

Development of an Abbreviated Qualitative Fit Test Using Bitter Aerosol

Nelson, T.J.^a, L.L. Janssen^b, M.D. Luinenburg^b, H. E. Mullins^b

^a NIHS Inc., 2401 East Mall Ardentown, DE 19810
Email: tjnelson1@comcast.net

^b 3M OH&ESD, St. Paul, MN 55144

ABSTRACT

Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.134 respiratory protection, requires qualitative fit tests (QLFT) to consist of seven, one minute exercises. This procedure is time consuming, and the benefit of the exercise duration is unknown. This study evaluated a bitter (Bitrex™) aerosol fit test with 15 second exercises. The shortened test was compared to a generated aerosol quantitative fit test (QNFT) using one minute exercise times. Results show that the shortened test has a test sensitivity of 0.92. A binary logistic regression analysis revealed a 0.33 probability of passing the Bitrex test with a fit factor of 100 and a 0.20 probability of passing with a fit factor of 50. These probability values are very similar to those of the widely used ambient aerosol QNFT. The 15 second Bitrex protocol sufficiently screens for adequate respirator fit in subjects with level 1 Bitrex taste sensitivity.

Keywords: qualitative fit test, Bitrex™, quantitative fit test, exercise

INTRODUCTION

Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.134, respiratory protection, requires qualitative fit tests (QLFT) to consist of seven, one minute exercises (Respiratory Protection, 2000). This procedure is time consuming, and the benefit of the exercise duration is unknown.

Many fit test procedures have a recommended test time of 30 seconds (Qualitative Fit Testing Protocols Under the Lead Standard 1981, Nelson 1984, American National Standards Institute 2001). ANSI standard Z88.10 (2001) Respirator Fit Testing Methods recommends a 30 second test exercise period (American National Standards Institute 2001). The Canadian respiratory protection standard also recommends a 30 second exercise time (Canadian Standards Association, 2002). Many workplace protection factor studies that were conducted before OSHA issued the revised respirator standard used a 30 second exercise period (Dixon, 1984).

Marsh studied the effect of exercise time comparing a 30 second exercise time to a one minute time (Marsh, 1984). Marsh did not find a significant effect of exercise time on fit test results.

The objective of this study was to determine if a bitter aerosol fit test method using 15 second exercise times gives fit test results that are similar to a generated aerosol QNFT using one minute exercise times. For the results to be similar, the fit of the respirator must not change significantly over time for each fit test exercise, and individuals whose fit is unsatisfactory must respond to the taste of Bitrex™ within the 15 second time period.

METHODS

Forty-three people participated in the study. Twenty people were female, 23 male. All were experienced respirator users.

Four models of elastomeric half facepiece respirators, each in three sizes, were used in the study. These were the 3M 6X00 with part number 2091 P100 filters, 3M 7X00 series with part number 7090 P100 filters (3M, St. Paul MN.), Moldex 800X series with part number 8940 P100 filters (Moldex, Culver City, CA.) and the Survivair 2000 (model B2X0000) series with part number 1050 P100 filters (Survivair, Santa Ana, CA.).

The 3M 7X00 and Survivair 2000 respirators were equipped with a fit test adapter, part numbers 601 and 420025 respectively. One end of the adapter was attached to the respirator and the filter was attached to the other end. A short piece of tubing was threaded through the inhalation valve and attached to the facepiece with a suction cup. The end of the tubing was situated at a point midway between the nose and the mouth.

The 3M 6000 and Moldex 8000 respirators were equipped with fixed probes located midway between the nose and mouth flush with the surface of the respirator. The Moldex respirator was probed just to the left of the midline point since the exhalation valve assembly prevented probe placement directly in the center.

A short piece of plastic tubing was connected to a metal probe on the respirator or adapter. The end of the tube was closed with a rubber septum during the QLFT and connected to a sample line that led to the particle counter during the QNFT.

The generated aerosol testing was performed in a 14.5 cubic meter quantitative fit testing chamber containing a corn oil aerosol. The aerosol was generated with a TSI 9306 six jet atomizer (TSI, St. Paul, MN). The nominal concentration in the chamber was 20 – 30 mg/m³. The aerosol particle size distribution was measured with a TSI Model 3071 Electrostatic Classifier (TSI, St. Paul, MN) used in conjunction with a TSI Model 3022A Condensation Particle Counter (CPC) (TSI, St. Paul, MN). The mass median aerodynamic diameter (MMAD) was approximately 0.5 μ m with a geometric standard deviation (GSD) of 1.6. Particle counts in the chamber (C_o) and inside the respirator facepiece (C_i) were determined with the 3022A CPC.

Particle counts in the chamber were collected in one second intervals for a 15 to 30 second period before and after the QNFT. Particle counts inside the respirator were collected in one second intervals for the 60 second exercise time for each exercise.

The bitter aerosol fit test followed the procedure outlined in the OSHA respirator standard, except that a 15 second exercise period was used (Respiratory Protection, 2000). A small hood was placed over the person's head and shoulders. The ability of a person to taste Bitrex was determined by spraying a taste sensitivity solution with a nebulizer into the hood while the person breathed through the mouth. Taste sensitivity was noted as level 1, 2 or 3. These levels correspond to 10 or less, 11 to 20 or 21 to 30 squeezes of the nebulizer bulb to achieve a taste reaction, respectively. The respirator was put on, the hood redonned and a test solution was sprayed into the hood. The test solution has a taste reaction approximately 100 times stronger than the sensitivity. An initial spray of the test solution corresponding to the sensitivity level (i.e. 10 squeezes for a level 1 sensitivity) was introduced into the hood. Half the number of squeezes of test solution used initially were sprayed into the hood every 30 seconds to replenish the concentration of material lost due to filtration.

Each person passed a Bitrex taste sensitivity screening test before being assigned one of the respirators. Attempts were made to generate both acceptable and unacceptable fits during the course of the study. Subjects were assigned respirators that were expected to fit well based on their Los Alamos National Laboratory panel grid size (Hack, 1978). Poor fits were accomplished by assigning a respirator that was expected to be one or two sizes too small or too large, based on grid size or observation of the subject's facial characteristics.

Experience in this laboratory has shown that people who participate in fit tests on a frequent basis and who are allowed to perform user seal checks, can adjust most respirators to fit well enough to pass a

fit test (Janssen, 2002). For this reason, the subjects were instructed to adjust the facepiece until comfortable but were not permitted to perform a user seal check.

Advisory criteria for evaluating new fit test methods outlined in Annex A2 to ANSI Standard Z88.10-2001 were used (American National Standards Institute, 2001). Sequential QNFT and QLFT were conducted in random order without disturbing the facepiece. Each fit test consisted of seven exercises. The exercises used were normal breathing, deep breathing, turning the head from side to side, moving the head up and down, reading a passage, bending over and a final normal breathing. Exercise duration was 15 seconds for bitter aerosol fit test and 60 seconds for QNFT. The participants were fit tested with one or more different models or sizes of respirator over a several day period.

Based on the long-standing OSHA and ANSI protocols, fit factors were calculated by dividing the average fractional penetration for the fit test into one. The average fractional penetration was calculated by dividing the average count inside the respirator (C_i) by the average chamber concentration (C_o). The average C_i count was determined by averaging the one second particle counts for each 60 second exercise time. Fractional penetration values for the individual 60 second exercise times were then averaged. The average C_o count was determined by averaging the particle counts in the chamber before and after each fit test. In the same manner, a 15 second fit factor was determined using the particle count for the first 15 seconds of each exercise period.

A required fit factor of 100 was used (Respiratory Protection, 2000). The fit factor for a single person with a fit factor near the required fit factor was measured five times without removing or disturbing the respirator to determine the variability of the fit factor measurement.

RESULTS

Only people who were able to taste the Bitrex within ten squeezes of the nebulizer bulb (level 1 sensitivity) were included in the data analysis. For people with level 2 and 3 sensitivities, the time required to replenish the initial concentration of the Bitrex was 10 to 20 seconds. Since the exercise time was 15 seconds, it was difficult to complete the replenishing during a single exercise. In addition, one person with a level 2 sensitivity failed to respond to the taste of Bitrex with fit factors less than 100. For these reasons, the bitter aerosol fit test with 15 second exercises is only practical with people who have a level 1 sensitivity.

A total of 172 paired tests for people with level 1 sensitivity were conducted. The fit factors (including those who passed and failed the QLFT) ranged from 3 to 96,300. Figure 1 shows the distribution of the fit factors. Fifty-four fit factors were less than the required fit factors of 100 and 118 were greater. Fit factors calculated for the first 15 seconds of the generated aerosol test ranged from 3 to 113,000. Three electronic fit test records were corrupted and 15 second fit factors could not be calculated for these tests. The 60 and 15 second fit factors are significantly correlated with an r^2 value of 0.97. The correlation is shown in Figure 2.

Repeated fit test measurements on a single individual had a mean fit factor of 172 with a standard deviation of 14. Five fit factors within one standard deviation of the required fit factor of 100 (86 to 114) were excluded from the data analysis as recommended by ANSI Z88.10.

The 15 second fit factor was greater than the 60 second fit factor 87 times. The 60 second fit factor was greater than the 15 second fit factor 63 times. In four cases, the difference in fit factor would have led to a different decision on the acceptability of the respirator fit. Two times the 15 second fit factor was below 100 while the 60 second factor was above 100. The reverse occurred twice. The differences in these fit factors were small. For example, in one case the 60 second fit factor was 117 and the 15 second fit factor was 99.

Test statistics calculated using a two by two contingency table as recommended by ANSI Z88.10 are shown in Table I. The test sensitivity of the Bitrex fit test with 15 second exercises is 0.92. This compares favorably with ANSI's recommended sensitivity value of 0.95 for new fit tests. Other statistics also compare favorably with the ANSI recommendations.

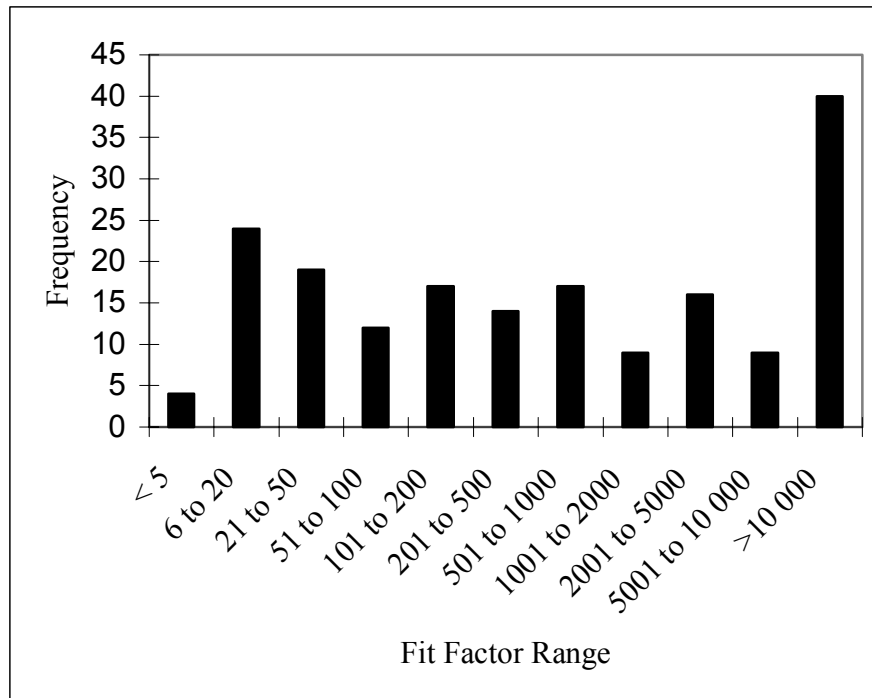


Figure1. Distribution of 60 second fit factors.

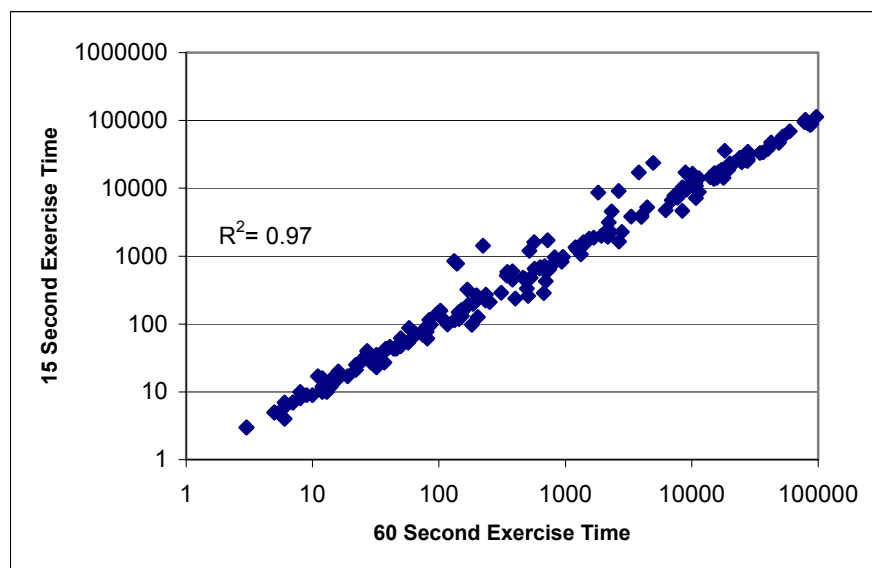


Figure 2. Correlation of fit factors, 60 vs. 15 second exercise times.

Table I. Two by Two Contingency Table and Test Statistics

	Fit Factor <100	Fit Factor >100	Total
Number Pass Candidate Test	A	B	(A + B)
Number Fail Candidate Test	C	D	(C + D)
<u>Statistic (Recommended Value)</u>			
Test Sensitivity (>0.95)	$= C / (A+C)$		
Predictive Value of a Pass (> 0.95)	$= B / (A+B)$		
Test Specificity (> 0.50)	$= B / (B+D)$		
Predictive Value of a Fail (> 0.50)	$= C / (C+D)$		
	Fit Factor <100	Fit Factor >100	Total
Bitrex Pass	4	95	99
Bitrex Fail	48	20	68
Total	52	112	167
<u>Results</u>			
Test Sensitivity	$= 0.92$		
Predictive Value of a Pass	$= 0.96$		
Test Specificity	$= 0.83$		
Predictive Value of a Fail	$= 0.71$		

Nelson (2002) has shown that the data set used to evaluate a fit test can affect the sensitivity calculation and suggested that a binary logistic regression analysis be used to evaluate candidate fit test methods. In this statistical test, a logistic regression analysis is made based on the outcome (pass/fail) at a given fit factor. A binary logistic regression analysis comparing the generated aerosol 60 second exercise time fit factor with the Bitrex fit test using 15 second exercises result shows a 0.33 probability of passing the Bitrex test with a fit factor of 100 and a 0.20 probability of passing with a fit factor of 50. This is shown in Figure 3. These probability values are very similar to those of the widely used ambient aerosol QNFT and the Bitrex method with 60 second exercises shown in Figure 3.

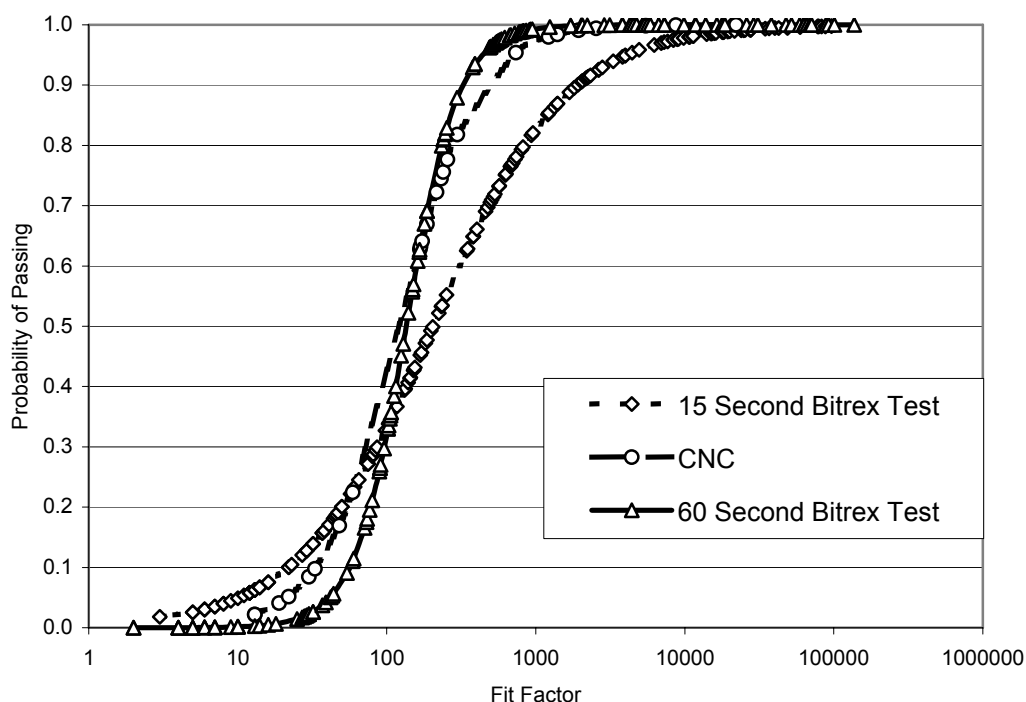


Figure 3. Probability of passing a fit test versus fit factor.

DISCUSSION

The ANSI criteria for accepting new fit tests are advisory and recognize that a reference standard for quantitative fit testing does not exist. Janssen *et. al.* (2002) have suggested that the generated aerosol method be used as the reference method for fit test evaluations since apparently different performances can be found if different methods are used as the standard.

A shortened bitter aerosol fit test method relies on two assumptions: that fit does not significantly change during an exercise and people being tested will respond to the bitter taste of Bitrex in the shorter time period. A comparison of 60 and 15 second exercise times shows that they are highly correlated. This indicates that exercise time does not affect the outcome of a fit test.

In many cases the 15 and 60 second generated aerosol fit factors were different. The reason for the differences can be discerned through examination of the second to second C_i count. In some cases, a leak occurred immediately after the start of the exercise and then the fit returned to a more stable condition. This resulted in a 15 second fit factor that was lower than the 60 second fit factor. In other cases, a leak occurred later in the exercise period, leading to a 60 second fit factor that was less than the 15 second fit factor.

A review of Figure 2 indicates that the variation between the 15 and 60 second exercise times occurs more in the middle of the data rather than at the extremes (fit factors from 100 to 10,000). A moving average is useful to view differences in data, smoothing out variations for individual data points. For low fit factors, a small numerical difference results in a large percent difference. For example, the percent difference between fit factors of six and eight is 33%. A plot of the moving average (10 sets of

data) of the percent difference between the 15 second and 60 second penetrations versus the moving average of the 60 second fit factor is shown in Figure 4. Positive values occur when the 15 second fit factor is greater than the 60 second fit factor.

The variation between the two exercise times is less at the extremes (either high or low penetration). This indicates that fit factors less than 100 or greater than ~ 6000 do not vary greatly over the 60 second time period measured in this study. In other words, those failing the Bitrex QLFT should have failed and those who pass should have passed.

A comparison of the result of the bitter aerosol fit test to the 60 second generated aerosol fit factor shows that the test sensitivity is 0.92. The ANSI recommendation is a value of 0.95 or higher. The difference between a sensitivity of 0.92 and a value greater than 0.95 in this comparison is one fit test where a person with a generated aerosol fit factor less than 100 passed the bitter aerosol fit test.

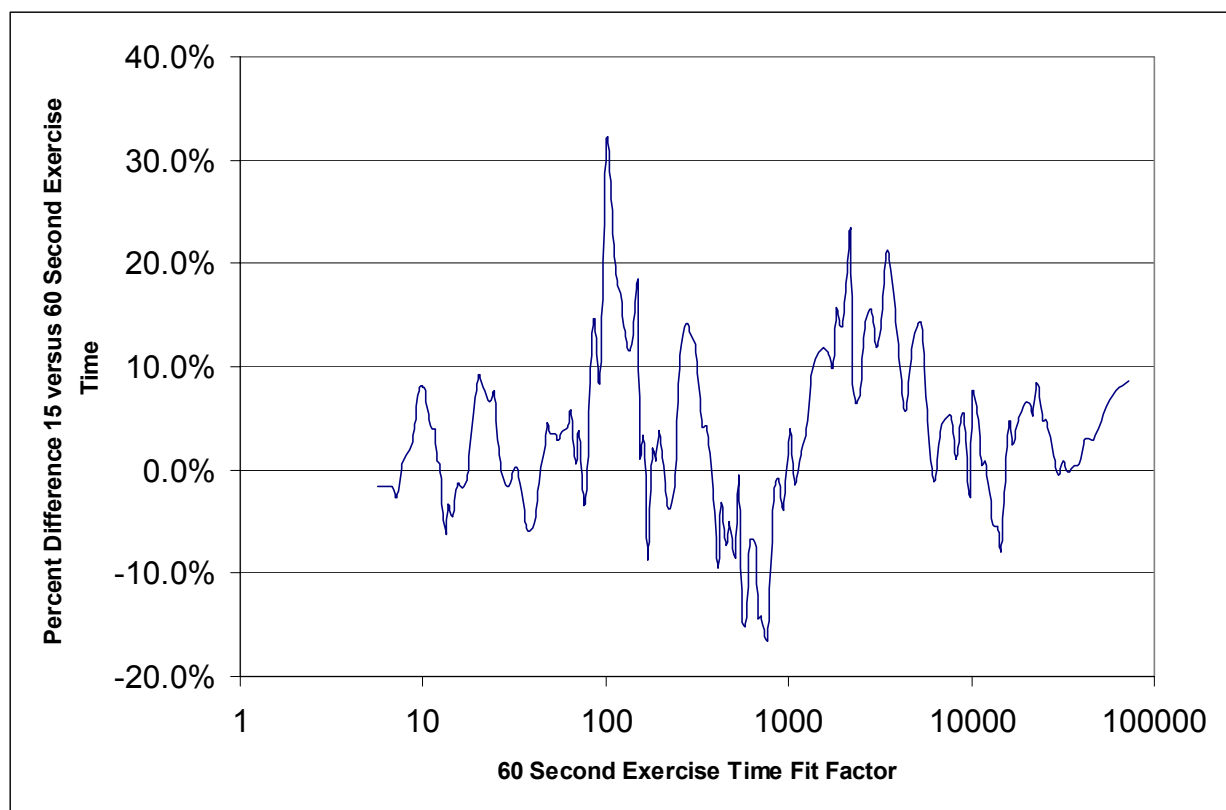


Figure 4. Moving average percent difference in penetration of 15 vs. 60 second exercise versus moving average of the 60 second exercise time fit factor.

Nelson (2002) has shown that the set of data used in an evaluation of a fit test method can affect the apparent ANSI recommended test statistics. Therefore a sensitivity calculation may not be the best indicator of fit test method performance. The binary logistic regression analysis shows that the result of the 15 second exercise time test is very similar to the ambient aerosol and 60 second bitter aerosol tests.

CONCLUSIONS

A bitter aerosol qualitative fit test with a 15 second exercise time gives comparable results to a 60 second exercise time fit test and an ambient aerosol quantitative test when analyzed by a binary logistic regression analysis. A test sensitivity of 0.92 compares favorably to the recommended value of 0.95 in the advisory criteria of ANSI Z88.10. The 15 second bitter aerosol protocol sufficiently screens for adequate respirator fit in subjects with level 1 Bitrex taste sensitivity.

Cautionary Note - The conclusions regarding the performance of the 15 second Bitrex test are the authors', based on their interpretation of the data. Readers are cautioned that this abbreviated fit test may not be substituted for the protocols listed in 29 CFR 1910.134, Appendix A, unless and until the data have been reviewed and formally accepted by OSHA.

REFERENCES

- American National Standards Institute (ANSI). (2001) American National Standard Respirator Fit Testing Methods (ANSI Z 88.10). Fairfax Va.: American Industrial Hygiene Association.
- Canadian Standards Association. (2002) *Selection, Use, and Care of Respirators* (Z94.4-02). Rexdale, Ontario, Canada: Canadian Standards Association.
- Dixon SW and Nelson TJ. (1984). Workplace Protection Factors for Negative Pressure Half-Mask Facepiece Respirators. *J. Int. Soc. Respir. Prot.* 2(4):347-361.
- Hack AL and McConville JT. (1978) Respirator Protection Factors: Part I - Development of an Anthropometric Test Panel. *Am. Ind. Hyg. Assoc. J.*, 39:570-578.
- Janssen LL, Luinenburg MD, Mullins HE, and Nelson TJ. (2002) Comparison of three commercially available fit-test methods. *Am. Ind. Hyg. Assoc. J.*, 63 (6) 762-767.
- Marsh JL. (1984) Evaluation of irritant smoke qualitative fitting test for respirators. *Am. Ind. Hyg. Assoc. J.* 45(4) 245-24.
- Mullins HE, Danisch SG and Johnston AR . (1995) Development of a new qualitative test for fit testing respirators. *Am. Ind. Hyg. Assoc. J.* 56(11):1068-1073.
- Nelson TJ, Skredtvedt OT, Loschiavo JL and Dixon SW. (1984). Development of an improved qualitative fit test using isoamyl acetate. *J. Int. Soc. Respir. Prot.* 2(2):225-248.
- Nelson TJ and Mullins HE. (2002) A Recommendation for Acceptance Criteria for Fit Tests Paper presented at the American Industrial Hygiene Conference and Exposition, San Diego CA. 1-6 June 2002.
- "Qualitative Fit Testing Protocols Under the Lead Standard" (Posthearing Data Submission, Docket No. H-049A). 3M, Box 33275, Building 275-6W-01, St. Paul, MN 55144, Oct 23, 1981.
- Respiratory Protection, *Code of Federal Regulations* 29, CFR 1910.134. 2000. pp. 402-427.