

An Examination of Issues Affecting the Current State of Quantitative Respirator Fit Testing

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Abstract

The consensus standard method for quantitative respirator fit testing, which is based on aerosol generation and measurement, has been in use for more than 20 years. Experimental evidence that validates the basic assumptions underlying the aerosol method has not been produced during this period. The value added to fit tests by inclusion of elaborate exercise protocols has also not been determined. The importance of method validation is substantially increased by the fact that aerosol fit-test systems cannot be directly calibrated. In the absence of a demonstrated correlation between measured fit factors and workplace protection factors, the meaning that can be attached to current standard respirator fit measurements seems to be based primarily upon assumption.

Much of the fit-test research that has been reported in recent years documents a significant number of problems associated with the current standard method. A list of recognized problems is presented. When the substantiated positive and negative aspects of the standard method are considered in concert, the current state of the art in respirator fit testing is open to serious question. The fact that the consensus standard method has been used as the validation source for other test methods, such as qualitative fit-test procedures, gives even more cause for concern.

A set of characteristics for an idealized method for quantitative respirator fit testing is outlined. These characteristics are compared to the capabilities of a new quantitative respirator fit-test method based on controlled negative pressure. The new technique eliminates most of the problems that limit the capability and widespread use of the current standard method. It also does not require an invasive probe, so that a worker's assigned respirator can be fit tested. The controlled negative-pressure technique has exhibited significant advantages over the current standard method in terms of simplicity, test speed, precision, portability, and training effectiveness.

Introduction

Testing the fit of respirators used to protect the health of workers is a fundamental part of a comprehensive respiratory protection program. Quantitative respirator fit testing (QNFT) provides an objective basis for selecting the best fitting respirator for an individual worker, and can play an important role in worker training. However, the majority of respirators provided to American workers are not issued on the basis of QNFT. Although the purpose of QNFT is to provide information for respirator selection and fit, which directly impacts the degree of protection achieved when respirators are worn in the workplace, the need for and credibility of QNFT methods have not been universally accepted. This paper examines some issues that affect the current state and use of quantitative respirator fit testing. It also compares and contrasts standard QNFT methods with more recently developed techniques based on the use of ambient aerosol and controlled negative pressure.

Basic Method

The basic QNFT methodology was developed and reported approximately 30 years ago (Burgess, 1961; Adley, 1962). The basic technique consists of measuring the concentration of a challenge agent both outside and inside a probed respirator. The ratio of outside and in-mask concentrations represents an indirect measurement of test agent leakage, or penetration, into the respirator. The measured ratio is used to express the fit of a respirator on a wearer's face. Ratios developed from integrated samples collected under actual work conditions can be used to express respirator protection factors (Myers, 1983).

for more than 20 years. Commercial QNFT systems have historically been based upon the use of aerosol challenge agents and optical detection systems, due in large part to the wide detection range associated with such detectors. The basic aerosol methodology has been used to develop assigned protection factors for respirator classes (ANSI, 1980). It has also defined the regulatory and consensus standard procedures for quantifying respirator fit (ANSI, 1989; Code of Federal Regulations, 1986). The validation of qualitative fit-test protocols is also based upon aerosol fit test results (Marsh, 1984; Hardis, 1983).

Various forms of the basic approach to QNFT have been used to a limited degree

Basic Assumptions

The standard aerosol QNFT methodology is based upon some fundamental assumptions. These assumptions include: 1) aerosol fit test results can be generally applied to all contaminant classes; 2)

aerosol samples taken inside the respirator are representative of actual respiratory-system exposures; and 3) exercise protocols incorporated into fit tests make them more representative, and therefore

more predictive, of respirator performance in the workplace. Although these assumptions are basic to the standard aerosol methodology, little scientific evidence supporting their validity can be found in the literature. To the contrary, a substantial portion of the published research on measuring respirator fit and performance has raised some serious questions regarding the validity of aerosol system results (Brown, 1992; Chen, 1992). These assumptions and questions need to be examined in more detail.

The ratio of outside and in-mask aerosol concentrations measured during a fit test is assumed to be representative of the general contaminant removal effi-

ciency of the respirator system. The validity of that assumption depends upon the relative leak penetration abilities of test agents and workplace contaminants. Research results and intuition both indicate that substantial variation in penetration occurs as a function of contaminant state and aerodynamic properties (Myers, 1986; Hinds, 1987; Holton, 1987). Fit-test results are also strongly influenced by the characteristics of the challenge agent used to conduct the test. A universal protocol for adjusting QNFT results for application to actual workplace contaminants whose aerodynamic properties can differ significantly from the test challenge aerosol does not currently exist.

Quality of In-Mask Samples

A second major assumption underlying the aerosol QNFT method involves the quality of the samples used to express aerosol penetration into the respirator. The aerosol method is based on an assumption that the in-mask sample is representative of actual contaminant insult to the respiratory system. Verification of this assumption would involve documenting a consistent relationship between 1) the infiltration of known volumes of air containing a known aerosol concentration and 2) the concentration of aerosol actually measured inside the respirator as it is worn by a subject. The in-mask sampling efficiency of aerosol systems has not been fully described nor validated.

Although respirator leakage is the desired measurement parameter during QNFT, the leak measurement capability of aerosol systems has not been substantiated on human subjects through comparison with a primary leak-flow measure-

ment system. A number of studies have documented factors such as leak location, sample probe location, sample flow rate, aerosol streamlining, and lung deposition, which significantly bias in-mask sample results (Myers, 1986; Hinds, 1987; Holton, 1987a; Holton, 1987b; Hinds, 1988; Oestenstad, 1990a, Oestenstad, 1990b; Bollinger, 1987; Carpenter, 1988; Xu, 1991). Comparisons of respirator leakage measured by either generated or ambient aerosol systems with leakage measurements made with negative-pressure systems have demonstrated that aerosol systems tend to underestimate air leakage into respirators by up to an order of magnitude (Crutchfield, 1992a; Crutchfield, 1993).

Fit-test measurements produced by aerosol systems have historically exhibited a great deal of variability (ANSI, 1989; Myers, 1986; Crutchfield, 1992a; Crutchfield, 1993; da Roza, 1983; Harris, 1990). Coefficients of variation exceeding

Table 1. Sources (Unranked) that contribute to the variability associated with aerosol respirator fit-test systems.

Size variation of aerosol challenge agents
Spatial and temporal non-uniformity of challenge agent concentrations
Size-dependent aerosol penetration through respirator leaks
Aerosol losses during penetration
Individual differences in respiration patterns
Individual differences in interpretation and execution of fit test protocols
Nose vs mouth breathing
Variable ratio of aerosol sample flow rate to breathing rate
Location and depth of aerosol sampling probe
Differential aerosol losses in chamber and mask sample lines
Incomplete mixing of aerosol in respirator volume
Streamlining of aerosol into respiratory system
Differential deposition and retention of aerosol in the lungs
Size-dependent photometric response
Temporal degradation of photometric optics and dark current caused by aerosol deposition
Time and expertise dependence of manual data reduction

100% are not uncommon. Potential sources of error that can contribute to aerosol test variability are listed in Table 1. The lack of precision associated with the aerosol QNFT method has raised doubts about its ability to determine which of two or more different brands or sizes of respirators actually provides the best fit for a specific worker (ANSI, 1988). Such determinations should be the primary purpose for conducting quantitative respirator fit testing.

The magnitude of variation exhibited by aerosol systems may require multiple repetitions of QNFT tests, with a subsequent selection of the most conservative result. It seems apparent that the extended time required to complete multiple tests could be a significant disincentive for industry to conduct quantitative fit testing. Limitations of the current standard method should not dictate such a course of events if other viable options are available.

Fit-Test Exercises

A third QNFT assumption involves fit-test exercises. The standard protocol for conducting quantitative respirator fit tests includes a series of test exercises designed to represent anticipated worker movements. The basic assumption is that, during these exercises, the respirator face seal will be compromised to some degree, thereby producing a lower fit factor. While this assumption seems logical, it has also not been validated.

The fundamental or basic fit of a respirator on a worker's face is best described by the normal breathing fit factor.

The remaining exercise fit factors presumably describe any alteration of fit caused by the head or facial movements dictated by the exercise. Analysis of some of the limited number of complete fit-test data sets that have been reported indicates that there is generally no significant difference between the first normal breathing (NB1) fit factor and the remaining exercise fit factors.

An analysis of log-transformed fit-factor data sets from several sources reporting individual exercise fit factors are presented in Tables 2–4 (Crutchfield,

Table 2. Comparison of log-transformed exercise fit factors to the first normal breathing (NB1) fit factor from various generated aerosol fit-test data sources.

Data Source ^a	Test Condition	Fit Test Exercise					Factor Analysis ^b
		DB	SS	UD	TALK	NB	
#26	NIL ^c	—	—	—	—	—	96%
#27	Photometer	>*	—	—	—	—	86%
	CNC	>*	—	—	—	—	80%
#21	NIL	—	—	—	—	—	94%
#28	Half-Mask, NIL	—	—	—	—	—	91%
	Half-Mask, IL ^d	>*	>*	—	>*	>*	94%
	Full-Face, NIL	—	—	—	—	—	96%
	Full-Face, IL	—	—	—	>*	>*	94%

^a Data from listed reference number

^b Percent of total test variation explained by NB1 fit test alone

^c NIL = No induced leakage

^d IL = Induced leakage

— = Not significantly different from NB1 fit factor at 0.05 level of significance

> = Greater than NB1 fit factor

< = Less than NB1 fit factor

* = Significantly different from NB1 fit factor at 0.05 level of significance

Table 3. Comparison of log-transformed exercise fit factors to the first normal breathing (NB1) fit factor from various ambient aerosol fit-test data sources.

Data Source ^a	Test Condition	Fit Test Exercise					Factor Analysis ^b
		DB	SS	UD	TALK	NB	
#26	NIL ^c	—	—	—	<*	—	87%
#27	NIL	—	—	—	<*	<*	89%
#29	NIL	N/A	>*	>*	N/A	>*	70%
#22	NIL	>*	>*	>*	<*	>*	81%
	IL ^d	>*	—	—	<*	—	84%

^a Data from listed reference number^b Percent of total test variation explained by NB1 fit test alone^c NIL = No induced leakage^d IL = Induced leakage

N/A = No fit factor reported for this exercise

— = Not significantly different from NB1 fit factor at 0.05 level of significance

> = Greater than NB1 fit factor

< = Less than NB1 fit factor

* = Significantly different from NB1 fit factor at 0.05 level of significance

Table 4. Comparison of log-transformed exercise fit factors to the first normal breathing (NB1) fit factor from various controlled negative-pressure fit-test data sources.

Data Source ^a	Test Condition	Fit Test Exercise					Factor Analysis ^b
		SL	SR	UP	DOWN	NB	
#29	NIL ^c	—	—	—	—	—	75%
#28	Half-Mask, NIL	—	—	—	—	—	82%
	Half-Mask, IL ^d	—	>*	>*	<*	>*	89%
	Full-Face, NIL	—	—	—	—	—	87%
	Full-Face, IL	—	>*	>*	—	>*	93%
#22	N I L	—	—	—	—	—	65%
	IL	—	—	—	—	—	93%

^a Data from listed reference number^b Percent of total test variation explained by NB1 fit test alone^c NIL = No induced leakage^d IL = Induced leakage

— = Not significantly different from NB1 fit factor at 0.05 level of significance

> = Greater than NB1 fit factor

< = Less than NB1 fit factor

* = Significantly different from NB1 fit factor at 0.05 level of significance

1992a; Crutchfield, 1992b; Rose, 1990; da Roza, 1991; Crutchfield, 1993a; Graffeo, 1992). Fit-test systems used to measure the data sets include generated aerosol, ambient aerosol, and controlled negative pressure QNFT systems. Student's t-test for paired data was used to compare NB1 fit factors with their corresponding exercise fit factors (Dowdy, 1983). A significance level of 0.05 was used to identify mean exercise fit factors that differed significantly from the mean NB1 fit factor. A factor analysis was also performed to estimate the percentage of total variation in measured fit in each exercise data set that could be explained by the NB1 fit factor alone.

As seen in Tables 2–4, statistically significant differences between individual exercise fit factors appear to be the exception rather than the rule. Of 98 individual exercise data sets analyzed, 26 were significantly different from their corresponding NB1 fit factor. Only six of the 26 significantly different exercise data sets contained mean exercise fit factors that were less than the corresponding NB1 fit factor. In the other 20 cases, the exercises produced mean fit factors higher than the NB1 fit factor. This finding is contrary to the anticipated effect of fit-test exercises.

It is interesting to note that in five of the six cases tested with mean exercise fit factors less than the NB1 fit factor, the talking exercise was involved. At first

glance, this observation seems consistent since reading the rainbow passage involves substantial movement of the mouth, which can stress the facepiece-to-face seal. However, talking occurs only during periods of exhalation when the respirator is positively pressurized. Aerosol penetration into respirators occurs primarily during inhalation. Therefore the significant increase in aerosol penetration reported during the talking exercise may be related more to improved aerosol mixing in the mask during talking (which involves an extended, modulated exhalation) than to an actual increase in aerosol penetration during inhalation. A significant decrease in measured fit factor relative to the normal breathing fit factor was reported by an ambient aerosol system when exhalations were extended and slightly modulated with no head or facial movements involved (Crutchfield, 1992a). There was no apparent source for the significant increase in respirator leakage reported by the aerosol system.

Based upon results of both t-test and factor analysis of the data sets, it seems evident that a substantial majority of the information derived from the fit-test data sets could be gained from the NB1 fit factors alone. While the exercise protocols required a lot of time to complete, and generated a lot of additional numbers, the actual value they added to the fit test was quite limited.

Fit Factors vs Protection Factors

It is logical to assume that a better fitting respirator will generally provide a higher degree of respiratory protection to a worker than one that fits less well. If this assumption is true, it follows that a strong relationship should exist between

measured respirator fit and measured respirator protection. Although it is difficult to imagine conditions in which such a relationship would not hold for properly worn respirators, a strong correlation between fit factors and protection factors

has not been demonstrated in any workplace protection factor studies reported to date (Dixon, 1984; Lenhart, 1984; Myers, 1984a; Myers, 1984b; Willeke, 1990). In general, measured fit factors tend to greatly exceed measured protection factors. The degree to which the disparity is related to measurement system constraints has been difficult to determine.

The highest correlation that has been observed by the authors between measured respirator fit and measured respirator protection was generated during a pilot study of respirator protection measurement by vapor breath analysis (Decker, 1992). A moderate correlation ($r = 0.82$) was found between fit factors measured with a controlled negative pressure system and protection factors measured by the breath-analysis technique. It is interesting to note that neither system relied upon in-mask sample extraction to determine respirator fit or protection. A simultaneous vapor sample collected from the test respirator probe during the exposure period was poorly

correlated with both measurements.

Perhaps it should not be surprising that the relationship between measured respirator fit and performance has not been established with any degree of clarity by workplace protection factor studies. It seems apparent that aerosol systems have generally failed to demonstrate the degree of measurement precision that may be required to clearly define that relationship.

When viewed in aggregate, the evidence supporting the recognized QNFT standard method appears to be both scant and poorly substantiated. By contrast, the research results that have been reported with increasing frequency during recent years document a wide array of variables that significantly impact the aerosol method's capability to generate reliable data. Generated aerosol technology represents our initial capability to quantify respirator fit. However, it is difficult to clearly interpret over 20 years of data collected with that technology.

Currently Available Alternatives

Problem recognition and definition are the first essential steps toward problem resolution. Given the documented problems associated with the current standard QNFT method, one possible approach toward solution would be to resolve recognized problems through system improvements. The condensation nucleus counter (CNC) technique represents an available exercise of this option (Willeke, 1981; Laye, 1987). It appears to have generally resolved the problems associated with aerosol generation and potential subject exposure to challenge agents. However, evidence is not generally available to

indicate that the CNC technique has resolved a significant number of the sampling problems associated with the current standard method.

As with the generated aerosol method, the CNC technology has not been fundamentally validated. It also suffers from the same limitations regarding direct system calibration. Significant variation has been observed in the response of multiple CNC instruments set up to simultaneously sample the same room air (Hackworth, 1987; Loebach, 1989). In addition, problems related to differential

aerosol penetration through respirator leak sites, as well as the range of in-mask sampling problems already identified, still persist. Additional problems of subject-generated aerosols and relatively low ambient aerosol concentrations conspire to substantially reduce the overall sensitivity of the CNC detection system for respirator fit testing (da Roza, 1991). Comparison of a CNC system with a standard generated-aerosol system raised questions about the reliability of CNC fit factors greater than 1000 when ambient aerosol was used as the challenge agent (da Roza, 1991).

The CNC method generally requires the use of a surrogate probed respirator, and still appears to generate highly variable fit factors (Harris, 1990; Rose, 1990;

da Roza, 1991; Graffeo, 1992). Attempts to resolve in-mask sampling problems by changing probe location and depth, or by pulse-sampling inhalation or exhalation streams, can at best yield only a small sample of the total flow of air and aerosol through the respirator system. The net effect of in-mask sampling biases is to under-sample aerosol penetration, and consequently over-estimate respirator fit. During a comparison study of commercially available ambient aerosol and controlled negative-pressure systems, the CNC system exhibited a sampling efficiency of less than 30% for known air leakage introduced into subject respirators (Crutchfield, 1992a). The negative-pressure system's measurement of the known leakage was consistently close to 100%.

Controlled Negative Pressure Method

An obvious need in the QNFT area is for a system that can determine a respirator fit that is 1) meaningful, 2) validated, and 3) precise enough to allow determination of the best-fitting respirator for a specific worker. An ideal system would meet as many of the ideal system characteristics listed in Table 5 as possible.

A new QNFT method based on the use of controlled negative pressure (CNP) has been developed (Crutchfield, 1991a; Crutchfield, 1991b). The technique is not subject to the in-mask sampling problems and sources of variation that characterize current aerosol system biases. The CNP method is based on exhausting air from a temporarily sealed respirator facepiece. The rate of air exhaust is controlled to generate and then maintain a constant negative pressure inside the facepiece. The constant negative pressure is pre-selected to replicate the mean inspiratory pressure that causes leakage into the

respirator under normal use conditions. Measurement of the exhaust stream yields an air-flow rate that is directly equivalent to the leakage-flow rate into the respirator.

The CNP technique is not based on pressure decay, and is consequently independent of the complexities associated with that method (Carpenter, 1988). CNP is independent of respirator volume, and is not affected by mask pliability, or the laminar vs turbulent nature of leakage flow into the respirator. Another advantage of the CNP technique is that it is conducted at a constant respirator pressure that is selected to replicate the inspiratory pressure that pulls leakage air into the respirator during normal wear.

Air represents one of the most rigorous, and therefore most conservative, fit test challenge agents that can be used. Air molecules are not subject to the variations

Table 5. Characteristics of an ideal quantitative respirator fit test system.

System should use the most rigorous and consistent agent possible to challenge respirator fit

System should be easy to use and maintain

System should generate fit-test results that are meaningfully related to the fundamental parameter of interest

System should be capable of testing a worker's actual mask

System should pose no increased exposure risk during test

System should be independent of variables related to air quality outside of the respirator during test

System should demonstrate sufficient measurement precision and repeatability to allow a confident selection of the best-fitting respirator for a specific worker

System should be field portable so that workers can be tested close to their work stations

System should be capable of quickly determining the fit of a worker's respirator as it is actually worn in the workplace

System should have sufficient speed and sensitivity to serve as a training aid for demonstrating the effects of respirator donning and wear on fit

System should be capable of being calibrated in the field

System should provide a fast, accurate, and cost-effective means of determining the best-fitting respirator for a worker

in size distribution or concentration that have been shown to affect aerosol test agents. They therefore represent an absolute challenge standard that can go where aerosols may not, without being affected by penetration losses. If air molecules can leak into a worker's respirator, contaminant (particulate or gaseous) leakage is a possibility. Contaminant leakage does not occur in the absence of air leakage. The preceding statement cannot be universally applied to aerosol challenge agents.

Since static pressure in ambient air equilibrates at sonic velocity, the CNP technique does not require an invasive sampling probe through the respirator

facepiece. Pressure equilibration is also independent of air-aerosol mixing rates in the respirator. Mask leakage rates are measured directly while mask pressures are held constant at levels selected to replicate inspiratory pressure during normal respirator use (Crutchfield, 1993b). The use of pressure as a transducer medium essentially eliminates in-mask sampling bias, which appears to be the largest and most formidable problem associated with aerosol systems. The measurement of differential pressure is a well defined art wherein response times of 1 ms and accuracies of 1% are readily achieved. Calibrated flow rates within 2% of primary flow standards have also been

demonstrated in a commercial CNP system (Dynatech Nevada, 1991).

The CNP method represents a defined technology that can rapidly and accurately measure air leakage paths into a respirator (Crutchfield, 1992a; Crutchfield, 1993a). Its elimination of systematic variation associated with surrogate respirator use, differential aerosol penetration losses, incomplete aerosol mixing, limited in-mask sample volumes, and photometric variation provides a means of precisely determining actual respirator leakage.

Initial verbal opposition to the CNP concept has been focused on the assumption that it is not representative of the real world since 1) individual CNP fit tests are conducted for only about 10 s, while the subject holds his/her breath, and 2) dynamic exercise protocols such as reading the rainbow passage cannot be

accomplished while measuring respirator leakage with the CNP method. The CNP technique has demonstrated that it can quickly measure, with substantially greater precision, the fundamental fit of a respirator when it is donned by a subject (Crutchfield, 1992a; Crutchfield, 1992b; Crutchfield, 1993a; Graffeo, 1992). The inherent simplicity, sensitivity and precision of the CNP method can also quickly determine how well a respirator reseals on the wearer's face following any form or level of vigorous exercise. This degree of respirator-fit information may well represent the majority of information that is needed to quickly and accurately select the best possible respirator for each individual worker.

The CNP technique has also proven to be a powerful training tool for demonstrating, on a real-time basis, the relationship between how a respirator is worn and the amount of air that can leak into it.

Summary

It seems evident that, despite its 20-year history, the current standard method for conducting quantitative respirator fit tests has left unanswered a number of fundamental questions regarding how well respirators fit workers, and how much protection is actually achieved with their use. Despite an obvious need, the percentage of American workers whose respirator issue and wear is based upon quantitative respirator fit-test results remains low. Some primary reasons for this situation are related directly to known problems associated with the generated aerosol technology upon which the current standard method is based. Simply stated, the current consensus standard method is too costly, too cumbersome, too complex, and too time consuming. Even when these shortcomings are

surmounted, the outcome is too often a numerical result that fails to provide a valid measure of respirator fit.

The field of quantitative respirator fit testing has entered a recent state of flux. New approaches have been developed that address some or all of the problems that beset the current standard method. The challenge currently before the professional bodies that represent the respirator supplier, user, and regulatory communities seems clear. Rather than merely acknowledge current problems and perpetuate current technological limitations, it is time to acknowledge and examine alternative approaches that seem to yield fundamental measures upon which a meaningful standard can be based with confidence.

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