

Evaluation of Three New Fit Test Protocols for Use with the TSI PortaCount

Roy T. McKay and Jeff Bradley

Dept. of Environmental Health, University of Cincinnati, 3223 Eden Avenue, Cincinnati, OH 45267; E-mail: Roy@DrMcKay.com

ABSTRACT

This study investigated three new quantitative fit testing protocols designed for use with the TSI PortaCount quantitative fit test system. Each of the three new protocols was designed to shorten the time required to perform an OSHA 8-exercise quantitative fit test. Results were compared to the acceptance criteria established by ANSI Z88.10-2001 (Annex A2: Criteria for Evaluating Fit Test Methods). A total of thirty subjects conducted 140 fit tests with a variety of good and poor fitting half and full facepiece respirators. Decreasing total fit test time was accomplished by decreasing the time required to obtain an in-facepiece sample and/or by eliminating exercise maneuvers. Two of the protocols in this study (protocols #2 and #3) utilized a shortened in-facepiece sampling time to reduce the length of each exercise maneuver from 60 to 40 seconds. This was achieved by reducing the in-facepiece sampling time from 40 to 20 seconds, while keeping ambient sample and purge times unchanged. Test sensitivity for protocol #2 was 0.97 when the reference method pass/fail criterion was set to either 100 or 500. This exceeds the ANSI recommendation for accepting a new fit test method. Protocol #3 used the same exercise time as protocol #2 (40 seconds), however, the total test time was further reduced by eliminating the first two exercise maneuvers while using a more stringent pass fail criterion of 200 and 1,000 (two times the OSHA requirement). Results for protocol #3 also exceeded the ANSI criterion for acceptance of a new fit test method. Test sensitivity for protocol #3 was 1.00. All three of the new test protocols were highly correlated with the reference fit test method. Correlation coefficients for protocols #1, #2, and #3 were 0.956, 0.988, and 0.982, respectively. This study demonstrated that reducing the exercise time with the TSI PortaCount had little effect on the ability of this instrumentation to identify poorly fitting respirators. In addition, eliminating the first two exercise maneuvers from the 1998 OSHA 8-exercise protocol in conjunction with doubling of the pass/fail criterion not only provides a significantly faster fit test protocol, but provides a more conservative fit test for quantitative respirator fit testing.

Keywords: Respirator fit testing, quantitative fit testing, respirators, TSI PortaCount, respiratory protection, fit factor

INTRODUCTION

In the United States, the Occupational Safety and Health Administration (OSHA) requires fit testing for all tight fitting respirators that are required to be worn (OSHA 1998). This includes negative and positive pressure elastomeric and filtering facepiece respirators. This standard also specifies the number, type, and length of different breathing and head movement exercises to be used for fit testing. The purpose of these exercises is to challenge the face seal by simulating the many different breathing patterns and head movements that may occur during respirator use. During qualitative and quantitative fit testing (with

aerosol-based systems), the length of each exercise for OSHA accepted protocols are one minute, with exception to an additional 15-second grimace maneuver for some quantitative fit test protocols. One purpose of fit testing is to verify mask size and donning competence by identifying the presence or absence of significant leakage into the facepiece. These leaks, are present initially or induced. Induced leak sites come in two basic types, those which are transient and occur during the active movement of the exercise, such as turning the head side-to-side, and those that are progressive (i.e., influenced by the preceding exercise movements). Currently, there is no scientific basis to support a one-minute exercise maneuver for all fit test methods.

The TSI PortaCount uses ambient aerosol particles as the challenge agent and is the most commonly used quantitative fit test instrument. The OSHA-accepted ambient aerosol protocol consists of seven one-minute exercises, plus a 15-second grimace maneuver (total of 8-exercises). During each one minute exercise, the TSI PortaCount collects a 40-second in-facepiece sample. The remaining 20 seconds of each exercise is used to collect an ambient sample or purge the ambient and sample collection tubes.

The purpose of this study was to investigate whether or not a shorter in mask sampling time would produce equivalent results when using the TSI PortaCount® Plus Model 8020 quantitative fit test system. Another purpose was to investigate the removal of one or more exercises. The results from three new test protocols were compared to the criteria recommended by ANSI Z88.10-2001 for validation of new fit test protocols and are presented here.

METHODS

All fit tests were conducted using a TSI PortaCount® Plus Model 8020 quantitative fit test system (TSI Inc., Shoreview, Minnesota, USA) at the University of Cincinnati. The study design was based upon the requirements established by ANSI Z88.10-2001 (Annex A2: Criteria for Evaluating Fit Test Methods). One important change to the fit testing software was a modification that permitted data acquisition at ten second intervals during the mask sample. This specially designed testing software allowed fit factors to be calculated after every ten seconds during the 40-second mask sample. This allowed the 10, 20, and 30-second fit factors to be compared to the 40-second fit factors as if they were different fit tests with identical donnings. In this study the 10 and 20-second mask samples are subsets of the 40-second data. Fit factors were calculated as usual (C_o/C_i). To calculate fit factors at ten second intervals, the same ambient value (C_o) before and after each mask sample (C_i) was used. Advantages of this study design were the “new” protocol could be compared to the “reference” method during the same donning. Donning to donning variation is recognized as the largest source of variation in respirator fit (Campbell, 2005). Obtaining a measurement for the new and reference protocols from the same donning, therefore, avoids many of the common problems associated with comparison studies of two different fit test methods. In addition, the test methodology employed in this study utilized the same sample probe location, size, flow, etc. To our knowledge, this approach has not been reported previously.

Thirty (30) subjects participated in this study. All subjects were medically cleared prior to participation. Human subject approval was obtained from the University of Cincinnati's Institutional Review Board prior to the start of data collection. All subjects wore a half and full facepiece respirator, although some wore more than one. Since a wide variety of respirator facepieces were available to study subjects, twenty four different make and model respirators were worn during this study. In-mask samples were obtained using sampling adapters provided by TSI or using probed facepieces provided by the respirator manufacturer. Study subjects were initially asked to select a respirator that appeared to fit based upon their personal assessment while holding the respirator to the face. This was based upon observation of the subject's facial characteristics and experience of the investigators. If a successful fit was obtained, then this facepiece was used to satisfy the need to find a respirator having a fit factor greater than the pass/fail criterion. If the respirator fit poorly, it was used to satisfy the need for a poorly fitting facepiece. Otherwise the procedure used to obtain a poorly fitting respirator, was to assign the subject a respirator having a facepiece one or two sizes less or greater than what was found to fit.

In all cases, study subjects were asked to don the respirator, position the facepiece in the most comfortable position, and adjust the straps so that the respirator was secure to the face. User seal checks were not conducted. Loosening the straps or the introduction of artificial leaks such as hypodermic needles or fine wires under the faceseal was not permitted. Pass-fail levels for the half mask and full facepiece respirators were set at 100 and 500, respectively. Prior to the start of data collection, the PortaCount was returned to the manufacturer for yearly calibration, maintenance, and cleaning. All manufacturer recommended operational checks were performed each day. Data and statistical analysis was performed using the data analysis tools provided with Microsoft Office Excel 2003.

The standard OSHA fit test protocol consists of the following eight one minute exercises: (1) normal breathing, (2) deep breathing, (3) turning head side to side, (4) moving head up and down, (5) talking, (6) grimace (15 seconds), (7) bending over, and (8) normal breathing. The grimace maneuver does not contribute towards the calculation of the overall fit factor. The three new fit test protocols differ from the standard OSHA protocol with respect to in-mask sampling times and/or number of exercises as follows (Table I).

Protocol #1: Total exercise time was reduced from 60 to 30 seconds. This was accomplished by reducing the in-facepiece sampling time from 40 to 10 seconds. Ambient sample times, purge times, and number of exercises remained the same.

Protocol #2: Total exercise time was reduced from 60 to 40 seconds. This was accomplished by reducing the in-facepiece sampling time from 40 to 20 seconds. Ambient sample times, purge times, and number of exercises remained the same.

Protocol #3: Total exercise time was reduced from 60 to 40 seconds. This was accomplished by reducing the in-facepiece sampling time from 40 to 20 seconds. Ambient sample and purge times remained the same. Number of exercises reduced from 8 to 6, by eliminating the first two OSHA exercises (normal and deep breathing).

Table I. Comparison of the Three New Protocols to the Standard OSHA Protocol

	OSHA Protocol	Protocol #1	Protocol #2	Protocol #3
Pass levels (half masks/full-facepiece respirators)	100/500	100/500	100/500	200/1000
Individual exercise time (seconds)*	60	30	40	40
In-facepiece sampling time	40	10	20	20
Normal breathing	X	X	X	-
Deep breathing	X	X	X	-
Turn head side to side	X	X	X	X
Move head up and down	X	X	X	X
Talking	X	X	X	X
Grimace (15 seconds)	X	X	X	X
Bending over	X	X	X	X
Normal breathing	X	X	X	X
Total test time (minutes:seconds)	7:15	3:45	4:55	3:35

* = All exercises except for grimace (15 seconds)

X = exercise maneuver included

The first two protocols are equivalent to the current OSHA protocol with exception to shorter exercise times of 30 and 40 seconds. The third protocol utilized a shorter exercise time of 40 seconds and eliminated the first two exercises.

RESULTS

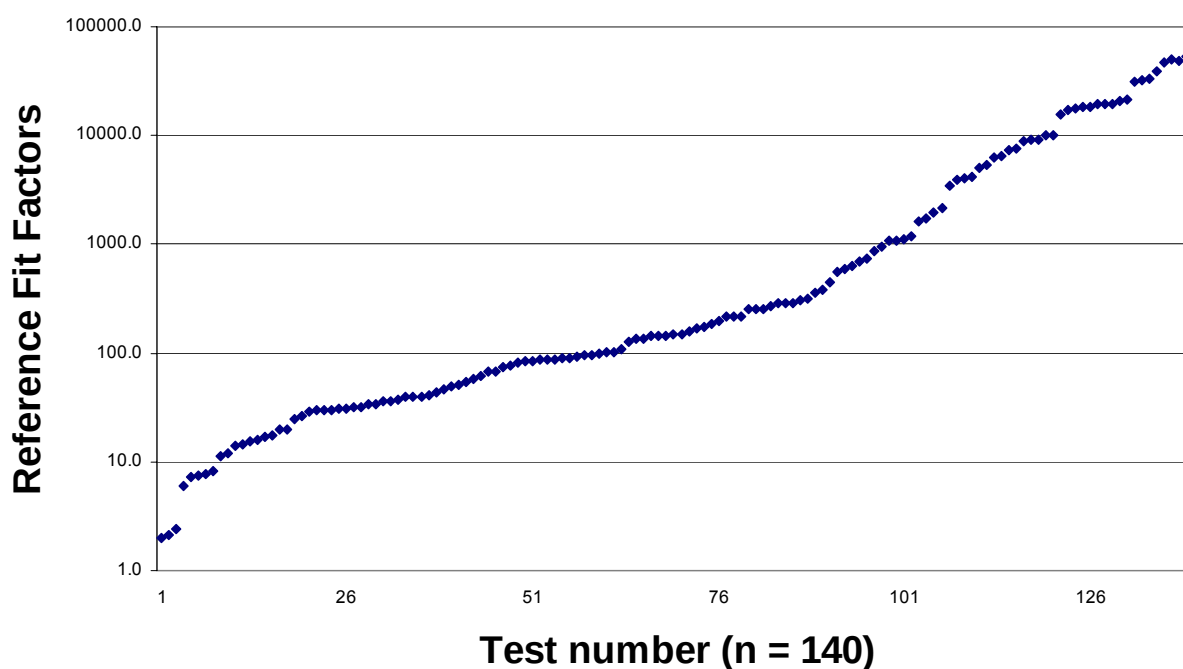
ANSI Z88.10-2001 establishes acceptance criteria for evaluating new fit test methods. These criteria include a minimum of 100 paired tests from at least 25 different subjects having at least 50 of the required fit factors from the reference method less than the required fit factor (i.e., 100 and 500) when using a variety of different size and model facepieces. In this study, all of these ANSI requirements were met. Results are summarized in Table II. ANSI Z88.10 also requires a cumulative distribution plot or histogram to visually confirm that the fit factors obtained from the reference method bracket the required fit factors of 100 and 500. The cumulative distribution plot shown in Figure 1 provides a visual confirmation that the reference fit factors ranged from 2 to 54,315 and appropriately bracketed the pass-fail criterion of 100 and 500, respectively.

Table II. ANSI Z88.10-2001: Protocol Criteria for a New Fit Test Method

	ANSI Criterion	Study Results
Minimum number of paired tests	100	140
Minimum number of test subjects	25	30
Minimum number of reference fit factors less than the required fit factor	50	57 < fit factor of 100* 91 < fit factor of 500
Make and model facepieces	"Variety"	24

* After excluding 3 tests with reference fit factors within ± 1 standard deviation (otherwise 60 reference fit factors were below 100).

Since reference fit factors have some error themselves, Z88.10-2001 recommends excluding tests with reference fit factors within one standard deviation of the required fit factor. This is necessary to minimize potential misclassification of the results. ANSI recommends obtaining repeated measurements near the required fit factor to identify the standard deviation (SD) of the reference method. Instrument noise was identified by repeatedly running the fit testing procedure on a high efficiency filter with a fixed leak size. Following the ANSI recommendation, the standard deviation for a nominal reference fit factor of 100 was 5.6 (mean = 112.9, n = 10), and 24.7 for the nominal fit factor of 500 (mean = 528.3, n = 13). As a result, five (5) tests were excluded for having reference fit factors within one standard deviation of 100. It was not necessary to exclude results for fit factors within one standard deviation of 500, since none of the reference fit factors were between 475.3 and 524.7. Table III summarizes the number of fit tests conducted, the facepiece style (half or full), and the number of reference fit factors above and below the respective pass/fail criteria.

Figure 1: Distribution of Reference Fit Factors**Table III. Number and Category of Fit Tests**

	Total Number of Fit Tests	Number of Fit Tests Remaining After Excluding Fit Tests Within 1 SD of the Reference Fit Factor Pass/Fail Criterion
Half Masks	69	64
Full Face	71	71
All Masks	140	135
Reference Fit Factors < 100	60	57
Reference Fit Factors > 100	80	78
Reference Fit Factors < 500	91	91
Reference Fit Factors > 500	49	49

ANSI Z88.10-2001 acceptable criteria and results for the three new testing protocols are summarized in Tables IVa, b & c. Of the five statistical test requirements recommended by ANSI, test sensitivity is the most important. Test sensitivity provides the probability that the new test method will correctly identify an inadequately fitting respirator. In essence, sensitivity provides a response to the following question. Of the reference method fit tests with unacceptable fits, what fraction also failed the new fit test method? ANSI recommends this fraction must be 0.95 or greater to ensure those respirators with unacceptable fits will fail the new fit test method. Sensitivity is sometimes called beta error. In addition to sensitivity, ANSI Z88.10 provides four additional descriptive statistics; however, while recommended, they are not required for acceptance of a new test method. The purpose of these four additional tests (specificity, predicted

value of a pass, predictive value of a fail, and Kappa statistic) compare other aspects of the new and reference fit test method to evaluate equivalency between methods. ANSI considers sensitivity (beta error) to be the most critical statistic. Specificity (sometimes called alpha error) is not as important for accepting a new fit test method. If a new method is not specific, it may fail a respirator that actually fits. While this may cause another respirator to be chosen, it does not put the employee at risk of wearing a poorly fitting respirator.

Table IVa. Acceptance Criteria and Results for Fit Test Protocol #1
Reference Fit Factor Pass/Fail Criterion = 100
30 Second Exercise Time

	ANSI Requirement	Results for this study	Pass or Fail ANSI requirement
Sensitivity	≥ 0.95	0.91	Fail
Predictive Value of a Pass	≥ 0.95	0.94	Borderline Fail
Specificity	> 0.50	0.99	Pass
Predictive Value of a fail	> 0.50	0.98	Pass
Kappa Statistic	> 0.70	0.91	Pass

Table IVb. Acceptance Criteria and Results for Fit Test Protocol #2
Reference Fit Factor Pass/Fail Criterion = 100
40 Second Exercise Time

	ANSI Requirement	Results for this study	Pass or Fail ANSI requirement
Sensitivity	≥ 0.95	0.97	Pass
Predictive Value of a Pass	≥ 0.95	0.98	Pass
Specificity	> 0.50	1.00	Pass
Predictive Value of a fail	> 0.50	1.00	Pass
Kappa Statistic	> 0.70	0.97	Pass

Table IVc. Acceptance Criteria for Fit Test Protocol #3
Reference Fit Factor Pass/Fail Criterion = 100
6 Exercises, 40 Second Exercise Time, Pass/Fail = 2 x OSHA Requirement = 200

	ANSI Requirement	Results for this study	Pass or Fail ANSI requirement
Sensitivity	≥ 0.95	1.00	Pass
Predictive Value of a Pass	≥ 0.95	1.00	Pass
Specificity	> 0.50	0.81	Pass
Predictive Value of a fail	> 0.50	0.79	Pass
Kappa Statistic	> 0.70	0.78	Pass

Table IVc shows results for protocol #3 which consists of a 40-second exercise duration, having six of the original eight exercises, in conjunction with a pass/fail criterion 2-times the OSHA requirement for a half mask respirator ($2 \times 100 = 200$). Protocol #3 detected 100% of the poorly fitting facepieces. These results demonstrate that the shorter, protocol (Protocol #3) is a more conservative fit test.

Tables Va, b & c are similar to Tables IVa, b & c, except that the reference pass/fail criterion is 500, a value that is recommended by OSHA as the pass/fail criterion for a full facepiece respirator. All three protocols exceeded the ANSI recommendation for sensitivity. In addition, all three of the new test protocols were highly correlated with the reference fit test method. Correlation coefficients for protocols 1, 2, and 3 were 0.956, 0.988, and 0.982, respectively.

Table Va. Acceptance Criteria for Fit Test Protocol #1
Reference Fit Factor Pass/Fail Criterion = 500
30 Second Exercise Time

	ANSI Requirement	Results for this study	Pass or Fail ANSI requirement
Sensitivity	≥ 0.95	0.97	Pass
Predictive Value of a Pass	≥ 0.95	0.94	Borderline Fail
Specificity	> 0.50	0.98	Pass
Predictive Value of a fail	> 0.50	0.99	Pass
Kappa Statistic	> 0.70	0.94	Pass

Table Vb. Acceptance Criteria for Fit Test Protocol #2
Reference Fit Factor Pass/Fail Criterion = 500
40 Second Exercise Time

	ANSI Requirement	Results for this study	Pass or Fail ANSI requirement
Sensitivity	≥ 0.95	0.97	Pass
Predictive Value of a Pass	≥ 0.95	0.94	Borderline Fail
Specificity	> 0.50	0.98	Pass
Predictive Value of a fail	> 0.50	0.99	Pass
Kappa Statistic	> 0.70	0.94	Pass

DISCUSSION

Three new quantitative fit test protocols were developed for ambient aerosol fit testing with the TSI PortaCount. The first two protocols are equivalent to the existing 8-exercise protocol recommended by OSHA with exception to shorter exercise times of 30 and 40 seconds. The third protocol utilizes a shorter exercise time of 40 seconds with 6-exercises. Protocol #3 is considerably faster and requires half masks and full-facepiece respirators to fit better to pass the test.

Two of the new protocols in this study (protocols 2 & 3) reduced the exercise time from 60 to 40 seconds. This was achieved by reducing the in-facepiece sampling time from 40 to 20 seconds, while keeping ambient sample and purge times unchanged. This study demonstrated that reducing the exercise time from sixty seconds to 40 seconds with the TSI PortaCount had little effect on the ability of

this instrumentation to identify good and poorly fitting respirators. In addition, eliminating the first two exercise maneuvers from the 1998 OSHA protocol in conjunction with doubling of the pass/fail criterion not only provides a significantly faster fit test protocol, but provides a more conservative fit test for quantitative respirator fit testing. Protocol #3 takes advantage of recent findings published by NIOSH investigators who identified the three most challenging exercises during quantitative fit testing to be talking, moving the head up and down, and bending at the waist (Zhuang, Coffey, Lawrence, 2004). NIOSH researchers have also proposed faster fit testing protocols. For example, Campbell has proposed reducing the sampling time in combination with a new exercise regime and multi donning procedure (Campbell, 2005). Our new protocol #3 eliminates the first two less challenging exercises, thus putting greater emphasis on the more challenging exercises. Since reducing the in-facepiece sampling time from 40 to 20 seconds has no significant effect, a considerably faster and more conservative fit test can be achieved.

Table Vc. Acceptance Criteria for Fit Test Protocol #3

Reference Fit Factor Pass/Fail Criterion = 500

6 Exercises, 40 Second Exercise Time, Pass/Fail = 2 x OSHA Requirement = 1000

	ANSI Requirement	Results for this study	Pass or Fail ANSI requirement
Sensitivity	≥ 0.95	1.00	Pass
Predictive Value of a Pass	≥ 0.95	1.00	Pass
Specificity	> 0.50	0.84	Pass
Predictive Value of a fail	> 0.50	0.92	Pass
Kappa Statistic	> 0.70	0.87	Pass

There is no significant body of evidence that identifies the "correct" length of fit test exercises. In the past, one-minute exercises were frequently used without scientific support and ultimately became the basis for OSHA substance specific standards and the current respiratory protection standard. One might speculate the most appropriate exercise time would be related to the methodology used. For example, current ambient aerosol fit test methods (including those used in this study) include purge times to clear the ambient and in-mask sample tubes. If a future technology eliminated the need to purge sample lines the exercise time should theoretically be shortened. This logic suggests exercise time could be instrument specific. Zhuang (2000) compared the standard set of six fit test exercises lasting 8 minutes with quantitative fit factors from a more comprehensive set of 17 exercises lasting 30 minutes. Results from these studies demonstrated that the quantitative fit factors were not significantly different between the two sets of exercises. This confirms this study's conclusion that little information is gained from additional or longer exercises. The most critical aspect of respirator fit testing is to include exercises that are mostly likely to identify leakage. Removing less strenuous exercises will therefore provide a faster and more conservative test to identify acceptably fitting facepieces.

One potential limitation of this study design is also its strength. Calculating fit factors in ten-second intervals required using the same ambient sample measured after a 40-second mask sample. Thus the 10 and 20 second mask samples in this study represent subsets of the same data and are not truly independent measurements. To be truly independent, mask samples of 10 and 20 seconds would need to be separate fit tests with an ambient sample obtained immediately afterwards. However, a truly independent study design also creates a situation where different mask donnings could influence the results. In addition, leaks that are influenced by previous respirator maneuvers could also influence the results. Thus the disadvantage of this study design is also one of its strengths. Obtaining a measurement from the same donning at the same point in time avoids many of the common problems

associated with comparison studies with completely independent tests. While this study design required using an ambient sample measured at the end of 40 seconds to calculate fit factors, ambient concentrations did not vary substantially within the very short length of time needed to conduct a fit test. In fact, ambient concentrations are more likely to vary between fit tests than within fit tests.

Decreasing the length of quantitative fit testing may not initially be well accepted among some members of the respiratory protection community. Understandably, it appears to be a minor inconvenience to request a yearly eight-minute fit test to help identify a poorly fitting respirator that may be worn in a hazardous environment. On the other hand, the time required to fit test large numbers of employees is frequently used as an excuse to ignore fit testing in favor of no fit testing or conducting fit testing using non-validated procedures. This study shows that a shorter 40-second exercise (i.e., 20 second in-facepiece sampling time) with the TSI PortaCount is not statistically different from the same testing equipment with a longer in-facepiece sampling time. The shorter in-facepiece sampling protocol meets and exceeds the validation requirements established in ANSI Z88.10-2001. This research also investigated the concept of voluntarily raising the pass-fail criterion for an alternative protocol (Protocol #3). It has been a long standing observation in our laboratory that a small percentage of half mask respirator wearers with fit factors slightly above 100 may detect some leakage during user seal check procedures. Since user seal check procedures are highly variable with respect to the flow rates generated, breath-hold times, hand pressure (which may alter respirator positioning) and other factors, it is unclear if these findings reflect an inadequate quantitative pass-fail criterion or inherent problems with the user seal check itself. None the less, there is no substantial body of evidence to suggest a pass-fail criterion of 100 is more appropriate than 200 or some other number. Clearly WPF studies have established that a pass-fail criterion of 100 for elastomeric half mask respirators is adequate to recommend an Assigned Protection Factor of 10. Therefore, those who are uncomfortable with the statistically equivalent shorter protocols could voluntarily use a higher pass-fail criterion and still benefit from the time savings. For example, using a pass-fail criterion of 200 increases the sensitivity of protocol number three to 100%. With today's improvements in respirator design and materials it is extremely easy to find elastomeric facepieces that achieve fit factors above 200 on most people. Using the shorter protocol described here in conjunction with a higher pass fail criterion of 200 identified 100% of the currently accepted poorly fitting respirators. The down side would be the rejection of a potentially good fitting respirator, yet this may be a small price to pay for peace of mind.

In summary, two of the three new protocols passed the ANSI Z88.10 criteria for acceptance of a new fit test method. It is hoped that regulators will consider these new protocols as a means to provide faster fit testing. Fit testers who must comply with OSHA requirements should not begin using these new protocols prior to written acceptance by OSHA. The new protocols published here should not be used with any other method of fit testing, since the technologies of other methods differ.

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