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PERFORMANCE OF FACESEAL FIT TESTS FOR RESPIRATORY PROTECTION PROGRAMS

NELSON A. LEIDEL

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This thesis has been read and approved by:

Thomas J. Smith, Ph.D.

David G. Jansson, Sc.D.

Henry A. Feldman, M.D.

PREFACE

This thesis consists of a technical report with appendices and two manuscripts to be submitted to the American Industrial Hygiene Association Journal for publication. Both of the manuscripts were coauthored by my doctoral advisor, Professor William Burgess. The research was supported by the National Institute for Occupational Safety and Health (NIOSH) with facilities provided by the Harvard School of Public Health and the Boston Fire Department.

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ABSTRACT

The use of respirators is an important method for controlling worker exposure to airborne contaminants in the occupational environment. The attainment and continued assurance of a high degree of protection for workers by means of respiratory protection programs is a challenging and difficult task. A vital element of these programs is the faceseal fit test used to screen out those employees who have inadequate fits so that other means of health protection can be provided. Respirator specialists have developed a limited number of qualitative and quantitative fitting tests to estimate the protection given respirator wearers. Most respiratory protection specialists maintain that the inexpensive qualitative tests do an adequate job. However, the statistical performance of the available qualitative and quantitative fit tests has not been previously examined to insure that the tests effectively screen out wearers with poorly fitting respirators.

Where faceseal fit tests are used in respiratory protection programs, the qualitative tests are in the vast majority. The main objective of this investigation was to evaluate the impact of both qualitative and quantitative fit tests on the reliability of programs in which negative pressure respirators are used. The subjective responses of respirator wearers to four commonly used qualitative fit tests were determined by means of a field study. The study group consisted of firefighters from the Boston Fire Department. This was done for the following tests, used individually and in three combinations: negative pressure, positive pressure, isoamyl acetate, and irritant smoke. It was demonstrated that the probit-transform of the proportion of wearers responding to any of the seven qualitative fit tests was a linear function of $\log_{10}$(average leakage), which was measured with quantitative fit test equipment. The response functions were estimated over a range of 0.03% to 50% mask leakage, which was measured as average leakage of polydisperse dioctyl phthalate.

Based on summary data published in the literature, distributions were developed describing the quantitative range of leakages found in several industrial user populations. These distributions are presented for 17 respirators in 3 classes of negative pressure devices: air-purifying halfmasks, air-purifying fullface masks, and self-contained breathing apparatus (SCBA) operated in the demand mode. The distributions are presented as cumulative distributions plotted on lognormal probability paper.

Appropriate statistical parameters for evaluating the performance of qualitative fit tests used as screening tests in respiratory protection programs were developed. These included the alpha-error, beta-error, AER (proportion of accepted employees with inadequate fits), and PAFR (proportion with adequate fits in those rejected by the screening test).

Estimates from the qualitative fit test response functions and leakage cumulative distribution functions, for low and high performance respirators, were used to calculate range estimates of performance statistics for several industrial user populations with three classes of negative pressure respirators. The response function characteristics necessary for an adequate qualitative fit test are discussed. Lastly it was determined, from data available in the literature and by using an analogous situation existing for occupational exposure measurements, that interday variability of faceseal leakage could substantially decrease the effectiveness of respiratory protection programs in which quantitative fit test procedures are used.

It is concluded that there is a very strong probability that currently recommended qualitative fit tests can present a serious health hazard in respiratory protection programs in which negative pressure respirators are used. In addition, these fit tests

create excessive expenses in respiratory protection programs because they incorrectly reject a very high proportion of adequate fits.

When quantitative fit test measurements are performed, multiple measurements should be obtained on different days for each wearer to determine the degree of protection afforded by the intended mask on each wearer. One-sided upper tolerance limits can be calculated for leakage measurements to determine if a wearer can achieve adequate protection on future days.

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INTRODUCTION

The need for respiratory protective devices to be worn by workers exposed to airborne toxic chemicals in the occupational environment has been recognized for many centuries. Modern use of industrial respirators dates from the mid-nineteenth century when practical, efficient filters and sorbents were developed. Modern respirators providing protection against particulates (dusts, fumes, and mists) were not feasible until efficient filters with low breathing resistance became available. Respirators capable of adequate protection against organic vapors and gases became possible with the discovery of the adsorptive properties of activated charcoal in 1854. World War I stimulated major improvements in gas sorbents for respirators.

Technical advances in respirator design[1] in the last 60 years have occurred slowly. Some major developments have been the introduction of relatively efficient, inexpensive filters with low breathing resistance designed for worker protection against low toxicity dusts. High efficiency particulate filters have been developed for protection against high toxicity dust, fumes, and mists. Single-use ("throw-away" or "disposable") respirators have been marketed for protection against low toxicity particulates, vapors, and gases. End-of-life indicators that alert the user to respirator sorbent exhaustion are a very recent development.

[1] Davies, C.N., ed.: Design and Use of Respirators, Proceedings of a Joint Meeting of the Ergonomics Research Society and the British Occupational Hygiene Society. Porton, Great Britain, July 5-6, 1961, Pergamon Press, NY (1962).

The use of industrial respirators is an important method for controlling worker exposure to airborne contaminants in the occupational environment and are in widespread use in American industry. However, estimates of the number of respirators in use and the general exposure levels they protect against are very difficult to obtain. Discussions with respirator specialists yield the following rough estimates of sales and usage for the three major classes of respirators (not including "disposable" types):

Respirator class	Estimated annual sales in 1978	Estimated total number in use in United States (1979)
Air-purifying halfmasks	2,000,000	10,000,000
Air-purifying fullface masks	200,000	1,000,000
Self-contained breathing apparatus (SCBA)	50,000	600,000

Respiratory Protection Programs and Faceseal Fit Tests

The attainment and continued assurance of a high degree of health protection for workers by means of a respiratory protection program is a challenging and difficult task with several critical elements. An adequate respiratory protection program must forge a "chain of protection" involving four major links:

- Select appropriate respirator
- Conduct fitting program
- Conduct training and maintenance program
- Continuing evaluation of respiratory protection effectiveness

Guidelines for the establishment and implementation of a respiratory protection program involving these four elements have been detailed by Pritchard (1). However, the second crucial link requiring an adequate fitting program has received little attention in typical respiratory protection programs. The fit tests used in the fitting program must screen out those employees that cannot achieve adequate fits so that other means of health protection can be provided.

An employer may select an appropriate respirator of excellent design and construction for his employees. But a worker cannot achieve adequate protection unless there is a proper seal or fit between the respirator facepiece sealing surface and the skin of the wearer. The proper fit of the respirator to the wearer's face can be influenced by factors such as the make and model respirator selected, the wearer's facial shape and texture, headstrap tension, minute volume, perspiration, and position of the mask on the face.

Respirator specialists have developed a limited number of fitting tests to aid the employer and user in determining which make and model respirator fits each wearer best and to help train each wearer to recognize when the respirator is worn properly. These fitting tests are classified as qualitative or quantitative. All present qualitative fit tests yield only a subjective response depending on the wearer's variable sensory reactions for detecting excessive leakage. The quantitative fit tests involve the use of a tracer gas or aerosol combined with instrumentation to measure and record the amount of tracer leakage into the air inhaled by the respirator wearer.

Until several years ago, quantitative fit test equipment was available only in research laboratories. But today commercial versions of quantitative fit test systems using the dioctyl phthalate and sodium chloride aerosols are available in several different

models. Unfortunately these systems are rarely used in industrial respiratory protection programs. The relatively high cost of quantitative systems ($6000+) compared to the qualitative fit tests (less than $50) has hindered the acceptance of the quantitative systems by companies for use in routine respiratory protection programs. Many respiratory protection specialists remain convinced that qualitative tests do an adequate job. As a practical matter, the use of quantitative fit test equipment is not a mandatory requirement of federal regulations governing respirator usage in the workplace.

Investigation Objectives

Where fit tests are used in respiratory protection programs, the qualitative fit tests are in the vast majority. In spite of the fact that industrial hygienists continue to rely upon qualitative fit tests and respirator specialists continue to recommend their use, the accuracy of the qualitative fit tests has not been previously questioned and investigated. Are qualitative fit tests reliable procedures for assuring that employees are receiving adequate protection with their respirators? That is, do the qualitative fit tests reliably screen and reject those employees with inadequate fits? Incredibly, the statistical performance of the available qualitative and quantitative fit tests has never been properly examined to insure that the tests satisfactorily screen out wearers with poorly fitting respirators.

In order to evaluate the effectiveness of qualitative fit tests for different classes of respirators, it would be necessary to determine the relationships between mask leakage and the proportions of wearers responding to four commonly used qualitative fit tests. Fit tests are vital to the reliability of respiratory protection programs in

which negative pressure respirators are used. It was decided to estimate the effectiveness of qualitative and quantitative fit tests for the three major classes of negative pressure respirators: air-purifying halfmask, air-purifying fullface, and self-contained breathing apparatus (SCBA) operated in the demand mode. The major objectives of this investigation were established as follows:

1. To determine, by means of a field study of respirator wearers, the subjective responses of wearers to four commonly used qualitative fit tests at measured mask leakages. The tests to be investigated included: negative pressure, positive pressure, isoamyl acetate, and irritant smoke. The evaluation was to be performed over a wide range of mask leakages measured with quantitative fit test equipment. Appropriate response functions were to be developed and used for estimating proportions of respirator wearers responding to the four qualitative fit tests, used individually and in combination, as a function of average mask leakage. A test response was the respirator wearer subjectively detecting excessive mask leakage (negative and positive pressure tests) or detecting the test agent (isoamyl acetate or irritant smoke).

2. To develop, using summary data published in the literature, cumulative distribution functions describing the range of respirator leakages found in several industrial user populations for three classes of negative pressure respirators: air-purifying halfmasks, air-purifying fullface masks, and self-contained breathing apparatus (SCBA) operated in the demand mode. Cumulative distribution functions are graphical relations plotted on lognormal probability paper that indicate the proportion of users achieving mask leakages less than indicated values.

3. To develop appropriate statistical parameters for evaluating the performance of respirator fit screening tests used in respiratory protection programs. These parameters were to be used to estimate the performance of four common qualitative fit tests, used individually or in combination, applied to several industrial user populations. Range estimates for the performance parameters were to be calculated for three classes of negative pressure respirators. Then the response function characteristics necessary for an adequate qualitative fit test were to be determined. Consideration of these necessary characteristics and the range estimates of the performance parameters for existing qualitative tests would allow determination of a possible health hazard due to the use of qualitative fit tests in respiratory protection programs in which negative pressure respirators are used.

4. To determine the effect of leakage measurement repeatability and interday variability of faceseal leakage on the reliability of respiratory protection programs in which quantitative fit test systems are used.

CHAPTER TWO

INDUSTRIAL RESPIRATORS AND RESPIRATOR FIT TESTS

Industrial Respirator Classifications

The function of an industrial respirator is to protect the wearer's respiratory system from harmful airborne physical or chemical agents present in the occupational environment. A respirator is an enclosure that covers the wearer's nose and mouth (masks) or the entire face or head (hoods or helmets).

A respirator acts as a barrier against contaminated air and serves as an enclosure to which air-purifying or atmosphere-supplying elements are attached. Most respirators have tight-fitting coverings called "facepieces." A facepiece is a respirator component designed to provide a gas-tight or dust-tight seal with the face and may include headstraps (typically elastic), valves, viewing windows, and inlet connections for the air-purifying or respirable air source. Facepieces are grouped into three basic configurations related to proportion of face covered by the facepiece. The typical "quarter-mask" shown in Figure 1 covers the mouth and nose with the lower part of the faceseal resting between the chin and mouth. Figure 2 shows a typical "halfmask" that fits over the nose and under the chin. A third type is the "fullface" respirator that covers from the forehead to below the chin as shown in Figure 3.

Air-purifying respirators provide respiratory protection to the wearer by removing the contaminant from the air before it is inhaled. These respirators are classified by the physical nature of the contaminant they are designed to remove from the inhaled

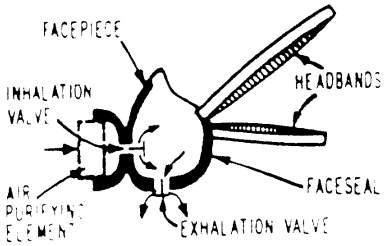


Figure 1
Typical quarter-mask respirator

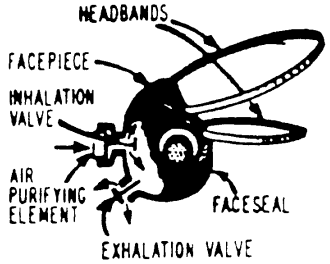


Figure 2
Typical half mask respirator

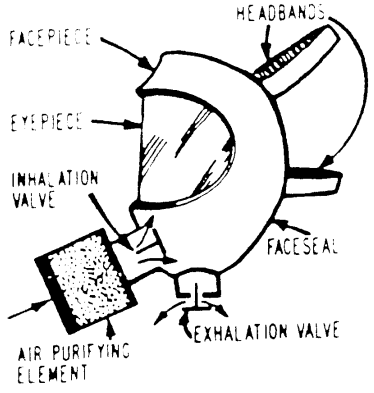


Figure 3
Typical fullface respirator with air-purifying cartridge

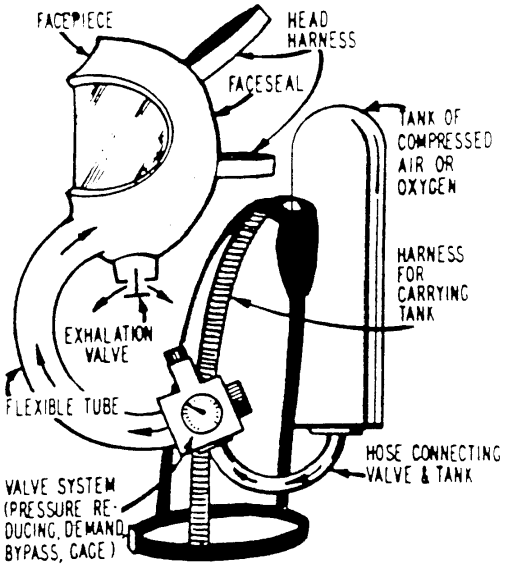


Figure 4
Typical Open-circuit SCBA respirator

air. The first class of air-purifying respirators contains the particulate-removing masks that are generally referred to as "dust," "fume," or "mist" respirators (or combinations thereof). All particulate-removing respirators use a filter element consisting of fibrous material that removes the contaminant from the air before it is inhaled. The second major class of air-purifying respirators consists of vapor- and gas-removing masks. These respirators remove the toxic vapor or gas by interaction of the airborne contaminant molecules with a granular, porous material called the sorbent. The most common sorptive mechanism used in vapor- and gas-removing respirators is adsorption, which retains the contaminant molecule on the surface of the sorbent. Activated charcoal is the most common adsorbent used in these respirator air-purifying elements. Absorption and catalysis are also used as air-purifying mechanisms for contaminant removal. A third class of air-purifying respirator consists of combinations of the previous two classes suitable for atmospheres containing both particulates and gases or vapors.

Air-purifying respirators have the filter/sorbent elements contained in cartridges or canisters. The facepiece mounted cartridges have sorbent volumes of typically 50 to 200 cm^3 with resulting short useful lifetimes. Chin-style canisters have volumes of about 250 to 500 cm^3 (1). The large front- or back-mounted canisters are connected to the facepiece with corrugated, flexible tubes or hoses and have volumes of 1000 to 2000 cm^3 (1). Canister service lives depend primarily on the airborne contaminant concentration and the user's minute volume, and may range from a few minutes up to eight hours.

Most air-purifying respirators are non-powered. That is, they depend on the respirator wearer's lung action to overcome the inhalation resistance of the filter/sorbent element. Under typical use conditions the maximum inhalation

resistances for sorbent cartridges are 0.39 to 0.69 kPa (40 to 70 mm of water) and 0.39 to 0.83 kPa (40 to 85 mm of water) for sorbent canisters. For filters on particulate-removing respirators the typical maximum inhalation resistances range from 0.12 to 0.49 kPa (12 to 50 mm of water).

For inhaled air to overcome the resistance of a filter/sorbent element and flow into the facepiece, the air pressure inside the facepiece must be negative (relative to atmospheric pressure outside the mask), when the wearer inhales. Any respirator that can attain a negative pressure inside the facepiece during inhalation is commonly referred to as a "negative pressure device." Any negative pressure respirator has the potential for inward leakage during inhalation. Since the contaminated air outside the facepiece is at a higher pressure than the purified air inside the facepiece, penetration of contaminated air into the facepiece can occur during negative pressure operating conditions.

Powered air-purifying respirators incorporate a blower that forces contaminated air through the filter/sorbent element and supplies the purified air to the respiratory-inlet covering. The blower may be worn on the respirator wearer or fixed at a stationary location. A major advantage of the powered air-purifying respirator is that it can supply enough air so that the pressure inside the facepiece remains positive at all times (2). Thus facepiece leakage is outward to the contaminated atmosphere and even with poor fitting facepieces inward leakage of contaminated air into the facepiece is minimal. Blowers should provide at least 113 L/min to tight-fitting facepieces (wearer work rate of 68 J/sec (415 kg-m/min)) and 170 L/min for high work rates (136 J/sec or 830 kg-m/min) to minimize inward leakage (2). Another important consideration is that there is no inhalation breathing resistance associated with the purified air. Thus these respirators are generally more comfortable to wear

and have higher worker acceptance than non-powered models. However, if the air supply rate is not sufficient, it is possible at higher work rates to attain a negative pressure in the facepiece, which causes inward leakage of contaminated air.

Atmosphere-supplying respirators contrast with air-purifying types in that they supply respirable air from a source independent of the surrounding contaminated air. These respirators are further classified as supplied-air and self-contained breathing apparatus (SCBA). Supplied-air types use a stationary source of air (at atmospheric or high-pressure) delivered through a hose or airline to the facepiece. The self-contained breathing apparatus (SCBA) enables the wearer to carry enough air or oxygen for up to four hours use. The wearer does not have to be connected to a stationary source, such as a compressor.

Open-circuit SCBA devices exhaust exhaled air to the atmosphere instead of re-circulating some of it through sorbents. These devices are available in "demand" and "pressure-demand" modes. The air supply regulator on the demand-mode SCBA has a valve that is closed when positive pressure exists in the facepiece (during the exhalation cycle). The valve opens in response to negative pressure inside the facepiece during the inhalation cycle. The respirable air is admitted from the self-contained supply only on "demand" from the wearer. In contrast, pressure-demand SCBA devices continually maintain about 0.39 to 0.78 kPa (40 to 80 mm water) positive pressure inside the facepiece, while supplying additional air for the wearer on "demand" during inhalation. A typical open-circuit SCBA respirator is shown in Figure 4.

With pressure-demand SCBA respirators leakage is outward from the facepiece, which greatly reduces inward leakage of contaminated air. The careful fitting of the

facepiece to the wearer's face is not as critical with pressure-demand SCBAs and they can provide very high protection to the wearer. However, with demand-type SCBAs the negative pressure inside the facepiece during inhalation is approximately the same as that created in an air-purifying respirator (1). Contaminated air may leak inward into the facepiece and this leakage can be of the same magnitude occurring with an air-purifying device.

Sources of Facepiece Leakage

A respirator facepiece is a covering that serves as a protective barrier to hold back contaminated air from the wearer's respiratory system. A perfect facepiece would be one that formed a perfect sealed barrier against a contaminated atmosphere and allowed only purified air or clean supplied air to reach the respiratory system. All facepieces have the potential for some leakage and it is the amount of inward leakage of contaminated air that governs the respiratory protection the wearer receives. This is especially true for the negative pressure respirators such as the non-powered air-purifying masks and demand-mode SCBAs.

An examination of Figures 1 through 4 indicates that a potential for leakage exists at any point on the facepiece where there is an opening and at the peripheral seal, known as the faceseal. Unwanted penetration of contaminated air into the facepiece can occur at three points:

1) Through the air-purifying element containing an inadequate filter or inoperative sorbent
2) Through the exhalation valve

3) At the facepiece-skin interface (faceseal leakage)

Very efficient filter and sorbent elements are available for use on industrial respirators. High-efficiency particulate filters are at least 99.97% efficient against 0.3 micrometer particles. For properly manufactured sorbent cartridges and canisters, the sorptive air-purification mechanisms are essentially 100% efficient until the sorbent's capacity to adsorb gases and vapors or catalyze their reaction is exhausted. Thus the path through the air-purifying element is usually not a major source of leakage for this type of respirator.

Exhalation (expiratory) valves are simple check valves designed to remain closed during inhalation and open only during exhalation to permit the exhaled air to exit from the facepiece. Burgess and Anderson (3) have examined the performance of respirator exhalation valves. They concluded that commercially available respirators containing mushroom, annular, or poppet valves could maintain valve leakages of less than 0.02%. The dynamic leakage of flap-type valves could be less than 0.10%. Thus, properly designed and functioning exhalation valves usually are a negligible source of leakage into air-purifying respirators.

Respirator specialists have long believed that leakage at the facepiece-to-skin interface constitutes the major source of leakage into properly constructed negative pressure respirators. In 1963 Hyatt (4,5) showed that leakage around the facepiece at the face is the main limitation of the halfmask and fullface mask. In Britain, Hounam (6) observed that low protection from high quality equipment was primarily the result of leakage at the seal between the mask and face. In major part it was the desire of respirator researchers to quantify leakage at the faceseal that led to the development of quantitative fit test equipment in the 1960's.

Factors Affecting Faceseal Leakage

Once respirator leakage measurement equipment became available, investigators were able to examine the factors affecting faceseal leakage of negative pressure respirators. These factors can be grouped into three major areas: respirator design, wearer facial conditions, and conditions of use. The facepiece leakage is determined by how well the facepiece fits the wearer and the way it is worn.

1. Respirator design considerations

The mask configuration such as quarter-mask, halfmask, and fullface mask strongly influences the potential for leakage. Interestingly, even though the quarter-masks and halfmasks have a considerably shorter peripheral sealing surface than fullface masks, the commercial fullface masks seal more reliably than the quarter or halfmasks. Adley and Wisehart (7) observed that variances in fit about the nose varies greatly with individuals wearing the same halfmask and account primarily for the pronounced differences in leakage they found between halfmasks and fullface respirators.

The facepiece dimensions and the size and shape of the mask strongly affect the leakage potential for a given user. This consideration was discussed by Hyatt et al. (8) who concluded that one type or size of facepiece cannot be expected to satisfactorily fit all of a given working population. The work of Sommer (9) has shown that the halfmask facepiece size governs the wearer's ability to obtain an adequate fit.

The sealing lip design in an important factor affecting faceseal leakage. Hounam et al. (10) found that a pneumatic cushion seal provided substantially less leakage than a flat face seal on fullface respirators. Griffin and Longson (11) also concluded that the pneumatic-type seal is greatly superior to the plain-type for fullface masks. Hyatt et al. (8) found that variances in the design of halfmask faceseals related to comfort and fit. Warncke and Schipke (12) investigated the sealing effect of five sealing lip designs. They concluded that a double sealing lip provided by far the best sealing among the masks examined.

Results reported by Hyatt (13) for two fullface masks suggest that facepiece material can influence faceseal leakage. Leakage test results for two fullface masks of the same size and shape made from a single mold indicated that the mask molded from a soft, pliable, silicone rubber provided better fits than the same mask molded from a hard, rigid, neoprene rubber. Warncke and Shipke (12) examined five sealing lip designs, two of which had the same shape, but one was a rubber lip and the other was chamois leather. The chamois leather lip was markedly inferior in sealing ability compared to the rubber lip.

2. Wearer facial conditions

Respirator specialists have long recognized the strong influence of facial form and dimensions on the respirator wearer's ability to obtain an adequate fit. These are referred to as anthropometric considerations. Two of the early quantitative leakage researchers, Adley and Wisehart (7), observed that facepiece leakage was affected by the facial characteristics of the individual wearer. In 1963 Hyatt (5) reported on the difficulty of fitting all types of faces with only one size of mask. He reported that, using a qualitative isoamyl acetate fit test, his laboratory personnel were able to

obtain a gas tight fit with quarter masks for only 40 to 50% of the men tested and for 40 to 90% of the individuals tested with commercially available halfmasks. He also reported that for four fullface masks tested, from 88 to 97% of the wearers were able to obtain a gas tight fit (against 500 ppm isoamyl acetate).

Sommer (9) reported on the range of facial sizes satisfactorily fitted by three different sizes of the same model halfmask. He concluded that the medium size adequately fitted the majority of wearers. But, an extra-large size is required for men with large faces, and a small size must be available for women.

Hyatt et al. (8) reported on the distribution of leakage values obtained for men wearing five makes of halfmasks and six makes of fullface respirators. The intraclass differences between the leakage distributions for the halfmask class and the fullface class were quite marked. Hyatt et al. (8) concluded that one type or size of facepiece cannot be expected to satisfactorily fit all of a given working population and that some consideration must be given to the relationship between facial characteristics and facepiece dimensions. Warncke and Schipke (12) also reported on the wide range of leakage values obtained for men of widely varying facial forms and dimensions wearing the same facemask.

Facial contours may prevent adequate sealing of facepieces. Pritchard (1) cautioned that scars, hollow temples, very prominent cheekbones, deep skin creases, and lack of teeth or dentures may cause respirator facepiece sealing problems. He advised that full dentures should be retained when wearing a respirator, but partial dentures may or may not have to be removed, depending upon the possibility of swallowing them.

The effect of beard growth on respirator faceseal leakage has been considered by respirator researchers. Hounam et al. (10) evaluated the effect of beard growth on leakage of several fullface respirators. Leakage increased several orders of magnitude after several days of growth. They concluded that protection afforded by respirators with a pneumatic cushion seal was less affected by several days' stubble growth, but eventually the performance for all fullface seals similarly degraded due to beard growth. Hyatt et al. (14) conducted an extensive study on the effect of facial hair on the performance of halfmask and fullface respirators. They concluded that persons with excessive facial hair such as facial stubble, beards, and wide sideburns that interfere with the respirator seal, cannot expect to obtain as high a degree of respirator performance as clean shaven individuals. The amount of performance degradation depended on many factors such as the length, texture, and density of hair as well as the extent of the interference with the sealing surface of the respirator.

Adley and Uhle (15) found that the wearing of glasses of a type used primarily under Army assault masks increased the leakage of SCBA (demand mode) respirators by factors of 100 to 1000. Cyr and Watkins (16) reported an investigation that showed the effect of spectacle wearing on fullface respirator leakage could range from essentially no effect up to a 1000-fold increase in leakage.

3. Conditions of use

For a given user and respirator, the optimum protection afforded by the respirator depends greatly on the proper establishment and maintenance of a tight seal on the face. The fitting procedures used by the wearer and subsequent use conditions such

as head and facial movements and amount of physical activity or work rate can strongly influence the seal tightness.

When a user dons a respirator, the fitting procedure used determines primarily the headstrap tension and position of mask on the face. Burgess et al. (17) has demonstrated that there is a direct relation between headstrap tightness and quality of the fit. However, tight headstraps cause wearer discomfort, which usually results in the worker not wearing the mask when it is needed for health protection. Optimal strap tension produces an adequate seal with minimal sealing pressure.

Hyatt et al. (8) investigated the effect of headstrap tension on the protection afforded by five halfmask respirators. They noted that, although the strap characteristics, mask design, and construction of the respirators differed, the average head and neck strap tensions preferred by the wearers fell in a fairly narrow range. The strap adjustment generally selected by the users resulted in about 4.4 N (1 pound) tension on the head straps and about 3.3 N (0.75 pound) on the neck straps. Hyatt et al. (8) noted that these tensions provided a good seal if the respirator had been properly sized.

Warncke and Schipke (12) investigated the effect of headstrap tension on faceseal leakage using six subjects. Mask leakages were first measured with the straps tightened purely by the feel of the wearer. Then the straps were tightened to a uniform tension of 9.8 N (2.2 pounds) and the leakage remeasured without removing the mask. By tightening the straps to a uniform 9.8 N (2.2 pounds) tension, facemask leakage was reduced by factors of 10 to 10,000!

The dramatic effect of proper facepiece adjustment during the fitting procedure was shown by Hounam et al. (10) in tests involving fullface respirators. Eight persons who had been issued fullface masks for their work were asked to don and adjust their masks in their normal manner. Leakages were measured and then remeasured after careful fitting. The distribution of leakages shifted to substantially lower leakages after careful fitting was performed. The percentage of fits exceeding 1% leakage dropped from 38% after the routine initial donning to only 9% after the careful adjustment.

White and Beal (18) also investigated the quantitative effect on leakage due to proper fitting by trained specialists. In their study, when fullface masks were self-fitted by the user, 68% of the wearers showed leaks of less than 0.5%. After being properly fitted by an expert, 94% of the wearers had less than 0.5% leakage. White and Beal (18) observed that during their study it was necessary to retrain the fitters thoroughly before they could achieve minimum leakage on test subjects. They concluded that it was not sufficient to rely upon an excellent respirator maintenance program to ensure adequate protection. Wearers of filter-type respirators must be well trained in fitting and adjusting them.

Head and facial movements can substantially affect a wearers' respirator leakage. This is especially true for quarter-masks and halfmasks since they are more easily dislodged from a proper fit than are fullface masks. Watson et al. (19) reported that frequent or extreme facial movements may significantly increase leakage into halfmask respirators. Interestingly, White and Beal (18) observed that in their tests many persons who exercised achieved slightly improved fit. They felt that the improvement could be caused by settling of the respirator on the face due to exercise

and by the formation of a better seal from perspiration which collects between the skin and faceseal.

Lastly, the amount of physical exertion the user undergoes can affect leakage. Hyatt (5) observed that fullface masks showed greater penetration during medium work load conditions than during sedentary tests. Burgess and Reist (2) showed that for powered air-purifying respirators an increased air supply rate is necessary at higher work rates in order to maintain a positive pressure at all times in the facepiece to minimize leakage.

Necessity of Respirator Fit Tests for Evaluating Protection Afforded Individual Respirator Wearers

Methodologies for quantitatively evaluating the actual protection afforded respirator wearers date from about 20 years ago at a time when researchers were investigating the protection given by air-purifying respirators against airborne radioactive contaminants. Burgess (20) in 1961 described a new technique using a uranine dye aerosol for evaluating the effectiveness of respirators. Tests conducted by Burgess (20) showed that even with careful fitting the best respirators then available were not always capable of providing dependable protection for all wearers.

Until recently, United States respirator manufacturers have produced each respirator model in only one faceseal shape and size. Although there is a wide range of facial sizes and shapes in the general population that must be accommodated (21,22), respirators are generally produced only in large sizes that fit men better than women.

Generally, fewer women than men can attain an adequate fit with available respirators because women tend to have narrower and shorter faces.

Hyatt (13) reported that qualitative fitting test results (isoamyl acetate or irritant smoke) accumulated over a 17 year period by government contractors indicated that the poorest fitting halfmask respirators provided a satisfactory fit for only about 60% of all men tested. He stated that the best fitting halfmask fitted about 80% of the men tested, while individual full-facepiece respirators provided an adequate fit for 85% to 95% of all the men tested. Hammond and Hill (23) reported on percent of men obtaining satisfactory fits with five makes of halfmask respirators worn in a nuclear material processing facility. Their data, summarized in Table 1, were based on testing with irritant smoke. Hyatt et al. (8,24) performed quantitative dioctyl phthalate (DOP) fit tests on wearers using fullface particulate respirators. Their reported results are summarized in Table 2. The leakage was measured only for wearers that had satisfactory fits as determined by the irritant smoke test.

It is not feasible to provide adequate protection with an air-purifying respirator to 100% of the potential users with a single-size respirator or even several sizes. Respirator fit tests are necessary to detect those wearer-respirator combinations that cannot give adequate protection because of improper matches between face and faceseal. Douglas et al. (25) state: "Because each of the different brands of commercial masks differs considerably in design, the availability of different brands and use of a fitting test is the most effective way at present time to provide adequate protection for much of the population."

Fit tests must be conducted on each user to select the respirator that provides adequate inhalation protection. In addition, fit tests must also be part of training

Table 1 - Percent of men obtaining satisfactory fits with halfmask respirators, from Hammond and Hill (23).

Mask	Plantwide	Pu areas	U areas
AO R6000	57	65	48
MSA Comfo	80	81	77
Willson 809/1009	69	74	62
Acme Duo-Seal	90	90	—
Welsh 7580	64	64	—

Table 2 - Percent of men with average DOP leakages greater than 1% (unsatisfactory fit where PF = 100 is desired), from Hyatt el al. (8, 24).

Mask	Number tested	Percent exceeding 1% leakage
Acme Full Vision	56	5
MSA Clearvue	84	4
MSA Ultravue	84	0
Welsh 7680S	104	3
Willson RFMW 809	32	22
Willson TFMW 809	33	24

programs that instruct the wearer how to properly don and wear the respirator. It must be emphasized to the wearer that the health protection potential of a respirator will not be achieved if the respirator is not worn properly. Fit tests must be used to demonstrate to the wearer the importance of proper strap tension in providing adequate protection. Overtight headstraps can be as wrong as loose headstraps, because after the fitting demonstration the wearer may be unable to tolerate excess faceseal pressure on the face during the wearing period. The necessity for proper positioning of the respirator on the face can be demonstrated to the wearer with fit tests. Correct facial positioning is especially critical for halfmask respirators since novice wearers tend to position halfmasks too high on the face.

Most employers providing respirators do not conduct any type of fitting program that includes fit tests (13). Where fit tests are part of respiratory protection programs, the qualitative tests predominate. Quantitative fit test equipment is rarely used in industry, primarily because it is relatively expensive.

Both supervisors and workers must be instructed in proper selection, safe use, and maintenance for the safe use of any respirator. Every respirator wearer must be given fitting instructions in how the respirator should be worn, how to adjust it, and how to determine if it fits properly. The facepiece fit must be checked by the wearer each time he puts on the respirator. Details for a training and quantitative fitting program have been described by Pritchard (1).

Qualitative Respirator Fitting Tests

There are four qualitative fit tests currently recommended by respirator specialists.

Negative pressure (or inhalation) test

The respirator air inlets are closed off by the wearer. This usually involves covering the inlets to the canister, cartridges, or filter with the palms of the hands. Then the wearer inhales gently so that the facepiece remains slightly collapsed and the breath is held for several seconds. If the respirator facepiece stays distorted inward, the fit is considered adequate. This test is described in references (1,25-28).

Positive pressure (or exhalation) test

The respirator exhalation valves are closed off by the wearer. This usually requires removing the exhalation valve covers. Then the wearer exhales gently into the facepiece. The fit is considered satisfactory if the wearer cannot detect any severe outward leakage. However, it is difficult to instruct users in the proper exhalation rate required to maintain the slight positive pressure required for this test. Wearers tend to blow too hard or too softly into the respirator. If the wearer blows too hard, the mask will lift off the face. Too soft an exhalation will not detect mask leakage. Then the exhalation valve cover must be very carefully replaced so as not to disturb the seal. This test is described in references (1,25-28).

Isoamyl acetate (IAA) (or banana oil) test

Isoamyl acetate vapor has a pleasant, sweet, banana-like odor detectable at concentrations in the range of 0.067 to 0.21 parts per million (ppm) (29). The saturated concentration of isoamyl acetate in air is approximately 6600 ppm at 24^{o} C. The isoamyl acetate test can only be used with air-purifying respirators equipped with organic vapor cartridges or canisters, airline respirators, and self-contained breathing

apparatus (SCBA). There are two variations of the test. In the basic version isoamyl acetate, on a cotton swab or cloth, is slowly passed around the respirator faceseal. Any odor detected by the wearer indicates an unsatisfactory fit. The second variation, sometimes referred to as a "semi-quantitative test", requires a chamber or room containing isoamyl acetate at known concentrations of 100 to 1000 ppm. Detailed instructions for these two variations are given in references (1,4,5,25-28,30).

Irritant smoke tube test

This test was first proposed by Hyatt (5) in 1963. He reported that the Mine Safety Appliances Company (MSA) Ventilation Smoke Tube, part #5645, produced an irritant fume suitable for fit testing. The MSA Smoke Tube contains stannous chloride impregnated pumice. When humid air is forced through the tube, by squeezing a rubber bulb, a fine fume consisting of hydrogen chloride absorbed on particulate is produced. This fume is in the size range 0.5 to 3.0 micrometer diameter (5). Since the smoke is very irritating if inhaled, the test must be performed with considerably more care and safeguards than any of the other qualitative tests. Test details are given in references (1,5,25,27,28).

The irritant fume test can only be used with air-purifying respirators equipped with high efficiency particulate (HEPA) filters, air line respirators, and self-contained breathing apparatus. Hyatt (5) observed that fit tests performed with the irritant fume test had about the same rejection rate as did fit tests performed with a 500 ppm isoamyl acetate test chamber. However Pritchard (1) stated that this test has a distinct advantage since the wearer will involuntarily react to faceseal leakage by coughing or sneezing.

Table 3 summarizes the advantages and disadvantages for four qualitative fit tests and two quantitative tests.

Present Uses of Qualitative Fitting Tests

OSHA regulations 29 CFR 1910.134

Occupational Safety and Health Administration (OSHA) requirements contained in the Code of Federal Regulations (29 CFR 1910.134) govern the use of industrial respirators in respiratory protection programs. The OSHA respirator use requirements apply when these devices are used to reduce inhalation exposures below exposure standards (29 CFR 1910 Subpart Z). The OSHA regulations contained in 29 CFR 1910.134, are based on the voluntary American National Standards Institute (ANSI) Standard Z88.2-1969 (27), and require in part:

> "Training shall provide the men an opportunity to handle the respirator, have it fitted properly, test its face-piece-to-face seal, wear it in normal air for a long familiarity period, and, finally, to wear it in a test atmosphere."

> "Every respirator wearer shall receive fitting instructions including demonstrations and practice in how the respirator should be worn, how to adjust it, and how to determine if it fits properly. Respirators shall not be worn when conditions prevent a good face seal."

Table 3 - Comparison of qualitative and quantitative fit tests.

Type of test	Advantages	Disadvantages
QUALITATIVE		
general	quick, easily performed, minimal hardware required, minimal training required	tests rely on wearer's attitude and subjective response so are relatively unreliable
negative pressure	can be performed by wearer only and no hardware required	wearer must handle mask after it has been positioned on face, which may alter seal; small leaks may go undetected
positive pressure	can be performed by wearer only and no hardware required	removing and replacing the exhalation valve cover may severely modify the seal
isoamyl acetate	fairly realistic, test agent is a vapor	depends on olfactory response and attitude of wearer
irritant fume	fairly realistic	smoke is very irritating and test must be performed with considerable care and safeguards
QUANTITATIVE		
	determines fit as percent penetration of a test aerosol or gas, thus giving direct indication of amount of protection afforded	equipment is relatively expensive (up to $10,000); well trained personnel required to conduct tests; most equipment designed for laboratory use; each test respirator must be modified with a sampling port connection

The requirement regarding a "test atmosphere" was adopted verbatim from section 7.4 of ANSI Standard Z88.2-1969 (12). Section 7.5 of this standard (27) states that "Potential users of respirators should also be required to test their facepiece fit by wearing the respirator under realistic test conditions." This section is followed by a description of the isoamyl acetate and irritant smoke tests. The implication is that the Z88 ANSI Standards Committee intended the isoamyl acetate and irritant smoke tube tests to be adequate fit tests for the purposes of their recommended standard, which was the basis of Federal Standard 29 CFR 1910.134.

Additionally, OSHA regulations require a user fit test each time the respirator is worn. Section 1910.134(e) (5) (i) of 29 CFR requires:

> "To assure proper protection, the facepiece fit shall be checked by the wearer each time he puts on the respirator. This may be done by following the manufacturer's facepiece fitting instructions."

Respirator manufacturers generally recommend the negative or positive pressure test as user fit tests. Norton Corporation respirators (formerly marketed by Welsh) have instructions that direct the user to "test for proper seal of facepiece" with the positive pressure or exhalation test (halfmask 7500-series and fullface 7600-series instructions). Mine Safety Appliances (MSA) Corporation markets Custom Comfo II halfmask respirators that include instructions that direct the user to test for leakage using the negative pressure or inhalation method.

The British counterpart of the American National Standards Institute (ANSI) is the British Standards Institution (BSI). The BSI recommended respirator use standard (31) states that "The fit of the facepiece is most important and wearers should receive

instructions including demonstrations and practice in how it should be fitted, and how to determine if it is fitting correctly." But section 5.2 of the BSI respirator standard lists only the negative pressure test as a recommended test procedure.

LASL and DOE contractor fit tests

The Los Alamos Scientific Laboratory (LASL) and Department of Energy (DOE) (formerly the Energy Research and Development Adminstration - ERDA) contractors frequently have employees working with highly toxic materials including radioactive contaminants. Many of the investigations in the late 1960's on the protection capabilities of commercial respirators for these contractors' employees were initiated and continue at LASL. It is vital that the contractors provide a very high degree of health protection for those employees who have to wear respirators when working with the toxic materials present in the nuclear energy industry.

Hyatt (13) stated, "Qualitative fitting results, using either isoamyl acetate or an irritant fume, have been used by LASL and other ERDA contractors to conduct fitting tests before issuing respirators for protection against highly toxic contaminants." The ERDA Respirator Manual by Douglas et al. (25) stated, "Fitting of respirators can be accomplished either with quantitative man tests or qualitative tests."

ERDA contractors have expressed confidence in the qualitative fit tests. Hammond and Hill (23) stated:

"The use of the smoke tube leaves little room for doubt." "If the mask leaks it is noticed immediately. . . . The ventilation smoke tube is well suited to a field respirator-fitting program."

Bolton and Whitson (32) prepared a pamphlet for employees being evaluated under the Oak Ridge National Laboratory respirator fitting program. Regarding their 500 ppm isoamyl acetate test they stated (32), " . . . any leak between the face and the mask will be readily detected." Also, "The tests were designed so that you will be aware of those respirators which give you a good fit and strikingly aware of those which will not fit your face."

Respirator protection factors (PF)

The respirator protection factor (PF) indicates the overall protection a respirator wearer can achieve with a given respirator. The PF is defined as the ratio of the concentration of contaminant in the ambient atmosphere to that inside the facepiece, under conditions of use. The protection factor can also be calculated as PF = (100)/(% leakage). The PF concept was used in the Joint NIOSH/OSHA Standards Completion Program as a basis for permissible use conditions tables for respiratory protection (33). Pritchard (1) has given examples of respirator selection using protection factors and the NIOSH-developed Respirator Decision Logic.

It is important to realize that protection factors are not assigned at a level of protection that 100% of the potential wearers could expect. Hyatt (13) stated the following regarding the derivation of protection factors from quantitative leakage measurements on test panels of respirator wearers:

> "A reasonable basis for assigning a protection factor to a single class of respirators would be to require that 95% of the subjects must meet the performance criteria to assign a given protection factor. In addition, the 5% of the people not meeting the performance criteria and the 5% not included in the panel must be identifiable by a stringent qualitative fitting test or by anthropometric facial measurements." (emphasis added)

Hyatt (13) also stated:

> "The important point to note is that purchasing three to four approved respirators of each type with different facepiece sizes and shapes will provide a satisfactory fit for approximately 99% of all the men tested, according to ERDA contractor reports."

If each wearer has the opportunity to choose from three or four makes of masks, ther all but a few percent of the users can receive adequate protection. However, ir many respirator programs the employer buys only one brand of mask. If the employer uses only a qualitative fit test, then the test must be able to identify the 20% to 40% of the employer's work force that cannot achieve adequate inhalation protection with the provided mask.

Selection of the proper halfmask size from multiple-size masks

At present in the United States, only a few makes of halfmask respirators have been certified by NIOSH in two or more facial sizes. Hack et al. (34) concluded that if a

manufacturer wants to market a model that will fit at least 95% of the U.S. adult facial sizes, then development of multiple-size masks is probably necessary.

Draeger of Germany produces halfmask respirator models in three different sizes, but they are not available in the United States. In a study designed to provide guidelines on the proper size respirator to be used for any particular employee, Sommer (9) of Draeger concluded that correct determination of suitable halfmask size was not possible by anthropometric gauge measurements. Thus, even if manufacturers produce multiple size respirator models marked with appropriate anthropometric size groups the mask is designed for, employers will still need to use fitting tests to select the best size mask for each employee.

NIOSH respirator certification testing

NIOSH currently tests and certifies industrial respirators at its Morgantown, West Virginia facility using test requirements specified in the Code of Federal Regulations (30 CFR Part 11). Five subparts of these regulations require the use of the qualitative isoamyl acetate fit test for facepiece testing (35). Table 4 summarizes the qualitative fit test applications and general conditions of use.

Quantitative Respirator Fitting Tests

Quantitative fitting tests developed over the last two decades have included both gases and aerosols as the challenge atmosphere. Early investigators included Burgess (20) using a uranine dye aerosol, Adley and Wisehart (7) using Freon 12 gas, and Hounam (6) using a sodium chloride aerosol. Other investigators utilizing halogenated hydrocarbon gases have included Morgan (36), Jones (37), Lipera and Kusian (38),

Table 4 - Use of isoamyl acetate test in NIOSH respirator certification testing (35).

Respirator type	30 CFR section	Isoamyl acetate test use
Self-contained breathing apparatus (SCBA)	11.85-19	100 ppm; only normal breathing; 6-person panel
Gas masks	11.102-3(e)	Halfmasks at 100 ppm; fullface or mouthpiece at 1000 ppm; four exercises used; panel size unspecified
Dust, fume, and mist	11.140-1(b) 11.140-2(b)	100 ppm; only normal breathing; panel size unspecified
Chemical cartridge	11.162-3(e)	Halfmasks at 100 ppm; fullface and mouthpieces, hoods and helmets at 1000 ppm; four exercises used; panel size unspecified
Pesticide	11.183-3(e)	Halfmasks at 100 ppm; fullface and mouthpieces, hoods and helmets at 1000 ppm; four exercises used; panel size unspecified

Adley and Uhle (15), and Watson et al. (19). However, respirator specialists now avoid the use of halogenated hydrocarbons for fit testing because of possible harmful physiological effects of high concentrations of these gases which the wearer might be exposed to in the event of severe mask leakage (16). Researchers have used two of the noble gases for fit testing, with argon being used by Griffin and Longson (11) and helium by Cyr and Watkins (16).

Sodium chloride (NaCl) and dioctyl phthalate (DOP) are the two aerosols used in commercial fit test systems. Researchers using sodium chloride have included Burgess and Reist (2), Hounam (6), Hounam et al. (10), Hyatt et al. (14), White and Beal (18), Burgess (39), and Ferber et al. (40). A thermally-generated dioctyl phthalate (DOP) system was developed at the Los Alamos Scientific Laboratory in 1970 (8). Since there was concern over the unknown toxicity of the thermally-generated monodisperse DOP the Los Alamos Scientific Laboratory developed an air-generated dioctyl phthalate aerosol system in 1971 (41).

The commercially available quantitative fit test systems incorporate dioctyl phthalate or sodium chloride tracer aerosols. These systems include a test aerosol generator and a shroud or booth where the respirator wearer is exposed to the test aerosol. They also use a detection device that samples both the challenge aerosol concentration and the concentration inside the test respirator facepiece, which has been fitted with an adapter to allow sampling the air inside the facepiece. The amount of test aerosol penetrating the faceseal is measured as a percentage of the challenge atmosphere in the test shroud and is reported as "percent penetration" or "percent leakage."

Dioctyl phthalate (DOP)

Both commercial systems employing dioctyl phthalate incorporate an aerosol generator and contain a forward light scattering photometer for aerosol detection and measurement. The compressed air generator with impactor produces a polydisperse aerosol with dioctyl phthalate mass median aerodynamic diameter (MMAD) of about 0.6 micrometer. Table 5 summarizes the cost of the two systems.

Sodium chloride (NaCl)

The two commercial sodium chloride systems contain a Wright nebulizer that produces a poly disperse aerosol with a MMAD in the range 0.7 to 0.8 micrometer. A propane burner flame-photometer is employed for particle detection and measurement. Table 5 also summarizes these two systems.

Table 5 - Commercial quantitative fit test systems.

Manufacturer	Dioctyl phthalate (portable unit)	Dioctyl phthalate (laboratory unit)	Sodium chloride (laboratory unit)
Air Techniques, Inc. 1717 Whitehead Road Baltimore, MD 21207 Ph. (301) 944-6037	TDA-80, $6500*	TDA-50, $5250**	TDA-60, $7300**
Frontier Enterprises P. O. Box 30041 Albuquerque, NM 87110 Ph. (505) 266-7932	FE250A, $9900*	FE259H, $7900**	FE560A, $8900**

*quoted price is for complete unit with recorder and test chamber (May 1979)

**quoted price is without recorder or test chamber (May 1979)

CHAPTER THREE

FIELD STUDY DESIGN AND EXPERIMENTAL METHODS

Field Study Design

The primary objective of this investigation was to evaluate the effectiveness of four commonly recommended qualitative fit tests, used individually and in combination. The four qualitative fit tests studied included those described in Chapter 2: negative pressure, positive pressure, isoamyl acetate on a cotton swab, and irritant smoke tube. These are the qualitative fit tests frequently recommended by respirator specialists. The three negative pressure respirators included in the investigation were halfmask air-purifying, fullface air-purifying, and self-contained breathing apparatus (SCBA) operated in the demand mode. These are the major types of negative pressure devices that must be used with adequate fit tests in order to assure the wearer of adequate protection.

In order to estimate the screening test levels of performance for the qualitative tests and to evaluate their impact on the reliability of programs in which negative pressure devices are worn, it was necessary to design the investigation in several stages. The first stage was a field study of respirator wearers, designed to determine their subjective responses to the four common qualitative fit tests (individually and in combination) over a wide range of leakages (0.01% to 50% leakage), measured with quantitative fit test equipment. Then it was necessary to develop appropriate

response functions for estimating proportions of wearers responding to each qualitative test as a function of mask leakage. The study hypothesis assumed that an appropriate transform of the proportion of respirator wearers giving a positive qualitative test response was a linear function of transformed average mask leakage. A positive test response was defined as a wearer's acknowledgement of excessive leakage, odor perception, or respiratory tract irritation. A group of volunteers from the Boston Fire Department served as subjects for the field study.

The second stage of the investigation required developing, using summary data published in the literature, leakage cumulative distribution functions describing the range of respirator leakages found in several industrial user populations. The cumulative distribution functions of respirator leakages are graphical relations on lognormal probability paper that present the cumulative proportion of users achieving leakages less than indicated values. These graphical functions were developed for three classes of respirators that operate in the negative pressure mode.

The third stage included the development of appropriate statistical parameters for evaluating the performance of respirator fit tests as used in respiratory protection programs. These parameters included the probabilities for false positives or negatives for each test or combination of tests. This stage of the investigation combined information from both the qualitative fit test response functions and the respirator leakage cumulative distribution functions. Range estimates were calculated for the proportion of wearers, who had passed a qualitative fit test, that actually had inadequate fits and were not receiving the expected inhalation protection. Range estimates were also calculated for the proportion of employees that could achieve a satisfactory fit with a given respirator, but would be rejected by the qualitative fit tests. Then the response function characteristics necessary for an

adequate qualitative fit test were examined. Thus, it was possible to estimate the impact of qualitative fit tests on the reliability of respiratory protection programs that use negative pressure respirators.

Additionally, the repeatability of quantitative leakage measurements was studied using previously reported data. The effect of quantitative measurement repeatability and interday variability of faceseal leakage on professional decisions regarding a user's ability to obtain satisfactory inhalation protection with future wearings was investigated. Thus, it was possible to estimate the effectiveness of using quantitative fit test equipment in respiratory protection programs.

The experimental methods and procedures described in the remainder of Chapter 3 are for the first stage of the investigation, where field study data were obtained for the development of the response functions. These functions would be used for estimating proportions of wearers responding to each qualitative fit test as a function of average mask leakage. Each time a respirator wearer dons a mask a particular "fit" is created. For a particular subject-mask combination, the amount of faceseal leakage or the mask "fit" is dependent upon many factors discussed in Chapter 2. The fit can vary during an 8-hour workshift and the average fit can vary between workdays. In this field study, only the average leakage over several minutes, at the time of the qualitative tests, was determined.

Qualitative Fit Tests Investigated

Four distinct qualitative fit tests were conducted for each mask-subject combination. During all four qualitative tests and quantitative leakage determinations the exhalation valve covers were removed from the air-purifying masks. This was done

for convenience in the positive pressure test. There is no reason to believe it biased the quantitative measurements.

Negative pressure (or inhalation) test

For these tests, the subject was instructed to cover the inlet valve port(s), inhale so as to collapse the mask against his face, and then hold his breath for several seconds. He was then asked if he detected any leakage into the facepiece and if he considered it a satisfactory fit.

Positive pressure (or exhalation) test

For these tests, the subject was instructed to cover the exhalation valve with the palm of the hand and exhale gently. He was asked if he noticed any leakage of air at the faceseal and if he considered it a satisfactory fit.

Isoamyl acetate (IAA) (or banana oil) test

During the orientation phase of each test sequence the subjects had been momentarily exposed to the IAA to make sure they would be able to recognize its odor during the test. During the testing an IAA-soaked cotton swab was stored in an evaporating dish covered with a watchglass to avoid contaminating the room with IAA vapor. For the air-purifying respirators, organic vapor (charcoal) cartridges were mounted before the IAA-test. The IAA-soaked swab was waved vigorously around the entire faceseal for 5 to 10 seconds. The swab was positioned 2 to 5 cm from the faceseal at all times. The subject was asked if he detected any trace of the banana-like odor.

Irritant smoke tube test

For this test, high efficiency particulate (HEPA) filters were fitted to the air-purifying respirators. The Mine Safety Appliances Company (MSA) Ventilation Smoke Tube (part no. 5645) fitted to a rubber squeeze bulb was used to generate the irritant smoke. First, several dilute clouds of smoke were directed at the respirator wearer from a distance of about 30 to 40 cm from the mask. If no leakage was indicated, the tube was moved to within about 5 cm of the faceseal and the smoke was directed at the entire faceseal.

Quantitative Leakage Measurements

The leakages of the test respirators worn by the test subjects were quantitatively determined using an Air Techniques Incorporated TDA-50 polydisperse dioctyl phthalate (PDOP) Aerosol Man Test System. The TDA-50 consists of two separate systems. The first is the PDOP aerosol generator, which is a Laskin type capillary air jet nozzle. The PDOP output from the nozzle is forced through a round jet, flat plate impactor which removes the larger diameter fraction of the aerosol by inertial impaction. The impactor output is diluted with filtered air and mixed thoroughly by a riffle system of baffles in a mixing chamber before entering the test shroud. The second system in the TDA-50 is a solid-state forward light scattering photometer. By adjusting the detector to 100% leakage when sampling the test shroud challenge atmosphere, the detection system linearly reads out the percent leakage into the facepiece. The lowest detectable leakage is about 0.01%.

The test shroud had been previously designed and constructed at the Harvard School of Public Health. It consisted of two concentric cylinders formed from clear plastic sheet. The cylinders were 62 cm and 66 cm in diameter and the shroud height was 50 cm. The shroud ceiling consisted of two metal plates with the top plate mounting the aerosol inlet, exhaust nozzles, and support hooks. The lower plate was perforated to act as a diffuser so that the test aerosol vertically entered the shroud at an approximately uniform rate. The shroud bottom was a cloth boot about 60 cm long, which was tightened around the test subject's waist with a drawstring.

The dynamic leakage was recorded on a Hewlett Packard model 7155B portable strip chart recorder. A 5 cm band of chart paper was used for recording the range 0 to 100% penetration at a 2 cm/min chart speed.

For each respirator fit, the dynamic leakage was recorded for at least one minute while the wearer was breathing normally. Several authors, including Pritchard (1), Hyatt (13), and Douglas et al. (25), have recommended that respirator fit leakage be evaluated as the average leakage from multiple maneuvers, not just average leakage during normal breathing. Typical maneuvers recommended include deep breathing, turning-head-side-to-side, moving head up-and-down, talking, and smiling. However, an analysis of data reported in reference (42) did not justify the inclusion of the additional maneuvers (see Appendix A). The data of (42) did not support a hypothesis of a significant difference between average leakage during normal breathing and average leakage determined from five maneuvers. Nor did the data support hypotheses of significant differences between average leakage during normal breathing and average leakage during any of four other maneuvers.

Pritchard (1) has recommended that average peak penetration be used to evaluate a particular fit. In the present study, the average leakage during the test period was estimated from the recorded dynamic leakage, not average peak leakage. This was done because cumulative distribution leakage data available in the literature (for masks in given populations) were based on average penetration values. For estimates of screening test performance, comparable subjective test response data and mask leakage distribution data were required.

Respirators Used in the Investigation

Three classes of negative pressure respirators were used to obtain subjective response data over almost four decades of faceseal leakage (0.01% to 50%). The first respirator model worn in each test sequence by a subject was a Scott 4.5 self-contained breathing apparatus (SCBA) operated in the demand mode. The second respirator worn was a Welsh 7600S-series fullface air-purifying respirator. (Welsh is now distributed under the Norton brand name). The third worn was a Welsh 7500-series halfmask air-purifying respirator (in some cases an MSA Custom Comfo II). Each mask was fitted with an adapter to allow sampling the air inside the facepiece.

Study Group Used in the Investigation

The study group consisted of 43 officers and firefighters from the Boston Fire Department. All test subjects were male volunteers. A quantitative leakage determination was made for each respirator from the three mask classes described in the previous section. All test subjects had previously worn fullface SCBA respirators for respiratory protection as part of their work.

Study Protocol

Each test subject was first given an orientation regarding the PDOP test equipment and the four qualitative tests. It was carefully explained to each individual that the study was not designed to investigate the leakage of any particular respirator, but rather to determine his response to each of the qualitative tests for the faceseal leakage present during the qualitative test sequence and then measured with the quantitative fit test equipment. He was told that he might be asked to keep the respirator straps loose in some cases to purposefully induce larger leakages. It was explained that the results from the study would help to improve fire department training procedures and help other workers that have to wear respirators as part of their job. The subject was briefly exposed to isoamyl acetate vapor to insure he could recognize its odor under the test conditions.

The subject was first asked to don the Scott 4.5 SCBA air tank and facepiece (without the regulator attached to enable the negative and positive pressure tests to be performed). The negative pressure and positive pressure tests were conducted. Once a particular facepiece fit had been achieved, before the first qualitative test, the subject was not allowed to adjust the headstraps or modify the fit at anytime during the succeeding qualitative and quantitative tests. The initial qualitative tests were not used to "fit" the respirator to achieve a tight seal. Then the IAA and irritant smoke tests were performed using the Scott 4.5 mask and finally the quantitative leakage was determined for the fit with this mask. The subject next donned the fullface air-purifying respirator and the same test sequence was followed. Finally the halfmask air-purifying respirator was worn for the test sequence. The test data obtained in this field study is summarized in Appendix D. It appears in the same sequence as the tests conducted under the above study protocol.

CHAPTER FOUR

DATA ANALYSIS AND RESULTS

Response Functions for Qualitative Fit Tests

The objective of the first stage of this investigation was to estimate the relationship between mask leakage and the proportion of wearers responding to each qualitative fit test. A similar estimation problem occurs frequently in the biological sciences. It is commonly referred to as "dose-response analysis." In this study the "dose" or "stimulus" was the average PDOP leakage for a given fit of a wearer-mask combination. This type of statistical analysis has also been described as "quantal response" analysis (presence or absence of a reaction) and "sensitivity data" testing (measured reactions) (43).

In this study it was assumed that each wearer had an associated critical leakage level for each qualitative fit test. If the mask leakage equalled or exceeded the critical level, then the wearer should have responded to the qualitative test. For a particular wearer, the exact critical leakage level cannot be determined. However, more than one wearer can be tested at a given leakage level or over a range of leakages and inferences can be made about the distribution of critical leakage levels in a population of wearers.

Most statistical methods for analysis of dose-response data rely on the assumption that the critical levels are normally distributed. That is, at a given stimulus level the

proportion of wearers which have critical levels between leakages (x) and (x + dx) is equal to the bounded area under some normal curve. Also, assumption of normality means that the expected proportion of wearers (p) responding at a given leakage (x) is given by

$$p(x) = \frac{1}{\sigma\sqrt{2\pi}} \int_{-\infty}^{x} \exp\left[-\frac{(u-\mu)^2}{2\sigma^2}\right] du$$

This is also the probability that an individual wearer has a critical leakage level $\leq (x)$. Generally the procedures are relatively insensitive to moderate departures from normality, provided the response functions are not extrapolated beyond the range of the data. The distribution of critical values, as measured in original units (such as average PDOP leakage in per cent) may not be a normal distribution. However, the logarithmic transform of the original data values can be used to approximately normalize the distribution of critical values.

Because the PDOP leakage measurements were distributed over almost four decades (0.01% to 50% leakage), a logarithmic transform of the leakage data was believed appropriate. It was hypothesized that the probit-transform of the proportion of wearers responding to each qualitative test was a linear function of $\log_{10}$(average PDOP leakage). The "average PDOP leakage" was the average leakage during a short test period of any given test subject estimated from the dynamic leakage measured during the period. The probit-transform for the proportion (p) is defined as:

$$\text{probit}\,(p) = 5 + z_p$$

where (z_p) is the standard normal variable such that

$$P = F(z_p) = \frac{1}{\sqrt{2\pi}} \int_{-\infty}^{z_p} \exp\left(-\frac{u^2}{2}\right) du$$

and $F(z_p)$ is the cumulative distribution function for the normal distribution. That is, z_p is a value such that P is the area under a standard normal distribution between $-\infty$ and z_p.

In this investigation P is estimated by p, the proportion of individuals rejected by the test (responding) at a given leakage level. Values of z_p are tabulated in most statistical texts. In practice for graphical presentations, the probit value corresponding to p need not be calculated. Commercial log-probit graph paper is available with a probit scale labeled in 100P and a logarithmic scale. On this graph paper, 100P plots linearly against average leakage when there is a lognormal distribution of critical average leakages.

Because 43 subjects were tested, each wearing 3 different respirators, 129 "responses" at mask leakages measured by quantitative fit equipment (reported as average PDOP leakage in percent) were available for analysis. Each quantitative fit measurement was matched with four different qualitative test responses. Additionally, three different combinations of the basic test response data were analyzed. Then by analyzing combinations of qualitative test responses, three additional subjective tests were created. A test "response" (detecting air leakage, smelling isoamyl acetate, or respiratory tract irritation from the irritant smoke) was classified as a test "rejection" because the fit would be considered unsatisfactory.

The three additional test data combinations examined in this study included:

a) Negative pressure with positive pressure - A rejection in either the negative pressure or positive pressure test was defined as a rejection for this combination.

b) Isoamyl acetate with irritant smoke tube - A rejection in either the IAA or irritant smoke tube test was defined as a rejection.

c) A series including all four basic qualitative tests - A response to any of the four separate basic tests was defined as a rejection for this series.

If it had been possible to restrict the average PDOP leakage values to predetermined levels, a graphical analysis might have been used. But since the responses were measured over a continuous range of PDOP leakage values, it was decided to use the SAS Probit computer program (44) to estimate each qualitative fit test response function. The computer program incorporated a modified Gauss-Newton algorithm to compute the equation parameter estimates (44). Some of the 129 average leakage values were the same due to measurement round-off. At leakage levels with multiple response determinations, the response proportion was between 0 and 1. At the leakage values with only one response determination the response proportion was 0 or 1. Probit analysis procedures are capable of analyzing this type of data.

The first stage of the response function analysis consisted of fitting linear response functions to transformed data from each mask type for the basic four qualitative tests. The number of dose levels available for each respirator was 37, 33, and 26 for the halfmask, fullface respirator, and SCBA device, respectively. The median dose

level for each respirator was 0.7%, 2%, and 0.19% leakage for the halfmask, fullface respirator, and SCBA mask respectively. To test the investigation hypothesis that the probit-transform of the proportion of wearers responding to each qualitative test was a linear function to $\log_{10}$(average PDOP leakage), the chi-square test for goodness-of-fit was used. For each of the 12 combinations of response data, a chi-square statistic was calculated to test the data for statistically significant departures from the fitted linear models. In all 12 cases the chi-square probabilities exceeded 0.05, indicating that there was no reason to believe that the response data were not adequately fitted by the linear models for the transformed data.

Next, the three fitted response functions for each qualitative test were examined to investigate possible differences in response function due to type of respirator. First, a visual comparison of the three functions for each qualitative test indicated some differences due to type of mask. However, these differences were primarily in the slope of the functions and not in central location. To examine the possibility that the differences could be attributed to random differences in the fitted functions, especially in light of the moderate sample sizes used to estimate the functions, several statistical parameters were calculated. The analysis indicated that there was no reason to believe that there were substantial differences between response functions from different types of respirators for each qualitative test.

Because the response functions from the three respirator types were essentially the same within each qualitative test, it was decided to pool the response data for each qualitative test. This was done to obtain a single estimated response function for each qualitative test that could be used for the three major types of negative pressure respirators and simplify the subsequent analyses. From the pooled data, there were 70 dose levels of average PDOP leakage available for analysis. Linear

response functions were fitted to data from each of the four basis tests and the three combinations. As before, chi-square statistics were calculated to test for significant departures from linearity and in all seven cases the statistics were not significant. This demonstrated that the linear model for the transformed response data was an adequate one.

Figures 5 through 11 present the seven qualitative fit test response function estimates plotted from the equation parameters calculated by the SAS Probit program (44). The approximate 75% fiducial limits for each response function are shown on Figures 5 through 11 as dashed lines bounding the approximate 75% fiducial intervals. Under the assumptions of the analysis, it can be stated with approximately 75% confidence that the true proportion of wearers (in the parent population for which the study group is a representative sample) responding to the test would fall in the approximate 75% fiducial intervals. The fiducial limits are approximate since the exact degrees of freedom for the estimated range function are not known.

Prior to the computer generated response functions, a preliminary analysis had been performed by grouping the data into seven PDOP leakage levels for each of the seven qualitative fit tests. The qualitative fit test response proportions at each of the seven leakage levels were converted to the Freeman-Tukey arc-sine transform (45) and plotted against $\log_{10}$(average PDOP leakage). A line-of-best-fit was visually estimated and drawn in. When these preliminary response function estimates were later compared to the computer generated function estimates, it was observed that the two estimates were effectively the same for all seven qualitative tests.

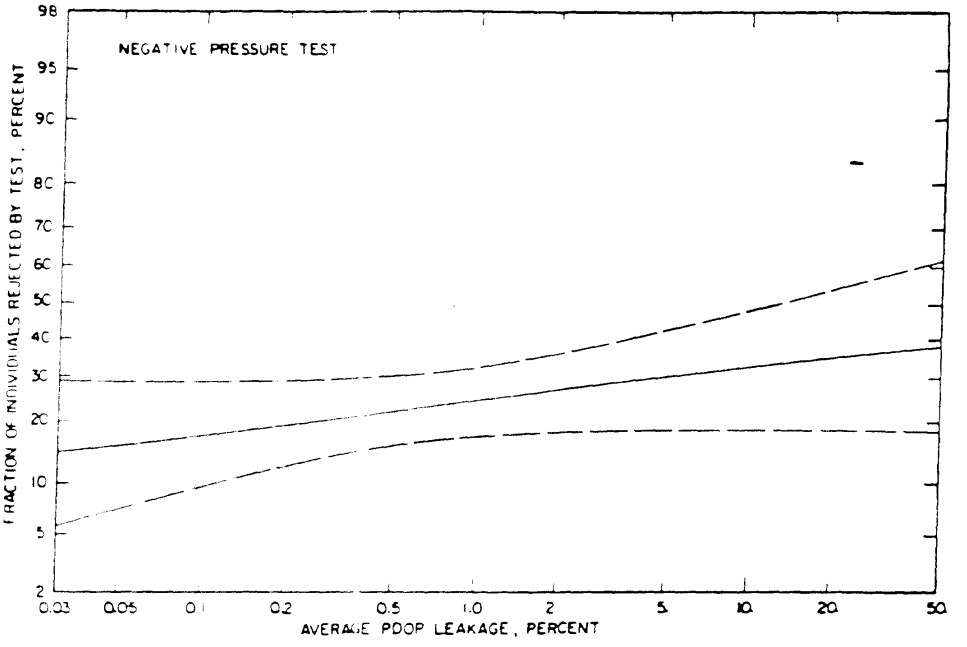


FIGURE 5 - NEGATIVE PRESSURE TEST RESPONSE FUNCTION.

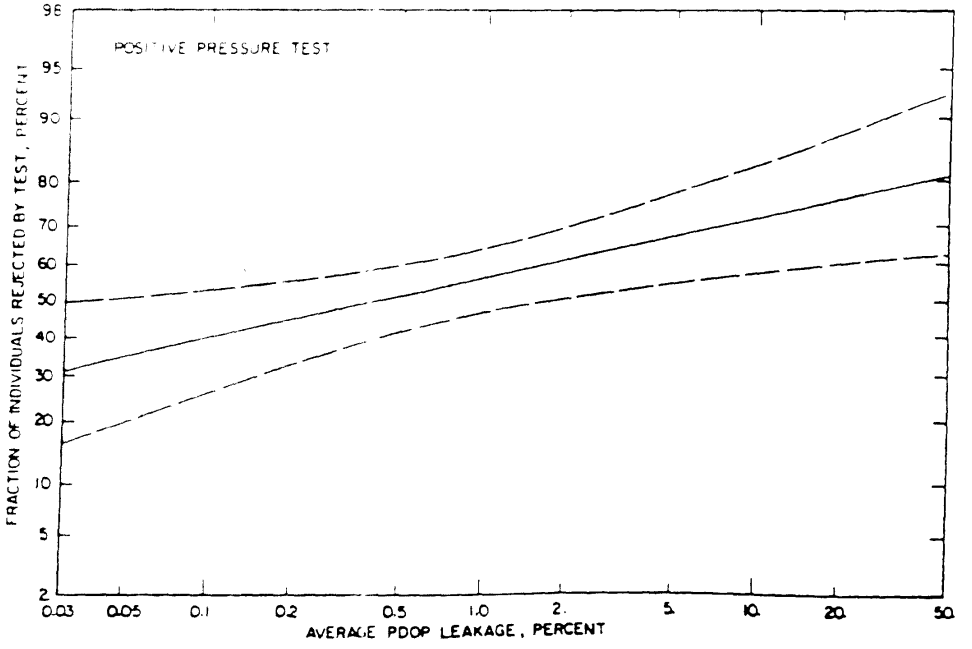
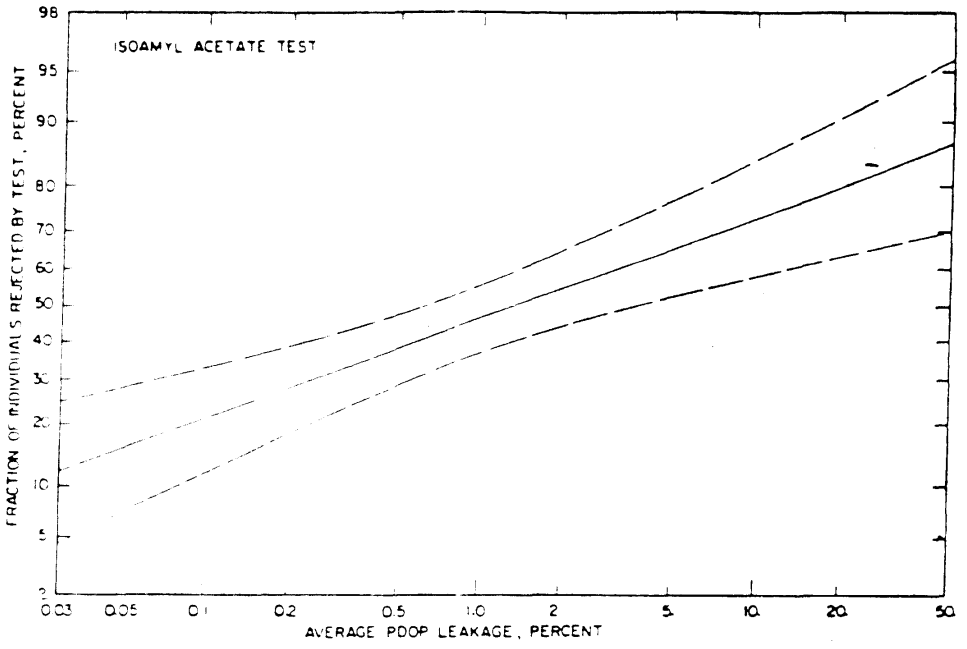
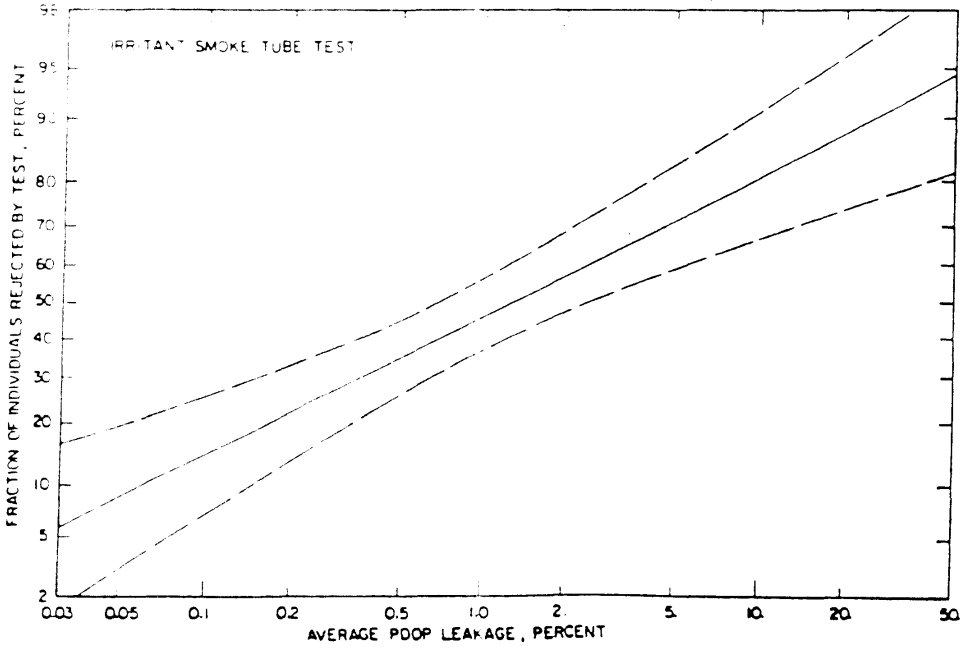


FIGURE 6 - POSITIVE PRESSURE TEST RESPONSE FUNCTION.



[illegible] ISOAMYL ACETATE TEST RESPONSE FUNCTION.



[illegible] IRRITANT SMOKE TUBE TEST RESPONSE FUNCTION.

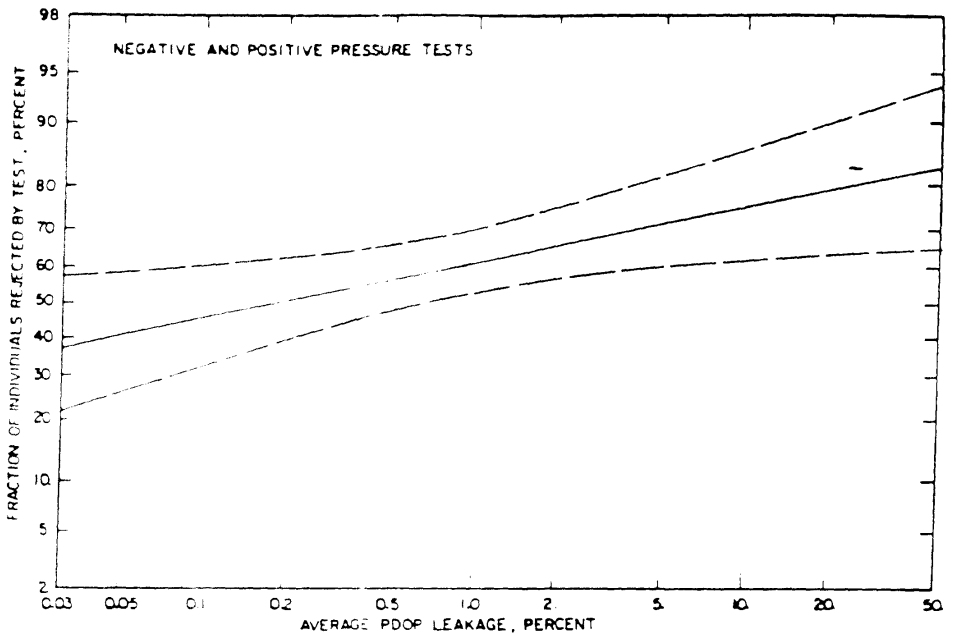


FIGURE [illegible] NEGATIVE AND POSITIVE PRESSURE TEST RESPONSE FUNCTION.

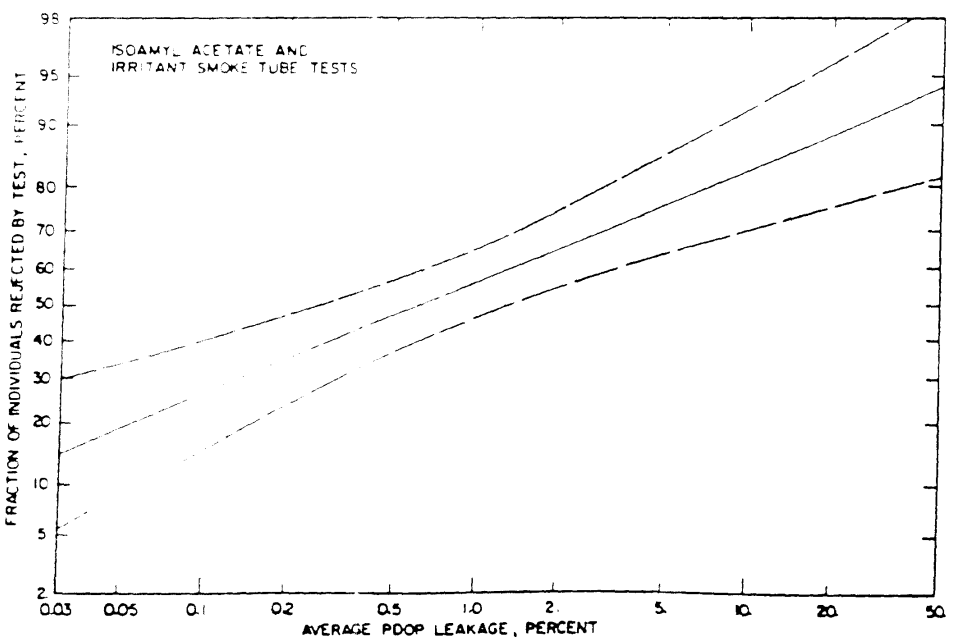


FIGURE [illegible] ISOAMYL ACETATE WITH SMOKE TUBE TEST RESPONSE FUNCTION.

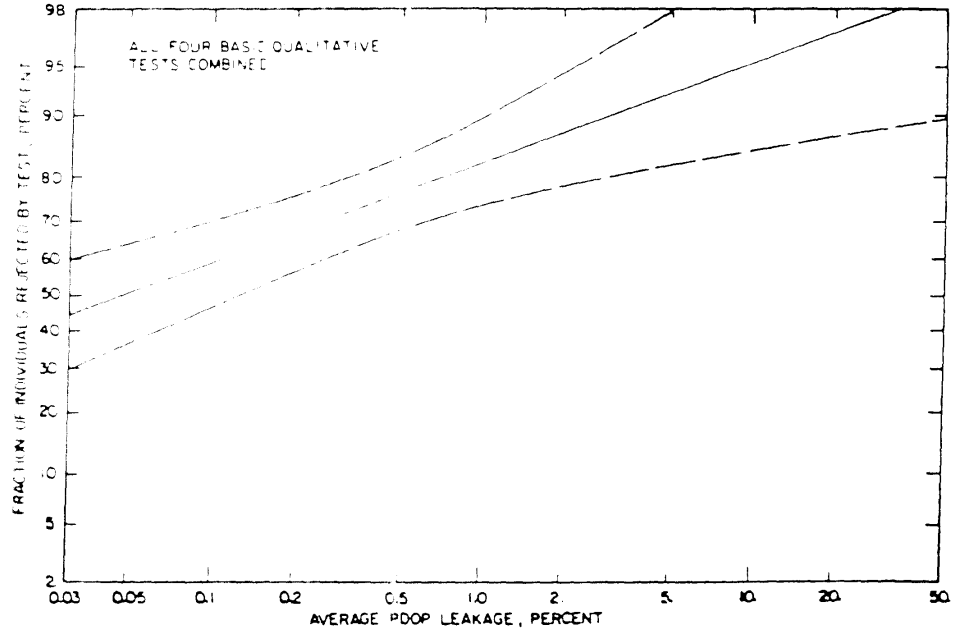


FIGURE 11 - ALL FOUR BASIC QUALITATIVE TEST COMBINED RESPONSE FUNCTION.

Cumulative Distribution Functions for Respirator Leakages in Given Populations

When a given model respirator is tested repeatedly for faceseal leakage on an individual or a population of individuals, a distribution of leakages is created. A leakage distribution is a function of many factors such as those discussed in Chapter 2, including the anthropometric distribution of facial sizes in the test population (21,22), head strap tension, and respirator faceseal design. Hounam (6,10) and Burgess (39) have observed that the penetration leakage distribution of a population of individuals tested on a given mask can be approximated with a lognormal distribution. In this investigation it was observed that lognormal probability paper (2- or 3-cycle) was a convenient way of plotting the cumulative distribution leakage functions for individual respirators. Leidel and Busch (46) have described a data transform to be used with lognormal probability paper for presenting respirator leakage data.

Respirator leakage data for anthropometrically representative panels or large industrial populations were not measured in this study. A literature search indicated that appropriate summary data were available for the three classes of negative pressure respirators included in the study. These data were used to develop the cumulative distribution functions for respirator leakages necessary for evaluation of the impact of qualitative fit tests on the effectiveness of typical respiratory protection programs.

Halfmask air-purifying respirators

Appropriate air-purifying halfmask respirator data were available in a report by Barghini and Wilmes (47). The Barghini and Wilmes (47) data for three halfmasks were obtained using a 35-person anthropometrically-weighted panel (Figure 12). The respirator fit leakage values were the average NaCl penetration for six maneuvers as measured with an Air Techniques, Incorporated model TDA-60 fit test system. The three halfmask models tested (Norton 7500, Willson 1210, MSA Custom Comfo II) were fitted with HEPA filter cartridges so that the leakage values were representative of leakage at the faceseal and exhalation valve.

Fullface air-purifying respirators

Appropriate air-purifying fullface respirator data were available in a report by Held et al. (48). The data for seven fullface respirators plotted in Figures 13 through 19 were obtained from testing performed on personnel at Lawrence Livermore Laboratory who wore or might have occasion to wear any type of fullface respiratory protective equipment. The respirator fit leakage values were average PDOP penetrations for six maneuvers.

Fullface SCBA respirators (demand mode)

Appropriate fullface self-contained breathing apparatus (SCBA) respirator data were available from testing performed at Los Alamos Scientific Laboratory and summarized by the Industrial Safety Equipment Association (49). The data for seven SCBA's operating in the demand mode (Figures 20 through 26) were obtained using a 31-man anthropometrically-selected panel. The respirator fit leakage values were

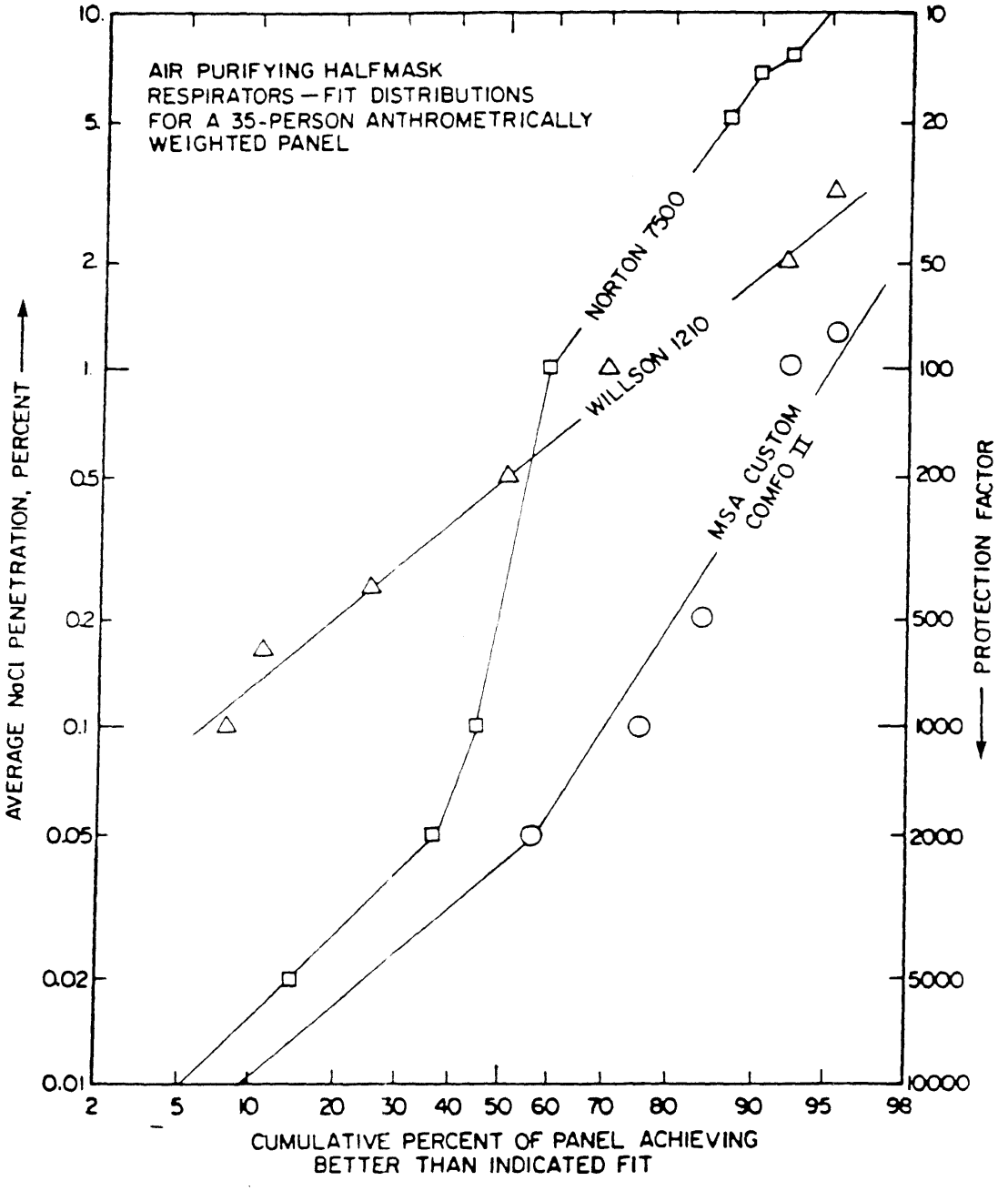


FIGURE 12 - HALFMASK RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTIONS, DATA FROM (47).

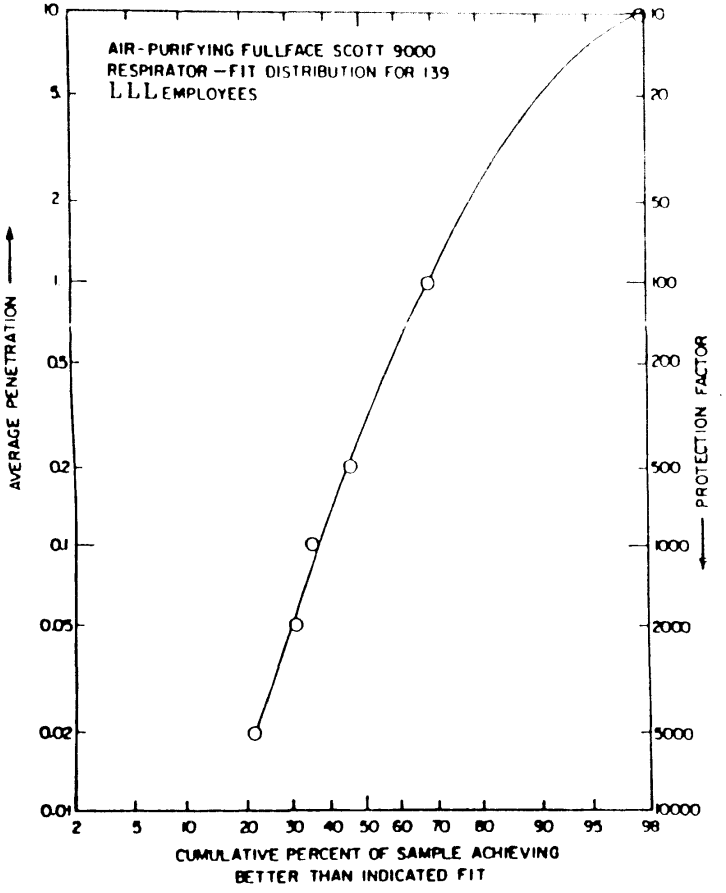


FIGURE 13 - FULLFACE RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR SCOTT 9000, DATA FROM (48).

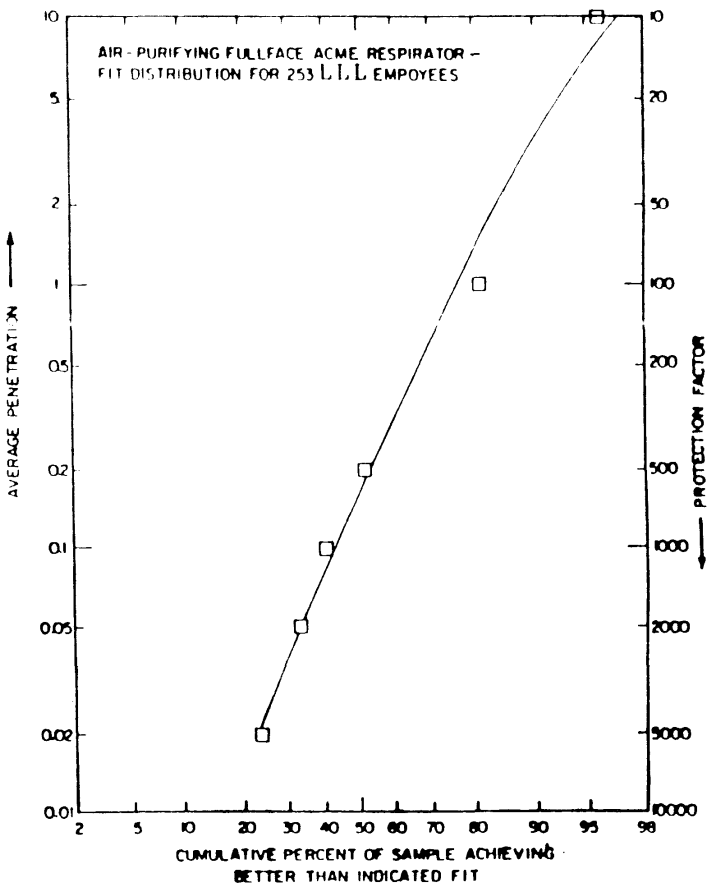


FIGURE 14 - FULLFACE RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR ACME, DATA FROM (48).

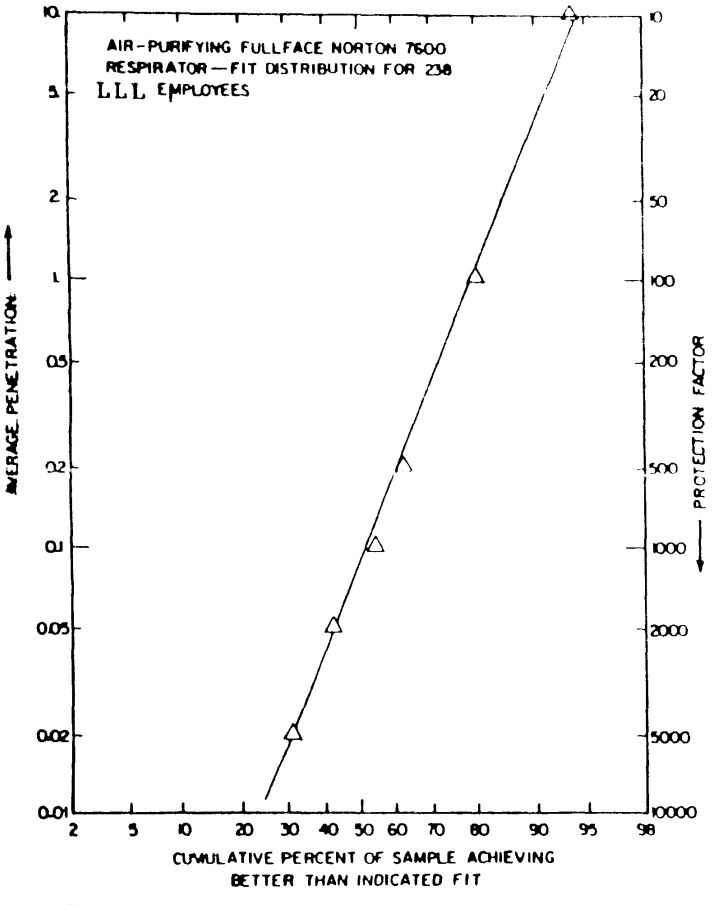


FIGURE 15 - FULLFACE RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR NORTON 7600, DATA FROM (48).

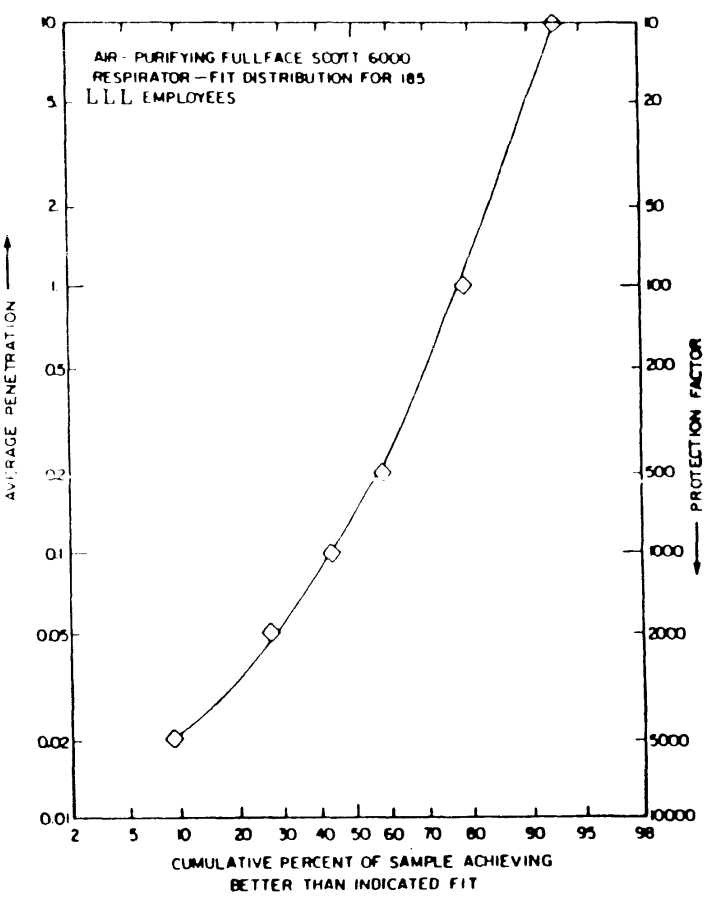


FIGURE 16 - FULLFACE RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR SCOTT 6000, DATA FROM (48).

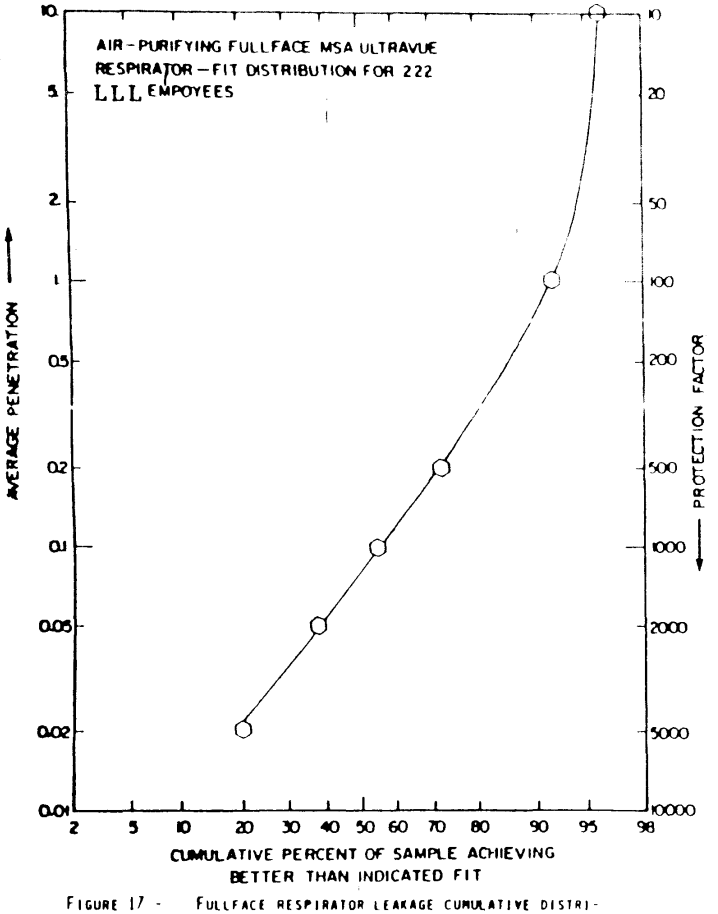


FIGURE 17 - FULLFACE RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR MSA ULTRAVUE, DATA FROM (48).

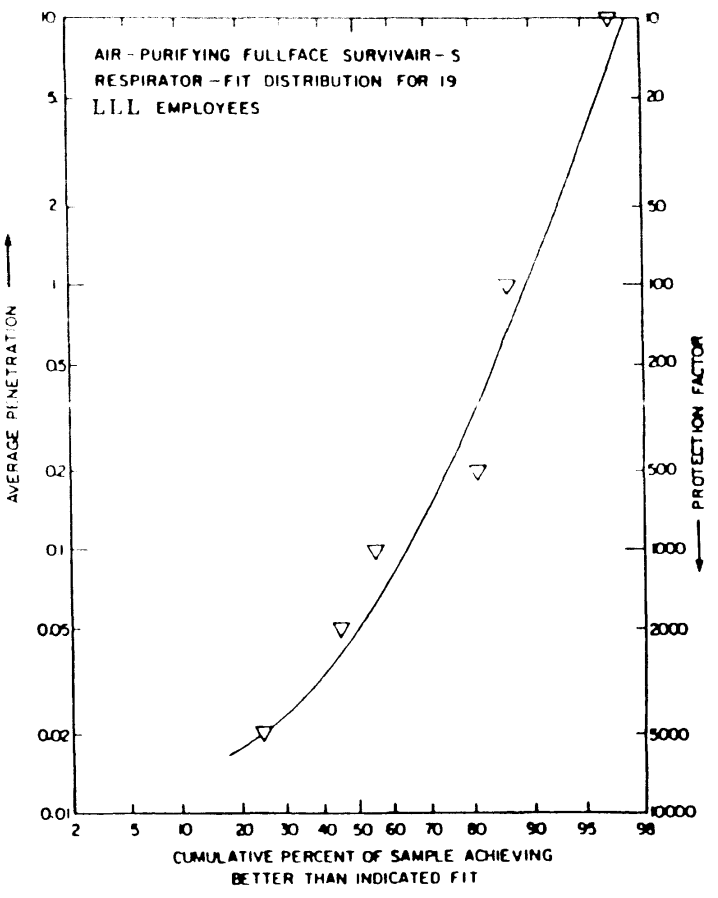


FIGURE 18 - FULLFACE RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR SURVIVAIR - S, DATA FROM (48).

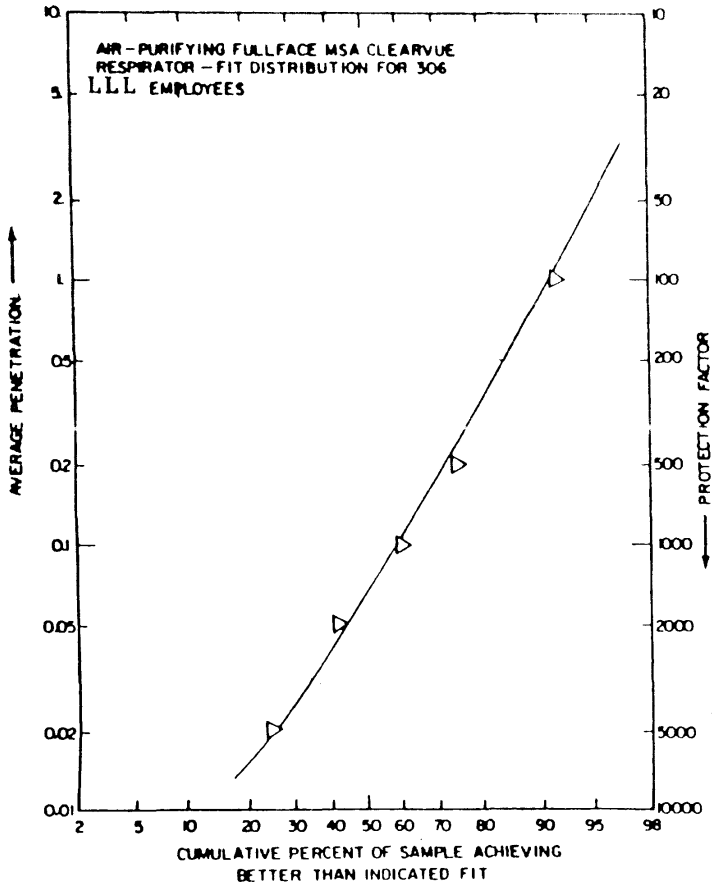


FIGURE 19 - FULLFACE RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR MSA CLEARVUE, DATA FROM (48).

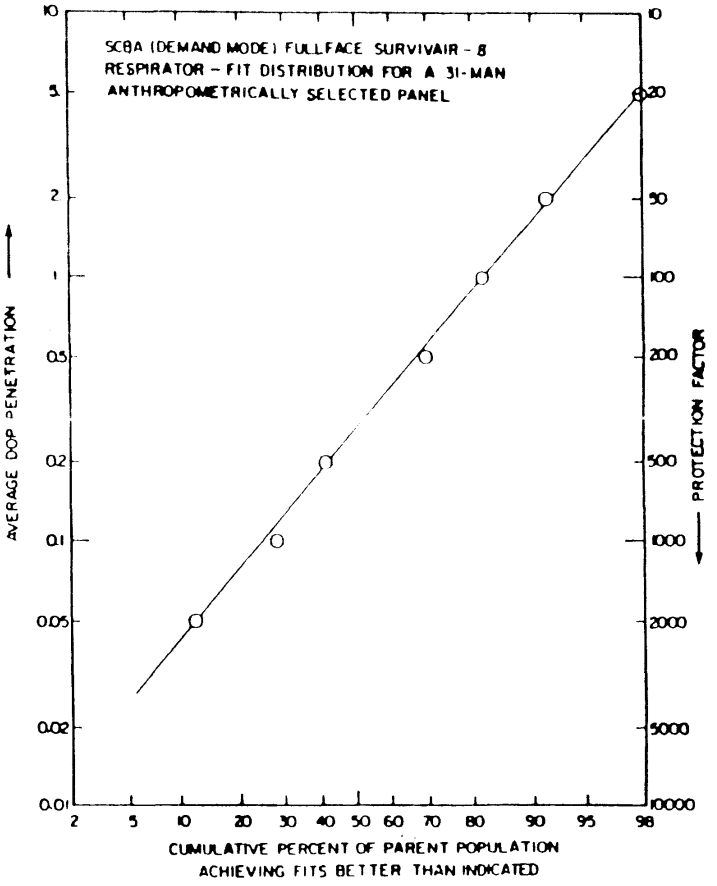


FIGURE 20 - SCBA RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR SURVIVAIR - 5, DATA FROM (49,50).

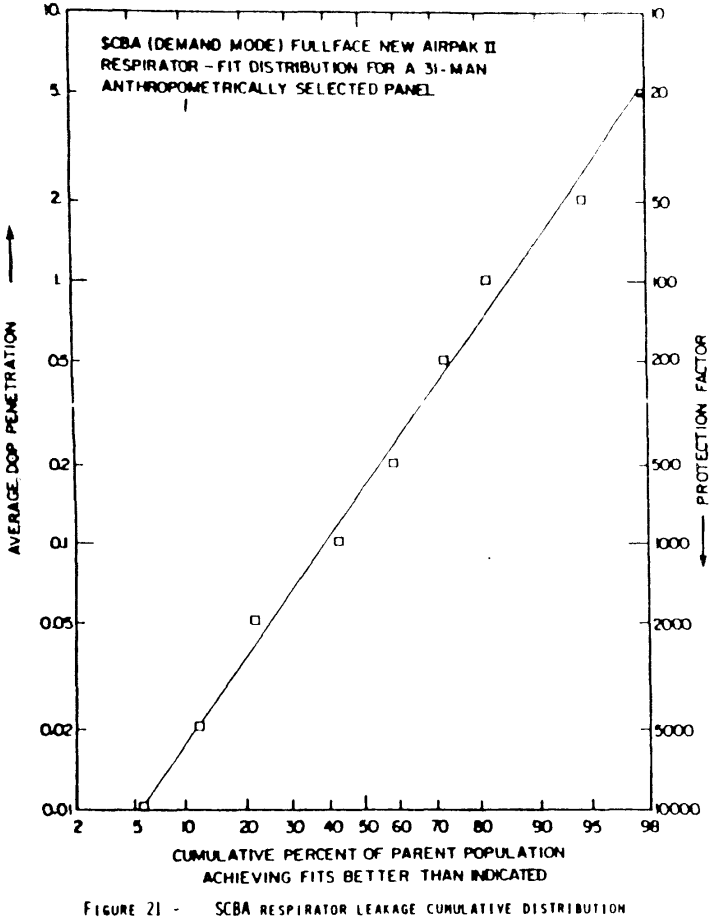


FIGURE 21 - SCBA RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR NEW AIRPAK II, DATA FROM (49,50).

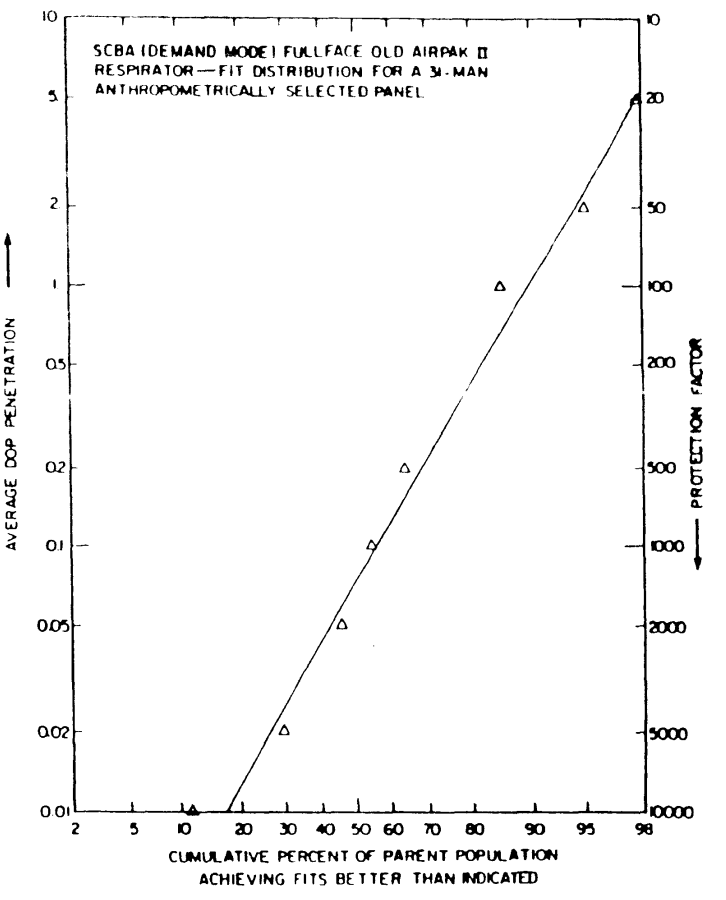


FIGURE 22 - SCBA RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR OLD AIRPAK II, DATA FROM (49,50).

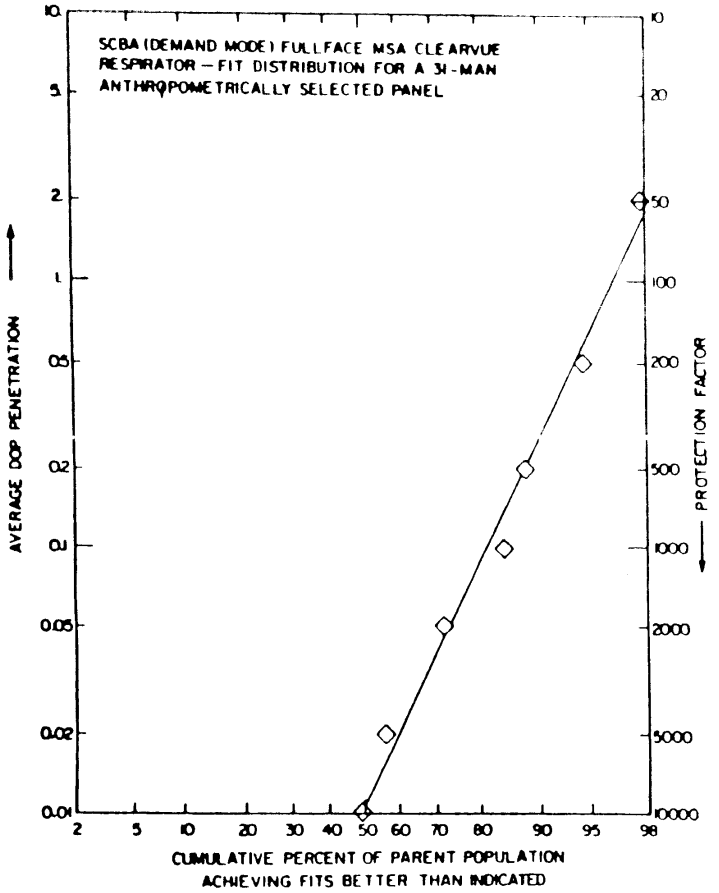


FIGURE 23 - SCBA RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR MSA CLEARVUE, DATA FROM (49,50).

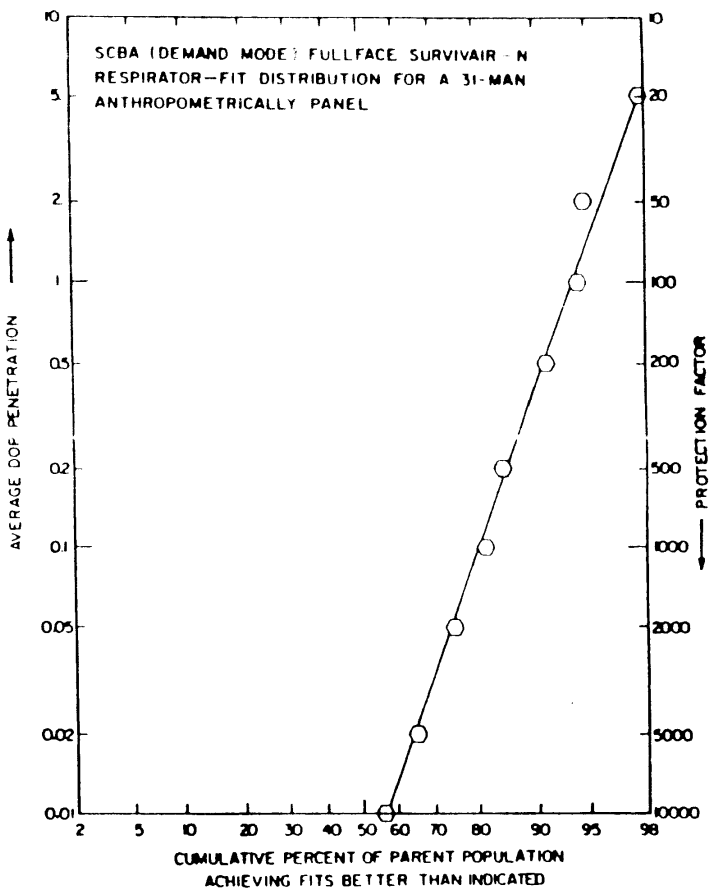


FIGURE 24 - SCBA RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR SURVIVAIR - N, DATA FROM (49,50).

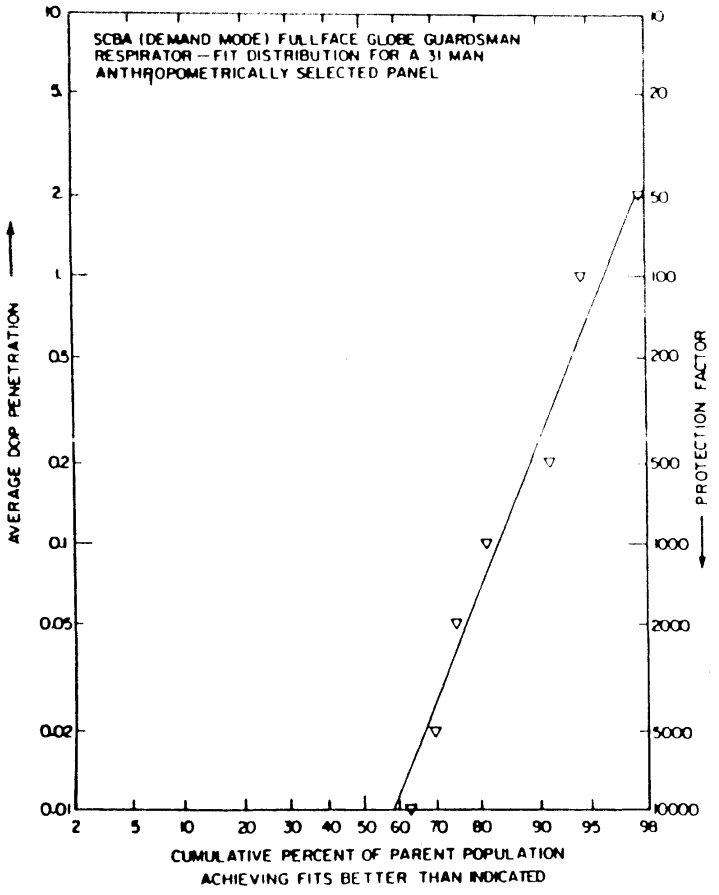


FIGURE 25 - SCBA RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR GLOBE GUARDSMAN, DATA FROM (49,50).

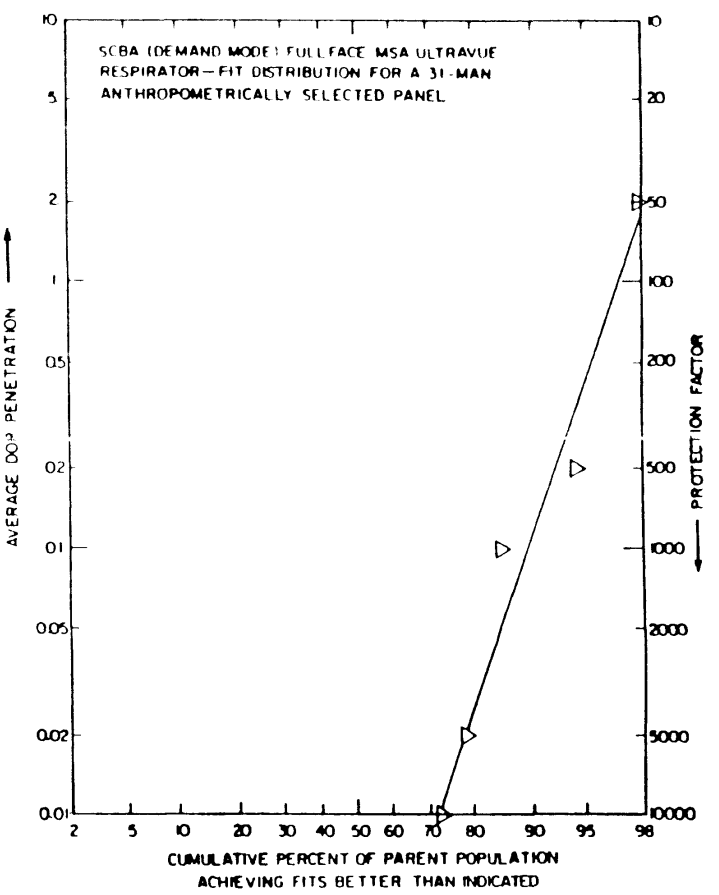


FIGURE 26 - SCBA RESPIRATOR LEAKAGE CUMULATIVE DISTRIBUTION FUNCTION FOR MSA ULTRAVUE, DATA FROM (49,50)

the average penetration for each SCBA operated in the demand mode (negative pressure in the facepiece). The test procedure and similar data were reported by Hyatt and Richards (50).

Evaluating the Statistical Performance of a Screening Test

In the medical field, frequent use has been made of screening tests, based either on clinical observations or laboratory techniques, that classify individuals as healthy or diseased. Most of these tests are quick, simple, and relatively inexpensive and thus tend to be imprecise and/or inaccurate. That is, healthy individuals will sometimes be classified as ill, while others who are truly ill may fail to be diagnosed as such. Statistical methods for evaluating the performance of medical screening tests have been described by Armitage (51), Colton (52), Grant (53), and Bay et al. (54).

The problem of evaluating the ability of the subjective qualitative fit tests to classify properly the fit of a particular respirator on an employee as adequate or inadequate was analogous to the evaluation of medical screening tests. In this study the classification of each fit as truly adequate or inadequate was governed by criterion values for the quantitative test measurements (average PDOP leakage). The adequate fit criteria were determined by the protection factor (PF) chosen for each class of respirator. When properly applied in a respiratory protection program, protection factors govern the maximum concentration of contaminant in which the respirators are used for inhalation protection (1). For air-purifying halfmasks a PF of 10 has been recommended by Pritchard (1), Hyatt (13), and Douglas et al. (25). A PF of 10 corresponds to a criterion of 10% average PDOP leakage. For fullface air-purifying respirators or SCBA's in the demand mode a PF of 50 has been

recommended in references (1,13,25). A PF of 50 corresponds to an adequate fit criterion of 2% average PDOP leakage. Some respirator specialists believe a PF of 100 should be assigned to fullface air-purifying respirators or SCBA's in the demand mode. A PF of 100 is equivalent to a 1% PDOP leakage criterion.

Table 6 summarizes the definitions used in this report for qualitative fit screening tests. Table 7 shows the typical format used for reporting the results of a screening test and used in this report. Of the 11 statistics defined in Table 6, four are particularly useful in the evaluation of qualitative fit tests. These are the alpha-error, beta-error, AER, and PAFR, which are discussed in the sections that follow.

Performance Statistics for Respirator Fit Screening Tests

Alpha-error, incorrect rejection of an adequate fit

A qualitative respirator fit screening test should have a low alpha-error, but this is due to economic rather than employee health considerations. There is no health hazard due to an alpha-error (false rejection of an adequate fit). In practice, if a wearer's respirator fit is rejected by the qualitative test, the individual first readjusts the fit (such as tightening the headstraps) and is retested. Or another size or brand of respirator is tested on the user. However, many employers do not have available more than one brand of respirator because of the greatly increased inventory and maintenance costs required. Thus, a high alpha-error introduces an unnecessary economic burden to the employer because employees rejected by the screening test must either be unnecessarily provided with different makes of respirators or not be allowed to work where they might be exposed to the toxic chemical.

Table 6 - Statistic definitions for qualitative fit screening tests.

Statistic	Definition
a	true positives, inadequate fits detected by screen
b	false negatives, inadequate fits not detected by screen
c	false positives, adequate fits rejected by screen
d	true negatives, adequate fits accepted by screen
$\alpha = c/(c + d)$	probability of a false positive among the adequate fits
$\beta = b/(a + b)$	probability of a false negative among the inadequate fits
$1 - \alpha = d/(c + d)$	specificity = probability that the screening test will correctly accept an adequate fit
$1 - \beta = a/(a + b)$	sensitivity = probability that the screening test will correctly reject an inadequate fit
$(a + b)/(a + b + c + d)$	prevalence of inadequate fits in total sample population
$AER = b/(b + d)$	accepted employee risk = proportion of accepted employees with inadequate fits
$PAPR = c/(a + c)$	proportion with adequate fits in those rejected by the screening test

Table 7 - Screening test summary table.

Quantitative PDOP classification based on adequate fit criterion	Qualitative test result		Total
	Reject (+)	Accept (-)	
Reject (+)	a	b	a + b
Accept (-)	c	d	c + d
Total	a + c	b + d	a + b + c + d

Beta-error, incorrect acceptance of an inadequate fit

Any qualitative fit test must have a very low beta-error (accepting an inadequate fit) because of wearer health considerations. The very serious consequence of a substantial beta-error is the possible exposure of the employee to toxic levels of airborne chemicals due to excessive mask leakage.

AER, accepted employee risk, proportion of inadequate fits in those accepted by the screening test

The AER is the proportion of those employees accepted by the qualitative test with fits that should have been rejected. The accepted employee risk or AER is a function of the alpha-error, beta-error, and the prevalence of inadequate fits in the tested population. The functional dependence of the AER on these three independent variables can be given as:

$$AER = \frac{\beta}{\beta + \left[1 - \alpha\right]\left[\frac{1}{prev} - 1\right]}$$

The AER indicates the health hazard to employees because it is the proportion of employees in the plant that have passed the screening test, but do not have the required health protection.

PAFR, proportion of adequate fits in those rejected by the screening test

The PAFR is the proportion of those employees rejected by the qualitative test with fits that should have been accepted. The PAFR is a function of the alpha-error, the beta-error, and the prevalence of poor fits in the tested population. The functional dependence of the PAFR on these three variables can be expressed as:

$$PAFR = \frac{\alpha}{\alpha + \left[1 - \beta\right]\left[\frac{prev}{1 - prev}\right]}$$

The PAFR imposes an economic burden on the employer since employees rejected by the screening test must be provided with a different model respirator or not allowed to work in hazardous exposure areas. The PAFR represents those employees that have been rejected by the screening test, but could have sufficient health protection if their respirators are properly worn.

Estimating Qualitative Fit Test Performance Based on Typical Respirator Leakage Functions

The qualitative fit test response data described in Chapter 4 and summarized in Appendix D were used to estimate response functions for seven qualitative test variations. These response function estimates were then combined with leakage cumulative distribution functions for "high" and "low" performance respirators to estimate the level of performance of the seven qualitative fit tests in respiratory protection programs.

From each of the three classes of respirators represented by the data in Figures 12 through 26, one respirator representing "high" performance and one representing "low" performance were selected. A "high" performance respirator had a relatively low percentage of individuals with leakages exceeding the adequate fit criterion (inadequate fits) and a "low" performance mask had a relatively high percentage exceeding the criterion. Table 8 summarizes the respirator brands selected for the analysis. These choices enable the calculation of range estimates for the alpha-error, beta-error, AER, and PAFR, as discussed in Chapter 4. Table 9 summarizes the estimated parameters for the predicted performance of the qualitative tests with halfmask respirators at a 10% criterion. Tables 10 and 11 present performance estimates for the qualitative tests applied to fullface respirators at 1% and 2% criteria, respectively. Tables 12 and 13 show the estimated performance statistics for qualitative tests applied to SCBA demand-mode masks at 1% and 2% adequate fit criteria, respectively. An example of the procedure used to obtain the estimates in Tables 9 through 13 is given in Appendix B.

Table 8 --Respirator brands selected for estimating screening test performance.

Respirator class	High performance example	Low performance example
Halfmask, air-purifying	MSA Custom Comfo II	Norton 7500
Fullface, air-purifying	MSA Clearvue	Scott 9000
Fullface SCBA (demand)	MSA Ultravue	SurvivAir A

Table 9 - Predicted statistical performace of qualitative fit tests on two halfmask air-purifying respirators (criterion = 10% average NaCl leakage). High performance respirator is MSA Custom Comfo II and low performance respirator is Norton 7500.

Estimated statistic	Respirator performance	Qualitative test						
		NP	PP	IAA	ST	NP+PP	IAA+ST	ALL
Alpha-error, probability of false rejection by qualitative test (%)	high	16.2	36.9	19.1	13.3	42.5	22.9	52.3
	low	20.4	56.1	34.0	31.9	52.4	40.4	66.5
Beta-error, probability of false acceptance by qualitative test (%)	high	65.7	21.4	20.0	10.0	20.0	10.0	2.9
	low	66.0	23.0	20.0	12.0	20.0	11.0	2.8
AER, % of accepted employees with inadequate fits	high	0.6	0.2	0.2	0.1	0.2	0.1	0.04
	low	4.2	2.7	1.6	0.9	2.2	1.0	0.4
PAFR, % of adequate fits in those rejected by qualitative fit test	high	98.8	98.4	96.4	95.6	98.6	97.4	98.7
	low	91.9	93.3	89.0	87.3	92.6	89.5	92.8

Table 10 - Predicted statistical performance of qualitative fit tests on two fullface air-purifying respirators (criterion = 1% average leakage). High performance respirator is MSA Clearvue and low performance is Scott 9000.

Estimated statistic	Respirator performance	Qualitative test						
		NP	PP	IAA	ST	NP+PP	IAA+ST	ALL
Alpha-error, probability of false rejection by qualitative test (%)	high	16.5	37.8	20.0	14.0	43.5	24.0	54.0
	low	17.1	39.3	22.2	16.5	45.1	26.7	56.5
Beta-error, probability of false acceptance by qualitative test (%)	high	72.4	35.2	41.0	36.2	30.5	29.5	9.5
	low	71.9	34.2	39.0	33.9	30.2	27.7	9.4
AER, % of accepted employees with inadequate fits	high	9.2	6.2	5.7	4.7	5.9	4.4	2.4
	low	28.0	20.2	18.4	15.4	19.8	14.5	8.8
PAFR, % of adequate fits in those rejected by qualitative test	high	82.6	83.3	74.3	65.1	84.2	74.4	83.6
	low	57.9	57.0	44.6	35.7	59.0	45.1	58.1

Table 11 - Predicted statistical performance of qualitative fit tests on two fullface air-purifying respirators (criterion = 2% average leakage). High performance respirator is MSA Clearvue and low performance is S cott 9000.

Estimated statistic	Respirator performance	Qualitative test						
		NP	PP	IAA	ST	NP+PP	IAA+ST	ALL
Alpha-error, probability of false rejection by qualitative test (%)	high	18.8	38.9	21.6	16.0	44.6	26.0	55.7
	low	18.2	41.9	25.8	21.1	47.6	31.1	60.2
Beta-error, probability of false acceptance by qualitative test (%)	high	69.6	30.4	33.6	26.8	26.8	21.4	7.1
	low	71.0	31.4	34.3	27.6	27.9	22.9	7.1
AER, % of accepted employees with inadequate fits	high	4.7	2.9	2.5	1.9	2.8	1.7	0.9
	low	18.7	12.6	10.9	8.5	12.4	8.1	4.6
PAFR, % of adequate fits in those rejected by qualitative test	high	90.4	90.4	84.6	78.6	91.1	84.8	91.0
	low	70.2	69.7	59.6	52.4	71.3	60.3	70.9

Table 12 - Predicted statistical performance of qualitative fit tests on two fullface SCBA respirators in the demand mode (criterion = 1% average DOP leakage). High performance respirator is MSA Ultravue and low performance respirator is SurvivAir S.

Estimated statistic	Respirator performance	Qualitative test						
		NP	PP	IAA	ST	NP+PP	IAA+ST	ALL
Alpha-error, probability of false rejection by qualitative test (%)	high	15.9	30.2	11.9	5.4	36.2	13.5	41.7
	low	19.2	44.9	28.3	23.3	50.6	34.8	65.6
Beta-error, probability of false acceptance by qualitative test (%)	high	70.8	33.3	41.7	35.4	29.2	29.2	10.0
	low	72.8	36.7	43.3	39.4	32.2	32.2	11.1
AER, % of accepted employees with inadequate fits	high	2.0	1.2	1.2	0.9	1.1	0.8	0.4
	low	16.5	12.7	11.7	10.1	12.5	9.8	6.6
PAFR, % of adequate fits in those rejected by qualitative test	high	95.0	94.9	89.2	77.4	95.4	88.6	94.9
	low	76.2	76.4	69.5	63.7	77.3	70.0	77.1

Table 13 - Predicted statistical performance of qualitative fit tests on two fullface SCBA respirators in the demand mode (criterion = 2% average DOP leakage). High performance respirator is MSA Ultravue and low performance respirator is SurvivAir S.

Estimated statistic	Respirator performance	Qualitative test						
		NP	PP	IAA	ST	NP+PP	IAA+ST	ALL
Alpha-error, probability of false rejection by qualitative test (%)	high	16.1	30.5	12.3	5.9	36.5	14.0	42.2
	low	19.9	46.5	30.8	26.5	52.2	37.7	67.8
Beta-error, probability of false acceptance by qualitative test (%)	high	71.4	28.6	35.7	25.0	28.6	21.4	7.1
	low	71.2	32.5	36.2	30.0	28.8	25.0	7.5
AER, % of accepted employees with inadequate fits	high	1.2	0.6	0.6	0.4	0.6	0.4	0.2
	low	7.2	5.0	4.4	3.4	5.0	3.4	2.0
PAFR, % of adequate fits in those rejected by qualitative test	high	97.2	96.8	93.1	84.7	97.3	92.6	97.0
	low	88.8	88.8	84.7	81.3	89.4	85.3	89.4

Repeatability of Quantitative Leakage Measurements

The repeatability of quantitative leakage measurements will be defined as the interday variability shown in leakage measurements obtained using a given apparatus on a user wearing a given mask on different days. The reproducibility of the measurements would include the variability reported as repeatibility plus the variability due to taking measurements in different locations with different equipment.

Interday leakage variability is a function of fit test equipment precision and the differences in faceseal fit due to the wearer donning the same mask on different days. However, interday leakage variability is largely due to factors such as differences in positioning the respirator on the face, headstrap position, headstrap tension, and beard growth. This is because the contribution to the interday variability from the equipment precision is small, as shown in a study by Lowry et al. (55). Their data indicated that at an average leakage of 5.1%, the NaCl method had a standard deviation of 0.37% (95% confidence interval: 0.22% to 0.83%) or a relative standard deviation of 7.3%. At an average leakage of 4.2%, the PDOP method had a standard deviation of 0.31% (95% confidence interval: 0.18% to 0.71%) for a relative standard deviation of 7.5%. The interday variability results in protection factor fluctuations and a different level of protection afforded the user each time the respirator is worn.

The Industrial Safety Equipment Association (ISEA) has observed (49):

"A significant lack of reproducibility of respirator performance test results is shown by the large number of tests carried out wherein the same test subject tested the same respirator several times achieving protection factors which vary over an extremely wide range."

It was a study objective to estimate the effect of repeatability of faceseal leakage measurements on the effectiveness of respiratory protection programs in which quantitative fit test systems are used. This was an important objective since the very few industrial respirator programs that incorporate quantitative PDOP or NaCl equipment do not routinely retest employees after the initial fit test measurement.

The data reproduced in the ISEA Report (49) were used to estimate leakage measurement repeatability. The appropriate parameter selected for evaluating the dispersion in multiple test leakage values on the same individual was the geometric standard deviation (GSD). The GSD is the dispersion parameter for the lognormal distribution and the logarithmic transform has been demonstrated to be a useful transform for normalizing most respirator leakage distributions (6,10,39,46). Table 14 presents 62 GSD's for five models of halfmask air-purifying respirators. Table 15 presents 43 GSD's for six models of fullface air-purifying respirators. The interpretation of varying GSD values is discussed in references (46) and (56).

Table 14 - Halfmask air-purifying respirator between-test geometric standard deviations (GSD).

Manufacturer/model	n	GSD	Manufacturer/model	n	GSD
Acme 8201-R	3	1.0	Welsh 7500	4	9.4
	5	7.0		9	5.9
	4	3.0		4	9.7
	5	8.1		4	24.0
	7	6.9		6	9.5
	3	10.4		6	6.7
	5	5.1		7	7.0
	10	5.3		4	24.0
	4	4.0		8	5.6
	5	3.5		7	3.9
				5	5.3
				3	4.8
American Optical AO R6000	3	10.4	Willson 1000	5	3.8
	3	2.3		4	2.7
	4	18.1		3	9.6
	9	18.8		5	2.6
	5	16.7		5	4.5
	5	2.7		3	1.7
	5	15.9		4	2.1
	4	11.9		4	6.6
	4	3.6		4	1.4
	5	7.0			
	3	2.2			
	3	3.3			
MSA Comfo	7	7.6			
	3	3.8			
	6	13.6			
	6	11.3			
	6	3.1			
	8	2.1			
	6	16.3			
	7	9.1			
	8	5.4			

Table 15 - Fullface air-purifying respirator between-test geometric standard deviations (GSD).

Manufacturer/model	n	GSD	Manufacturer/model	n	GSD
Acme Fullvision 601	7	3.2	Welsh 7680S	10	7.8
	4	4.2		4	2.8
	3	4.8		3	2.5
	3	4.8		3	2.2
	4	2.6		5	7.0
	4	1.9		6	3.4
	4	3.0		3	2.5
	3	3.3		6	2.6
	4	3.1		3	4.8
	4	2.2		3	3.3
	3	8.1			
Scottoramic Hi Effic	3	15.6	Willson TFMW Mono	4	2.1
	3	3.3		3	5.0
				3	10.4
				3	2.5
				3	5.6
				3	3.3
MSA Clearvue	5	10.2	Willson RFMW 809	4	9.1
	4	4.7		3	2.2
	3	1.0		4	19.4
	4	9.1		4	5.5
	6	7.8		3	2.2
	3	4.8		3	10.4
	4	6.9			
	3	10.0			

CHAPTER FIVE

DISCUSSION OF RESULTS

Response Functions for Adequate Qualitative Fit Tests

In order to discuss the implications of the results obtained in this study, it is useful to describe the fundamental characteristics required for an adequate qualitative fit test. The response function for an adequate qualitative fit test should have a very sharp discrimination ability in the region of the adequate fit criterion or screen level. Figure 27 shows the nature of realistic and desirable response functions for criteria of 1%, 2%, and 10% average PDOP leakage. An adequate response function would show a vertical line (infinite slope) at the screen level on a graph such as Figure 27.

That is, none of the wearers should respond to the test at leakages less than the adequate fit criterion, while 100% should respond at leakages greater than the fit criterion. However, any test depending on a subjective response by the wearer will have a finite slope due to response differences between individuals. The examples shown on Figure 27 were arbitrarily chosen to have a steep slope and reject 95% of the wearers at the adequate fit criteria (screen levels). To keep the beta-error and accepted employee risk (AER) acceptably low for respirators with a high prevalence of poor fits, the qualitative test must reject about 95% of the fits at the desired criteria. The response function for an adequate qualitative fit test should also exhibit a very steep slope so that alpha-errors and PAFR's will be acceptably low.

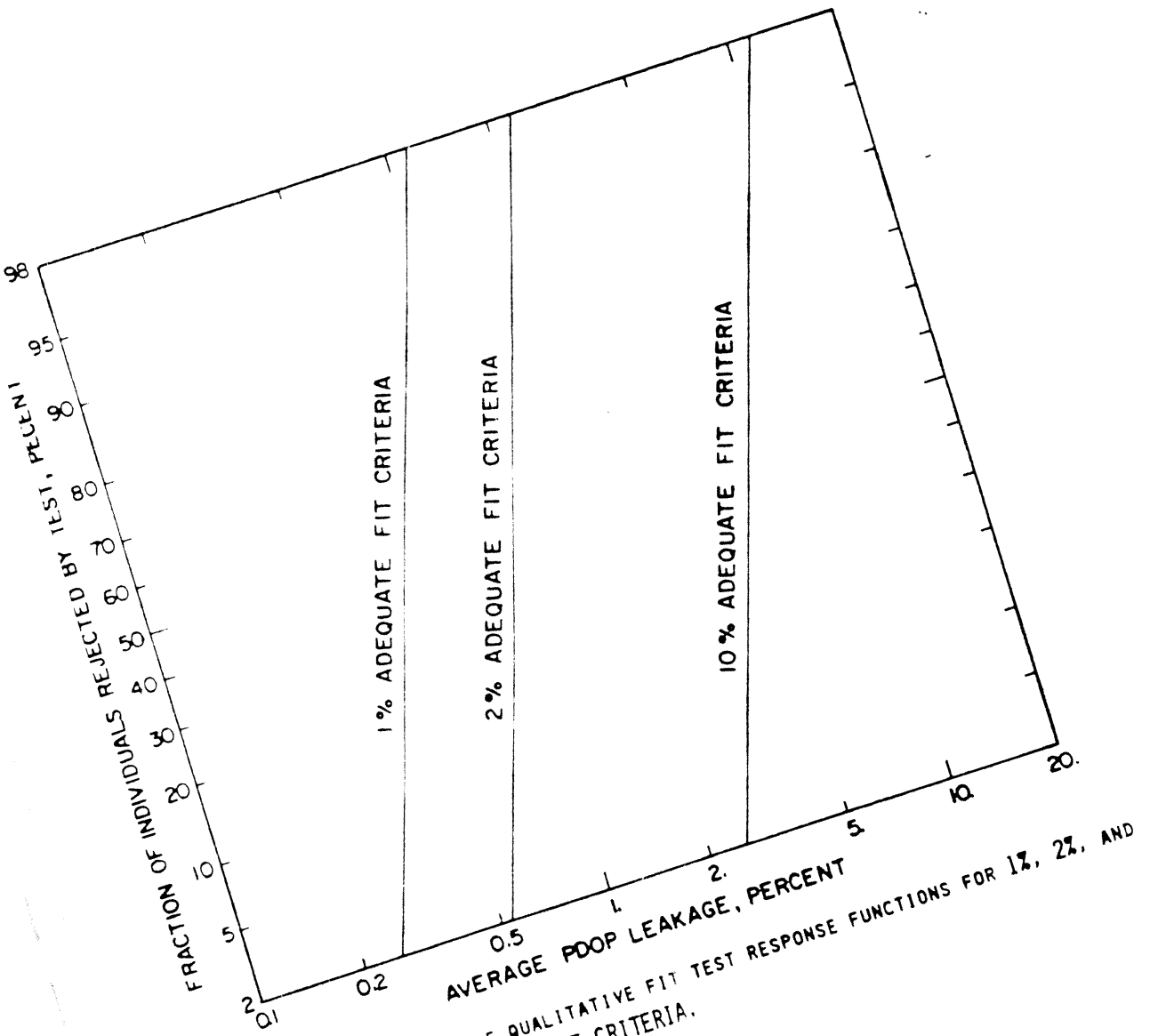


FIGURE 27 - DESIRABLE QUALITATIVE FIT TEST RESPONSE FUNCTIONS FOR 1%, 2%, AND 10% ADEQUATE FIT CRITERIA.

For example, consider the screening test statistics estimated in this study for the Scott 9000 fullface air-purifying respirator given in Table 10 for a 1% leakage criterion. The same statistics were estimated for theoretical qualitative tests of the type shown in Figure 27. Two theoretical screening tests were examined. The first had the same slope as the Figure 27 functions, but with 50% of the respirator wearers rejected at 1% leakage. The second test, shown as the "1% adequate fit criteria" function on Figure 27, had 95% of the wearers rejected at 1% leakage. The best qualitative test in Table 10 (for a low AER) was a combined test sequence consisting of the four basic fit tests. The results for the three tests are compared in Table 16, which indicates that an adequate qualitative test must reject at least 95% of the wearers at the adequate fit criterion so that beta-errors and AER's will be acceptably low (about 0.1%).

The rejection characteristics of the basic four qualitative fit tests, used individually and in combination, are summarized in Table 17. The information in Table 17 was obtained from Figures 5 through 11.

Table 16 - Comparison of actual to theoretical qualitative fit tests for the Scott 9000 respirator at 1% leakage adequate fit criterion.

Statistic	All four basic tests combined (from Table 10)	Theoretical test with 50% rejection at 1% leakage	Theoretical with 95% r tion at 1%
Alpha-error (%)	56	3	13
Beta-error (%)	9	5	0.3
AER (%)	9	2	0.2
PAFR (%)	58	7	23

Table 17 - Rejection characteristics of the of seven qualitative fit tests at three acceptable fit criteria.

Qualitative test	Estimated Percentage of wearers responding to test at: 1% leakage*	2% leakage*	10% leakage*
Negative pressure	25 (18-32)	28 (19-36)	32 (19-48)
Positive pressure	56 (48-64)	62 (51-70)	72 (58-82)
Isoamyl acetate	46 (37-55)	55 (44-65)	73 (58-84)
Irritant smoke tube	47 (38-57)	57 (48-69)	81 (66-91)
Negative with positive pressure	61 (52-70)	66 (56-75)	75 (62-85)
Isoamyl acetate with irritant smoke tube	57 (48-65)	65 (55-75)	82 (70-92)
All four basic tests in series	82 (74-90)	88 (78-94)	95 (84-99)

*Approximate 75% fiducial limits on estimates in parentheses

The estimates in Table 17 and Figures 5 through 11 indicate all the common qualitative fit tests, used individually or in combination, differ markedly from the fundamental characterists required for an adequate qualitative fit test. That is, the ability to reject at least 95% of the wearers at the adequate fit criterion and a steep slope for the graphical response function. For the basic four qualitative tests used individually the irritant smoke tube test had the best response function, and this test had essentially the same response function as the isoamyl acetate test. However, the proportions of users rejected by the irritant smoke tube test at or above the acceptable fit criteria of 1%, 2%, and 10% leakage were not large enough to obtain low beta-errors. Tables 9 through 13 indicate that the ranges of estimated beta-errors for the irritant smoke tube test are about 0.34 to 0.39 for a 1% leakage criterion, 0.25 to 0.30 for 2% leakage, and 0.10 to 0.12 for 10% leakage.

The three combinations of basic qualitative fit tests examined had substantially better response functions than the individual tests. However, only the combination of all basic four tests used in sequence achieved a high rejection rate of 95%, and this occurred only for the criterion of 10% leakage. This test combination achieved the lowest beta-error of about 0.03 at the 10% leakage criterion. But the response function for all basic four tests used in sequence did not have a steep enough slope (Figure 11) to maintain low alpha-errors. This test combination at a 10% leakage criterion had the highest estimated alpha-errors of about 0.52 to 0.66.

Effectiveness of Respirator Fitting Programs

The reliability of health protection afforded by a respiratory protection program is dependent upon the effectiveness of the component elements of the program including:

- respirator selection
- respirator fitting
- respirator wearing
- respirator maintenance

In many instances respirators are used for worker exposure situations where no other effective control measures can be implemented. There are many jobs in industry where feasible engineering controls cannot be used, are inadequate, or cannot be implemented on short notice.

In contrast to respiratory protection programs, the reliability of health protection afforded by engineering controls is dependent upon the effectiveness of the following elements:

- o design and installation
- o operation and maintenance

Engineering controls, when properly designed and applied, can reliably protect workers against toxic contaminants under routine conditions. The effectiveness of engineering controls, such as ventilation systems, is readily evaluated. The adequacy of design, installation, and performance should be evaluated after installation with worker exposure measurements and system air flow measurements. To assure system performance is maintained, simple air flow measurements should be periodically performed. It is possible to design and operate highly reliable engineering control systems.

Compared to engineering controls, it is difficult to evaluate routinely the effectiveness of respirators used to control exposure to industrial air contaminants. Determination of the protection afforded workers in typical occupational settings generally involves concurrent personal exposure measurements of ambient air and the air inside the respirator facepiece. Because of the difficulty associated with this type of dual exposure monitoring, respirator effectiveness evaluations have been limited to research studies of coal mining operations (57), cotton textile plants (58), abrasive blasting operations (59), and paint spraying operations (60).

There are many uncertainties involved in the wearing of respirators that affect the reliability of respiratory protection they provide (Chapter 2). And there are many

difficulties with evaluating respiratory protection provided by respirators under actual use conditions. Because of these considerations the author feels that respirator specialists should have very high confidence in the respirator fitting tests used as part of respiratory protection programs.

The statistical parameter derived in this study to judge the impact of qualitative fit tests on the effectiveness of respiratory protection programs was the accepted employee risk (AER). The AER is the estimated proportion of respirator wearers in a given population that have passed the qualitative fit test, but actually had fits that should have been rejected because the mask leakages exceed the acceptable fit criterion used in the respirator program. The author believes that an acceptable qualitative fit test should have an AER of 0.1% or less. That is, of the users who pass the qualitative fitting test and are assigned respirators, one in a thousand or less should fail to achieve the acceptable fit criterion used in the respiratory protection program. An acceptable AER criterion of 0.1% may seem conservative, but the reliability of health protection for a qualitative fitting program should approach the reliability of a quantitative fitting program. Hyatt et al. (8) concluded over seven years ago, "Where a reliable degree of protection is desired, it is advisable to use a quantitative method of respirator fitting. Qualitative methods are less reliable."

When respiratory protection programs are used in lieu of engineering controls, their reliability should approach that possible with engineering controls. Far too often respirators are worn in unknown concentrations of toxic contaminants that give no warning at hazardous levels. Industrial hygienists must be conservative when the failure or incorrect use of personal protective equipment can put the wearer at considerable risk, particularly if failure is not readily apparent and can result in acute or chronic health effects.

Possible Limitations of Study Group

Since the qualitative test response functions were estimated from test data obtained from male firefighters that were predominantly Caucasian, the possibility for biased results that could limit the inferences from the investigation must be examined. There are 200,000 paid professional firefighters and 2,000,000 part-time firefighters in the United States. Firefighters are routinely exposed to a variety of air contaminants, which may modify their response to odors and irritants. This is of course true for many occupational groups that use respirators for respiratory protection against toxic air contaminants.

An examination of the literature discussing odor response testing and the physiological basis of odor failed to discover any definitive research information regarding predicting the effect of variables on individual odor response. Some of the variables that were speculated on by several authors included sex, age, race, smoking habits, respiratory diseases, domestic environment, occupational environment, physical and mental fatigue, thirst and hunger, and onset of a head cold.

The preceding variables could not substantially affect the response functions obtained for the negative pressure and positive pressure tests, since they do not rely on the olfactory sense. The irritant smoke test does not rely on just olfactory response, since it is supposed to invoke an involuntary response through irritation. It is possible that different response functions might be obtained if study groups of differing races, ages, or including women, were to be tested with isoamyl acetate. However, in order to change substantially the estimated statistics reported in Tables 9 through 13, the new response functions would have to be similar to the adequate response functions discussed earlier.

Qualitative Fit Tests Applied to Halfmask Air-Purifying Respirators

The true in-plant performance of a particular qualitative test will depend on the response function, the leakage distribution function, and adequate fit criterion for each employee population it is applied to. However, the performance statistics estimated in this investigation are presented to indicate the predicted level of performance of qualitative fit tests applied to commercially available respirators in industrial populations.

Table 9 summarizes the estimated range of screening test performance statistics for halfmask air-purifying respirators. For a high performance respirator the irritant smoke tube test has an acceptably low AER (0.1%). But this qualitative test and the six others have very large PAFR's. All seven qualitative test PAFR's for the high performance respirator exceeded 95%. Of those employees rejected by any of the fit tests, 95 or more per 100 rejected can actually achieve a protection factor of 10 (10% or less leakage). Providing other respirators for the incorrectly rejected employees or transfering them to lower exposure areas can create increased costs for the employer. However, for the low performance respirator in Table 9, the range of AER's is too high (0.4% to over 4%). Both of the respirators used for the performance estimates in Table 9 have NIOSH certifications. The employer has effectively no way of knowing (or controlling) which respirator might provide high or low protection in his respiratory protection program. Therefore, there is a very high probability that the existing qualitative fit tests can present a health hazard with halfmask air-purifying respirators where a protection factor of 10 is intended.

In the introduction it was estimated by the author that there were about 10,000,000 air-purifying halfmasks in use in the United States in 1979. Table 9 indicates that an

average performance halfmask would have an AER of about 0.5% to 2% with the basic four qualitative tests. If all of the users were qualitatively fit tested, then an estimated 50,000 to 200,000 of the 10,000,000 accepted users would not be receiving a protection factor of 10 or more. Finally, if one assumes that about 10% of the respirator users are wearing their masks in airborne concentrations of about 10 times the health standard, a very rough estimate of 5,000 to 20,000 overexposed workers is obtained, with overexposure attributable to the use of qualitative fit tests with halfmask wearers.

Qualitative Fit Tests Applied to Fullface Air-Purifying Respirators

Tables 10 and 11 summarize the estimated ranges of qualitative fit test performance for fullface air-purifying respirators at 1% and 2% adequate fit criteria (PF = 100 and PF = 50, respectively). Even for a 2% criterion the high AER values for all seven tests represent the potential for a hazardous situation if a PF = 50 is used for a respiratory protection program involving fullface air-purifying respirators. For those respirators with low performance, the AER can be as high as 5% to 19%. This range of qualitative fit test AER values is far too high where fullface air-purifying respirators are used to obtain a high degree of health protection. There is a very strong probability that the existing qualitative fit tests can present a serious health hazard for use with fullface air-purifying respirators where protection factors of either 50 or 100 are intended.

The AER estimates for a PF = 100 estimated in this investigation for fullface respirators were compared to summary data reported by Hyatt et al. (8,24) and summarized in Table 2. Their protocol consisted of testing each subject with the irritant smoke test (normal breathing only) before measuring the quantitative mask

leakage in a DOP man test chamber. Only subjects that had obtained adequate seals with the irritant smoke were tested with the DOP procedure. However, for some of the six masks tested, substantial proportions of wearers were not receiving a PF = 100 after passing the irritant smoke test. The AER-equivalent values reported for the six masks were 5%, 4%, 0%, 3%, 22%, and 24%. This range of AER values is the same as the range of about 5% to 15% reported in Table 10 for this investigation. This indicates that the response function reported as Figure 8 for the irritant smoke test is not substantially different than that of the Hyatt et al. (8,24) test population.

It was estimated by the author that about 1,000,000 workers were wearing fullface air-purifying respirators for protection in 1979. Table 11 indicates that an average performance fullface mask would have an AER of about 5% to 10% with any of the basic four qualitative tests (2% leakage adequate fit criterion). If all of the fullface mask users were qualitatively fit tested and accepted, then about 50,000 to 100,000 of the users would not be receiving a protection factor of 50 or more. If one assumes that about 5% of the users are wearing their masks in airborne concentrations of about 50 times the health standard, a very rough estimate of 2,500 to 5,000 overexposed workers is obtained, with overexposure attributable to the use of qualitative fit tests with fullface mask wearers.

Qualitative Fit Tests Applied to SCBA Fullface Respirators (Demand Mode)

Tables 12 and 13 contain the estimated ranges of qualitative screening test statistics for SCBA fullface respirators (demand mode) at 1% and 2% adequate fit criteria, respectively. As with the air-purifying fullface respirators, at the 2% leakage criterion (PF = 50) the AER values are unacceptably high. For a high performance

SCBA the AER ranges from 0.2% to 1%, but for a low performance SCBA the AER can be as high as 2% to 7%. This range of qualitative fit test AER values is not sufficiently low so that respirator wearers can be assured of a strong degree of health protection. There is a very high probability that the existing qualitative fit tests can present a serious health hazard with SCBA fullface respirators in the demand mode where a PF of 50 or 100 is intended.

It was estimated by the author that about 600,000 workers were using SCBA (demand mode) respirators for protection in 1979. Of these, an estimated 400,000 would be operated in the demand-mode. Table 13 shows that an average performance SCBA demand-mode mask would have an AER of about 2% to 4% with any of the basic four qualitative fit tests (2% leakage adequate fit criterion). If all of the demand-mode SCBA users were qualitatively fit tested and accepted, then about 8,000 to 16,000 of the users would not be receiving a protection factor of 50 or more. If one assumes that about 10% of the users are wearing their masks in airborne concentrations of about 50 times the health standard, a very rough estimate of 800 to 1,600 overexposed workers is obtained, with overexposure attributable to the use of qualitative fit tests with SCBA respirators. Combining the estimates for the three classes of negative pressure respirators leads to totals of about 8,000 to 27,000 overexposed workers, if all these respirator wearers were tested and passed by the qualitative fit tests.

Quantitative Fit Retest Action Level

Presently, for many respiratory protection programs based on fit tests using either PDOP or NaCl equipment, the professional judgment regarding the quantitative

protection afforded an employee with a given respirator is made on the basis of only one test. This is analogous to making a professional decision regarding an employee's exposure status on the basis of only one days' exposure measurement out of many possible exposure days. Leidel et al. (61) demonstrated that an employee exposure measurement action level was necessary to indicate the need for additional exposure measurements because of the between-day variability of daily exposure averages. The action level, which triggered additional exposure monitoring for high exposure risk employees, affected those employees with moderate to high risk of being overexposed on 5% or more of their workdays.

The goal of an employer should be to design a respirator fit program that minimizes the probability that even a very low percentage of daily protection factors will fall below the stated protection factor used in the respirator program. That is, the program used by the employer should provide a high degree of confidence that a very high percentage of daily leakages are below the value equivalent to the protection factor used in the program. The author believes that the employer should try to achieve 95% confidence that at least 95% of the daily fits attained by each employee with his or her assigned respirator have less than 2% leakage for a desired protection factor of 50 or less than 10% leakage for a PF of 10.

If a single fit measurement indicated less than 2% leakage (for a fullface air-purifying respirator), one could not conclude that for all other wearings that employee will have average leakages less than 2%. This is because the measured leakage for a particular fit was drawn from a highly variable distribution of all other leakages. The particular measured leakage might have come from the low leakage portion of the distribution. Even though the one leakage was less than the screening level, there is a risk of leakages on other days exceeding the screening value. This

results in employee protection less than that indicated by the respective protection factors.

Figure 28 (Leidel et al. (61)) was calculated to estimate overexposure risk for an employee where the distributions of daily exposure averages were adequately described by lognormal distributions. This figure was used to estimate appropriate action levels for which quantitative retesting of an employee's respirator fit is indicated. Table 14 contains 62 GSD's for halfmask air-purifying respirators with essentially all exceeding 2.0. Figure 28 indicates that employees with between-day GSD's exceeding 2.0 and measurements exceeding 10% of a adequate fit criterion have greater than a 5% probability that at least 5% of the other days' measurements will exceed the criterion. Thus, an appropriate action level for quantitative fit retesting is 10% of the maximum desired respirator leakage. Table 15 contains 43 GSD's for fullface air-purifying respirators. Essentially all of these exceed 2.0, so a 10% fit retest action level is also suitable for fullface air-purifying respirators. Table 18 summarizes the recommended quantitative fit retest action levels.

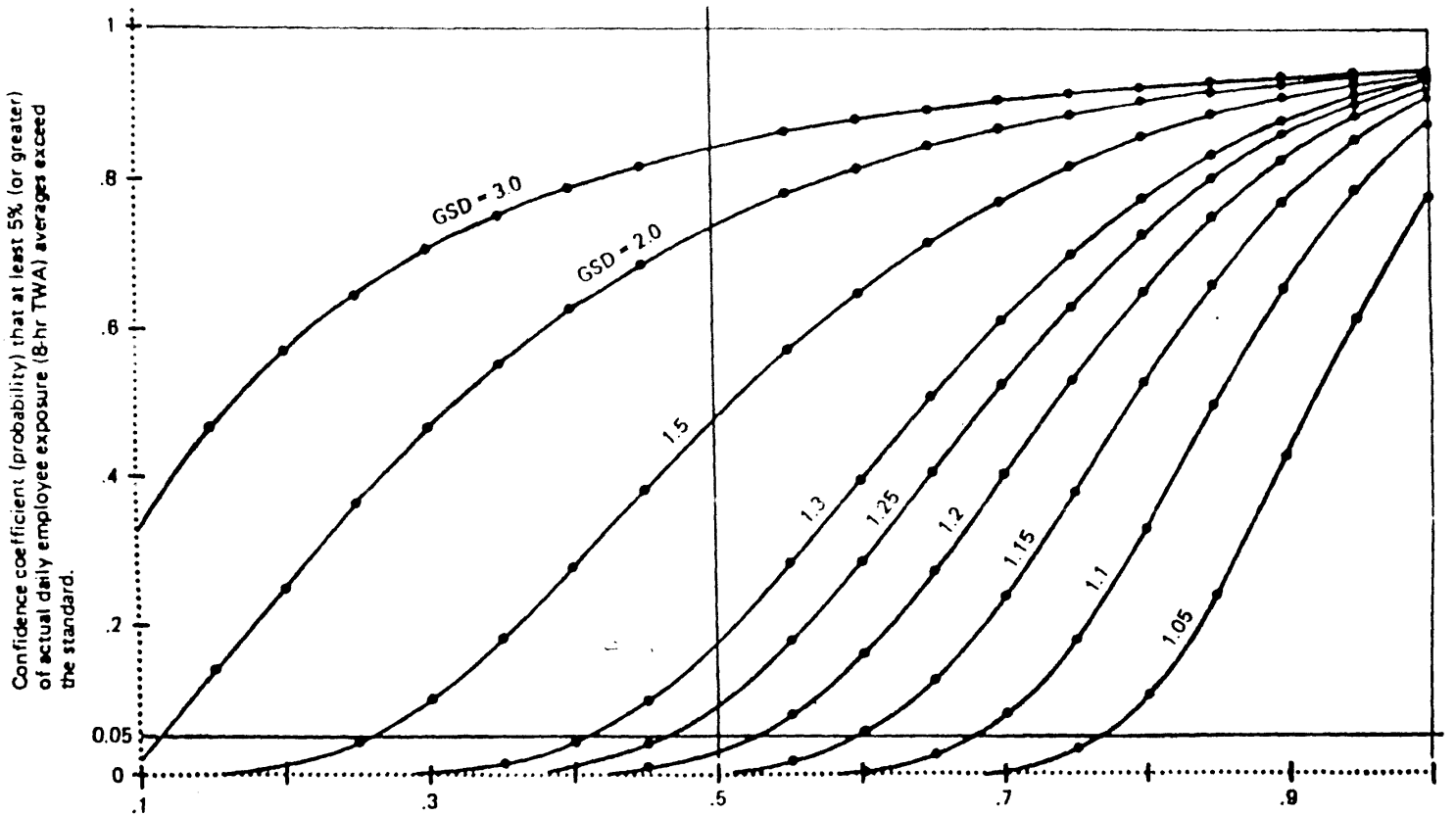


FIGURE 28 - EMPLOYEE OVEREXPOSURE RISK CURVES FOR ONE 8-HOUR TWA EXPOSURE MEASUREMENT (FROM LEIDEL ET AL. (61)).

Table 18 - Quantitative fit test action levels for retesting.

Desired PF for respiratory protection for at least 95% of the wearings	Desired maximum allowable average PDOP leakage (%) for at least 95% of the wearings	Retest fit of respirator on employee on a different day if first leakage exceeds this value (%)
10	10	1
50	2	0.2
100	1	0.1

CHAPTER SIX

SUMMARY AND CONCLUSIONS

The subjective responses of respirator wearers to four commonly used qualitative fit tests were determined by means of a field study. The study group consisted of firefighters from the Boston Fire Department. This was done for the following tests, used individually and in three combinations: negative pressure, positive pressure, isoamyl acetate, and irritant smoke tube. It was demonstrated that the probit-transform of the proportion of wearers responding to any of the seven qualitative fit tests was a linear function of $\log_{10}$ (average PDOP leakage), which was measured with quantitative fit test equipment. The seven response functions were estimated over a range of 0.03% to 50% mask leakage which was measured as average polydisperse dioctyl phtalate (PDOP) leakage, for three types of negative pressure respirators.

Based on summary data published in the literature, distributions were developed describing the quantitative range of respirator leakages found in several user populations. These distributions were presented for 17 respirators in 3 classes of negative pressure devices: air-purifying halfmasks, air-purifying fullface masks, and self-contained breathing apparatus (SCBA) operated in the demand mode. The distributions were presented as cumulative distributions plotted on lognormal probability paper.

Appropriate statistical parameters for evaluating the performance of qualitative fit tests used as screening tests in respiratory protection programs were developed. The statistics used included the alpha-error, beta-error, AER (proportion of accepted employees with inadequate fits), and PAFR (proportion with adequate fits in those rejected by the screening test). Estimates from the qualitative fit test response functions and the leakage cumulative distribution functions, for low and high performance respirators, were used to calculate range estimates of performance statistics for several user populations with three classes of negative pressure respirators. The response function characteristics necessary for an adequate qualitative fit test were examined and discussed. This allowed evaluation of the effectiveness of qualitative fit tests used in respiratory protection programs.

Lastly it was determined, from data available in the literature and by using an analogous situation existing for occupational exposure measurements, that interday variability of faceseal leakage could substantially decrease the effectiveness of respiratory protection programs in which quantitative fit test procedures are used. In many cases, a series of quantitative fit tests on different days, for a given user-mask combination, would be indicated.

Prior to this investigation, the statistical performance of the available qualitative and quantitative fit tests had never been properly examined to insure that the tests satisfactorily screen out wearers with poorly fitting respirators. Reliable fit tests are vital to the reliability of respiratory protection programs in which negative pressure respirators are used. The investigation of Hyatt et al. (8,24) indicated in 1972 that the irritant smoke and isoamyl acetate tests are not reliable and not infallible. However, many respiratory protection specialists remain convinced that qualitative tests do an adequate job.

The range of AER estimates reported in this investigation for the irritant smoke test at a PF = 100 for air-purifying fullface respirators are the same as those observed by Hyatt et al. (8,24). However, since the study population used in this investigation consisted of individuals with prior exposures to odorous and irritant air contaminants and because the following conclusions contradict accepted professional practice, it is recommended that the field study be repeated in other populations. These populations should include women, differing races, ages, and occupational groups. The response data from these populations should be analyzed by the statistical methods of this investigation or equivalent procedures for comparibility and to confirm the level of estimated performance statistics. It is hoped that other laboratories with suitable data will perform similar statistical analyses.

Because commercial versions of quantitative fit test systems are available today, the author believes that an acceptable qualitative fit test should have an accepted employee risk (AER) of 0.1% or less. The reliability of health protection afforded by a qualitative fitting program should approach the reliability of a quantitative fitting program. When respiratory protection programs are used in lieu of engineering controls, the reliability of their health protection should approach that possible with engineering controls. Industrial hygienists must be conservative when the failure or improper use of personal protective equipment can put the wearer at considerable risk, particularly if the inadequate protection is not readily apparent and can result in acute or chronic health effects. A failure in the fitting program cannot be compensated for by the other elements of the respiratory protection program.

Based on the results of the investigation reported herein, the following conclusions have been reached:

There is very strong probability that currently recommended qualitative fit tests can present a serious health hazard in respiratory protection programs in which negative pressure respirators are used.

The true in-plant performance of a particular qualitative test will depend on the response function, the leakage distribution function, and adequate fit criterion for each employee population it is applied to. However, it is concluded that the estimated performance statistics, reported in Tables 9 through 13 and discussed in Chapter 5, indicate the level of performance of qualitative fit tests applied to commercially available respirators in industrial populations. Also, the response functions estimated in this investigation indicated that all the common qualitative fit tests, used individually and in combination, differ markedly from the fundamental characteristics required for an adequate qualitative fit test.

For a low performance air-purifying halfmask respirator, the accepted employee risk (AER) estimates in Table 9 range from 0.4% to over 4%, depending on the qualitative test or test sequence relied upon. Because the AER indicates the health hazard to users, it is concluded that these values are unacceptably high, when a protection factor of 10 is chosen for the respiratory protection program.

For a low performance air-purifying fullface respirator and a 2% adequate fit criterion, the AER estimates in Table 11 range from 5% to 19% depending on the qualitative test. For 1% leakage, the AER estimates in Table 10 range from 9% to 28%. There is a very strong probability that the existing qualitative fit tests can present a serious health hazard with fullface air-purifying respirators where a protection factor of 50 or 100 is intended.

For a low performance SCBA (demand mode) respirator and a 2% adequate fit criterion, the AER estimates in Table 13 range from 2% to 7% depending on the qualitative test. For 1% leakage, the AER estimates in Table 12 range from 7% to 16%. There is a very strong probability that the current qualitative fit tests can present a serious health hazard with SCBA fullface respirators in the demand mode where a protection factor of 50 or 100 is intended.

The negative pressure and positive pressure qualitative fit tests recommended and required as user fit tests for negative pressure respirators are incapable of giving the wearer positive assurance of proper protection.

For air-purifying halfmask respirators tested with the negative pressure test, the accepted employee risk (AER) estimates in Table 9 range from 0.6% to 4.2%, depending on the make of halfmask relied upon (10% leakage criterion). With the positive pressure test applied to halfmasks , the AER can range from 0.2% to 2.7%. For air-purifying fullface masks, the AER estimates in Table 11 range from about 5% to 19% with the negative pressure test and 3% to 13% with the positive pressure test (2% leakage criterion). Lastly, for SCBA (demand mode) respirators, AER estimates in Table 13 range from 1% to 7% for the negative pressure test and 0.6% to 5% with the positive pressure test (2% leakage criterion).

Currently recommended qualitative fit tests create excessive expenses in respiratory protection programs because these tests incorrectly reject a very high proportion of adequate fits.

The estimates for the proportion of adequate fits rejected (PAFR) by the qualitative tests for low and high performance respirators were discussed in Chapter 5. For air-purifying halfmask respirators, the PAFR estimates in Table 9 range from 89% to almost 99%, depending on the qualitative test used. For air-purifying fullface respirators, the PAFR estimates in Table 11 range from about 60% to 91% for a 2% leakage adequate fit criterion. And for SCBA (demand mode) respirators, the PAFR estimates in Table 13 range from about 81% to 97%. These very high PAFR's create a needless economic burden for the employer since wearers rejected by the screening test must be provided with a different model respirator or not allowed to work in hazardous exposure areas.

Currently used and accepted qualitative fit tests based on human responses or senses have inadequate response functions and are unreliable tests for detecting excessive respirator leakage.

Current qualitative fit tests can not reject 95% of respirator wearers at adequate fit criteria such as 1%, 2%, and 10% leakage, typically used in respiratory protection programs. Quantitative fit test equipment (dioctyl phthalate, sodium chloride, or equivalent) should be used to measure faceseal leakage.

When quantitative fit test measurements are performed, multiple measurements should be obtained on different days for each user with an initial leakage determination exceeding a retest action level equal to 10% of the adequate fit criterion.

It is concluded that an initial leakage measurement exceeding 10% of the adequate fit criterion indicates an unacceptably high risk of leakages on other days exceeding the criterion. The need for a quantitative fit retest action level is discussed in Chapter 5. Any respiratory protection program should be capable of assuring that each user has at least 95% of all fit leakages below the criterion determined by the protection factor used in the program. In order to have this assurance, the employer should retest those employees with initial leakage measurements exceeding 10% of the adequate fit criterion. Additional leakage measurements would be indicated if the initial measurement exceeds 0.2% leakage (for a PF of 50) or 1% leakage (for a PF of 10).

One-sided upper tolerance limits can be calculated for quantitative fit test measurements obtained on different days to determine if a wearer can achieve adequate protection on future days.

When quantitative fit retesting is performed, leakage tolerance limits should be used to determine when enough additional tests have been obtained. The retest program should be designed to obtain sufficient tests on different days such that the employer can state with 95% confidence that 95% of the fits for the particular employee have leakages less than the maximum desired leakage. Appendix C explains how one-sided tolerance limits can be used to achieve this objective.

The typical maneuvers used in quantitative fit test protocols have no substantial effect on respirator performance measured while the wearer is breathing normally.

The typical maneuvers, demonstrated in Appendix A as having no significant effect on leakage, include deep breathing, moving head from side to side, and nodding head up and down. More meaningful maneuvers or exercises should be developed that are realistic and which stress the ability of the respirator to provide inhalation protection.