MEMORANDUM FOR THE ADVISORY COMMITTEE ON CONSTRUCTION SAFETY & HEALTH (ACCSH)

FROM: Bill Perry, Director, Directorate of Standards and Guidance

SUBJECT: Notice of Proposed Rulemaking (NPRM) for Additional Portacount® Quantitative Fit Test Protocols under Appendix A of the Respiratory Protection Standard

Background

OSHA's Respiratory Protection Standard, 29 C.F.R. § 134, contains mandatory qualitative and quantitative fit testing procedures in Appendix A, Part I. In response to stakeholder recommendations for OSHA to consider the adoption of new fit test methods that might be developed at a later date, OSHA also included Appendix A, Part II of the standard, which contains procedures that allow individuals to submit new fit test protocols for a notice-and-comment rulemaking under section 6(b)(7) of the OSH Act.

One of the OSHA-accepted quantitative fit test protocols listed in Appendix A is the ambient aerosol condensation nuclei counter (CNC) quantitative fit test protocol (QNFT), referred to as the PortaCount® protocol. On July 10, 2014, TSI Inc. (TSI) requested that OSHA approve three additional PortaCount® quantitative fit test protocols to add to Part I.C of Appendix A. The new PortaCount® protocols are referred to as "Fast-Full method" for elastomeric full-facepiece respirators, "Fast-Half method" for elastomeric half-mask respirators, and "Fast-FFR method" for filtering facepiece respirators.

Previously, in 2006, TSI submitted two QNFT protocols for acceptance under the Respiratory Protection Standard. OSHA issued a notice of proposed rulemaking (NPRM) on January 21, 2009, (74 FR 3526-01), which it withdrew on January 27, 2010 (75 FR 4323-01). In withdrawing the NPRM, OSHA concluded that study data failed to adequately demonstrate that these protocols were sufficiently accurate or as reliable as the quantitative fit testing protocols already listed in Appendix A. OSHA found that the studies submitted with the application did not differentiate between results for half-mask and full-facepiece respirators. OSHA also determined that TSI had not demonstrated that its previous PortaCount® QNFT protocols would accurately determine fit for filtering facepiece respirators.

TSI's current application seeking approval of three new fit test protocols is accompanied by three new studies which purport to address the deficiencies OSHA noted in 2010. The application meets OSHA's criteria for initiating a rulemaking under section 6(b)(7) of the OSH Act, because it is supported by articles that have been published in a peer-reviewed industrial hygiene journal describing each of the proposed protocols and explaining how test data support the protocols' accuracy and reliability.

All three new PortaCount® protocols differ from the OSHA-accepted PortaCount® protocol by the exercise sets, exercise duration, and sampling sequence. The major difference between the proposed Fast-Full method and the OSHA-accepted PortaCount® protocol in Part I.C. of Appendix A is it includes only 3 of the 7 current test exercises (i.e., bending, head side-to-side, and head up-and-down) plus a new exercise (i.e., jogging-in-place), and it reduces each exercise duration from 60 seconds to 30 seconds, thereby reducing the total test duration from 7.2 minutes to 2.5 minutes. The same is true for

the proposed Fast-Half method. The major difference between the proposed Fast-FFR method and the OSHA-accepted PortaCount® protocol in Part I.C. of Appendix A is it includes 4 of the 7 current test exercises (i.e., bending, talking, head side-to-side, and head up-and-down), and it reduces each exercise duration from 60 seconds to 30 seconds, thereby reducing the total test duration from 7.2 minutes to 2.5 minutes. TSI performed sequential paired fit tests using their protocol and a reference method as recommended in the American National Standards Institute (ANSI) Z88.10-2010 Annex A2, "Criteria for Evaluating New Fit Test Methods." The reference method used by TSI for statistical comparisons was the standard set of OSHA-accepted exercises minus the "grimace" exercise. All new protocols met the required acceptance criteria for test sensitivity, predictive value of a pass, test specificity, predictive value of a fail, and kappa statistic according to the statistical procedures utilized in the study.

Notice of Proposed Rulemaking

The NPRM will seek public comment on the proposed addition of three new PortaCount® fit test protocols. Using the information obtained from this notice-and-comment rulemaking, OSHA will determine whether to amend the accepted fit testing procedures of the Respiratory Protection Standard to include the three proposed new protocols.

Key Issues

The key issue to be addressed in this rulemaking is whether the proposed new PortaCount® fit test protocols identify poor respirator fits *at least as well* as the OSHA-accepted quantitative fit test protocols listed in Part I.C. of Appendix A to the Respiratory Protection Standard. A related issue to be addressed in this rulemaking is whether the proposed new PortaCount® fit test protocols meet the sensitivity, specificity, predictive value, and other criteria contained in the ANSI Z88.10-2001, Annex A2, "Criteria for Evaluating Fit Test Methods."

Recommendation of the Committee

Pursuant to 29 C.F.R. § 1911.10(a), OSHA seeks a recommendation from the Committee on whether OSHA should publish a NPRM seeking public comment on incorporating TSI's modified PortaCount® fit test protocols into Appendix A, Part I, of the Respiratory Protection Standard, 29 C.F.R. § 1910.134.

Attachments

Richardson, A.W., Hofacre, K.C., Weed, J., Holm, R. and R. Remiarz (2013) Evaluation of a faster fit testing method for full-facepiece respirators based on the TSI PortaCount®. *Journal of the International Society for Respiratory Protection* 30(2): 116-128.

Richardson, A.W., Hofacre, K.C., Weed, J., Holm, R. and R. Remiarz (2014) Evaluation of a faster fit testing method for elastomeric half-mask respirators based on the TSI PortaCount®. *Journal of the International Society for Respiratory Protection* 31(1): 9-22.

Richardson, A.W., Hofacre, K.C., Weed, J., Holm, R. and R. Remiarz (2014) Evaluation of a faster fit testing method for filtering facepiece respirators based on the TSI PortaCount®. *Journal of the International Society for Respiratory Protection* 31(1): 43-56.

TSI application letter for acceptance of three new quantitative respirator fit test protocols (July 10, 2014)

TSI White Paper: Analysis of the Talking Exercise Used for Respirator Fit Testing

Richardson, A.W., Hofacre, K.C., Weed, J., Holm, R. and R. Remiarz (2013) Evaluation of a faster fit testing method for full-facepiece respirators based on the TSI PortaCount®. Journal of the International Society for Respiratory Protection 30(2): 116-128.

Evaluation of a Faster Fit Testing Method for Full-Facepiece Respirators Based on the TSI PortaCount®

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ABSTRACT

In the United States, employees that wear tight-fitting respirators in the workplace are required to be fit tested annually using an Occupational Safety and Health Administration (OSHA)-accepted protocol. Given the large number of fit tests performed annually, industry would benefit if the time required to complete a fit test was reduced. TSI, Inc. (Shoreview, MN) has developed a method for full-facepiece respirators that is a modification of the OSHA-accepted 'Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol' that reduces the test duration from about 7.2 min to 2.5 min. The objective of this study was to compare the fit factors measured with the TSI modified method to that of a reference method. The method comparison approach was based on American National Standards Institute (ANSI) Z88.10-2010 Annex A2, "Criteria for Evaluating New Fit Test Methods". Sequential, paired fit tests were performed on test participants with the modified (i.e., faster) method and a reference method during the same respirator donning. The fit factors for both methods were measured using the PortaCount® Model 8030, a CNC-based instrument. The exercises for the reference method were the standard OSHA exercise set without the grimace. The exercise set for the modified method included bending, jogging, head side-to-side, and head up-and-down. The results demonstrated that the new faster method can identify poorly fitting respirators as well as the reference method, as the test sensitivity of 0.98 was greater than the requirement (≥0.95) defined in ANSI Z88.10-2010. This new method also met the requirements for the predictive value of a pass, test specificity, predictive value of a fail, and the kappa statistic contained in the ANSI standard.

Keywords: respirator fit, quantitative fit test, full-facepiece respirators

INTRODUCTION

In the United States, employees that wear tight-fitting respirators in the workplace are required to be fit tested annually using an Occupational Safety and Health Administration (OSHA)-accepted protocol. The OSHA-accepted fit test protocols are defined in Title 29 Code of Federal Regulations (CFR) Part 1910.134 (OSHA, 1998). One of these OSHA-accepted protocols is the 'Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol', which takes over 7 min to execute for each respirator wearer. Given the large number of fit tests performed annually, industry would benefit if this time were reduced. For example, an Institute of Medicine (IOM) report indicates that "fit testing is a critical requirement for ensuring the efficacy of respirators" but that "it may not always be complied with for various reasons, including time and cost" and recommends more efficient fit test methods should be explored (IOM, 2008). Less burdensome fit test methods for tight-fitting respirators may help increase compliance (NIOSH, 2013). TSI, Inc. (Shoreview, MN) has developed a modified method to the 'Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol' that reduces this test duration to about 2.5 min. The objective of this study was to assess whether the modified, faster fit test method was comparably effective as an existing method at identifying poorly fitting full-face respirators.

The American National Standards Institute (ANSI) standard Z88.10-2010 Annex A2, "Criteria for Evaluating New Fit Test Methods" (ANSI, 2010) defines an approach to evaluate new fit test methods to ensure they can identify poorly fitting respirators as effectively as an accepted method. The standard recommends performing sequential paired fit tests with the new method and a reference method during the same respirator donning for comparison. In the current study, the Reference method was defined as the OSHA-accepted CNC-based protocol except the grimace was not included in the exercise set. The new method was the faster CNC method and will be referred to as the Fast-Full method. All testing was performed on full-facepiece respirators. An ambient aerosol challenge augmented with sodium chloride (NaCl) aerosol was used for both methods. In addition, both methods were based on the TSI PortaCount® Model 8030, a CNC-based fit-testing device. The methods differed by the exercise sets, exercise duration, and sampling sequence.

METHODS

Test Participants and Respirators

The study plan was reviewed and approved by Battelle's Institutional Review Board (IRB). All participants were non-smokers and clean shaven in the areas where the respirator sealed against the face. Anthropometric measurements, specifically face width (bizygomatic breadth) and face length (menton-sellion length), of the participant's faces were made and are compared with the National Institute for Occupational Safety and Health (NIOSH) bivariate fit test panel in Figure 1. As shown, the test participants were distributed across the panel and thus represented a wide range of the respirator-wearing population. At least one participant was within each cell with exception of the two extremes (cells 1 and 10). Note, there was not a requirement to meet a specific distribution of face size. Test participants were not required to have any prior experience wearing a respirator. The participants were trained to perform the exercises properly and consistently by viewing a video created for that purpose.

The test administrator selected the respirator and assisted the participant with donning to ensure that it was secure. The ANSI comparison requires at least 50 fit test pairs in the data set for analysis where the Reference method has a fit factor below the pass/fail criteria (i.e., 500 for a full-face respirator). Modern elastomeric respirators are constantly improving as manufacturers take advantage of new technologies and materials to improve the facial seal. Anecdotally, the percentage of failed fit tests for these respirators is low which would cause a large number of trials to collect at least 50 failures. Thus,

participants were sometimes provided mis-sized respirators to obtain fit factors below the pass/fail criterion. In addition, consistent with observations by Janssen et al. (2002), the wearer did not perform a seal check to increase the potential for "poor" fits. The test administrator assisted with donning to ensure that the respirator was tight to the face to minimize the potential for slippage. Artificial leak paths were not used because the objective was to evaluate the Fast-Full method in its entirety including the exercise set used to produce real-world, dynamic leaks between the respirator and wearer's faces. The use of artificial leak paths (e.g., capillary tubes, etc.) would not have allowed evaluation of dynamic leaks that are caused by exercising.

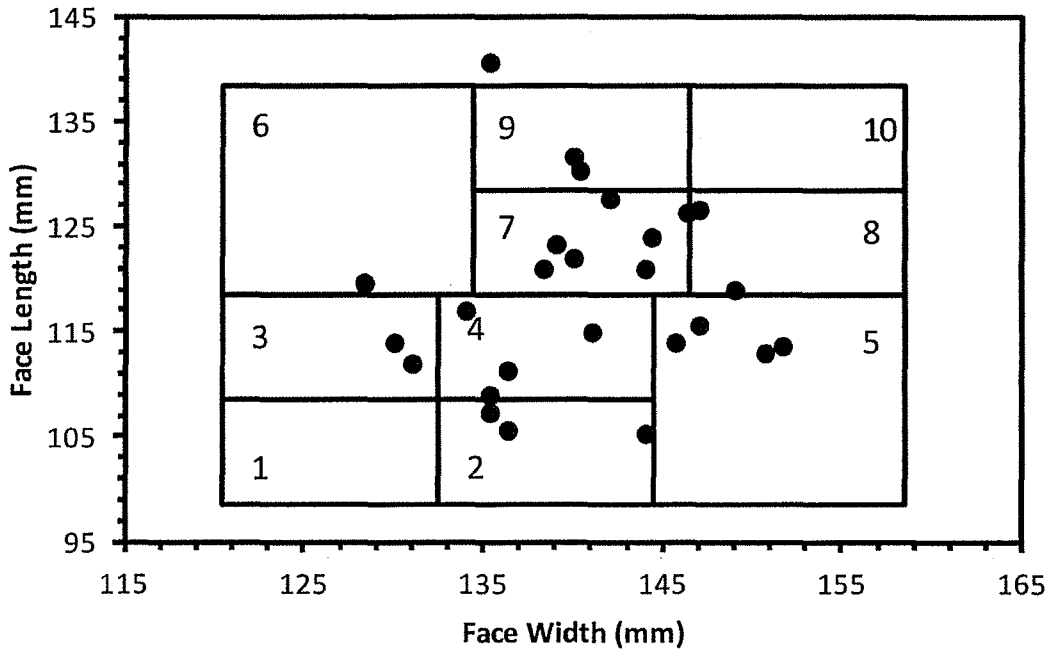

Figure 1. Distribution of Participant Facial Sizes Overlaid on the NIOSH Bivariate Chart.

Three different models of NIOSH-approved, full-face air-purifying respirators from leading U.S. mask manufacturers were used and each was tested in three different sizes. The respirators models/sizes were used approximately the same number of times in the study. The specific respirators will not be identified because the intentional mis-sizing and lack of performing a user seal check would misrepresent performance of these respirators when used as part of a proper respiratory protection program. The respirators were equipped with P100 filters. In-mask samples were collected from the breathing zone between the nose and mouth using a non-flush sample probe that was permanently installed inside the nose cup. The probes generally extended about 0.6 cm into the breathing zone. Bergman et al. (2012) observed no practical differences in measured fit factors using flush versus deep probes.

Fit Factor Measurements

The system used to measure the fit factors included a chamber (~3 x 2 x 2.5 m) that was large enough to test two participants simultaneously. Large, clear plastic windows allowed the test administrator to observe the test participants. The chamber contained the ambient laboratory aerosol

which was augmented with NaCl aerosol generated using a Model 8026 Particle Generator (TSI, Inc.). A mixing fan was used to distribute the aerosol throughout the chamber. The target aerosol concentration was 10,000 particles/cm^3 with an acceptable range of 5,000 to 20,000 particles/cm^3. Zhuang et al. (2004) concluded that the ambient aerosol concentration did not affect the measured fit factor. The challenge and in-mask aerosol concentrations were measured using the PortaCount® Model 8030. Aerosol sampling lines of equal length and internal diameter were used for the challenge and in-mask samples. Laptop computers with custom software developed and supplied by TSI, Inc. were used to execute scripts that controlled the instrument sampling sequences and data collection during each trial. The measured in-mask and challenge aerosol concentrations were captured electronically and imported into Microsoft® Excel® for calculation of the fit factors and to determine the statistical values defined in the ANSI standard.

After donning the respirator, the test participants entered the chamber and began a 5-minute "comfort assessment period" to allow the respirator to settle on the face and to purge ambient aerosol from the mask. The comfort assessment period is an OSHA requirement for all fit test methods. During this time, adjustments could be made to the respirator and the test participants breathed normally. The respirator was not adjusted after this period (i.e., once the fit test initiated). After the 5-minute acclimation period, the participants performed exercise sets for two fit test methods in succession, without pause in between. The test administrator instructed them on the exercises to perform and observed them to ensure the exercises were performed properly. Any anomalies were recorded. Prior to this study, the test administrator had extensive experience performing quantitative respirator fit tests in industry.

Exercise Sets

The Reference method used the standard OSHA exercises with grimace omitted. The set consisted of seven exercises performed while standing: normal breathing, deep breathing, turning head side-to-side, moving head up-and-down, talking, bending over, and normal breathing. The eighth exercise, grimacing, required per 29 CFR 1910.134 is intended to break the respirator seal to the face. This potentially results in a shift of the respirator and, thus, was not used. A shift in the respirator may confound comparison of the two fit test methods. Each of the seven exercises was performed for one minute. Test participants were instructed to take a single breath at each extreme during the head side-to-side exercise, at the bottom of the bend during the bending exercise, and when looking up during the head up-and-down exercise. It was optional for the test participants to take breaths at other times during these exercises. The sample timing of the PortaCount® used for the Reference method is summarized in Table I.

The Fast-Full method included four exercises: bending, jogging in place, head side-to-side, and head up-and-down. The duration of each exercise was 30 sec. This is the minimum exercise duration recommended in ANSI Z88.10-2010 and CSA Z94.4-11. Test participants were instructed to take two breaths at each extreme during the head side-to-side and head up-and-down exercises and at the bottom of the bend during the bending exercise. It was optional for the test participants to take breaths at other times during these exercises. The PortaCount® sample timing for the Fast-Full method is summarized in Table II. The PortaCount® sampled the ambient aerosol at the start and end of the fit test rather than in between each exercise. This is acceptable because the shorter method leaves less time for the ambient concentration to drift during the test. The ambient measurements were separated by only 2.3 min. The Fast-Full method reduced the fit test time by about 65% relative to the Reference method (2.5 min vs. 7.2 min).

Table I. Exercise Set and PortaCount® Sampling Sequence for the Reference Fit Test Method

Exercise Number	Exercise	PortaCount® Sample	Time (s)
1	Normal Breathing	Challenge Purge	4
		Challenge Sample 1	5
		Mask Purge	11
		Mask Sample	40
2	Deep Breathing	Challenge Purge	4
		Challenge Sample 2	5
		Mask Purge	11
		Mask Sample	40
3	Head Side-to-Side	Challenge Purge	4
		Challenge Sample 3	5
		Mask Purge	11
		Mask Sample	40
4	Head Up-and-Down	Challenge Purge	4
		Challenge Sample 4	5
		Mask Purge	11
		Mask Sample	40
5	Talking	Challenge Purge	4
		Challenge Sample 5	5
		Mask Purge	11
		Mask Sample	40
6	Bending	Challenge Purge	4
		Challenge Sample 6	5
		Mask Purge	11
		Mask Sample	40
7	Normal Breathing	Challenge Purge	4
		Challenge Sample 7	5
		Mask Purge	11
		Mask Sample	40
		Challenge Purge	4
		Challenge Sample 8	5
		Total Test Time	**429 sec = 7:09 min**

Table II. Exercise Set and PortaCount® Sampling Sequence for the Fast-Full Test Method

Exercise Number	Exercise	PortaCount® Sample	Time (s)
1	Bending	Challenge Purge	4
		Challenge Sample 1	5
		Mask Purge	11
		Mask Sample	30
2	Jogging-in-Place	Mask Sample	30
3	Head Side-to-Side	Mask Sample	30
4	Head Up-and-Down	Mask Sample	30
		Challenge Purge	4
		Challenge Sample 2	5
		Total Test Time	**149 sec = 2:29 min**

Fit Factor Vetting

The fundamental premise of the ANSI approach to compare the Reference and Fast-Full methods in the same respirator donning is that the baseline fit of the respirator remains the same throughout the procedure. The baseline fit was defined as the fit factor measured during normal breathing. To quantify undesirable changes in the baseline fit, a 5-second normal breathing fit factor check was added to the beginning, middle (i.e. after the first exercise set and before start of the second), and end of each fit test pair. A fit test pair was omitted from analysis if the ratio of the maximum to minimum normal breathing fit factor check was greater than 100, signifying that the baseline fit of the respirator changed during the trial. When comparing the Fast-Full and Reference methods, the order was randomized with respect to which method occurred first in the test pair. The test administrator noted any observed anomalies that may be indicative of respirator slippage or other problems. Following each trial, the test participants were queried regarding whether they felt the respirator slip or any sudden sensations of air rushing into the respirator from around the peripheral seal that may also be indicative of respirator slippage. All comments/observations were recorded on the trial data sheet.

Calculation of Fit Factors

Fit factors were calculated for the individual exercises and represented the ratio of the measured challenge to in-mask aerosol concentration. For the Reference method, the challenge concentration was based on the average of the measurements made immediately before and after the in-mask sample for that specific exercise (Refer to Table I for PortaCount® sample timing), which is consistent with the scheme currently used for OSHA-compliant fit testing. For the Fast-Full method, the challenge concentration was based on the average measured at the start and finish of the entire fit test. The overall fit factor for both methods was the harmonic mean of the fit factors measured for each exercise. Each trial generated two overall fit factors per test participant, referred to as a fit test pair. It was this overall fit factor that was used for the ANSI analysis to compare test methods.

Calculation of the Exclusion Zone

The study was comprised of two parts; key study design parameters/requirements for each part are summarized in Table III. The first part characterized the variability of the Reference method. The ANSI standard specifies 'exclusion criteria', one of which is that "Reference method fit factors within one (1) Coefficient of Variation (CV) of the required fit factor should be excluded". In the current study, an "exclusion zone" was defined as the range of Reference fit factors that bracketed the pass/fail fit factor criterion inside which the pass/fail determination was deemed to be unreliable due to the observed variability. The ANSI standard does not mandate the approach to determine the CV for the reference method but suggests making multiple fit factor measurements on a subject during a single facepiece donning. The subject should have a fit factor near the required fit factor. McKay and Bradley (2005) previously determined an exclusion range of 475 to 525 for fit testing of full-facepiece respirators by determining the variability associated with the TSI PortaCount® Plus Model 8020. Repeated measurements were made by performing the fit test procedure on a high efficiency filter with a fixed leak that provided fit factors near the pass/fail requirement (i.e., 500 for a full-facepiece respirator). This approach only accounted for the variability of the instrument and not the overall fit test method as specified in the ANSI standard. This approach resulted in a CV of about 0.05. The CV associated with generated aerosol quantitative fit test methods can range from 0.23 to 0.82 (ANSI, 2010).

A different approach was used in the current study to determine the variability associated with the overall Reference method. Fit test pairs were collected across multiple subjects that consisted of two Reference method fit tests performed sequentially during the same respirator donning, without any adjustment between the two. The measured overall fit factors as determined for both Reference methods in each pair were log (base 10) transformed and their difference (i.e, $\log(FF_1)-\log(FF_2)$) was determined.

The standard deviation (σ) of the log differences across all trials was calculated. The high and low fit factors defining the boundaries of the Reference method exclusion zone were calculated as follows:

Upper Bound Fit Factor of Exclusion Zone = 10^(log(500) + σ)

Lower Bound Fit Factor of Exclusion Zone = 10^(log(500) – σ)

where σ is the standard deviation of the log-transformed difference and 500 is the pass/fail criterion for a full-face respirator. This has the effect of defining the exclusion zone as the range within one standard deviation of the pass/fail criterion.

Table III. Summary of Key Study Design Parameters

Task	Study Design
1	• ***Objective:*** Establish exclusion zone of the Reference fit test method • ***Number of Fit Test Pairs:*** 50 (target minimum) • ***Number of Participants:*** 15 (target minimum) • ***Number of Fit Test Pairs Below Pass/Fail Criterion:*** N/A • ***Respirator models/sizes:*** 3 models each with 3 sizes, Use each equally
2	• ***Objective:*** Use ANSI Z88.10-2010 method to compare fit factors measured using the Reference and Fast-Full method during same respirator donning • ***Number of Fit Test Pairs:*** 100 (ANSI minimum requirement) • ***Number of Participants:*** 25 (ANSI minimum requirement) • ***Number of Fit Test Pairs Below Pass/Fail Criterion:*** At least 50 measured Reference fit factors need to be between 5% of the pass/fail and the lower bound of the exclusion zone (ANSI requirement) • ***Respirator models/sizes:*** 3 models each with 3 sizes, Use each equally

ANSI Comparison

The second part of the study compared the Reference and Fast-Full fit test methods using the approach described in the ANSI standard. Again, fit test pairs were collected during the same respirator donning, without any adjustment between the two sequential fit tests. In each fit test pair, one fit factor was measured using the Fast-Full method and one with the Reference method. The order was randomized with respect to whether the Fast-Full or Reference method occurred first in the test pair. Per the ANSI standard, a minimum of 100 fit test pairs were collected and at least 25 different participants were used. At least 50 of these fit test pairs had to have Reference fit factors between 5% of the pass/fail criterion and the lower bound of the exclusion zone.

The ANSI standard specifies the 2x2 contingency table shown in Table IV where A, B, C, and D represent the number of observations in each cell. To meet the requirement in the ANSI standard, the Fast-Full method needs to achieve a test sensitivity of at least 0.95. The test sensitivity is defined in Table V and provides the probability that the Fast-Full test method will correctly identify an inadequate fit (as determined by the Reference method). The ANSI standard recommends, but does not require, meeting the criteria for the other four statistics defined in Table V: (1) predictive value of a pass, (2) test specificity, (3) predictive value of a fail, and (4) Kappa statistic. The Kappa statistic is a measure of the agreement between the two methods. It is the ratio of the proportion of times the two methods provided the same outcome to the proportion of times that the two methods would agree by chance if independent (ANSI, 2010).

Table IV. 2 x 2 Contingency Table Specified by ANSI Z88.10-2010 Standard

	Failed Reference Test	Passed Reference Test
Passed Fast-Full Test	A	B
Failed Fast-Full Test	C	D

Table V. Test Statistics Defined in ANSI Z88.10-2010 Standard

Statistic	Equation	Criterion
Test Sensitivity	C / (A+C)	≥ 0.95
Predictive Value of a Pass	B / (A +B)	≥ 0.95
Test Specificity	B / (B + D)	≥ 0.50
Predictive Value of a Fail	C / (C + D)	≥ 0.50
Kappa Statistic[a, b]	$(P_o - P_e) / (1 - P_e)$	>0.7

[a] $P_o = (B + C) / (A + B + C + D)$

[b] $P_e = [(A + B)(B + D) + (C + D)(A + C)] / (A + B + C + D)^2$

RESULTS AND DISCUSSION

Exclusion Zone Determination

A total of 62 fit factor pairs across 17 participants (7 female and 10 male) were collected to determine the exclusion zone. The log difference between the two overall Reference fit factors (i.e., $\log(FF_1) - \log(FF_2)$) within each pair are plotted by rank in Figure 2. Five of these pairs were omitted as the ratio of the maximum to minimum fit factor during the normal breathing check was greater than 100. The symbols for these omitted data are filled in black in Figure 2 and tend to lie at the two extremes (i.e., largest log differences) which is consistent with a shift in respirator fit during the test. An additional three points (the symbols filled in white in Figure 2) were omitted as outliers because they were more than three (3) standard deviations from the mean of the remaining data points. After exclusion, the log differences were found to be normally distributed based on a Shapiro-Wilk test. Note that excluding these data points tightened the exclusion zone around the pass/fail criterion of 500, ultimately making it more difficult for the Fast-Full method to meet the ANSI criteria.

Good correlation (>0.95) was observed between the two Reference fit factors within each pair as shown in Figure 3. The best-fit regression nearly coincides with the 1:1 line shown as a dashed line. All of the fit factors within each individual pair were within a factor of three. The average log difference was 0.026 with a standard deviation of 0.16. Based on this standard deviation, the exclusion zone for the Reference method was 345 to 726.

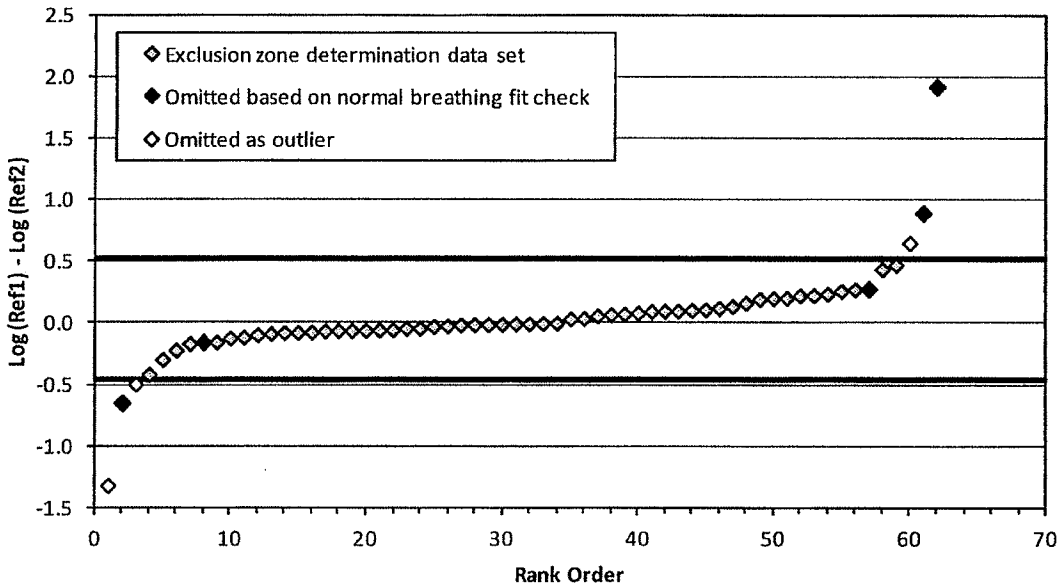

Figure 2. Distribution of Log Differences in Overall Reference Fit Factors Used in Determination of the Exclusion Zone.

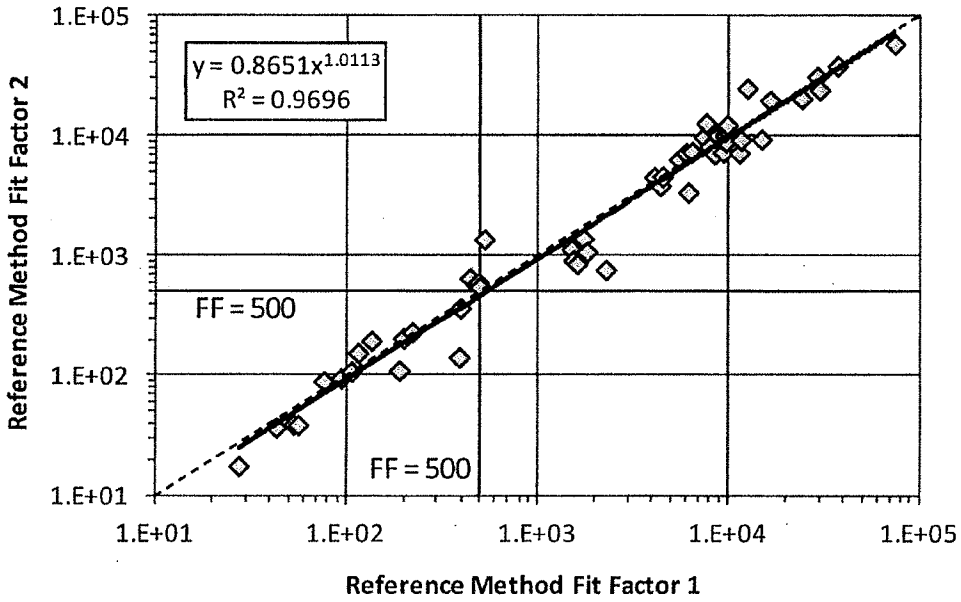

Figure 3. Comparison of Reference Overall Fit Factors Used in Determination of Exclusion Zone.

Comparison of Fast-Full and Reference Method

A total of 148 fit factor pairs across 27 participants including 11 females (41%) and 16 males (59%) were collected to compare the Reference and Fast-Full fit test methods. The ANSI standard requires a minimum of 25 participants. As was shown in Figure 1, the participants were well-distributed across the NIOSH Bivariate Fit Test Panel. The respirator models and sizes were used in nearly equal proportion.

Eleven fit factor pairs were omitted from the analysis because the ratio of the maximum to minimum fit factor during the normal breathing checks was greater than 100 indicating a shift in the baseline fit. One additional fit factor pair was omitted due to an anomaly (a torn piece of a cleaning wipe was observed in the respirator during the test). Thus, the data set for the comparison included 136 fit factor pairs. The distribution of Reference fit factors is summarized in Table VI and shown graphically in Figure 4. As required by the ANSI standard, at least 50 Reference fit factors were between 25 (5% of the pass/fail criterion) and 345 (lower bound of the exclusion zone). These Reference method fails were evenly distributed as shown in Figure 4 and not weighted toward the lowest fit factors. Figure 4 also demonstrates that the Reference method fit factors bracketed the pass/fail criteria (500 for full-face respirator).

Figure 5 compares the measured Reference and Fast-Full fit factors within each pair. Good agreement was observed between the pairs as the data points tend to lie near the 1:1 line (dotted black line). The majority (89%) of the fit factors within each pair were within a factor of three. The average magnitude of the log difference was -0.067 with a standard deviation of 0.38.

Table VI. Distribution of Reference Fit Factors in ANSI Comparison

Reference Fit Factor Range	Number of Observations (ANSI Requirement)
Total Number of Tests	136 (N/A)
12 < FF < 25	5 (N/A)
25 < FF < 345	54 (50)
345 < FF < 726 (Exclusion Zone)	12 (N/A)
726 < FF < 51,261	65 (N/A)
Total Number of Tests Outside of Exclusion Zone	124 (100)

There was a single instance outside of the exclusion zone where the Reference fit factor failed and the Fast-Full method passed (upper left quadrant in Figure 5). In this instance, the measured Reference fit factor was 131 which is greater than 10% of the pass/fail criterion. Thus, there were no instances where the Reference fit factor was below 10% of the pass/fail criterion (i.e., 50) and was passed by the Fast-Full method, which would have disqualified the method per ANSI.

Table VII compares the measured descriptive statistics with the requirements from the ANSI standard. The primary requirement is the test sensitivity and the other statistics are for comparison purposes. The Fast-Full method met the requirement in all cases indicating excellent agreement between the Fast-Full and the Reference method. From a safety perspective, the test sensitivity demonstrates that the Fast-Full method can identify poorly fitting respirators as well as the Reference method.

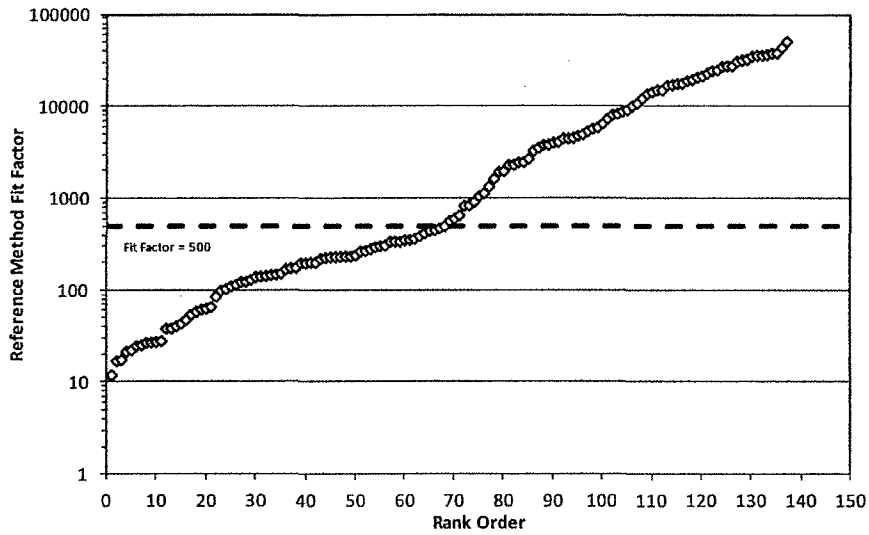

Figure 4. Distribution Reference Overall Fit Factors in ANSI Comparison.

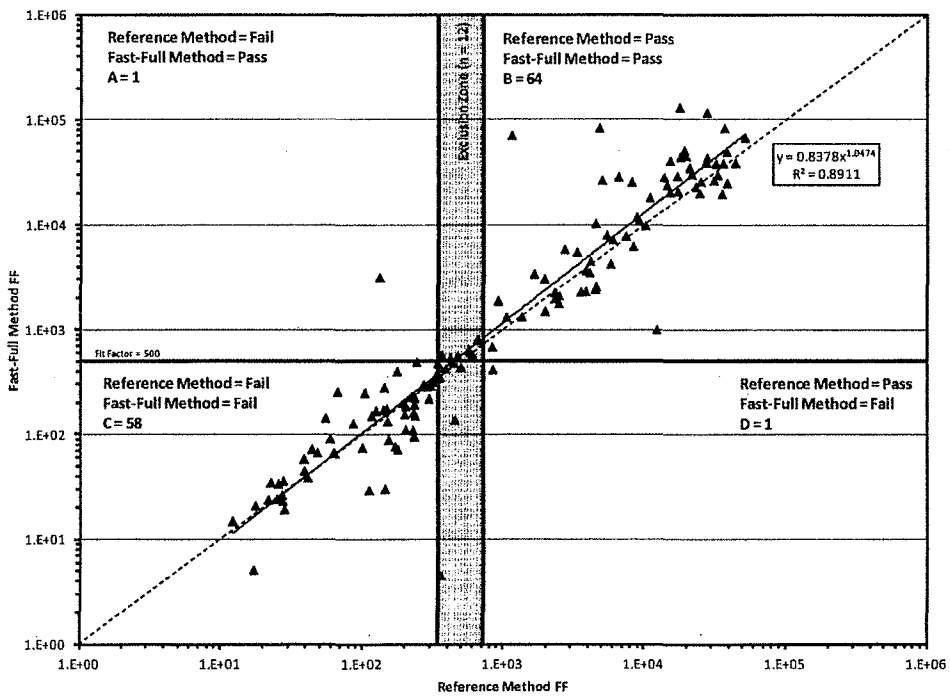

Figure 5. Comparison of Overall Fit Factors Measured Using Reference and Fast-Full Fit Test Methods.

Table VII. Comparison of Measured ANSI Analysis Statistics with ANSI Criteria for Fast-Full Method to be Acceptable

Criterion	ANSI Requirement	Measured
Sensitivity	≥0.95	0.98
Predictive Value of a Pass	≥0.95	0.98
Test Specificity	>0.50	0.98
Predictive Value of a Fail	>0.50	0.98
Kappa Statistic	>0.70	0.97

Analysis of the data indicates that the Fast-Full method would have passed the test sensitivity requirement until the lower bound of the exclusion zone exceeded 473. It is also important that the Fast-Full method exceeded the target for test specificity (0.98). This statistic represents the fraction of passing fit factors with the Fast-Full method that also passed the Reference method. Thus, use of the Fast-Full method will not cause the false rejection of adequately fitting respirators and subsequent unnecessary retesting.

CONCLUSIONS

A new fit test method (termed the Fast-Full fit test method) for full-face respirators based on the PortaCount®, a CNC-based instrument, that reduces the test duration from 7.2 min to 2.5 min (~65% reduction relative to the Reference method) has been successfully developed and assessed. Given the large number of fit tests performed annually, this reduction in time would benefit industry given the reduced time and burden. The Fast-Full method can identify poorly fitting respirators as well as the Reference method, as the test sensitivity of 0.98 was greater than the requirement (≥0.95) as defined by ANSI Z88.10-2010. The Fast-Full method also met the requirements for the predictive value of a pass, test specificity, predictive value of a fail, and the kappa statistic contained in the ANSI standard. The Fast-Full method requires acceptance by OSHA prior to implementation in industry. It is planned to submit this method to OSHA for consideration. Future testing is recommended to develop and evaluate faster fit test methods for use with half-face respirators and filtering facepiece respirators.

Acknowledgements

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Evaluation of a Faster Fit Testing Method for Elastomeric Half-Mask Respirators Based on the TSI PortaCount®

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ABSTRACT

In the United States, employees that wear tight-fitting respirators in the workplace are required to be fit tested annually using an Occupational Safety and Health Administration (OSHA)-accepted protocol. Given the large number of fit tests performed annually, industry would benefit if the time required to complete a fit test was reduced. TSI, Inc. (Shoreview, MN) has developed a method for elastomeric half-mask respirators that is a modification of the OSHA-accepted 'Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol' that reduces the test duration from about 7.2 min to 2.5 min. The objective of this study was to compare the fit factors measured with the TSI modified method to that of a reference method. The method comparison approach was based on American National Standards Institute (ANSI) Z88.10-2010 Annex A2, "Criteria for Evaluating New Fit Test Methods". Sequential, paired fit tests were performed on test participants with the modified (i.e., faster) method and a reference method during the same respirator donning. The fit factors for both methods were measured using the PortaCount® Model 8030, a CNC-based instrument. The exercises for the reference method were the standard OSHA exercise set without the grimace. The exercise set for the modified method included bending, jogging, head side-to-side, and head up-and-down. The results demonstrated that the new faster method can identify poorly fitting respirators as well as the reference method, as the test sensitivity of 0.96 was greater than the requirement (≥0.95) defined in ANSI Z88.10-2010. This new method also met the requirements for the predictive value of a pass, test specificity, predictive value of a fail, and the kappa statistic contained in the ANSI standard.

Keywords: respirator fit, quantitative fit test, elastomeric half-mask respirators

INTRODUCTION

In the United States, employees that wear tight-fitting respirators in the workplace are required to be fit tested annually using an Occupational Safety and Health Administration (OSHA)-accepted protocol. The OSHA-accepted fit test protocols are defined in Title 29 Code of Federal Regulations (CFR) Part 1910.134 (OSHA, 1998). One of these OSHA-accepted protocols is the 'Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol', which takes over 7 min to execute for each respirator wearer. Given the large number of fit tests performed annually, industry would benefit if this time were reduced. Fit testing is an important part of a respirator program and less burdensome fit test methods for tight-fitting respirators may help increase compliance (NIOSH, 2013; IOM, 2008). TSI, Inc. (Shoreview, MN) has developed a modified method to the 'Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol' that reduces this test duration to about 2.5 min. The objective of this study was to assess whether the modified, faster fit test method was comparably effective as an existing method at identifying poorly fitting half-face respirators.

The American National Standards Institute (ANSI) standard Z88.10-2010 Annex A2, "Criteria for Evaluating New Fit Test Methods" (ANSI, 2010) defines an approach to evaluate new fit test methods to ensure they can identify poorly fitting respirators as effectively as an accepted method. The standard recommends performing sequential paired fit tests with the new method and a reference method during the same respirator donning for comparison. In the current study, the Reference method was defined as the OSHA-accepted, CNC-based protocol except the grimace was not included in the exercise set. The new method was the faster CNC method and will be referred to as the Fast-Half method. All testing was performed on elastomeric half-mask respirators. An ambient aerosol challenge augmented with sodium chloride (NaCl) aerosol was used for both methods. In addition, both methods were based on the TSI PortaCount® Model 8030, a CNC-based fit-testing device. The methods differed by the exercise sets, exercise duration, and sampling sequence.

METHODS

Test Participants and Respirators

The study plan was reviewed and approved by Battelle's Institutional Review Board (IRB). All participants were non-smokers and clean shaven in the areas where the respirator sealed against the face. Anthropometric measurements, specifically face width (bizygomatic breadth) and face length (menton-sellion length), of the participant's faces (except for one due to subject unavailability at the time of measurement) were made and are compared with the National Institute for Occupational Safety and Health (NIOSH) bivariate fit test panel in Figure 1. As shown, the test participants were distributed across the panel and thus represented a wide range of the respirator-wearing population. Note, there was not a requirement to meet a specific distribution of face size. Test participants were not required to have any prior experience wearing a respirator. The participants were trained to perform the exercises properly and consistently by viewing a video created for that purpose.

The test administrator selected the respirator and assisted the participant with donning to ensure that it was properly donned. The ANSI comparison requires at least 50 fit test pairs in the data set for analysis where the Reference method has a fit factor below the pass/fail criteria (i.e., 100 for a half-face respirator). Modern elastomeric respirators are constantly improving as manufacturers take advantage of new technologies and materials to improve the facial seal. Anecdotally, the percentage of failed fit tests for these respirators is low which would require a large number of trials to collect at least 50 failures. Thus, participants were sometimes provided mis-sized respirators to obtain fit factors below the pass/fail criterion. The wearer did not perform a user seal check to increase the potential for "poor" fits that are

needed for the ANSI comparison (OSHA, 2010; Janssen et al., 2002; McKay and Bradley, 2005). The test administrator assisted with donning to ensure that the respirator was properly donned to minimize the potential for slippage. Artificial leak paths were not used because the objective was to evaluate the Fast-Half method in its entirety including the exercise set used to produce real-world, dynamic leaks between the respirator and wearer's faces. The use of artificial leak paths (e.g., capillary tubes, etc.) would not have allowed evaluation of dynamic leaks that are caused by exercising.

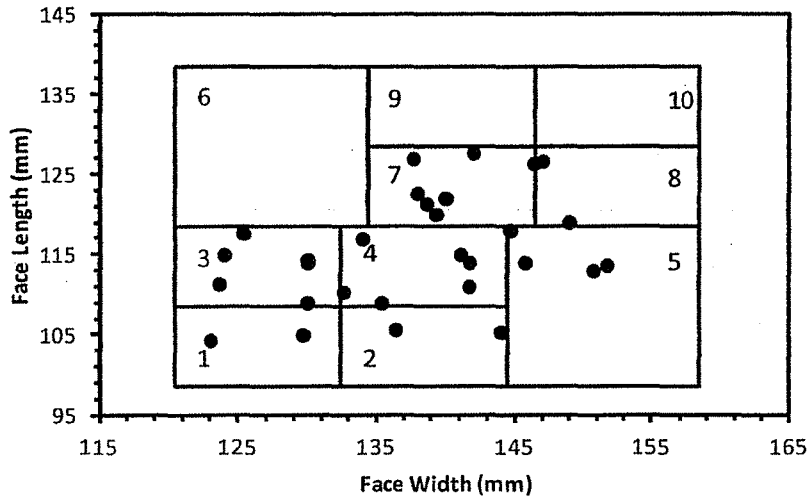

Figure 1. Distribution of Participant Facial Sizes Overlaid on the NIOSH Bivariate Chart.

Three different models of NIOSH-approved, half-face air-purifying respirators from leading U.S. mask manufacturers were used and each was tested in three different sizes for a total of nine respirators). The respirators models/sizes were used approximately the same number of times in the study. The specific respirators will not be identified because the intentional mis-sizing and lack of performing a user seal check would misrepresent performance of these respirators when used as part of a proper respiratory protection program. The respirators were equipped with P100 filters. In-mask samples were collected from the breathing zone between the nose and mouth using a flush sample probe that was permanently installed.

Fit Factor Measurements

The system used to measure the fit factors included a chamber (~3 x 2 x 2.5 m) that was large enough to test two participants simultaneously. Large, clear plastic windows allowed the test administrator to observe the test participants. The chamber contained the ambient laboratory aerosol which was augmented with NaCl aerosol generated using a Model 8026 Particle Generator (TSI, Inc.). A mixing fan was used to distribute the aerosol throughout the chamber. The target aerosol concentration was 10,000 particles/cm^3 with an acceptable range of 5,000 to 20,000 particles/cm^3. Zhuang et al. (2004) concluded that the ambient aerosol concentration did not affect the measured fit factor. The challenge and in-mask aerosol concentrations were measured using the PortaCount® Model 8030. Aerosol sampling lines of equal length and internal diameter were used for the challenge and in-mask samples. Laptop computers with custom software developed and supplied by TSI, Inc. were used to execute scripts that controlled the instrument sampling sequences and data collection during each trial. The measured in-mask and challenge aerosol concentrations were captured electronically and imported into Microsoft®

Excel® for calculation of the fit factors and to determine the statistical values defined in the ANSI standard.

After donning the respirator, the test participants entered the chamber and began a 5-minute "comfort assessment period" to allow the respirator to settle on the face and to purge ambient aerosol from the mask. The comfort assessment period is an OSHA requirement for all fit test methods. During this time, adjustments could be made to the respirator and the test participants breathed normally. The respirator was not adjusted after this period (i.e., once the fit test initiated). After the 5-minute acclimation period, the participants performed exercise sets for two fit test methods in succession, without pause in between. The test administrator instructed them on the exercises to perform and observed them to ensure the exercises were performed properly. Any anomalies were recorded. Prior to this study, the test administrator had extensive experience performing quantitative respirator fit tests in industry.

Exercise Sets

The Reference method used the standard OSHA exercises with grimace omitted. The set consisted of seven exercises performed while standing: normal breathing, deep breathing, turning head side-to-side, moving head up-and-down, talking, bending over, and normal breathing. The eighth exercise, grimacing, required per 29 CFR 1910.134 is intended to break the respirator seal to the face. This potentially results in a shift of the respirator and, thus, was not used. A shift in the respirator may confound comparison of the two fit test methods. Each of the seven exercises was performed for one minute. Test participants were instructed to take a single breath at each extreme during the head side-to-side exercise, at the bottom of the bend during the bending exercise, and when looking up during the head up-and-down exercise. It was optional for the test participants to take breaths at other times during these exercises. The sample timing of the PortaCount® used for the Reference method is summarized in Table I.

The Fast-Half method included four exercises: bending, jogging in place, head side-to-side, and head up-and-down. The duration of each exercise was 30 sec. This is the minimum exercise duration recommended in ANSI Z88.10-2010 and CSA Z94.4-11. Test participants were required to take two breaths at each extreme during the head side-to-side and head up-and-down exercises and at the bottom of the bend during the bending exercise. It was optional for the test participants to take breaths at other times during these exercises. The PortaCount® sample timing for the Fast-Half method is summarized in Table II. The PortaCount® sampled the ambient aerosol at the start and end of the fit test rather than in between each exercise. This is acceptable because the shorter method leaves less time for the ambient concentration to drift during the test. The ambient measurements were separated by only 2.3 min. The Fast-Half method reduced the fit test time by about 65% relative to the Reference method (2.5 min vs. 7.2 min).

The most strenuous exercises were generally selected for the Fast-Half fit test method. Zhuang et al. (2004) recommends talking, bending, and moving head up-and-down for protocols that use fewer and/or shorter exercises. Of these, the Fast-Half method included bending and head up-and-down. In addition, it included two other exercises that are aggressive in terms of evaluating the respirator seal, head side-to-side and jogging.

Table I. Exercise Set and PortaCount® Sampling Sequence for the Reference Fit Test Method

Exercise Number	Exercise	PortaCount® Sample	Time (s)
1	Normal Breathing	Challenge Purge	4
		Challenge Sample 1	5
		Mask Purge	11
		Mask Sample	40
2	Deep Breathing	Challenge Purge	4
		Challenge Sample 2	5
		Mask Purge	11
		Mask Sample	40
3	Head Side-to-Side	Challenge Purge	4
		Challenge Sample 3	5
		Mask Purge	11
		Mask Sample	40
4	Head Up-and-Down	Challenge Purge	4
		Challenge Sample 4	5
		Mask Purge	11
		Mask Sample	40
5	Talking	Challenge Purge	4
		Challenge Sample 5	5
		Mask Purge	11
		Mask Sample	40
6	Bending	Challenge Purge	4
		Challenge Sample 6	5
		Mask Purge	11
		Mask Sample	40
7	Normal Breathing	Challenge Purge	4
		Challenge Sample 7	5
		Mask Purge	11
		Mask Sample	40
		Challenge Purge	4
		Challenge Sample 8	5
		Total Test Time	**429 sec = 7:09 min**

Table II. Exercise Set and PortaCount® Sampling Sequence for the Fast-Half Test Method

Exercise Number	Exercise	PortaCount® Sample	Time (s)
1	Bending	Challenge Purge	4
		Challenge Sample 1	5
		Mask Purge	11
		Mask Sample	30
2	Jogging-in-Place	Mask Sample	30
3	Head Side-to-Side	Mask Sample	30
4	Head Up-and-Down	Mask Sample	30
		Challenge Purge	4
		Challenge Sample 2	5
		Total Test Time	**149 sec = 2:29 min**

Fit Factor Vetting

The fundamental premise of the ANSI approach to compare the Reference and Fast-Half methods in the same respirator donning is that the baseline fit of the respirator remains the same throughout the procedure. The baseline fit was defined as the fit factor measured during normal breathing. To quantify undesirable changes in the baseline fit, a 5-second normal breathing fit factor check was added to the beginning, middle (i.e. after the first exercise set and before start of the second), and end of each fit test pair. A fit test pair was omitted from analysis if the ratio of the maximum to minimum normal breathing fit factor check was greater than 100, signifying that the baseline fit of the respirator changed during the trial. When comparing the Fast-Half and Reference methods, the order was randomized with respect to which method occurred first in the test pair. The test administrator noted any observed anomalies that may be indicative of respirator slippage or other problems. Following each trial, the test participants were queried regarding whether they felt the respirator slip or any sudden sensations of air rushing into the respirator from around the peripheral seal that may also be indicative of respirator slippage. All comments/observations were recorded on the trial data sheet.

Calculation of Fit Factors

Fit factors were calculated for the individual exercises and represented the ratio of the measured challenge to in-mask aerosol concentration. For the Reference method, the challenge concentration was based on the average of the measurements made immediately before and after the in-mask sample for that specific exercise (Refer to Table I for PortaCount® sample timing), which is consistent with the scheme currently used for OSHA-compliant fit testing. For the Fast-Half method, the challenge concentration was based on the average measured at the start and finish of the entire fit test. The overall fit factor for both methods was the harmonic mean of the fit factors measured for each exercise. Each trial generated two overall fit factors per test participant, referred to as a fit test pair. It was this overall fit factor that was used for the ANSI analysis to compare test methods.

Calculation of the Exclusion Zone

The study was comprised of two parts; key study design parameters/requirements for each part are summarized in Table III. The first part characterized the variability of the Reference method. The ANSI standard specifies 'exclusion criteria', one of which is that "Reference method fit factors within one (1) Coefficient of Variation (CV) of the required fit factor should be excluded". In the current study, an "exclusion zone" was defined as the range of Reference fit factors that bracketed the pass/fail fit factor criterion inside which the pass/fail determination was deemed to be unreliable due to the observed variability. The ANSI standard does not mandate the approach to determine the CV for the reference method but suggests making multiple fit factor measurements on a subject during a single facepiece donning. The subject should have a fit factor near the required fit factor. McKay and Bradley (2005) previously determined an exclusion range of about 94 to 106 for fit testing of elastomeric half-mask respirators by determining the variability associated with the TSI PortaCount® Plus Model 8020. Repeated measurements were made by performing the fit test procedure on a high efficiency filter with a fixed leak that provided fit factors near the pass/fail requirement (i.e., 100 for a half-mask respirator). This approach only accounted for the variability of the instrument and not the overall fit test method as specified in the ANSI standard. This approach resulted in a CV of about 0.06. The CV associated with generated aerosol quantitative fit test methods can range from 0.23 to 0.82 (ANSI, 2010).

A different approach was used in the current study to determine the variability associated with the overall Reference method. Fit test pairs were collected across multiple subjects that consisted of two Reference method fit tests performed sequentially during the same respirator donning, without any adjustment between the two. The measured overall fit factors as determined for both Reference methods

in each pair were log (base 10) transformed and their difference (i.e, $\log(FF_1)-\log(FF_2)$) was determined. The standard deviation (σ) of the log differences across all trials was calculated. The high and low fit factors defining the boundaries of the Reference method exclusion zone were calculated as follows:

Upper Bound Fit Factor of Exclusion Zone = 10^(log(100) + σ)
Lower Bound Fit Factor of Exclusion Zone = 10^(log(100) – σ)

where σ is the standard deviation of the log-transformed difference and 100 is the pass/fail criterion for a half-face respirator. This has the effect of defining the exclusion zone as the range within one standard deviation of the pass/fail criterion.

Table III. Summary of Key Study Design Parameters

Task	Study Design
1	• ***Objective:*** Establish exclusion zone of the Reference fit test method • ***Number of Fit Test Pairs:*** 50 (target minimum) • ***Number of Participants:*** 15 (target minimum) • ***Number of Fit Test Pairs Below Pass/Fail Criterion:*** N/A • ***Respirator models/sizes:*** 3 models each with 3 sizes, Use each equally
2	• ***Objective:*** Use ANSI Z88.10-2010 method to compare fit factors measured using the Reference and Fast-Half method during same respirator donning • ***Number of Fit Test Pairs:*** 100 (ANSI minimum requirement) • ***Number of Participants:*** 25 (ANSI minimum requirement) • ***Number of Fit Test Pairs Below Pass/Fail Criterion:*** At least 50 measured Reference fit factors need to be between 5% of the pass/fail and the lower bound of the exclusion zone (ANSI requirement) • ***Respirator models/sizes:*** 3 models each with 3 sizes, Use each equally

ANSI Comparison

The second part of the study compared the Reference and Fast-Half fit test methods using the approach described in the ANSI standard. Again, fit test pairs were collected during the same respirator donning, without any adjustment between the two sequential fit tests. In each fit test pair, one fit factor was measured using the Fast-Half method and one with the Reference method. The order was randomized with respect to whether the Fast-Half or Reference method occurred first in the test pair. Per the ANSI standard, a minimum of 100 fit test pairs were collected and at least 25 different participants were used. At least 50 of these fit test pairs had Reference fit factors between 5% of the pass/fail criterion and the lower bound of the exclusion zone.

The ANSI standard specifies the 2x2 contingency table shown in Table IV where A, B, C, and D represent the number of observations in each cell. To meet the requirement in the ANSI standard, the Fast-Half method needs to achieve a test sensitivity of at least 0.95. The test sensitivity is defined in Table V and provides the probability that the Fast-Half test method will correctly identify an inadequate fit (as determined by the Reference method). The ANSI standard recommends, but does not require, meeting the criteria for the other four statistics defined in Table V: (1) predictive value of a pass, (2) test specificity, (3) predictive value of a fail, and (4) Kappa statistic. The Kappa statistic is a measure of the agreement between the two methods. It is the ratio of the proportion of times the two methods provided the same outcome to the proportion of times that the two methods would agree by chance if independent (ANSI, 2010).

Table IV. 2 x 2 Contingency Table Specified by ANSI Z88.10-2010 Standard

	Failed Reference Test	Passed Reference Test
Passed Fast-Half Test	A	B
Failed Fast-Half Test	C	D

Table V. Test Statistics Defined in ANSI Z88.10-2010 Standard

Statistic	Equation	Criterion
Test Sensitivity	C / (A+C)	≥ 0.95
Predictive Value of a Pass	B / (A +B)	≥ 0.95
Test Specificity	B / (B + D)	≥ 0.50
Predictive Value of a Fail	C / (C + D)	≥ 0.50
Kappa Statistic[a, b]	$(P_o - P_e) / (1 - P_e)$	>0.7

[a] $P_o = (B + C) / (A + B + C + D)$

[b] $P_e = [(A + B)(B + D) + (C + D)(A + C)] / (A + B + C + D)^2$

RESULTS AND DISCUSSION

Exclusion Zone Determination

A total of 59 fit factor pairs across 16 participants (6 female and 10 male) were collected to determine the exclusion zone. The log difference between the two overall Reference fit factors (i.e., $\log(FF_1) - \log(FF_2)$) within each pair are plotted by rank in Figure 2. Six of these pairs were omitted as the ratio of the maximum to minimum fit factor during the normal breathing check was greater than 100. The symbols for these omitted data are filled in black in Figure 2 and tend to lie at the two extremes (i.e., largest log differences) which is consistent with a shift in respirator fit during the test. An additional five points (the symbols filled in white in Figure 2) were omitted as outliers because they were more than three (3) standard deviations from the mean of the remaining data points. After exclusion, the log differences were found to be normally distributed based on a Shapiro-Wilk test. Note that excluding these 11 data points tightened the exclusion zone around the pass/fail criterion of 100, ultimately making it more difficult for the Fast-Half method to meet the ANSI criteria.

Good correlation (>0.95) was observed between the fit factors within each pair as shown in Figure 3. The best-fit regression, shown as a dashed line, nearly coincides with the 1:1 line (not shown). All of the fit factors within each individual pair were within a factor of three. The average log difference was -0.0001 with a standard deviation of 0.09. Based on this standard deviation, the exclusion zone for the Reference method was 82 to 123.

Comparison of Fast-Half and Reference Method

A total of 134 fit factor pairs across 25 participants (9 female and 16 male) were collected to compare the Reference and Fast-Half fit test methods. The ANSI standard requires a minimum of 25 participants. As was shown in Figure 1, the participants were well-distributed across the NIOSH Bivariate Fit Test Panel. The respirator models and sizes were used in nearly equal proportion.

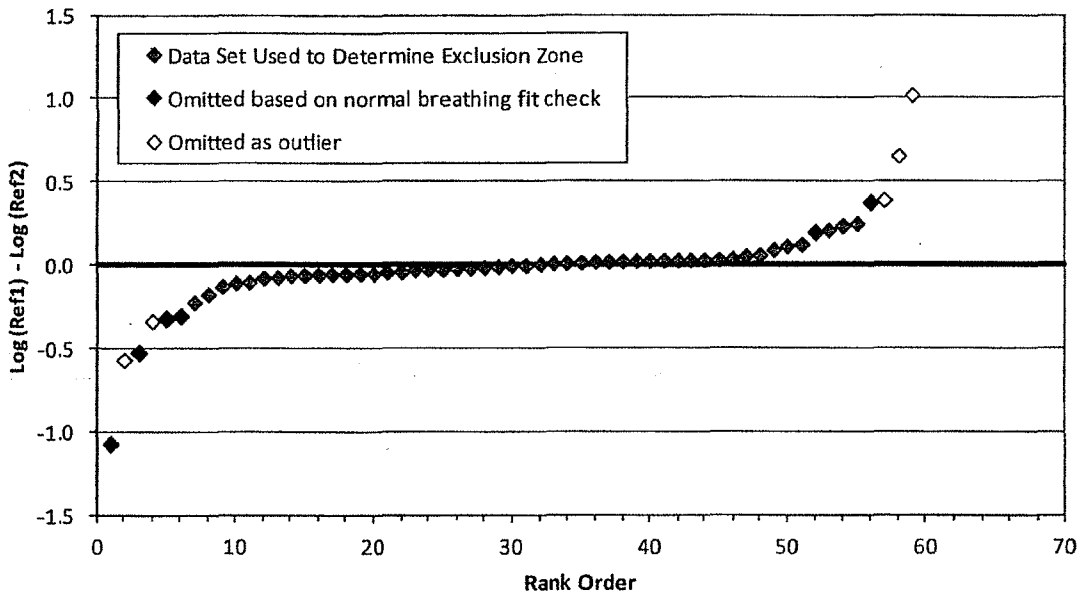

Figure 2. Distribution of Log Differences in Overall Reference Fit Factors Used in Determination of the Exclusion Zone.

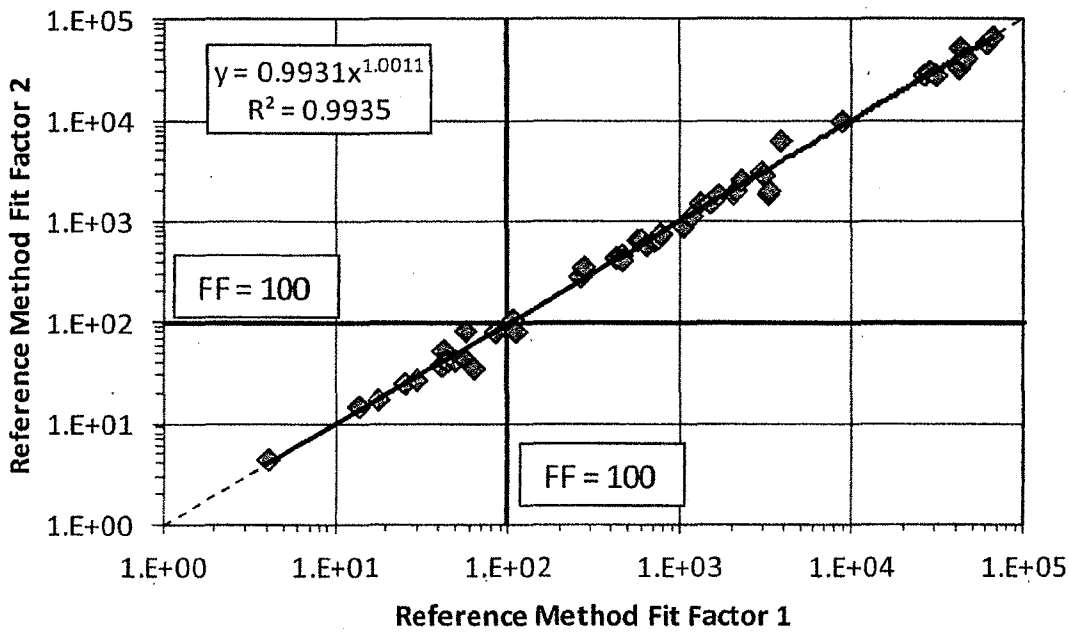

Figure 3. Comparison of Reference Overall Fit Factors Used in Determination of Exclusion Zone.

Eleven fit factor pairs were omitted from the analysis because the ratio of the maximum to minimum fit factor during the normal breathing checks was greater than 100 indicating a shift in the baseline fit. One additional fit factor pair was omitted due to an anomaly (sample line detached from respirator during test). Thus, the data set for the comparison included 122 fit factor pairs. The distribution of Reference fit factors is summarized in Table VI and shown graphically in Figure 4. As required by the ANSI standard, at least 50 Reference fit factors were between 5 (5% of the pass/fail criterion) and 82 (lower bound of the exclusion zone). These Reference method fails were evenly distributed as shown in Figure 3 and not weighted toward the lowest fit factors. Figure 4 also demonstrates that the Reference method fit factors bracketed the pass/fail criteria (100 for half-mask respirators).

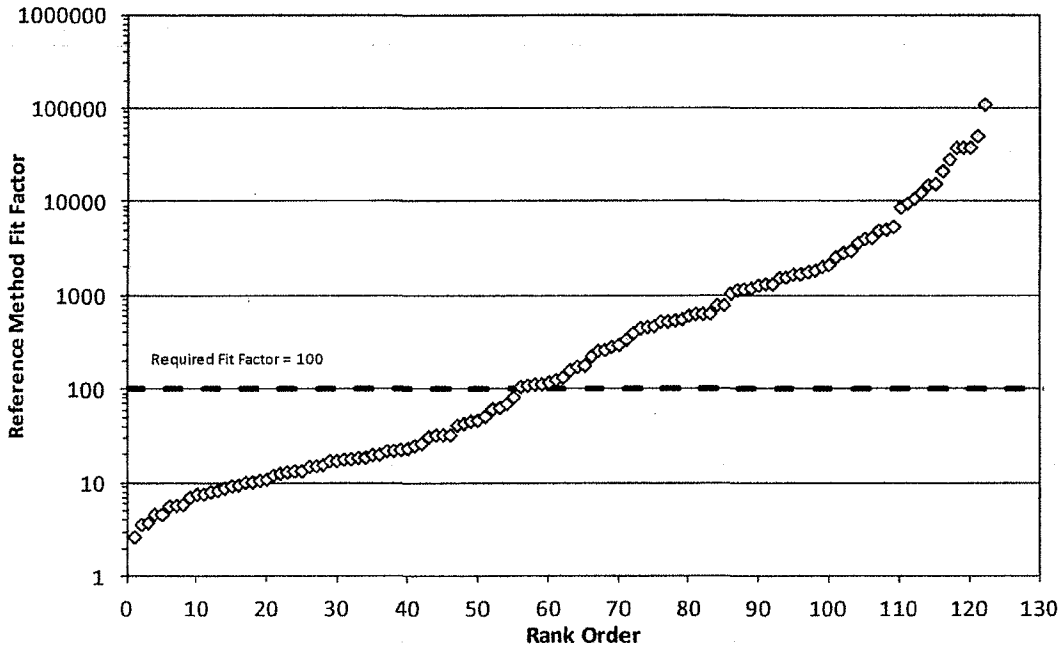

Figure 4. Distribution Reference Overall Fit Factors in ANSI Comparison.

Table VI. Distribution of Reference Fit Factors in ANSI Comparison

Reference Fit Factor Range	Number of Observations (ANSI Requirement)
Total Number of Tests	122 (N/A)
3 ≤ FF < 5	3 (N/A)
5 ≤ FF < 82	51 (50)
82 ≤ FF ≤ 123 (Exclusion Zone)	6 (N/A)
123 < FF ≤ 112,000	62 (N/A)
Total Number of Tests Outside of Exclusion Zone	116 (100)

Figure 5 compares the measured Reference and Fast-Half fit factors within each pair. Good agreement was observed between the pairs as the data points tend to lie near the 1:1 line (dotted black line). The majority (93%) of the fit factors within each pair were within a factor of three. The average magnitude of the log difference was 0.030 with a standard deviation of 0.44.

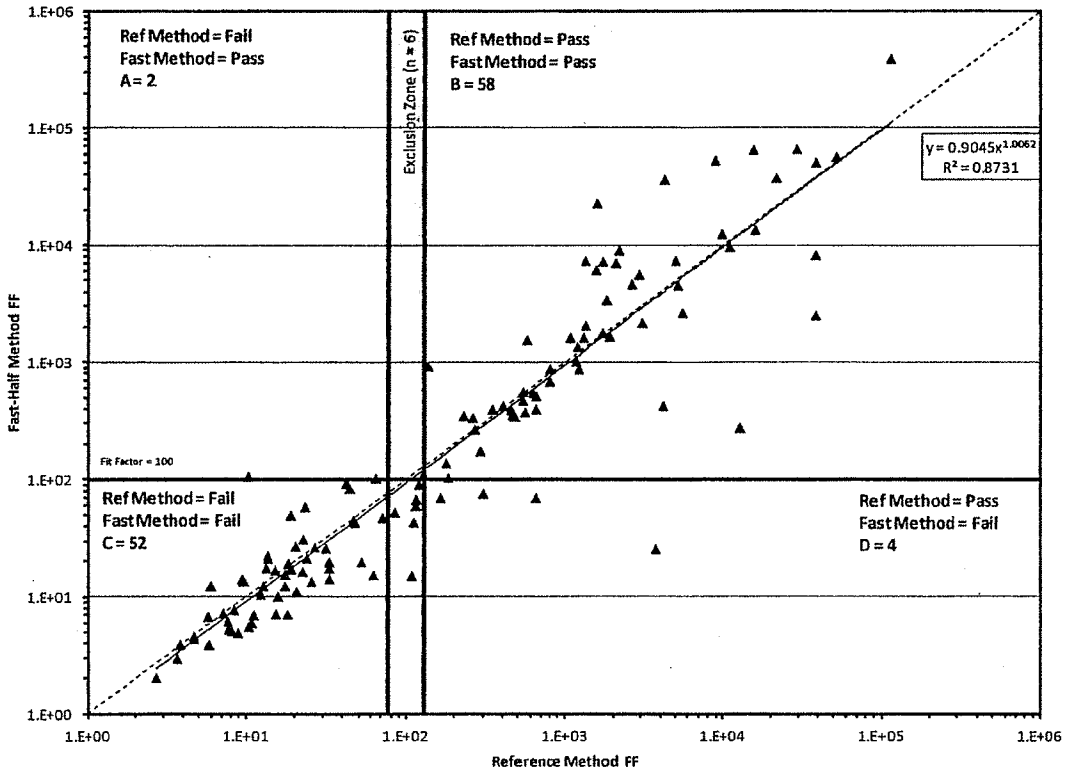

Figure 5. Comparison of Overall Fit Factors Measured Using Reference and Fast-Half Fit Test Methods.

There were two instances outside of the exclusion zone where the Reference method fit factor failed and the Fast-Half method fit factor passed (upper left quadrant in Figure 5). In both instances, the Fast-Half method was very nearly a fail (fit factors of 102 and 106). The Reference fit factors were 64 and 10, respectively, in these two fit test pairs. The Reference fit factor of 10 is 10% of the pass/fail criterion (i.e., 10% of 100). The ANSI standard states that "any reference fit factor below 10% of the required fit factor accepted by the new fit test method shall disqualify the method." It should be noted that the measured Reference fit factor was rounded down to 10 and, thus, was not less than 10% of the pass/fail criterion. It should also be noted that the test participant commented that the respirator shifted during the fit test, specifically during the jogging exercise of the Fast-Half method. In this fit test pair, the Fast-Half method was performed first so it was the second exercise. Review of the fit factor data by exercise supports that a shift in the respirator occurred as a high fit factor (greater than 2,000) was observed during the first exercise (bending) and then dropped during the jogging to below 100. The fit factor was below 100 for all remaining exercises in that fit test pair. The normal breathing fit factor check at the start of the test was 142 and at the end of the test was only 8 (a ratio of 18) further supporting the occurrence

of a shift. Despite the convincing evidence of respirator shift, the data pair was retained in the final data set because the normal breathing ratio check did not exceed the study criterion of 100.

Table VII compares the measured descriptive statistics with the requirements from the ANSI standard. The primary requirement is the test sensitivity and the other statistics are for comparison purposes. The Fast-Half method met the requirement in all cases indicating excellent agreement between the Fast-Half and the Reference method. From a safety perspective, the test sensitivity demonstrates that the Fast-Half method can identify poorly fitting respirators as well as the Reference method.

Table VII. Comparison of Measured ANSI Analysis Statistics with ANSI Criteria for Fast-Half Method to be Acceptable

Criterion	ANSI Requirement	Measured
Sensitivity	≥0.95	0.96
Predictive Value of a Pass	≥0.95	0.97
Test Specificity	>0.50	0.94
Predictive Value of a Fail	>0.50	0.93
Kappa Statistic	>0.70	0.90

It is also significant that the Fast-Half method exceeded the target for test specificity (0.94 as compared to a target of >0.50). This statistic represents the fraction of passing fit factors with the Fast-Half method that also passed the Reference method. Thus, use of the Fast-Half method will not cause the false rejection of adequately fitting respirators and subsequent unnecessary retesting.

It was important in this study to have dynamic leak paths to evaluate the exercise sets selected for the Fast-Half method. The ratios of the maximum to minimum fit factors measured across the exercises within each fit test were determined. A frequency distribution of the magnitude of this ratio is summarized in Table VIII. A ratio of one would indicate that the maximum and minimum fit factors within the fit test were the same. As shown in Table VIII for the Reference method, the highest fit factors were greater than 9 times the lowest fit factors (nearly an order-of-magnitude) in over 50% of the fit factor measurements. Similarly, this ratio exceeded 9 in about 35% of the measurements with the Fast-Half method.

Table VIII. Summary of Observed Ratios of Maximum to Minimum Fit Factors within Each Exercise Set

Ratio of Maximum to Minimum Fit Factor	Reference Method (n=218)			Fast-Half Method (n=122)		
	Frequency	Percent	Cumulative Percent	Frequency	Percent	Cumulative Percent
< 3	57	26.2%	26.2%	46	37.7%	37.7%
3 ≤ Ratio < 9	40	18.3%	44.5%	34	27.9%	65.6%
9 ≤ Ratio < 27	44	20.2%	64.7%	16	13.1%	78.7%
27 ≤ Ratio < 81	34	15.6%	80.3%	15	12.3%	91.0%
81 ≤ Ratio < 243	17	7.8%	88.1%	6	4.9%	95.9%
243 ≤ Ratio < 729	14	6.4%	94.5%	4	3.3%	99.2%
≥ 729	12	5.5%	100.0%	1	0.8%	100.0%

Zhuang et al. (2004) previously evaluated the affect of exercise on quantitative fit factors measured with the PortaCount® by calculating the mean ratios of individual exercise fit factors to the high fit factor among all exercises within each fit test. Leakage was associated with dynamic leaks and not fixed leak pathways. For comparison, the mean ratios calculated are summarized in Table IX. The values ranged from 0.38 to 0.63. These ratios were similar to those measured by Zhuang et al. and are another indication that the test method was not inducing fixed leak paths.

Table IX. Summary of Mean Ratio of Exercise Fit Factor to the Highest Fit Factor within Each Exercise Set

Exercise	Mean Ratio	Standard Deviation
Reference Method (n = 218)		
Normal Breathing	0.56	0.34
Deep Breathing	0.55	0.33
Head Side-to-Side	0.46	0.36
Head Up-and-Down	0.43	0.37
Talking	0.53	0.38
Bending	0.38	0.33
Normal Breathing	0.49	0.36
Fast-Half Method (n = 122)		
Bending	0.56	0.38
Jogging	0.59	0.33
Head Side-to-Side	0.62	0.33
Head Up-and-Down	0.63	0.36

CONCLUSIONS

A new fit test method (termed the Fast-Half fit test method) for elastomeric half-mask respirators based on the PortaCount®, a CNC-based instrument, that reduces the test duration from 7.2 min to 2.5 min has been successfully developed and assessed. Given the large number of fit tests performed annually, this reduction in time would benefit industry given the reduced time and burden. The Fast-Half method can identify poorly fitting respirators as well as the Reference method, as the test sensitivity of 0.96 was greater than the requirement (≥0.95) as defined by ANSI Z88.10-2010. The Fast-Half method also met the requirements for the predictive value of a pass, test specificity, predictive value of a fail, and the kappa statistic contained in the ANSI standard. The Fast-Half method requires acceptance by OSHA prior to implementation in industry. It is planned to submit this method to OSHA for consideration. Future testing is recommended to develop and evaluate faster fit test methods for use with filtering facepiece respirators.

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Evaluation of a Faster Fit Testing Method for Filtering Facepiece Respirators Based on the TSI PortaCount®

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ABSTRACT

In the United States, employees that wear tight-fitting respirators in the workplace are required to be fit tested annually using an Occupational Safety and Health Administration (OSHA)-accepted protocol. Given the large number of fit tests performed annually, industry and the healthcare community would benefit if the time required to complete a fit test was reduced. TSI, Inc. (Shoreview, MN) has developed a method for filtering facepiece respirators that is a modification of the OSHA-accepted 'Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol' that reduces the test duration from about 7.2 min to 2.5 min. The objective of this study was to compare the fit factors measured with the TSI modified method to that of a reference method. The method comparison approach was based on American National Standards Institute (ANSI) Z88.10-2010 Annex A2, "Criteria for Evaluating New Fit Test Methods". Sequential, paired fit tests were performed on test participants with the modified (i.e., faster) method and a reference method during the same respirator donning. The fit factors for both methods were measured using a CNC-based instrument, the PortaCount® Pro+ Model 8038 operated in the optional N95 Mode (i.e., with the DMA active). The exercises for the reference method were the standard OSHA exercise set without the grimace. The exercise set for the modified method included bending, talking, head side-to-side, and head up-and-down. The results demonstrated that the new faster method can identify poorly fitting respirators as well as the reference method, as the test sensitivity of 1.0 was greater than the requirement (≥0.95) defined in ANSI Z88.10-2010. This new method also met the requirements for the predictive value of a pass, test specificity, predictive value of a fail, and the kappa statistic contained in the ANSI standard.

Keywords: respirator fit, quantitative fit test, filtering facepiece respirators

INTRODUCTION

In the United States, employees that wear tight-fitting respirators in the workplace are required to be fit tested annually using an Occupational Safety and Health Administration (OSHA)-accepted protocol. The OSHA-accepted fit test protocols are defined in Title 29 Code of Federal Regulations (CFR) Part 1910.134 (OSHA, 1998). One of these OSHA-accepted protocols is the 'Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol', which takes over 7 min to execute for each respirator wearer. Given the large number of fit tests performed annually, industry would benefit if this time were reduced. Fit testing is an important part of a respirator program and less burdensome fit test methods for tight-fitting respirators may help increase compliance (NIOSH, 2013; IOM, 2008). TSI, Inc. (Shoreview, MN) has developed a modified method to the 'Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol' that reduces this test duration to about 2.5 min. The objective of this study was to assess whether the modified, faster fit test method was comparably effective as an existing method at identifying poorly fitting filtering facepiece respirators (FFRs).

The American National Standards Institute (ANSI) standard Z88.10-2010 Annex A2, "Criteria for Evaluating New Fit Test Methods" (ANSI, 2010) defines an approach to evaluate new fit test methods to ensure they can identify poorly fitting respirators as effectively as an accepted method. The standard recommends performing sequential paired fit tests with the new method and a reference method during the same respirator donning for comparison. In the current study, the Reference method was defined as the OSHA-accepted, CNC-based protocol except the grimace was not included in the exercise set. The new method was the faster CNC method and will be referred to as the Fast-FFR method. An ambient aerosol challenge augmented with sodium chloride (NaCl) aerosol was used for both methods. Both methods were based on the PortaCount® Model 8038 (TSI, Inc.), a CNC based fit-testing device that was operated in the optional N95 Mode (i.e., with the DMA active). The methods differed by the exercise sets, exercise duration, and sampling sequence.

METHODS

Test Participants and Respirators

The study plan was reviewed and approved by Battelle's Institutional Review Board (IRB). All participants were non-smokers and clean shaven in the areas where the respirator sealed against the face. Anthropometric measurements, specifically face width (bizygomatic breadth) and face length (menton-sellion length), of the participant's faces were made and are compared with the National Institute for Occupational Safety and Health (NIOSH) bivariate fit test panel in Figure 1. As shown, the test participants were distributed across the panel and thus represented a wide range of the respirator-wearing population. At least one participant was within each cell with exception of the cells 9 and 10. Note, there was not a requirement to meet a specific distribution of face size. Test participants were not required to have any prior experience wearing a respirator. The participants were trained to perform the exercises properly and consistently by viewing a video created for that purpose.

The test administrator selected the FFR and assisted the participant with donning to ensure that it was properly donned. The ANSI comparison requires at least 50 fit test pairs where the Reference method has a fit factor below the pass/fail criteria (i.e., 100 for a FFR). Participants were sometimes provided mis-sized respirators to encourage lower fit factors. The wearer did not perform a user seal check to increase the potential for "poor" fits that are needed for the ANSI comparison (OSHA, 2010; Janssen et al., 2002; McKay and Bradley, 2005). The test administrator assisted with donning to ensure that the respirator was properly donned to minimize the potential for slippage. Artificial leak paths were not used because the objective was to evaluate the Fast-FFR method in its entirety including the exercise

set used to produce real-world, dynamic leaks between the respirator and wearer's faces. The use of artificial leak paths (e.g., capillary tubes, etc.) would not have allowed evaluation of dynamic leaks that are caused by exercising.

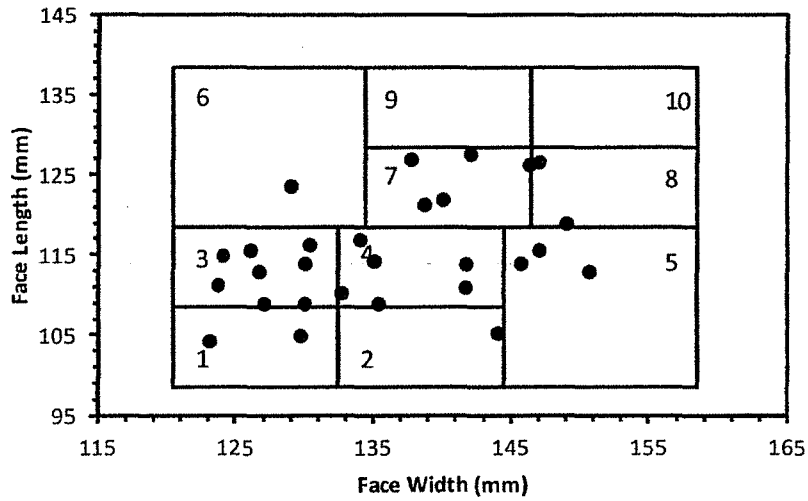

Figure 1. Distribution of Participant Facial Sizes Overlaid on the NIOSH Bivariate Chart.

Ten different models of NIOSH-approved N95 FFRs selected from six leading U.S. mask manufacturers were used. The respirators selected represented the styles and sizes commercially available including six cup-shaped, two horizontal flat-fold, and two vertical flat-fold models. The respirator models were used approximately the same number of times in the study. The specific respirators will not be identified because the intentional mis-sizing and lack of performing a user seal check would misrepresent performance of these respirators when used as part of a proper respiratory protection program. Internally flush sample probes (N95 Probe Kit, Model 8025-N95, TSI, Inc.) were inserted into the center of the cup-shaped FFRs to collect samples from the breathing zone between the nose and mouth. For horizontal flat-fold FFRs, the probe was centered near the fold on the outer edge of the bottom panel. For vertical flat-fold FFRs, the probe was mounted near the fold on the outer edge of either the left or right side. The last 50 cm of sample tubing was replaced with lightweight 0.3-cm ID x 0.5-cm OD Tygon® tubing for both the in-mask and ambient samples. The total length and inside diameter of sample tubing was unchanged. This lightweight tubing was used with both the Reference and the Fast-FFR methods as an extra precaution to prevent the weight of the sample tubing from pulling the FFR from the face. In addition, the test participants wore a neck strap that attached to the tubing for support also to prevent the tubing from pulling the FFR from the face.

Fit Factor Measurements

The system used to measure the fit factors included a chamber (~3 x 2 x 2.5 m) that was large enough to test two participants simultaneously. Large, clear plastic windows allowed the test administrator to observe the test participants. The chamber contained the ambient laboratory aerosol which was augmented with NaCl aerosol generated using a Model 8026 Particle Generator (TSI, Inc.). A mixing fan was used to distribute the aerosol throughout the chamber. The challenge and in-mask aerosol concentrations were measured using the PortaCount® Pro+ Model 8038 operated in N95 Mode (DMA active). The target aerosol concentration was greater than 400 particles/cm^3 as measured by the Model 8038 PortaCount® in N95 Mode. Aerosol sampling lines of equal length and internal diameter were used for the challenge and in-mask samples. Laptop computers with custom software developed and

supplied by TSI, Inc. were used to execute scripts that controlled the instrument sampling sequences and data collection during each trial. The custom software does not constrain FFR fit factors to an upper limit of 200, like the commercial software does. The measured in-mask and challenge aerosol concentrations were captured electronically and imported into Microsoft® Excel® for calculation of the fit factors and to determine the statistical values defined in the ANSI standard.

After donning the respirator, the test participants entered the chamber and began a 5-minute "comfort assessment period" to allow the respirator to settle on the face and to purge ambient aerosol from the mask. The comfort assessment period is an OSHA requirement for all fit test methods. During this time, adjustments could be made to the respirator and the test participants breathed normally. The respirator was not adjusted after this period (i.e., once the fit test initiated). After the 5-minute acclimation period, the participants performed exercise sets for two fit test methods in succession, without pause in between. The test administrator instructed them on the exercises to perform and observed them to ensure the exercises were performed properly. Any anomalies were recorded. Prior to this study, the test administrator had extensive experience performing quantitative respirator fit tests in industry.

Exercise Sets

The Reference method used the standard OSHA exercises with grimace omitted. The set consisted of seven exercises performed while standing: normal breathing, deep breathing, turning head side-to-side, moving head up-and-down, talking, bending over, and normal breathing. The eighth exercise, grimacing, required per 29 CFR 1910.134 is intended to break the respirator seal to the face. This potentially results in a shift of the respirator and, thus, was not used. A shift in the respirator may confound comparison of the two fit test methods. Each of the seven exercises was performed for one minute. Test participants were instructed to take a single breath at each extreme during the head side-to-side exercise, at the bottom of the bend during the bending exercise, and when looking up during the head up-and-down exercise. It was optional for the test participants to take breaths at other times during these exercises. The sample timing of the PortaCount® used for the Reference method is summarized in Table I.

The Fast-FFR method included four exercises: bending, talking, head side-to-side, and head up-and-down. The duration of each exercise was 30 sec. This is the minimum exercise duration recommended in ANSI Z88.10-2010 and CSA Z94.4-11. Test participants were required to take two breaths at each extreme during the head side-to-side and head up-and-down exercises and at the bottom of the bend during the bending exercise. It was optional for the test participants to take breaths at other times during these exercises. The PortaCount® sample timing for the Fast-FFR method is summarized in Table II. The PortaCount® sampled the ambient aerosol at the start and end of the fit test rather than in between each exercise. This is acceptable because the shorter method leaves less time for the ambient concentration to drift during the test. The ambient measurements were separated by only 2.3 min. The Fast-FFR method reduced the fit test time by about 65% relative to the Reference method (2.5 min vs. 7.2 min).

The most strenuous exercises were generally selected for the Fast-FFR fit test method. Zhuang et al. (2004) recommends talking, bending, and moving head up-and-down for protocols that use fewer and/or shorter exercises. The Fast-FFR method included all three of these exercises. In addition, it included another exercise that is aggressive in terms of evaluating the respirator seal, moving the head side-to-side.

Table I. Exercise Set and PortaCount® Sampling Sequence for the Reference Fit Test Method

Exercise Number	Exercise	PortaCount® Sample	Time (s)
1	Normal Breathing	Challenge Purge	4
		Challenge Sample 1	5
		Mask Purge	11
		Mask Sample	40
2	Deep Breathing	Challenge Purge	4
		Challenge Sample 2	5
		Mask Purge	11
		Mask Sample	40
3	Head Side-to-Side	Challenge Purge	4
		Challenge Sample 3	5
		Mask Purge	11
		Mask Sample	40
4	Head Up-and-Down	Challenge Purge	4
		Challenge Sample 4	5
		Mask Purge	11
		Mask Sample	40
5	Talking	Challenge Purge	4
		Challenge Sample 5	5
		Mask Purge	11
		Mask Sample	40
6	Bending	Challenge Purge	4
		Challenge Sample 6	5
		Mask Purge	11
		Mask Sample	40
7	Normal Breathing	Challenge Purge	4
		Challenge Sample 7	5
		Mask Purge	11
		Mask Sample	40
		Challenge Purge	4
		Challenge Sample 8	5
		Total Test Time	**429 sec = 7:09 min**

Table II. Exercise Set and PortaCount® Sampling Sequence for the Fast-FFR Test Method

Exercise Number	Exercise	PortaCount® Sample	Time (s)
1	Bending	Challenge Purge	4
		Challenge Sample 1	5
		Mask Purge	11
		Mask Sample	30
2	Talking	Mask Sample	30
3	Head Side-to-Side	Mask Sample	30
4	Head Up-and-Down	Mask Sample	30
		Challenge Purge	4
		Challenge Sample 2	5
		Total Test Time	**149 sec = 2:29 min**

Fit Factor Vetting

The fundamental premise of the ANSI approach to compare the Reference and Fast-FFR methods in the same respirator donning is that the baseline fit of the respirator remains the same throughout the procedure. The baseline fit was defined as the fit factor measured during normal breathing. To quantify undesirable changes in the baseline fit, a 5-second normal breathing fit factor check was added to the beginning, middle (i.e. after the first exercise set and before start of the second), and end of each fit test pair. A fit test pair was omitted from analysis if the ratio of the maximum to minimum normal breathing fit factor check was greater than 100, signifying that the baseline fit of the respirator changed during the trial. When comparing the Fast-FFR and Reference methods, the order was randomized with respect to which method occurred first in the test pair. The test administrator noted any observed anomalies that may be indicative of respirator slippage or other problems. Following each trial, the test participants were queried regarding whether they felt the respirator slip or any sudden sensations of air rushing into the respirator from around the peripheral seal that may also be indicative of respirator slippage. All comments/observations were recorded on the trial data sheet.

Calculation of Fit Factors

Fit factors were determined for the individual exercises and represented the ratio of the measured challenge to in-mask aerosol concentration. For the Reference method, the challenge concentration was based on the average of the measurements made immediately before and after the in-mask sample for that specific exercise (Refer to Table I for PortaCount® sample timing), which is consistent with the scheme currently used for OSHA-compliant fit testing. For the Fast-FFR method, the challenge concentration was based on the average measured at the start and finish of the entire fit test. The overall fit factor for both methods was the harmonic mean of the fit factors measured for each exercise. Each trial generated two overall fit factors per test participant, referred to as a fit test pair. It was this overall fit factor that was used for the ANSI analysis to compare test methods.

Calculation of the Exclusion Zone

The study was comprised of two parts; key study design parameters/requirements for each part are summarized in Table III. The first part characterized the variability of the Reference method. The ANSI standard specifies 'exclusion criteria', one of which is that "Reference method fit factors within one (1) Coefficient of Variation (CV) of the required fit factor should be excluded". In the current study, an "exclusion zone" was defined as the range of Reference fit factors that bracketed the pass/fail fit factor criterion inside which the pass/fail determination was deemed to be unreliable due to the observed variability. The ANSI standard does not mandate the approach to determine the CV for the reference method but suggests making multiple fit factor measurements on a subject during a single facepiece donning. The subject should have a fit factor near the required fit factor. McKay and Bradley (2005) previously determined an exclusion range of about 94 to 106 for fit testing of elastomeric half-facepiece respirators by determining the variability associated with the TSI PortaCount® Plus Model 8020. Repeated measurements were made by performing the fit test procedure on a high efficiency filter with a fixed leak that provided fit factors near the pass/fail requirement (i.e., 100 for a half-facepiece respirator). This approach only accounted for the variability of the instrument and not the overall fit test method as specified in the ANSI standard. This approach resulted in a CV of about 0.06. The CV associated with generated aerosol quantitative fit test methods can range from 0.23 to 0.82 (ANSI, 2010).

A different approach was used in the current study to determine the variability associated with the overall Reference method. Fit test pairs were collected across multiple subjects that consisted of two Reference method fit tests performed sequentially during the same respirator donning, without any adjustment between the two. The measured overall fit factors as determined for both Reference methods in each pair were log (base 10) transformed and their difference (i.e, $\log(FF_1)-\log(FF_2)$) was determined.

The standard deviation (σ) of the log differences across all trials was calculated. The high and low fit factors defining the boundaries of the Reference method exclusion zone were calculated as follows:

Upper Bound Fit Factor of Exclusion Zone = 10^(log(100) + σ)
Lower Bound Fit Factor of Exclusion Zone = 10^(log(100) – σ)

where σ is the standard deviation of the log-transformed difference and 100 is the pass/fail criterion for FFRs. This has the effect of defining the exclusion zone as the range within one standard deviation of the pass/fail criterion.

Table III. Summary of Key Study Design Parameters

Task	Study Design
1	• ***Objective:*** Establish exclusion zone of the Reference fit test method • ***Number of Fit Test Pairs:*** 50 (target minimum) • ***Number of Participants:*** 15 (target minimum) • ***Number of Fit Test Pairs Below Pass/Fail Criterion:*** N/A • ***Respirator models/sizes:*** 10 models, Use each equally
2	• ***Objective:*** Use ANSI Z88.10-2010 method to compare fit factors measured using the Reference and Fast-FFR method during same respirator donning • ***Number of Fit Test Pairs:*** 100 (ANSI minimum requirement) • ***Number of Participants:*** 25 (ANSI minimum requirement) • ***Number of Fit Test Pairs Below Pass/Fail Criterion:*** At least 50 measured Reference fit factors need to be between 5% of the pass/fail and the lower bound of the exclusion zone (ANSI requirement) • ***Respirator models/sizes:*** 10 models, Use each equally

ANSI Comparison

The second part of the study compared the Reference and Fast-FFR fit test methods using the approach described in the ANSI standard. Again, fit test pairs were collected during the same respirator donning, without any adjustment between the two sequential fit tests. In each fit test pair, one fit factor was measured using the Fast-FFR method and one with the Reference method. The order was randomized with respect to whether the Fast-FFR or Reference method occurred first in the test pair. Per the ANSI standard, a minimum of 100 fit test pairs were collected and at least 25 different participants were used. At least 50 of these fit test pairs had to have Reference fit factors between 5% of the pass/fail criterion and the lower bound of the exclusion zone.

The ANSI standard specifies the 2x2 contingency table shown in Table IV where A, B, C, and D represent the number of observations in each cell. To meet the requirement in the ANSI standard, the Fast-FFR method needs to achieve a test sensitivity of at least 0.95. The test sensitivity is defined in Table V and provides the probability that the Fast-FFR test method will correctly identify an inadequate fit (as determined by the Reference method). The ANSI standard recommends, but does not require, meeting the criteria for the other four statistics defined in Table V: (1) predictive value of a pass, (2) test specificity, (3) predictive value of a fail, and (4) Kappa statistic. The Kappa statistic is a measure of the agreement between the two methods. It is the ratio of the proportion of times the two methods provided the same outcome to the proportion of times that the two methods would agree by chance if independent (ANSI, 2010).

Table IV. 2 x 2 Contingency Table Specified by ANSI Z88.10-2010 Standard

	Failed Reference Test	Passed Reference Test
Passed Fast-FFR Test	A	B
Failed Fast-FFR Test	C	D

Table V. Test Statistics Defined in ANSI Z88.10-2010 Standard

Statistic	Equation	Criterion
Test Sensitivity	C / (A+C)	≥ 0.95
Predictive Value of a Pass	B / (A +B)	≥ 0.95
Test Specificity	B / (B + D)	≥ 0.50
Predictive Value of a Fail	C / (C + D)	≥ 0.50
Kappa Statistic[a, b]	$(P_o - P_e) / (1 - P_e)$	>0.7

[a] $P_o = (B + C) / (A + B + C + D)$

[b] $P_e = [(A + B)(B + D) + (C + D)(A + C)] / (A + B + C + D)^2$

RESULTS AND DISCUSSION

Exclusion Zone Determination

A total of 63 fit factor pairs across 14 participants (5 female and 9 male) were collected to determine the exclusion zone. The log difference between the two overall Reference fit factors (i.e., $\log(FF_1) - \log(FF_2)$) within each pair are plotted by rank in Figure 2. Two of these pairs were omitted as the ratio of the maximum to minimum fit factor during the normal breathing check was greater than 100. The symbols for these omitted data are filled in black in Figure 2 and tend to lie at the two extremes (i.e., largest log differences) which is consistent with a shift in respirator fit during the test. An additional six points (the symbols filled in white in Figure 2) were omitted as outliers because they were more than three (3) standard deviations from the mean of the remaining data points. After exclusion, the log differences were found to be normally distributed based on a Shapiro-Wilk test. Note that excluding these eight data points tightened the exclusion zone around the pass/fail criterion of 100, ultimately making it more difficult for the Fast-FFR method to meet the ANSI criteria.

Good correlation (>0.95) was observed between the fit factors within each pair as shown in Figure 3. The best-fit regression nearly coincides with the 1:1 line shown as a dashed line. All of the fit factors within each individual pair were within a factor of three. The average log difference was 0.002 with a standard deviation of 0.10. Based on this standard deviation, the exclusion zone for the Reference method was 78 to 128.

Comparison of Fast-FFR and Reference Methods

A total of 114 fit factor pairs across 29 participants (11 female and 18 male) were collected to compare the Reference and Fast-FFR fit test methods. The ANSI standard requires a minimum of 25 participants. As was shown in Figure 1, the participants were well-distributed across the NIOSH Bivariate Fit Test Panel. The respirator models were used in nearly equal proportion.

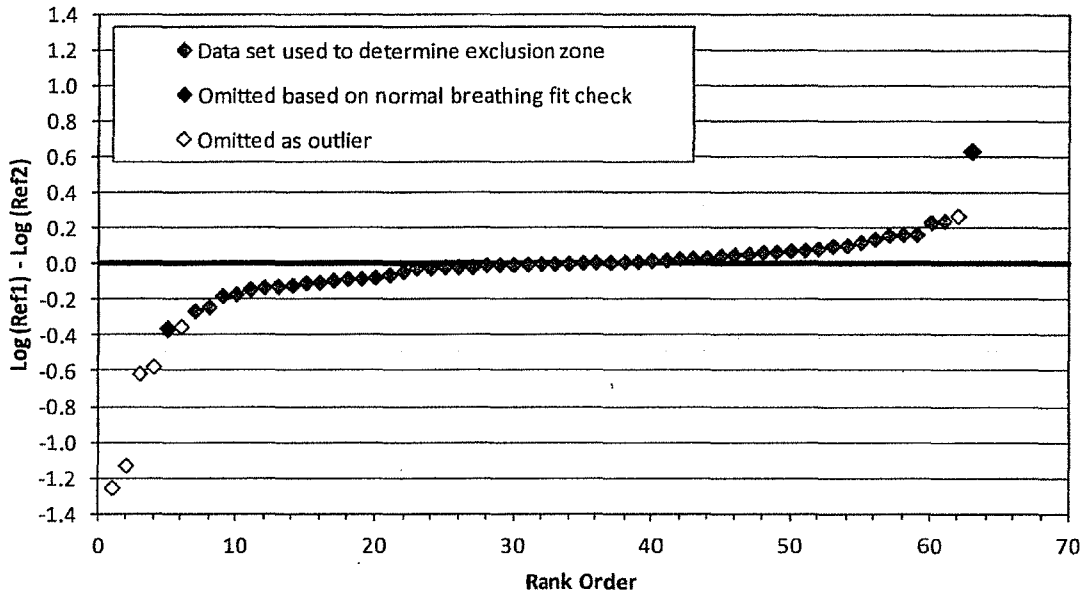

Figure 2. Distribution of Log Differences in Overall Reference Fit Factors Used in Determination of the Exclusion Zone.

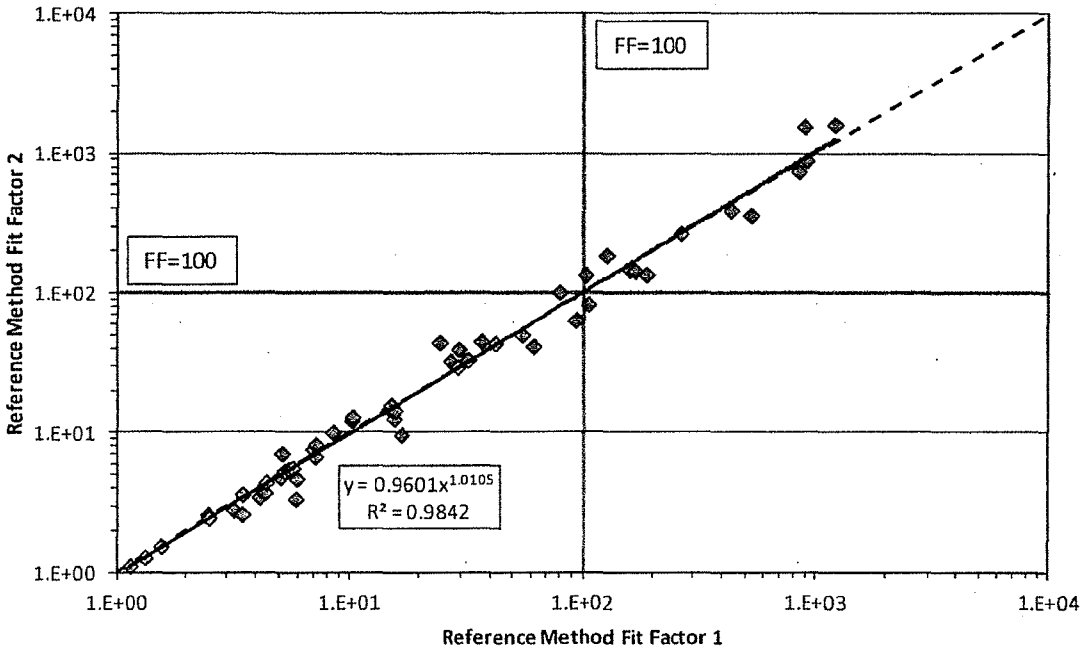

Figure 3. Comparison of Reference Overall Fit Factors Used in Determination of Exclusion Zone.

Two fit factor pairs were omitted from the analysis because the ratio of the maximum to minimum fit factor during the normal breathing checks was greater than 100 indicating a shift in the baseline fit. Thus, the data set for the comparison included 112 fit factor pairs. The distribution of Reference fit factors is summarized in Table VI and shown graphically in Figure 4. As required by the ANSI standard, at least 50 Reference fit factors were between 5 (5% of the pass/fail criterion) and 78 (lower bound of the exclusion zone). These Reference method fails were evenly distributed as shown in Figure 4 and not weighted toward the lowest fit factors. Figure 4 also demonstrates that the Reference method fit factors bracketed the pass/fail criteria (100 for FFRs).

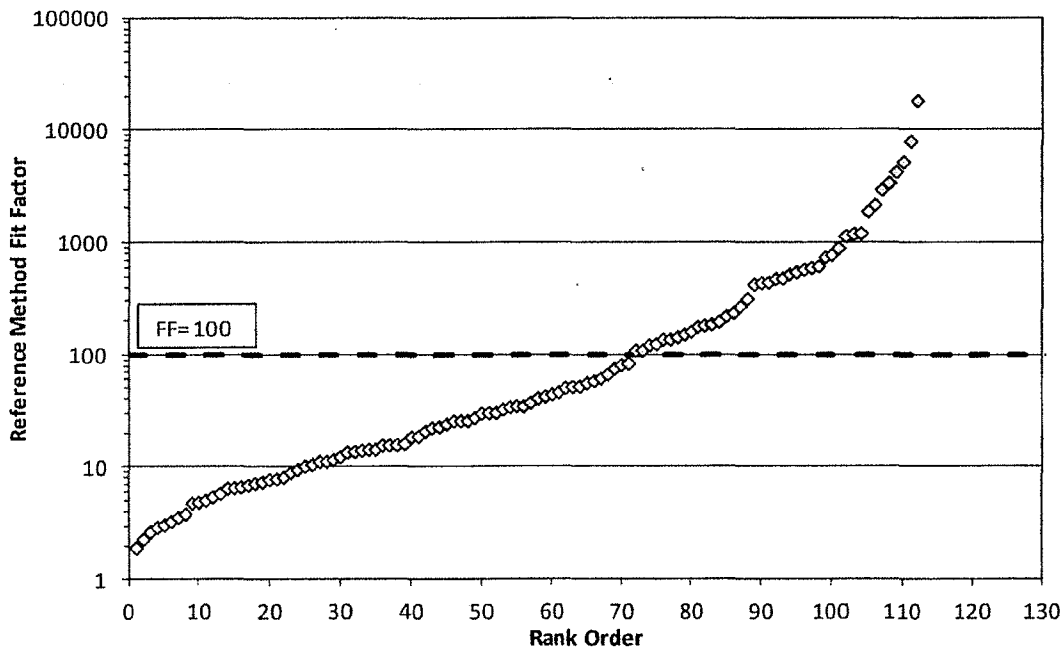

Figure 4. Distribution Reference Overall Fit Factors in ANSI Comparison.

Table VI. Distribution of Reference Fit Factors in ANSI Comparison

Reference Fit Factor Range	Number of Observations (ANSI Requirement)
Total Number of Tests	112 (N/A)
$2 \leq FF < 5$	8 (N/A)
$5 \leq FF < 78$	61 (50)
$78 \leq FF \leq 128$ (Exclusion Zone)	6 (N/A)
$128 < FF \leq 18269$	37 (N/A)
Total Number of Tests Outside of Exclusion Zone	106 (100)

Figure 5 compares the measured Reference and Fast-FFR fit factors within each pair. Good agreement was observed between the pairs as the data points tend to lie near the 1:1 line (dotted black line). The majority (95%) of the fit factors within each pair were within a factor of three. The average magnitude of the log difference was 0.037 with a standard deviation of 0.23.

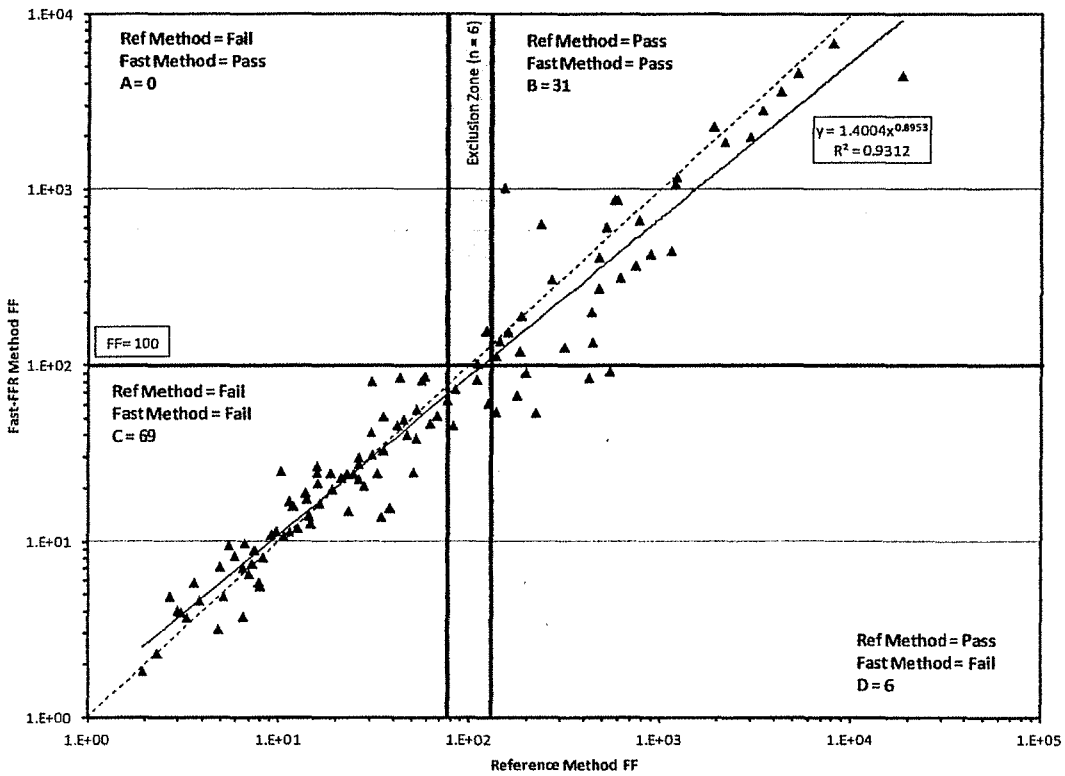

Figure 5. Comparison of Overall Fit Factors Measured Using Reference and Fast-FFR Fit Test Methods.

There were no instances where the Reference fit factor was a fail (i.e., less than 100) and the Fast-FFR method passed (upper left quadrant in Figure 5). In fact, there were not even any instances of this within the exclusion zone. Thus, in all 71 fit test pairs where the Reference method had a fit factor less than 100, the Fast-FFR method also had a fit factor of less than 100. In contrast, there were 8 instances (including the 2 within the exclusion zone) where the Fast-FFR method had a fit factor less than 100 but the OSHA method resulted in fit factors greater than 100.

Table VII compares the measured descriptive statistics with the requirements from the ANSI standard. The primary requirement is the test sensitivity and the other statistics are for comparison purposes. The Fast-FFR method met the requirement in all cases indicating excellent agreement between the Fast-FFR and the Reference method. From a safety perspective, the test sensitivity demonstrates that the Fast-FFR method can identify poorly fitting respirators as well as the Reference method.

Table VII. Comparison of Measured ANSI Analysis Statistics with ANSI Criteria for Fast-FFR Method to be Acceptable

Criterion	ANSI Requirement	Measured
Sensitivity	≥0.95	1.00
Predictive Value of a Pass	≥0.95	1.00
Test Specificity	>0.50	0.84
Predictive Value of a Fail	>0.50	0.92
Kappa Statistic	>0.70	0.87

Analysis of the data indicates that the Fast-FFR method would have passed the test sensitivity requirement even without the exclusion zone. It is also significant that the Fast-FFR method exceeded the target for test specificity (0.84 relative to a target of >0.50). This statistic represents the fraction of passing fit factors with the Fast-FFR method that also passed the Reference method. Thus, use of the Fast-FFR method will not cause excessive false rejection of adequately fitting respirators and subsequent unnecessary retesting.

It was important in this study to have dynamic leak paths to evaluate the exercise sets selected for the Fast-FFR method. The ratios of the maximum to minimum fit factors measured across the exercises within each fit test were determined. A frequency distribution of the magnitude of this ratio is summarized in Table VIII. A ratio of one would indicate that the maximum and minimum fit factors within the fit test were the same. As shown in Table VIII for the Reference method, the highest fit factors were more than 3 times the lowest fit factors in over 70% of the fit factor measurements. Similarly, this ratio exceeded 3 in about 50% of the measurements with the Fast-FFR method.

Table VIII. Summary of Observed Ratios of Maximum to Minimum Fit Factors within Each Exercise Set

Ratio of Maximum to Minimum Fit Factor	Reference Method (n=218)			Fast-FFR Method (n=122)		
	Frequency	Percent	Cumulative Percent	Frequency	Percent	Cumulative Percent
< 3	61	27.5%	27.5%	55	49.1%	49.1%
3 ≤ Ratio < 9	93	41.9%	69.4%	36	32.1%	81.3%
9 ≤ Ratio < 27	35	15.8%	85.1%	16	14.3%	95.5%
27 ≤ Ratio < 81	16	7.2%	92.3%	4	3.6%	99.1%
81 ≤ Ratio < 243	16	7.2%	99.5%	1	0.9%	100%
243 ≤ Ratio < 729	1	0.5%	100%	0	0%	100%
≥ 729	0	0.0%	100%	0	0%	100%

Zhuang et al. (2004) previously evaluated the affect of exercise on quantitative fit factors measured with the PortaCount® by calculating the mean ratios of individual exercise fit factors to the high fit factor among all exercises within each fit test. Leakage was associated with dynamic leaks and not fixed leak pathways. For comparison, the mean ratios calculated are summarized in Table IX. The values ranged from 0.48 to 0.74. These ratios were similar to those measured by Zhuang et al. and are another indication that the test method was not inducing fixed leak paths.

Table IX. Summary of Mean Ratio of Exercise Fit Factor to the Highest Fit Factor within Each Exercise Set

Exercise	Mean Ratio	Standard Deviation
Reference Method (n = 222)		
Normal Breathing	0.48	0.30
Deep Breathing	0.54	0.31
Head Side-to-Side	0.43	0.29
Head Up-and-Down	0.49	0.30
Talking	0.73	0.34
Bending	0.44	0.31
Normal Breathing	0.47	0.30
Fast-FFR Method (n = 112)		
Bending	0.70	0.29
Talking	0.74	0.30
Head Side-to-Side	0.55	0.30
Head Up-and-Down	0.49	0.30

CONCLUSIONS

A new fit test method (termed the Fast-FFR fit test method) for filtering facepiece respirators based on the PortaCount®, a CNC-based instrument, that reduces the test duration from 7.2 min to 2.5 min has been successfully developed and assessed. Given the large number of fit tests performed annually, this reduction in time would benefit industry given the reduced time and burden. The Fast-FFR method can identify poorly fitting respirators as well as the Reference method, as the test sensitivity of 1.0 was greater than the requirement (≥0.95) as defined by ANSI Z88.10-2010. The Fast-FFR method also met the requirements for the predictive value of a pass, test specificity, predictive value of a fail, and the kappa statistic contained in the ANSI standard. The Fast-FFR method requires acceptance by OSHA prior to implementation in industry. It is planned to submit this method to OSHA for consideration.

Acknowledgements

This study was funded by TSI, Inc. The authors would like to thank Elisa Walker of Safex (Westerville, OH) for administering the respirator fit tests for this study.

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TSI application letter for acceptance of three new quantitative respirator fit test protocols (July 10, 2014)

TSI INCORPORATED

500 Cardigan Road, Shoreview, MN 55126 USA
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July 10, 2014

US Department of Labor - OSHA
Andrew Levinson, Deputy Director
Directorate of Standards and Guidance
Room N-3718
200 Constitution Avenue NW
Washington, DC 20210

RE: Application for acceptance of three new quantitative respirator fit test protocols.

Dear Mr. Levinson:

Please accept the enclosed materials as the formal application for approval of three new quantitative respirator fit testing protocols for inclusion in Appendix A of the OSHA Respiratory Protection Standard 29CFR1910.134.

Currently, 29CFR1910.134 Appendix A, Part II A, B and C establish the requirements for this submittal. The submitter is required to support the application with either a test report from an independent government laboratory or an article published in a peer-reviewed industrial hygiene journal.

We have chosen to submit a separate article for each of the three new fit test protocols. All three studies were done at Battelle Memorial Institute in Columbus, Ohio and funded by TSI Incorporated. They have been published in the Peer-reviewed Journal of the International Society for Respiratory Protection (JISRP) and are included in the attachments with this document. The three articles are:

Richardson, Aaron W., Kent C. Hofacre, Jeff Weed, Ricky Holm, and Richard Remiarz (2013) "Evaluation of a Faster Fit Testing Method for Full-Facepiece Respirators Based on the TSI PortaCount®," Journal of the International Society for Respiratory Protection, Vol. 30, No. 2, pp. 116-128.

Richardson, Aaron W., Kent C. Hofacre, Jeff Weed, Ricky Holm, and Richard Remiarz (2014) "Evaluation of a Faster Fit Testing Method for Elastomeric Half-Mask Respirators Based on the TSI PortaCount®," Journal of the International Society for Respiratory Protection, Vol. 31, No. 1, pp. 9-22.

Richardson, Aaron W., Kent C. Hofacre, Jeff Weed, Ricky Holm, and Richard Remiarz (2014) "Evaluation of a Faster Fit Testing Method for Filtering Facepiece Respirators Based on the TSI PortaCount®," Journal of the International Society for Respiratory Protection, Vol. 31, No. 1, pp. 43-56.

The entire study plan for the three articles was informally shared with NIOSH and OSHA experts prior to execution in an effort to eliminate potential flaws.

The data from the above articles is attached to this application. If OSHA determines that additional information or analysis is needed before or during the rulemaking process, TSI will be pleased to cooperate.

Description of Exercise Protocols

We analyzed information from numerous sources to select exercises that effectively challenge respirator face seals, and to eliminate those exercises that do not. Literature reviews, internal TSI laboratory work and discussions with very experienced individuals doing hands-on fit testing were taken into consideration.

The three new protocols are summarized below. There are separate protocols for Full-face, Half-face (elastomeric) and Filtering-facepiece (FFR) respirators. More detailed information can be found in the supporting materials attached.

1- Fast-Full Protocol for full-face respirators – Pass/Fail = 500 - 2:29 minutes

Bending.....	(50 seconds, inhale 2 times at bottom. Includes 20 second ambient sample followed by a 30 second mask sample)
Jogging-in place.....	(30 seconds)
Head Side-to-Side.....	(30 seconds, inhale 2 times at each extreme)
Head Up-and-Down...	(39 seconds, inhale 2 times at each extreme. Includes 30 second mask sample followed by 9 second ambient sample)

2- Fast-Half Protocol for half-face elastomeric respirators - Pass/Fail = 100 - 2:29 min.

Bending.....	(50 seconds, inhale 2 times at bottom. Includes 20 second ambient sample followed by a 30 second mask sample)
Jogging-in place.....	(30 seconds)
Head Side-to-Side.....	(30 seconds, inhale 2 times at each extreme)
Head Up-and-Down...	(39 seconds, inhale 2 times at each extreme. Includes 30 second mask sample followed by 9 second ambient sample)

3- Fast-FFR Protocol for filtering-facepiece respirators – Pass/Fail = 100 - 2:29 minutes

Bending.....	(50 seconds, inhale 2 times at bottom. Includes 20 second ambient sample followed by a 30 second mask sample)
Talking.....	(30 seconds)
Head Side-to-Side.....	(30 seconds, inhale 2 times at each extreme)
Head Up-and-Down...	(39 seconds, inhale 2 times at each extreme. Includes 30 second mask sample followed by 9 second ambient sample)

ANSI Z88.10-2010 Method for Comparing Fit Test Methods

The studies used to support the proposed protocols employ the methodology described in ANSI Z88.10-2010 Respirator Fit Test Methods, Annex A2, Criteria for Evaluating New Fit Test Methods.

This approach was chosen because it represents the only published method for respirator fit test comparison in existence. A copy of ANSI Z88.10-2010 is attached.

The ANSI Z88.10 method for evaluating fit test protocols was first published in 2001 and received minor revision in 2010. The current version requires generated-aerosol QNFT as the reference method. OSHA allows new protocols to be compared to any already-accepted OSHA protocol. The reference method used in the three articles is the OSHA "Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol" from 29CFR1910.134 Appendix A part I.C.3.

The ANSI evaluation method involves the statistical comparison of overall fit factor pairs. Each pair consists of the overall fit factor from the reference method and the overall fit factor from the new method. Human subjects perform the numerous fit test pairs in succession without adjusting the respirator at any time. The premise is that the fundamental respirator fit does not change between test protocols. Only pass/fail results are used in the analysis. Theoretically, if the two protocols being tested are exactly equivalent, the resulting sensitivity value would be 1.00. There are other criteria as well. The table below summarizes the ANSI method results described in the three articles.

Results for ANSI Z88.10-2010 Method Comparison

Criterion	ANSI Requirement	Fast-Full Protocol Pass=500	Fast-Half Protocol Pass = 100	Fast-FFR Protocol Pass = 100
Sensitivity	≥0.95	0.98	0.96	1.00
Predictive Value of a Pass	≥0.95	0.98	0.97	1.00
Test Specificity	>0.50	0.98	0.94	0.84
Predictive Value of a Fail	>0.50	0.98	0.93	0.92
Kappa Statistic	>0.70	0.97	0.90	0.87

Additional Statistics

The ANSI comparison method has not been well-vetted in the literature. In fact, Annex A2 is not a mandatory part of ANSI Z88.10, partly for that reason. Some well-regarded statisticians have remarked that the ANSI method is overly complex, and that if the standard deviation and means of the fit test pairs are the same, then the protocols are the same. Consequently, conventional statistics were also computed and are presented below. The standard deviation and means are well matched.

Conventional Statistics Comparing the Reference Method to the New Fast Methods

	Fast-Full Testing		Fast-Half Testing		Fast-FFR Testing	
	Ref*	New*	Ref*	New*	Ref*	New*
Standard Deviation (log)	1.018	1.129	1.152	1.240	0.885	0.821
Mean (log)	2.975	3.040	2.272	2.243	1.750	1.713
Correlation coefficient (r)	0.94		0.93		0.96	

*Data includes fit test pairs inside exclusion zone

The statistical analysis used in the JISRP article for the Fast-Full method (full-face respirators) was done using a fit factor of 500 as the pass/fail level. Since there are cases where higher pass/levels are used, the analysis is repeated here using pass/fail levels of 1000 and 2000. The table below shows that the ANSI criteria were exceeded in all cases.

Results for ANSI Z88.10-2010 Method Comparison for Fast-Full Protocol at Pass/Fail Fit Factor Levels of 500, 1000 and 2000

Criterion	ANSI Requirement	Fast-Full Protocol Pass=500	Fast-Full Protocol Pass = 1000	Fast-Full Protocol Pass = 2000
Sensitivity	≥0.95	0.98	0.99	0.98
Predictive Value of a Pass	≥0.95	0.98	0.98	0.98
Test Specificity	>0.50	0.98	0.98	0.95
Predictive Value of a Fail	>0.50	0.98	0.98	0.95
Kappa Statistic	>0.70	0.97	0.97	0.93

Summary

TSI, with the help of Battelle Memorial Institute and many others has developed new fast fit test protocols for full-face, half-face and filtering-facepiece respirators. These three new protocols have been analyzed in peer-reviewed studies using a method detailed in ANSI Z88.10 and have been shown to exceed all of the ANSI criteria when compared to the existing "Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol." Conventional statistics are favorable as well. These analyses prove that the proposed new protocols are accurate, reliable and at least as rigorous as the existing protocols.

It is impossible to predict issues that may be raised as a result of the required public comment period. We look forward to an open dialog with OSHA throughout the rulemaking process and will accommodate any request for clarification or additional documentation. We are also open to modification of the proposed protocols, should OSHA deem it necessary, as long as the modification does not require TSI to resubmit this application.

We respectfully request that OSHA initiate the rulemaking process for adding these protocols to 29CFR1910.134 Appendix A in a timely manner. Formal contact with TSI concerning this application should be directed to:

Gregory Olson
Global Product Manager
TSI Incorporated
Phone: +1-651-490-4042
Email: greg.olson@tsi.com

Sincerely,

Darrick Niccum
Vice President Marketing
TSI Incorporated

Attachments:

- (x3) JISRP peer reviewed studies
- Copy of ANSI Z88.10-2010
- Raw data from studies in Excel Spreadsheets
- "Analysis of the Talking Exercise used for Respirator Fit Testing", TSI White Paper

TSI White Paper: Analysis of the Talking Exercise Used for Respirator Fit Testing

ANALYSIS OF THE TALKING EXERCISE USED FOR RESPIRATOR FIT TESTING

TSI WHITE PAPER

Introduction

During late 2012 and early 2013, TSI Incorporated conducted respirator fit testing studies to help determine which of the current fit test exercises called out in OSHA Respiratory Protection Standard 29CFR1910.134 are the most useful for identifying poor-fitting respirators. Results supported the conclusions made by Zhuang[1] (2004) where he found that the three exercises head up-and-down, talking, and bending were the most rigorous.

However, additional analysis of the TSI data uncovered an unexpected trend within the data for the talking exercise. It was found that the talking exercise frequently resulted in the lowest fit factor within each fit test when all fit tests were grouped together, but when only the poor-fitting[A] respirators were in the group, the talking exercise was rarely the lowest. Conversely, the talking exercise was very frequently the lowest when only good-fitting[B] respirators were grouped. This document describes the analysis done on the talking exercise data and the results found.

The data analysis in this document is divided into three parts:

Part I: Full-face Elastomeric Respirators

Part II: Half-face Elastomeric Respirators

Part III: Filtering-facepiece Respirators (FFR)

The data used in this analysis consisted of fit test pairs performed as part of another study. The purpose behind conducting the fit test pairs was to accommodate a future analysis of the repeatability of the OSHA fit test protocol. This document discusses and analyzes the talking fit test exercise only, and not the comparison of the overall fit factors for the fit test pairs. A paired t-test of log transformed overall fit factors for the fit test pairs showed no significant difference between the first and second overall fit factor (p-value >0.005). Therefore, it was determined that the fit test pairs could be separated as individual fit tests for the purpose of this talking exercise analysis.

[A] **Poor-fitting respirators** were defined as those having at least one exercise fit factor below the pass/fail level of 100, 100 and 500 for FFR, elastomeric half-face and full-face respirators respectively. All but a few in this group had failed overall fit factors.

[B] **Poor-fitting respirators** were defined as those having at least one exercise fit factor below the pass/fail level of 100, 100 and 500 for FFR, elastomeric half-face and full-face respirators respectively. All but a few in this group had failed overall fit factors.

Data was separated into three groups for exercise analysis:

- All respirators
- Poor-fitting respirators where at least one exercise fit factor failed during the fit test.
- Good-fitting respirators where no exercises failed

The data group for poor-fitting respirators is of primary interest because we are attempting to identify the exercises that are the best for challenging the face seal and identifying poor fitting respirators. Exercises with fit factors that are above the pass level do not help identify poor fits.

Good-fitting respirators were analyzed separately to show that exercises affecting good-fitting respirators are not necessarily the exercises that affect poor-fitting respirators. Specifically, the talking exercise often had the lowest fit factor among good-fitting respirators, but was rarely lowest for poor-fitting respirators.

Equipment

Fit testing was done using TSI Model 8030 PortaCount® Pro Respirator Fit Testers for full-face and half-face respirators. The Model 8038 PortaCount Pro+ in N95 mode was used for N95 filtering-facepiece respirators. Custom software controlled the PortaCount Respirator Fit Testers and recorded the data for later analysis in Microsoft® Excel® spreadsheet program.

Ambient aerosol concentrations were supplemented with sodium chloride aerosol from a TSI Model 8026 Particle Generator. Aerosol concentration was stabilized via use of a fit test chamber large enough (4 ft wide x 8 ft long x 7 ft high) for two subjects to be fit tested at the same time. A small fan inside the chamber was used to promote even aerosol distribution.

Procedures Common to All Testing

Male and female fit test subjects with little or no respirator experience were recruited for fit testing. Subjects were all non-smokers and were not allowed to have facial hair under the respirator sealing surfaces.

In a good respirator program, where users are well-trained to don respirators, the percentage of failing overall fit factors can be less than 10%. In an effort to generate a high percentage of poor fits, researchers would sometimes intentionally mis-match the respirator size and face size (via visual estimation). Since the subjects were not trained, and to avoid gross slippage resulting in a change in fundamental fit, researchers "helped" subjects don the respirator properly by making sure straps were not too tight or too loose, and there were no visible gaps or hair in the face seal. Subjects were not permitted to perform user seal checks. Subjects were given instruction on how to shape the nose band when donning filtering-facepiece respirators that were so equipped.

Fit test software implementing the standard OSHA exercise protocol was programmed such that two complete OSHA fit tests could be run without pausing in-between. Ambient samples were recorded before and after each exercise just like is done with the commercial version of the PortaCount software. This had the effect of creating one very long (14-exercise) fit test. The grimace exercise was not included because that exercise is designed to break the face seal, which if accomplished, would negate the critical assumption that the fundamental fit of the respirator does not change over the course of the fit test pair.

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® Microsoft and Excel are registered trademarks of Microsoft Corporation.

The OSHA 29CFR1910.134 exercises used for this study:

1- NB1 - Normal Breathing – 1 to 60 seconds

2- DB - Deep Breathing – 60 seconds

3- SS - Head Side-to-Side – 60 seconds

4- UD - Head Up-and-Down – 60 seconds

5- T - Talking – 60 seconds

6- B - Bending – 60 seconds

7- NB2 - Normal Breathing – 2 to 60 seconds

Test subjects donned a pre-selected respirator, waited 5 minutes, and were then guided through the fit test pair. The 5-minute wait is an OSHA requirement known as the "comfort assessment period" which allows time for the facepiece to settle on the face. Each fit test pair included two OSHA fit tests in a row, with no pauses or respirator adjustments allowed. Subjects performed all exercises while standing.

Researchers attempted to use the available respirator models and sizes with approximately equal frequency. A truly random respirator selection scheme was not used because it would have required some absurd face/respirator mismatches, for example, a large facepiece on a petite face where gaps could be seen, or a small respirator on a very large face where vision was obscured.

Part I: Full-face Respirators

Full-face elastomeric respirators from three manufacturers were used. Each model had three sizes (9 respirators total). Facepieces were probed such that in-mask samples were taken from the breathing zone in front of the nose and mouth. The sample inlet inside the mask extended into the breathing zone (i.e. not flush). Respirators were equipped with P100 filters.

Ambient aerosol concentration was maintained at a high level (62,000 particles/cc average) to ensure accurate high value fit factors, sometimes exceeding 100,000. The accurate high fit factors were necessary considering the original purpose for which the data was collected. This study is more concerned with fit factors near and below the pass level, so the high ambient levels would not have been necessary. However, Zhuang (2004) showed that fit factors near the pass level are not significantly affected by ambient challenge concentration.

Seventy-one (71) fit test pairs were included in the final data set, representing 142 OSHA fit tests on 71 donnings. Males and females were equally represented. A paired t-test of log transformed overall fit factors for the fit test pairs showed that the data was not significantly different (p-value > 0.05), so the exercise data was analyzed as 142 unique fit tests.

The poor-fitting group included 32 fit tests where 93 out of 224 exercises had failed fit factors (pass/fail level = 500). Twenty three (23) of the 32 fit tests had overall fit factors below 500.

Table FF1: Percentage of Times Exercise was Lowest for Full-face Respirators

Exercise:	NB1	DB	SS	UD	T	B	NB2
All Fit Tests (n=142)	1	11	17	11	28	24	8
Poor-fitting only (n=32)	0	0	19	16	3	44	19
Good-fitting only (n=110)	2	14	16	10	35	18	5

Table FF1 shows that for all full-face respirators, the talking exercise was the lowest for 28% (40/142) of the fit tests. However, when poor-fitting respirators were isolated, that number was reduced to only 3% (1/32). Of the 32 poor-fitting respirators, talking was lowest only once. The remaining 39 fit tests where the talking exercise was lowest had no failed exercises (pass/fail fit factor = 500).

Table FF2: Mean Ratio of Log Transformed Exercise Fit Factor to Log Transformed Highest Fit Factor of Fit Test (Full-face Respirators)

	All Tests		Poor-fitting		Good-fitting	
Exercise	**Mean Ratio**	**Std Dev**	**Mean Ratio**	**Std Dev**	**Mean Ratio**	**Std Dev**
NB1	0.94	0.06	0.92	0.10	0.95	0.05
DB	0.90	0.08	0.90	0.11	0.90	0.06
SS	0.88	0.13	0.78	0.22	0.91	0.08
UD	0.85	0.16	0.66	0.21	0.91	0.08
T	0.88	0.11	0.82	0.16	0.89	0.09
B	0.82	0.19	0.62	0.28	0.88	0.08
NB2	0.92	0.11	0.81	0.19	0.94	0.05

NB=normal breathing, DB=deep breathing, SS=head side-to-side, UD=head up-and-down, T=talking, B=bending

Table FF2 shows the mean ratio of log transformed exercise fit factor to the log transformed fit factor that was highest within each fit test. This is an indication of how variable an exercise is, where lower ratios reveal greater variability than high ratios.

Mean ratios for all fit tests indicate that B, UD, T, and SS had the lowest ratios. However, when only poor-fitting respirators are examined, B, UD and SS ratios dropped significantly while T hardly changed. This indicates that the talking exercise does not contribute significantly towards the identification of poor-fitting respirators.

It is interesting to compare the mean ratios for poor-fitting vs. good-fitting respirators. For the good-fitting respirators, the mean ratios are remarkably similar for all exercises (range 0.88 – 0.95), while the ratios for poor-fitting respirators vary widely from 0.62 to 0.92. Also, the standard deviations for good-fitting respirators are 2 to 4 times lower than those for poor-fitting. These statistics indicate that none of the exercises make much difference when the respirators fit well, and further supports the authors premise that the poor-fitting respirators must be analyzed separately to determine which exercises are most rigorous.

Part II: Half Face Respirators

Half-face elastomeric respirators from three manufacturers were used. Each model had three sizes (9 respirators total). Facepieces were probed such that in-mask samples were taken from the breathing zone in front of the nose and mouth. The sample inlet inside the mask was flush with the inside surface. Respirators were equipped with P100 filters.

Ambient particle concentration was maintained at a high level (27,000 particles/cc average) to ensure accurate high value fit factors, sometimes exceeding 100,000. The accurate high fit factors were necessary considering the original purpose for which the data was collected. This study is more concerned with fit factors near and below the pass level so the high ambient levels would not have been necessary; however Zhuang (2004) showed that fit factors near the pass level are not significantly affected by ambient challenge concentration.

Forty-two (42) fit test pairs were included in the final data set, representing 84 OSHA fit tests on 42 donnings. Subjects were predominantly male (93%). A paired t-test of log transformed overall fit factors for the fit test pairs showed that the data was not significantly different (p-value > 0.05), so the exercise data was analyzed as 84 unique fit tests.

The poor-fitting group included 21 fit tests where 85 out of 147 exercises had failed fit factors (pass/fail level = 100). Sixteen (16) of the 21 fit tests had overall fit factors below 100.

Table HF1: Percentage of Times Exercise was Lowest for Half-face Respirators

Exercise:	NB1	DB	SS	UD	T	B	NB2
All Fit Tests (n=84)	7	5	13	10	44	14	7
Poor-fitting (n=21)	14	14	14	14	10	19	14
Good-fitting only (n=63)	5	2	13	10	56	13	5

Table HF1 shows that for all half-face respirators, the talking exercise was the lowest for 44% (37/84) of the fit tests. However, when poor-fitting respirators were isolated, that number was reduced to only 10% (2/21). The overall fit factor in both those cases was a pass. Of the 21 poor-fitting respirators, talking was lowest only twice. The remaining 35 fit tests where the talking exercise was lowest had no failed exercises at all (pass/fail fit factor = 100).

Table HF2: Mean Ratio of Log Transformed Exercise Fit Factor to Log Transformed Highest Fit Factor of Fit Test (Half-face Respirators)

	All Tests		Poor-fitting		Good-fitting	
Exercise	**Mean Ratio**	**Std Dev**	**Mean Ratio**	**Std Dev**	**Mean Ratio**	**Std Dev**
NB1	0.88	0.15	0.71	0.19	0.94	0.09
DB	0.87	0.12	0.78	0.18	0.90	0.08
SS	0.87	0.14	0.73	0.16	0.91	0.09
UD	0.85	0.15	0.69	0.19	0.90	0.09
T	0.84	0.14	0.89	0.18	0.82	0.12
B	0.82	0.17	0.69	0.26	0.87	0.09
NB2	0.87	0.14	0.72	0.16	0.92	0.10

NB=normal breathing, DB=deep breathing, SS=head side-to-side, UD=head up-and-down, T=talking, B=bending

Table HF2 shows the mean ratio of log transformed exercise fit factor to the log transformed fit factor that was highest within each fit test. This is an indication of how variable an exercise is, where lower ratios reveal greater variability than high ratios.

Mean ratios for all fit tests indicate that B, T and UD were the lowest. However when only poor-fitting respirators are considered, B and UD were lowest and T actually increased. Again, as with full-face respirators, this shows that the talking exercise does not contribute significantly towards the identification of poor-fitting half-mask elastomeric respirators.

As was found for full-face respirators, the mean ratios for good-fitting respirators are remarkably similar for all exercises (range 0.82 – 0.94), while the ratios for poor-fitting respirators vary widely from 0.69 to 0.89. Standard deviations for good-fitting respirators are about half of those for poor-fitting. These statistics indicate that none of the exercises make much difference when the respirators fit well, and further supports the authors premise that the poor-fitting respirators must be analyzed separately to determine which exercises are most rigorous.

Part III: N95 Filtering-Facepiece Respirators (FFR)

N95 Filtering-facepiece respirators (FFR) from four manufacturers were used, representing eight model/size combinations. FFR styles included five cup-shaped, two horizontal fold (duck-bill) and one tri-fold.

Facepieces were probed such that in-mask samples were taken from the breathing zone in front of the nose and mouth. The sample inlet inside the mask was flush with the inside surface.

The TSI PortaCount Pro+ Model 8038 in N95 mode was used. Unlike the software sold with the instrument, the custom fit test software used for this study did not limit N95 mode fit factors to 200. Since the study was focused on exercise fit factors below 100, allowing fit factors to exceed 200 made little difference. A recalculation of overall fit factors for all FFR fit tests using an upper limit fit factor of 200 showed that only 1 of 76 overall fit factors changed from a pass to a fail (FF changed from106 down to 96). This is because the overall fit factor is calculated as the harmonic mean of the exercise fit factors, which is weighted towards low values.

Ambient particle concentration was maintained at an average of 360 particles/cc. The lower concentration in N95 mode is due to the particle size-selective function of the internal DMA that limits particle size to a range of about 40 to 60 nanometers.

Researchers were concerned that the weight of the sample tubing could cause the FFR to shift slightly during exercises so approximately 45 cm of the standard PVC sample tubing was replaced with thin-wall (light-weight and flaccid) PVC tubing with the same inside diameter. Subjects were also instructed to support the tubing with one hand at chest level such that the tubing would have enough slack to prevent it from pulling on the respirator. The head up-and-down exercise was the one that needed the most slack.

Thirty-eight (38) fit test pairs were included in the final data set, representing 76 OSHA fit tests on 38 donnings. Females represented 78% of fit tests. A paired t-test of log transformed overall fit factors for the fit test pairs showed that the data was not significantly different (p-value > 0.05), so the exercise data was analyzed as 76 unique fit tests.

The poor-fitting group included 43 fit tests where 93 out of 301 exercises had failed fit factors (pass/fail level = 100). Twenty nine (29) of the 43 fit tests had overall fit factors below 100.

Table FFR1: Percentage of Times Exercise was Lowest for Filtering-Facepiece Respirators

Exercise:	NB1	DB	SS	UD	T	B	NB2
All fit tests (n=76)	4	1	17	14	22	33	8
Poor-fitting (n=43)	7	2	19	19	2	37	14
Good-fitting only (n=33)	0	0	15	9	48	27	0

Table FFR1 shows that for all filtering-facepiece respirators, the talking exercise was the lowest for 22% (17/76) of the fit tests. However, when poor-fitting respirators were isolated, that number was reduced to only 2% (1/43). Of the 43 poor-fitting respirators, talking was lowest only once, and the overall fit factor in that case was a pass (FF ≥ 100). The remaining 16 fit tests where the talking exercise was lowest had no failed exercises at all.

Table FFR2: Mean Ratio of Log Transformed Exercise Fit Factor to Log Transformed Highest Fit Factor of Fit Test (FFR Respirators)

	All Tests		Poor-fitting		Good-fitting	
Exercise	**Mean Ratio**	**Std Dev**	**Mean Ratio**	**Std Dev**	**Mean Ratio**	**Std Dev**
NB1	0.897	0.130	0.85	0.15	0.95	0.05
DB	0.887	0.126	0.87	0.16	0.91	0.06
SS	0.861	0.146	0.85	0.16	0.88	0.12
UD	0.843	0.134	0.80	0.15	0.90	0.07
T	0.868	0.123	0.92	0.08	0.80	0.13
B	0.818	0.135	0.80	0.16	0.84	0.08
NB2	0.891	0.141	0.85	0.16	0.95	0.07

NB=normal breathing, DB=deep breathing, SS=head side-to-side, UD=head up-and-down, T=talking, B=bending

Table FFR2 shows the mean ratio of log transformed exercise fit factor to the log transformed fit factor that was highest within each fit test. This is an indication of how variable an exercise is, where lower ratios reveal greater variability than high ratios.

Mean ratios for all fit tests indicate that B, T,UD and SS were the lowest, however when only poor-fitting FFR respirators are considered, B and UD were lowest and T actually increased. Again, as with full-face and half-face respirators, this shows that the talking exercise does not contribute significantly towards the identification of poor-fitting FFR.

Unlike what was found for full-face and half-face respirators, the range of mean ratios for good-fitting respirators vs. poor-fitting was about the same (0.80 – 0.95 and 0.80 – 0.92 respectively). However, the drop in standard deviations for good-fitting vs. poor-fitting respirators was similar to the full- and half-face results with the exception of talking, which increased. These statistics indicate that none of the exercises stand out as being more rigorous than the others for FFR fit testing.

Discussion

The authors suspect that the phenomenon regarding the talking exercise is due to body-generated particles. Talking involves the high-frequency vibration of wet vocal chords. This may be generating particles (droplets) in a way that does not occur during the other exercises where the subject is not talking. Sub-micrometer body-generated particles are likely to be mis-interpreted as leakage particles by particle counting instruments.

For poor-fitting respirators, the body-generated particles are insignificant in number compared to those that enter the breathing zone through moderate to large face seal leaks that exist when fit factors are near or below the pass level, thus having little influence on fit factors. When the facepiece fit is above the pass level, the number of body-generated particles becomes significant compared to the few leak particles, resulting in artificially lower (but passing) fit factors for the talking exercise.

Talking Fit factor = $C_{ambient} / C_{mask} = C_{ambient} / (C_{leak} + C_{body})$

When $C_{leak} >> C_{body}$, (high to moderate faceseal leakage, low fit factor)

Talking Fit factor = $C_{ambient} / C_{leak}$

When $C_{body} >> C_{leak}$, (low faceseal leakage, high fit factor)

Talking Fit factor = $C_{ambient} / C_{body}$

(C = concentration in particles/cm^3)

Zhuang found that one of the most rigorous exercises was talking. However that study did not analyze poor-fitting respirator fit tests separately from all respirator fit tests. The authors believe that if Zhuang's data were re-examined, it would reveal that talking is not an important exercise for identifying poor-fitting respirators. To Zhuang's credit, he did acknowledge that test subjects can exhale body-generated particles that cannot be differentiated from leakage particles by particle-counting instruments like the PortaCount Respirator Fit Tester.

It should also be noted that the Zhuang study involved only half-face and filtering-facepiece respirators and that there were more fit tests analyzed (4334 vs. 302).

Anecdotally, experienced fit testers appear to favor the use of the talking exercise for FFR because those respirators are much less securely held to the face compared to elastomeric respirators. The jaw motion associated with talking can, in some cases, cause the respirator to shift up or down, exposing a poor size choice, such as when a cup-shaped FFR respirator is too small in the vertical direction. Extreme poor size choices were avoided in this study.

Conclusion

Analyzing the fit test results for poor-fitting respirators as a separate group from all respirators is necessary to determine the efficacy of fit test exercises for the purpose of identifying poor-fitting respirators.

Previous work identifying the talking out loud exercise as being one of the more rigorous OSHA fit test exercises was based on fit test data for all respirators. This study reveals that talking is not rigorous when only poor-fitting respirators are analyzed separately, and that the reason may be due to sub-micrometer, talking-induced, body-generated particles that are mis-interpreted as leakage by particle counting instruments.

References

1. Zhuang, Z., C. C. Coffey, and R. B. Lawrence. "The Effect of Ambient Aerosol Concentration and Exercise on PortaCount Quantitative Fit Factors." *Journal of the International Society for Respiratory Protection* **21** (2004): 11-20.

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