to obtain estimates of fit test errors in the context of respiratory protection programs.

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