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Quantitative Respirator Fit Testing: Probed Facepiece versus Probed Cartridge

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QUANTITATIVE RESPIRATOR FIT TESTING:

Probed Facepiece versus Probed Cartridge

by

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ABSTRACT

QUANTITATIVE RESPIRATOR FIT TESTING:
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This study was performed to determine if there is a quantifiable difference between quantitative fit testing using a probed facepiece and a probed cartridge. Four subjects were tested on four different respirators. The respirators used were MSA & 3M full and half face respirator. Each subject performed each method five times per respirator. The results indicated no correlation between the two fit testing methods overall. However, a moderate correlation was found between the MSA respirators and the two methods. This study found many variables which influence fit testing. These include the type of respirator used (brand and facepiece), the probe location, the probe depth, and the variability found between donnings.

In conclusion, the probed cartridge method is an acceptable method for conducting quantitative fit tests. The probed cartridge would provide for a method to use a wearers own respirator to perform the quantitative fit test. This method would result in a more representative individual fit factor.

DEDICATION

This study is dedicated to the loving memory of my grandfather, Andrew H. Bunton.

ACKNOWLEDGEMENTS

I would like to thank my family, Mr. and Mrs. Ivan Bunton, Kelly Bunton, and Mr. and Mrs. Eugene Seward for their encouragement and love during the course of my accomplishment. My friends for their patience during my data collection. But most of all, I thank my husband, Chris Seward, for his patience, enthusiasm and support. May I always provide him with the same.

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CHAPTER 1

INTRODUCTION

Over two million American workers routinely depend upon respirators to prevent inhalation of toxic air contaminants (Rosenthal & Paull, 1985). Respirators are used for protecting the wearer from toxic fumes, dust, vapors, gases, nuisance dust and odors. The respirator facepiece must cover both the mouth and nose, and the respirator system either filters out the hazardous material or provides a clean air supply to the wearer. Respirators vary in size from one that covers only the mouth and nose, to one which covers the entire body.

Respiratory protective devices are used in work environments to control employee exposures when engineering controls are not feasible or are being installed. They are also used when administrative are controls unfeasible and under certain temporary or transient operating conditions. When a respirator is chosen as a means of protection from a harmful substance, careful consideration must be given to the user, the work environment, the requirements of the job, the contaminant, and the particular characteristic of the respirator (Beckett & Billings, 1985). Due to the importance of protecting the health and safety of the wearer, there must be a high level of commitment to the respirator's design, safety, quality assurance and

utilization (Birkner, 1988) .

Since the early days of the Occupational Safety and Health Act (OSHA), the National Institute of Occupational Safety and Health (NIOSH) has played a pivotal role in providing assurance that the respirators used in industry are effective and meet generally accepted construction and quality standards (Birkner, 1988). NIOSH's testing and certification role has been applied aggressively to respirator usage. The Bureau of Mines, under the Mining Enforcement Safety Act (MESA), and NIOSH jointly approve respiratory equipment (Douglas, 1978). The specific regulations concerning respirator approval are found in the Code of Federal Regulations 30CFR Part 11.

Many factors must be implemented to ensure a wearer is being given the proper protection required by the respirator. These factors include a respiratory protection program, proper respirator selection, and, most importantly, proper fit testing.

STATEMENT OF THE PROBLEM

The only means to ensure proper protection when wearing a respirator is by performing a respirator fit test. The current quantitative fit testing method involves testing the wearer with a specially designed probed facepiece respirator. This results in a fit factor for the probed facepiece respirator, not the respirator which the wearer

will actually use. A method which will allow for the actual testing of the wearer's own respirator has been proposed by Miller, Foltz and Mote (Ayer & Svetlik, 1986), and investigated by Ayer and Svetlik (1986) at the University of Cincinnati, Institute of Environmental Health. This method involves placing a probe in the center of a sealed-off cartridge and substituting it for one of the cartridges used on the respirator. The Occupational Safety and Health Association's (OSHA) Standard 29CFR 1910.58, Appendix C, Quantitative Fit Test Procedures 3.f, merely states: "the sampling port on the test specimen respirator shall be placed and constructed so that there is no detectable leak around the port, a free airflow is allowed into the sampling line at all times, and so there is no interference with the fit or performance of the respirator" (30CFR 1910).

STATEMENT OF THE PURPOSE

The purpose of this study is to determine if there is a quantifiable difference between these two methods, and if there is, to develop a correlation between the fit factors achieved with both methods. This study will involve quantitative fit testing of subjects with both the probed facepiece and probed cartridge, using a ambient aerosol PORTACOUNT Quantitative Fit Tester.

ASSUMPTIONS

It is hypothesized that the probed cartridge will result in a lower fit factor due to the increased breathing resistance which results from breathing through only one cartridge. This breathing resistance will cause a higher negative pressure within the facepiece cavity, and therefore, will lead to a greater probability of leaks. The use of the probed cartridge during fit testing will allow wearers to be tested in his/her own respirators, and it will also provide for a less expensive method to perform fit tests without exposing the wearer to any potentially toxic substances. But most importantly, the probed cartridge method will give a more representative test of the actual fit of the wearers own respirator, and will also allow for the inspection of personal hygiene and up-keep of their respirator.

DELIMITATIONS

The delimitations involved in this study include the following:

1) By not removing the respirator between the two test methods, the face-to-facepiece seal will remain constant.
2) Controlling the fluctuation of the room concentration by testing pre and post ambient particle room concentrations.

3) Controlling PORTACOUNT system leaks by checking the system prior to each fit test.
4) Using the same respirator during fit testing of both methods.
5) Having all subjects breath through the mouth during the fit testing.
6) Cleaning the respirator of any ambient particles prior to testing to ensure the PORTACOUNT does not count dust particles in the respirator.
7) The study will be performed using a single setting.
8) The testing will be performed using the same cartridges for each test.

LIMITATIONS

The limitations involved in this study include the following:

1) The inability to control the ambient room concentration.
2) The inability to control the turbulence within the respirator facepiece.
3) The inability to control the locations of any leaks.
4) The inability to control variations between subjects.
5) The inability to control subject fit variability.
6) The use of only two brands of respirators.
7) The sample selection will be a sample of convenience and will include four subjects (two male and two female).

DEFINITIONS

Aerosol. A class of substances which consist of particles (0.01 to 100 micrometers), solid or liquid, suspended in air (Colton, 1988).

Cartridge. A container with a filter, sorbent, or catalyst, or any combination thereof, which removes specific contaminants from the air drawn through it (Colton, 1988).

Collection Efficiency. The percentage of a specific substance removed from the air by an air purifying or sampling device (Colton, 1988).

Contaminant. A harmful, irritating, or nuisance substance that is foreign to the normal atmosphere (Colton, 1988).

Engineering Control. Methods of controlling employee exposures by changing the source or reducing the amount of contaminants released into the work environment (Colton, 1988).

Filter. A fibrous media used in respirators to remove particles from the air drawn through it (Colton, 1988).

Fit Factor. The ratio of the ambient airborne concentration of the contaminant to the concentration inside the respirator facepiece (Colton, 1988).

Hazardous Material. Any substance or compound which has the capability of producing adverse effects on the health and safety of humans (Colton, 1988).

High Efficiency Particulate Air Filter (HEPA). A respirator filter with a particle removal efficiency of 99.97% for 0.3

micrometer particles (Colton, 1988).

Immediately Dangerous to Life or Health (IDLH). A description of an atmosphere where employee exposure can cause serious injury or death within a short time period (Colton, 1988).

Protection Factor. A number designation given to a respirator by OSHA/NIOSH, which is based on past data and includes a safety factor (Colton, 1988).

Respirator. A device which functions to protect the wearer from inhalation of harmful substances (Colton, 1988).

Sorbent. A material which removes toxic gases and vapors from inhaled air through a cartridge (Colton, 1988).

Time Weighted Average. The average concentration of a contaminant in air during a specific time period (Colton, 1988).

Wearer. An employee who must use a respirator as a result of his required work task or work environment (Colton, 1988).

CHAPTER 2

LITERATURE REVIEW

OSHA requires numerous programs such as training and fit testing for those who wear respirators. The value of a respirator, however, lies in it's proper selection, fit and use. To ensure quality control in the selection, maintenance and use of respirators, a respirator program must be instituted at each workplace. Under 29 CFR Part 1910.134, a respiratory protection program must be established when respiratory protection is needed. This respiratory protection program must include written standard operating procedures governing the selection and use of respirators, and instructions on the selection and use of respirators in the workplace. In addition, the respiratory protection program must contain methods for appropriate surveillance of work area conditions and degree of employee exposure, and a regular inspection and evaluation procedure to determine the continued effectiveness of the program.

The effectiveness of such a respirator program can be assessed directly by determining the inhalation exposure of individuals in the program (Rosenthal et al., 1985). Two possible ways of performing such an assessment are biological monitoring and in-mask respirator sampling during actual workshifts (Rosenthal et al., 1985). Biological monitoring is limited in two ways. First, it can only be

used for a restricted group of substances, and secondly, it may not be a true index of inhalation exposure for substances which may be ingested or absorbed through the skin. Furthermore, individuals may differ in their rates of accumulation and clearance of the monitored substance, thus making inter-subject comparisons difficult (Rosenthal et al., 1985).

The second method of assessing the effectiveness of respirator programs is in-mask sampling of the respirator. This method will provide an objective means of evaluating the effectiveness of respirator programs. At this time, however, there is not an agreed upon protocol for sampling from within the respirator facepiece which avoids all sampling bias. Many methods of in-mask sampling have been researched, each with it's own strengths and weaknesses.

TYPES OF RESPIRATORS

Respirator facepieces may be classified as either tight fitting or loose fitting. The tight fitting facepiece is designed to adhere tightly to the skin of the wearer, thereby forming a tight facepiece-to-face seal (Douglas, 1978). Leaks in the respirator usually occur around this facepiece-to-face seal. Respirators are available as a quarter mask, half-face and full-face. The full-face provides better eye protection and a more secure facepiece-to-face seal (Teresinski & Cheremisinoff, 1983). The

facepiece-to-face seal of the full-face respirator results in lower leak values than obtained with half-face and quarter-masks (Johanson & Morgan, 1984).

The tight fitting facepiece is made up of various parts. These parts include the cartridge/filter cradle, suspension, inhalation valve(s), exhalation valve, and exhalation valve cover. Tight fitting facepieces are designed so a variety of air-purifying or supplied air units may be attached via a cartridge/filter cradle. These parts are crucial to the performance of the respirator. Except, however, according to Douglas (1978), inhalation valves are normally not considered essential for respirators. They protect the sorbants and aerosol filters (used for air purification) from possible detrimental effects by preventing exhaled air from coming in contact with them (Douglas, 1978). Therefore, the absence of the inhalation valves will not effect the performance of the respirator.

The second type of respirator facepiece is the loose fitting facepiece. Loose fitting facepieces may include a hood which covers the head, neck and upper torso. The wearer is provided air by a hose which enters into the hood. The supplied air ensures that there is always an outward flow of air which prevents contaminants from entering the interior of the hood (Douglas, 1978).

Air Purifying Respirators

Respiratory protective devices fall into three classes: air purifying; atmosphere or air supplying devices; and combination air purifying and atmosphere supplying devices.

The most commonly used respirator is the air purifying negative pressure respirator. Air purifying devices, as the name implies, cleanses the contaminated air. The pressure within an air-purifying respirator's facepiece may either be above or below the outside pressure. If the facepiece pressure is below the outside air pressure, it is called a negative pressure respirator. If the facepiece pressure is above the outside air pressure, it is called a positive pressure respirator. These pressure concepts are extremely critical when considering potential facepiece leakage. A negative pressure respirator, however, must have a tight fitting facepiece to ensure a proper fit (Douglas, 1978).

A negative pressure air-purifying respirator operates on lung power. When the user inhales, a suction or "negative pressure" is created in the face piece ("The Two Respirator," 1987). The air is then pulled through the cartridges by this negative pressure. The basic theory of it's operation is that the wearer will inhale through the air-purifying element and the respirator will create a negative pressure thereby causing the respirator to collapse and adhere around the face seal. If the respirator is fitting improperly, air will enter the respirator upon

inhalation in the area where there is an inadequate face seal.

Air-purifying negative pressure respirators include the mechanical filter respirator, the chemical cartridge respirator, combination mechanical filter/chemical cartridge respirator, gas masks, and powered air purifying respirators. Mechanical filter respirators provide protection against airborne particulate matter (aerosols), such as dust, mist, metal fumes, and smoke. They do not, however, provide protection from vapors and gases. This respirator is fitted with a mechanical filter made of fibrous materials that removes harmful particles by trapping them as air is inhaled through the material (Colton, 1988). Inhalation and exhalation valves are used to draw the air in from the filter and exhale the CO2 air out (Teresinski et al., 1983). The filter must be highly efficient, however, to trap the smaller, inhalable particles.

There are many classes of mechanical filter respirators which are specifically designed for the various types of airborne particulate matter. The NIOSH-MSHA approves respirators for one or any combination of particulate hazards - nuisance, fibrosis-producing, and/or toxic dusts, mists, and fumes (Colton, 1988).

MECHANICAL FILTERS

The removal of particulates, such as aerosols, mists, dust and smoke, from the air is accomplished using a variety of filtration mechanisms. The mechanisms used, however, must be effective enough to remove the hazardous substance. The mechanical cartridges (also known as High Efficiency, Particulate Air or HEPA) are based on the principle that particulate matter is retained when air is passed through a filter of fibrous or other material (Teresinski et al., 1983). The material used as the media may be cellulose, plastic, glass, wool, or combinations of any of these.

The efficiency of aerosol removal is related to the size of the aerosol and the filter fiber media used (Douglas, 1978). The efficiency is improved as the filter fiber diameter is decreased (Douglas, 1978). The resistance to air flow usually increases as the fiber diameter decreases, which may be a limiting factor because the respiratory system provides the force moving the air through the filter (Douglas, 1978). As more particulates adhere to the surface of the filter, the efficiency of the filter tends to improve. Therefore, the efficiency of the filters improve with use. This in turn, however, may increase breathing resistance.

As the respirator filter becomes more effective or loaded with material, the pressure drop is changed (Teresinski et al., 1983). Particle size, shape, density,

surface characteristics, packing characteristics of deposited material, air contaminant levels and related density, and humidity all have an effect on this pressure drop (Teresinski et al., 1983).

In regards to particulates, the function of a respirator is to reduce the total amount of respirable particulates entering the respiratory tract. Therefore, a mechanical filter designed for toxic dusts must also be capable of removing submicron particles from the inhaled air (Tuomi, 1985). The fibrous filter efficiency is dependent on particle size, filtration velocity and filter solidity (Tuomi, 1985). To evaluate the protection provided by a respirator against aerosols with different size distributions the dependence of penetration on particle size should be known (Tuomi, 1985).

In a study performed by Tuomi (1985), an optical particle counter connected to a multichannel pulse height analyzer was used to measure respirator efficiency as a function of particle size in the diameter range of 0.3 to 10 um. Tuomi found that particle sizes of 0.3 to 1 um with flow velocities up to 30 cm/s was the minimum size and velocity at which the filter was efficient.

Another study performed by Brosseau, Evans, Ellenbecker & Feldstein (1989), evaluated collection efficiency for ten respirator manufacturers's electrostatically charged dust\mist filters challenged with eight sizes of latex

spheres, and found that minimum efficiency occurred at or below the smallest size of 0.102 um, and that appreciable differences were found in the performances of filters distributed by the manufacturers. The velocity used in this experiment was 2,700 cm^3/min, as compared to the NIOSH test air flow of 32,000 cm^3/min. The results revealed a strong dependence of collection efficiency on particle size.

As a result of a study by Stevens and Moyer (Brosseau, Evans, Ellenbecker & Feldstein, 1989), it was found that for continuous airflows between 16,000 and 85,000 cm^3/min, particles with diameters between 0.03 and 0.1 um were collected least efficiently by dust\mist filters.

Differences in filters may exist because each resp manufacturer specifies the amount of resin, the porosity and nature of the filter material, and the degree of processing (needling or other methods used to condition the material) used in its filter medium (Brosseau et al., 1989). The manufacturer may also process the filter material further after it is received from the supplier, therefore leading to filter differences (Brosseau, Evans, Ellenbecker & Feldstein, 1989).

The strong dependence of filter efficiency on particle size, the variability of industrial aerosol size distributions, and the recognition that lung dose depends on particle size as well as on mass concentration suggest that information about fractional penetration over a range of

sizes would allow users to select filters appropriate for their particular operations (Brosseau et al., 1989). The current NIOSH certification protocol, using a single aerosol with a specific size distribution, does not provide such information.

PROTECTION FACTORS

A protection factor is a set number for a type of respirator, which is set by OSHA/NIOSH, and is based on past data with a safety factor included. Protection factors are used in the selection process to determine the maximum use concentration for the respirator (Colton, 1988). This is determined by multiplying the TLV by the protection factor given to the particular respirator (Colton, 1988). Protection factors are designated for different types of respirators. The protection factor represents the efficiency of a respirator. They are used only after the requirements of a minimal acceptable respirator program have been met and satisfactory fit testing has been performed (Colton, 1988). There is then reasonable assurance that the respirator fit is adequate to utilize the protection factor recommended (Douglas, 1978).

After the protection factor has been considered, it is necessary to determine whether eye irritation is a factor - if so, a full-face respirator, which provides eye protection, is recommended. One should consult ANSI Z88.2

"Practices for Respiratory Protection" for more detailed information when selecting a respirator. If there is no eye hazard involved, a half-face respirator may suffice. Half face respirators equipped with HEPA filters are approved for use up to ten times the TLV, according to it's protection factor (Teresinski et al., 1983). For example, if the ACGIH TLV were 20 ppm and the TWA concentration measured were 2,000 ppm, the protection factor required would be 100 (Teresinski et al., 1983).

OSHA FIT FACTOR REQUIREMENTS

As stated previously, proper protection will not be provided if the respirator does not fit the wearer properly. Due to the variety of face sizes and shapes, respirator manufacturers produce respirators in more than one size. In addition, the size and shape of each respirator varies among the different manufacturers. For this reason, several different manufacturers respirators in different sizes must be available to conduct a respirator fit-testing program.

The OSHA Standard, 29CFR1910.134 requires that all negative pressure respirators be fit tested by exposure to a test atmosphere. All respirators must pass a fit test to determine that the face-to-facepiece seal is effective, and in the case of hoods and helmets, to ensure that they are not likely to develop a negative pressure during use

(Douglas, 1978). This can be achieved by either performing a qualitative or quantitative fit test.

Positive/Negative Fit-Check

Before any of the two fit tests are conducted, the wearer must perform a positive/negative fit-check to determine a fit estimate. The positive fit-check consists of blocking the exhaust port with the palm of the hand and slightly exhaling. The positive pressure of slight exhalation should cause the respirator to lift slightly off the subjects face. The negative fit-check consists of blocking the inhalation ports with the palms of the hands and slightly inhaling. The negative pressure of slight inhalation should cause the respirator to collapse slightly around the face seal without any leaks. If these two fit-checks are passed, the respirator probably fits satisfactory and the wearer may then have a fit test performed. If however, the wearer experiences any leaks during these fit checks, he/she should either readjust the respirator or select another size or manufacturer.

QUANTITATIVE FIT TESTING

The primary goal of any sampling system designed to measure the concentration of airborne contaminants is to provide a quantitative estimate of the airborne concentration in the environment from which it is obtained

(Myers, Allender, Plummer & Stobbe, 1986). The environment is the facepiece cavity, which is the cavity between the body of a respirator and a wearer's face. The first aspect is sample collection, which involves collecting a sample of contaminant from within the facepiece cavity. The second aspect is sample analysis which involves quantifying the amount of contaminant present. Quantitative fit testing is an analytical evaluation of the difference between the atmosphere inside the facepiece cavity and the atmosphere outside the facepiece. The purpose of the quantitative fit test is to determine the proper fit and degree of the fit under actual wearing conditions. It is designed to provide the best method of fitting the respirator to the individual, using sensitive methods of detection for leakage or malfunction. The greatest advantage of a quantitative fit test is that it indicates respirator fit numerically and does not rely on a subjective response (Johanson et al., 1984). This is important when facepiece leakages must be minimized in areas of highly toxic atmospheres.

Quantitative fit testing involves having the wearer perform various exercises, calculating a fit factor for each exercise, and then averaging the fit factors to determine an overall fit factor. The exercises performed are used to simulate normal work conditions. A fit factor is an index that indicates how well the respirator fits the wearer, and the higher the number, the better the fit (Colton, 1988).

For example, the asbestos standard requires that any individual being fit tested on a half-face negative pressure respirator must achieve a minimum fit factor of 100, and 1000 for a full-face negative pressure respirator. The general respirator standard at this time is very vague in that it states that respirators shall be fitted properly and be tested for their facepiece-to-face seal. Fit factors produced by quantitative fit testing are commonly used to determine whether the fit of a respirator meets certain minimum criteria or whether a particular brand or size of a facepiece fits better than any other (Myers, Allender, Iskander & Stanley, 1988).

The conventional method for performing a quantitative fit test includes the following steps: a relatively non-toxic gas, vapor or aerosol test atmosphere is generated inside a chamber (at a concentration of approximately 20 mg/m^3), and a means of constantly monitoring the concentration is provided; the subject enters the chamber wearing a respirator modified with a probe to permit the removal of an air sample; during the test an air sample is constantly being withdrawn from the facepiece and analyzed; the concentration inside the facepiece as a percentage of the test atmosphere inside the chamber is calculated - this is simple called "penetration"; and the subject performs a series of exercises (Douglas, 1978 and Teresinski, 1983).

This method involves using as the test agent, substances such as dioctylphthalate (DOP), corn oil, dichlorodifluoromethane, and sodium chloride. The test can be conducted with a gas or an aerosol. Aerosols have the advantage of a detector system with such rapid response that when sampling inside a mask, the contaminant penetration can be determined with each inhalation (Douglas, 1978). The gas or vapor detection system has a slower responding detector that gives an average value of the contaminant inside the facepiece (Douglas, 1978).

Each test respirator must be equipped with a sampling probe to allow continued removal of an air sample from within the facepiece. Due to the probe, the same respirator cannot be worn in actual service because the test orifice negates the approval of the respirator (Teresinski et al., 1983). Presently the respirators which are used to perform a quantitative fit test have facepieces which are probed along the midline in front of the nose and mouth. Generally, the probe is attached directly to the wall of the respirator. The internal diameter of the sampling probe and the sampling flow rate used for in-facepiece sampling are not standardized and vary widely (Myers et al., 1986).

The American National Standards Institute (ANSI) new standard for respirator fitting requires quantitative fitting to prove that a certain device ensures the user a known protection level (da Rosa, Cadena-Fix, Carlson, Hardis

& Held, 1983). According to the standard, if qualitative fitting methods are only used, each type of respirator must be assigned a maximum protection factor one-tenth of that allowed with quantitative fitting (da Rosa et al., 1983). The different types of masks have different criteria for adequate fits because a respirator wearer is generally able to obtain a better fit with a full face mask than with a half mask (Hardis, Cadena, Carlson, da Rosa, & Held, 1983). The maximum protection factor allowed for half-masks is 100 and for full faces is 1000. It is proposed that for each make and type of resp to be worn, three quantitative fittings must be run; then, the respirator can be credited only with the lowest protection factor found during the tests (da Rosa et al., 1983).

When high efficiency cartridges are used for filtering particulate matter, the leakage through the filters is assumed to be negligible and any detected leakage is assumed to have entered through the faceseal (Holton, Tackett & Willeke, 1987). Without unbiased sampling, data interpretations such as 'goodness of fit' selections, pass-fail criteria decisions on acceptable fit, etc., must be made with the recognition of the limitations imposed by unrepresentative sampling data (Myers, Allender et al., 1988).

QUANTITATIVE FIT TESTING BIAS

Recently published data has demonstrated that the procedures commonly used in the United States for quantitative fit testing is subject to large sampling biases (Myers & Hornung, 1990). Factors that appear to contribute significantly to this bias include: incomplete mixing within the facepiece due to the inspired airflow patterns and facepiece design; the location and depth of the sampling probe; location of the face seal leak; whether the wearer is breathing through the nose or mouth; and the size of the aerosol (Myers et al., 1990 and Holton, Tackett & Willeke, 1987).

Quantitative fit testing rests on the assumption that leakage through the faceseal perimeter mixes uniformly and completely within the facepiece cavity (Myers et al., 1986). But recent research indicates that this is not the case. According to Carpenter & Willeke (1988), when aerosols leak into the respirator cavity, a complex and incomplete mixing process results. During the short inhalation and exhalation cycles, the leaked aerosol cannot mix throughout the respirator volume (Carpenter & Willeke, 1988). Their study upheld the conclusion that the concentration of aerosols sampled from the respirator cavity depends on the position of the sampling probe relative to the flow entries and exits: leak site(s), and purified air intake(s).

Leaks result from the negative pressure within the facepiece cavity during the inhalation phase of each breathing cycle (Myers, Allender et al., 1988). The design features of the facepiece are able to influence the magnitude of the leak and bias associated with in-facepiece sampling. One such design feature may be the location of inhalation valves in relation to probe location (Myers, Allender et al., 1988). According to Myers (Myers, Allender et al., 1988), the geometry between the inhalation valves and the sampling probe mouth may be such that air, cleaned by the respirator air-purifying elements, could be "washed" over the sampling probe during each inhalation. In such a case the resulting air sample collected by in-facepiece sampling would reflect concentrations more representative of the penetration through the air-purifying element, even though the intent of the sampling is to measure penetration through the face-seal (Myers, Allender et al., 1988).

Various studies have evaluated different sampling procedures which included varying the location of the probe at different depths with different sampling rates. The probe locations used in a study by Myers et al., (1990), included mid-nose mouth probing and deep-front of mouth probing. The results were compared with the conventional method of sampling (continuous sampling, low flow, flush probe). Of all the sampling, the pulsed sampling (pulses of air were collected from the facepiece only during

exhalation), deep probe gave the lowest sampling bias and the best precision for both full and half-face respirators (Myers et al., 1990). This study confirmed that the sampling bias is influenced by the probe and leak location in that varying the probe and leak location affected the total measured leakage and resulted in a mean bias range of -21.3 to 0.7 (Myers et al., 1990).

Another study performed by Myers (Myers, Allender et al., 1988), was undertaken to: (1) identify parameters of the person-respirator system which could affect sampling results; and (2) determine whether varying these parameters within specific limits causes sampling bias. The results suggest that the magnitude of sampling bias can be reduced by locating the probe deeper into the facepiece cavity, and that more consistent sampling is achieved with mouth breathing than with nose breathing (according to Myers, Allender et.al., 1988, respirator wearers generally breathe through their nose during quantitative fit testing, but breathe through their mouth while working). Sampling rate was found to have no important effects on in-facepiece sampling in any of the half-facepieces, however, it was noted that the sampling rate itself caused a small amount of artificial (i.e. non-inhalation caused) face-seal leakage.

This study fully supports the hypothesis that face-seal leakage does not mix well within the cavity of the respirator during the inhalation phase of the respiratory

cycle, therefore leading to sampling error (Myers & Allender 1988). According to this research, different magnitudes of sampling error would be caused by changes in sampling probe locations, probe depths, facepiece design and area of leakage and breathing pattern interactions.

Another bias experienced in quantitative fit testing involves breathing methods. Leak site locations will change somewhat randomly during a fit test as head-face movements change. According to Myers (Myers, Allender et al., 1988), sampling inaccuracy and variability caused by such changes could be reduced by having the test subject breath entirely through the mouth. On the other hand, the leak location may remain static. This may be true for particular wearer-respirator combinations. In these cases mouth breathing may not improve sampling accuracy (Myers. Allender et al., 1988).

Particle size is one factor which determines the effect of the inhalation of hazardous materials and qualitative fit test results. Particle size determines the lung deposition, sampling efficiency and collection efficiency of aerosols (Holton et al., 1987).

Particle size is also a major determinant of particle behavior and for that reason one investigation examined the effect of hole location and probe location on particle size-dependent leakage into negative pressure half-mask respirators (Holton et al., 1987). The study performed by

Holton et al., (1987) involved four comparison tests in which the leakages through two hole locations and the sampling through three probe locations were examined.

The hole locations which were used were bottom, center, and top. The greatest leakage measured was found at the bottom hole location. They concluded that this was due to the bottom hole being located such that the air entering through the filter cartridge carries the aerosol leaking through the bottom hole into the sampling area near the nose. The top hole, however, was not close to the airflows between the filter cartridges and the nose, and aerosols leaked to the inside may not be as readily drawn past the sampling probe. The sample pulled by the top probe near the leak site was likely to have been less diluted by clean air than the center probe sample which was near the clean air supply coming through the filters. They also found that the center probe, which is nearer the nose, samples more exhaled air; therefore, because of increased lung losses, fewer small particles and fewer large particles are being counted. In addition, their results indicated that the center probe, further from the leak site, may be measuring decreasing numbers of particles smaller that 0.1um because of some diffusional losses within the mask cavity and measuring decreasing numbers of particles in the 2.3 to 4.4 um size range because of settling and inertial losses within the mask cavity.

These findings indicate not only that there is incomplete mixing of leaked aerosols inside the mask, but it also supports the findings of Myers et al., (1990). According to the study by Holton et al., (1987), the further the sampling probe is from the leak site and the closer to the clean air supply, the smaller the overall leakage that is measured. This study also indicated that there may be some settling losses of particles larger than 1um and diffusional losses of particles smaller than 0.2um within the respirator. This indicates that particle size also affects the sampling efficiency.

During quantitative fit testing samples are collected during both the inhalation and exhalation phases of the respiratory cycle. One study set out to investigate how certain parameters of the man/respirator system, such as inhalation and exhalation, may affect the representativeness of samples collected by current in-facepiece sampling techniques (Myers et al., 1986). Myers et al., (1986), noted from questioning a number of respirator wearers that most would breathe through their nose during quantitative facepiece fit testing, but breath through their mouth while working (Myers et al., 1986). As a result, the three breathing patterns chosen for this study were: inhalation flow evenly divided between nose and mouth; all inhalation flow through the mouth; all inhalation flow through the nose.

The results indicated a sampling bias associated with in-facepiece sampling during inhalation, which may contributed to the variability often experienced with quantitative facepiece fit results (Myers et al., 1986). This research further supported the finding that faceseal leakage is not mixing instantaneously and uniformly within the facepiece cavity, and that turbulent air flow occurs within the facepiece (Myers et al., 1986).

Another investigation showed that the size distribution of an aerosol test agent and the measurement method have an effect on the leakage measured in a quantitative fit test (Holton & Willeke, 1987). The study performed by Holton & Willeke (1987) showed that the maximum leakage through holes in a respirator facepiece occur approximately between 0.2um to 1um, and that larger and smaller particle sizes do not enter through the leak sites as easily. The ratios of the fit factors, however, between most of the current quantitative fit test methods, are smaller than 2:1 (Holton & Willeke, 1987). This would indicate that most of the current quantitative fit test methods have approximately the same sensitivity (Holton & Willeke, 1987).

A question many researchers ask is "does the sampling rate have an effect on the fit testing?" A study performed by Myers & Allender (1988), which investigated fit test results in relation to sample rate found that sampling in full-face respirators was not affected by sampling at rates

of 1,2, or 3 L/min. This research once again confirmed the fact that in-facepiece sampling from full facepiece respirators is affected by a number of parameters, leading to the collections of unrepresentative samples. The parameters identified in this research were: location and depth of the sampling probe; area on the face-seal where penetration occurs; breathing pattern; and design of the facepiece.

PORTACOUNT

One question we must ask is how safe are exposures to fit testing agents used in quantitative fit tests? Agents commonly used include argon, ethylene, dichlorodifluoromethane, helium, n-pentane, sulfur hexafluoride, saccharin, dioctylphthalate (DOP), and corn oil. Saccharin is no longer used as a fit testing agent due to data classifying it as a carcinogen. DOP, on the other hand, is a suspected carcinogen and is still used as a fit testing agent. The health effects of these other substances on respiratory systems are uncertain at this time.

This uncertainty and the considerable expense of buying and operating an aerosol generator, an aerosol exposure chamber or tent, and an aerosol detection and recording instrument led to the development of quantitative, less expensive techniques such as the ambient aerosol method.

K. Willeke of the University of Cincinnati discovered in 1980 that the aerosol generator and exposure facility become redundant if the aerosol detector counts ultrafine particles, of which ten thousand to several hundred thousand are generally present per cubic centimeter of air space in most air environments (Carpenter et al., 1988). Since most of these ultrafine particles are optically invisible in their natural state, he used a continuous-flow condensation nuclei counter to record them (Carpenter et al., 1988).

Willeke examined a variety of aerosols as respirator test media and judged that ambient aerosol particulates could provide some advantages, which include inertness and simplicity, but, the concentration in the test medium cannot be controlled (Ernstberger, Gall & Turok, 1988). Room atmospheres, with the exception of specially filtered "clean rooms," contain appreciable concentrations of dust particles in the 0.3um to 1um range, and therefore, could function as a test medium (Ernstberger et al., 1988).

The ambient aerosol method for quantitative respirator fit testing is similar to the intentionally produced aerosol method except that the ambient method uses the existing ambient dust particles of normal room atmospheres as a test medium. This method eliminates the need for a test chamber and for an intentionally produced aerosol. This method, as with the conventional chamber method, requires a respirator with a sample probe in the facepiece to draw a sample from

within the facepiece cavity. The atmosphere outside the respirator also is measured to provide the remaining data for the leakage calculation (Ernstberger et al., 1988). The subject is tested for respirator inleakage by comparing the particulate count concentration inside the subject's respirator to that of the room atmosphere outside the respirator (Ernstberger et al., 1988).

This method is less expensive and simpler to administer than the use of oil or other deliberately produced aerosols because it uses an existing ambient test medium. Published statistical analyses of the test data indicates favorable comparison with the conventional chamber-aerosol method (Ernstberger et al., 1988). Additionally, this method can be used for field testing of respirator fit without requiring special equipment or facilities which are not readily portable.

The Willeke Particle Count Test has been confirmed independently and recently has become available commercially (Carpenter et al., 1988). It is known as the TSI PORTACOUNT. (The following information is from the "PORTACOUNT Instruction Manual," by TSI). It has been accepted by OSHA and the Nuclear Regulatory Commission (NRC), and a similar CNC is being used by the Department of Energy (DOE) (TSI, 1990). The PORTACOUNT is based on a miniature, continuous flow condensation nucleus counter (CNC), in that it takes particles that are too small to be

easily detected, enlarges them to a larger, easily detectable size, and then counts them. The PORTACOUNT grows submicrometer particles to supermicrometer alcohol droplets and then measures the concentration of the alcohol droplets. This allows the PORTACOUNT to be sensitive to particles having diameters as small as 0.02 um, but insensitive to variations in particle size, shape, composition, and refractive index. Therefore, quantitative fit testing can be performed with virtually any aerosol, including ambient air.

The aerosol is drawn through the PORTACOUNT by a diaphragm vacuum pump operation at a flowrate of 0.7 L/min. The sample enters the instrument through either the ambient port or the sample port, and there is a switching valve which determines which port is used. The outlet of the switching valve leads to the saturator end cap where the flow splits. A flowrate of 0.1 L/min enters the saturator and passes through the condenser, nozzle, and sensing volume. The remaining 0.6 L/min then passes through the excess air line and is remixed with the sampled flow downstream of the sensing volume.

The PORTACOUNT sensor consists of a saturator, condenser and optical elements. The saturator is lined with an alcohol-soaked felt and a thermoelectric device (TED) is mounted between the saturator and condenser. The purpose of the TED is to transfer heat from the condenser to the

saturator, cooling the condenser and heating the saturator to just above the ambient temperature. After passing through the saturator the aerosol - now saturated with alcohol vapor - enters the condenser tube. The alcohol vapor then condenses on the particles, causing them to grow into droplets. The droplets then pass through the nozzle and into the sensing volume.

The focussing optics in the sensor consist of a laser diode, a collimating lens, and a cylindrical lens. The optics focus the laser light into a sensing volume (1.2 mm wide by 13 um thick) just above the nozzle. Each particle passing through the sensing volume scatters light, and the light is collected by a pair of lenses in the receiving optics and focussed onto a photodiode. The photodiode generates an electrical pulse from the scattered light from each droplet that passes through the sensing volume. The final particle concentration is determined by counting the number of pulses generated.

The PORTACOUNT has a display which registers the particle concentration and the results of the test (i.e., pass or fail). It also comes with computer software which enables it to be controlled through via computer. The computer software allows for developing an exercise regime and entering the relevant fit test data such as name, social security number, date, and the respirator information. Each sample sequence of the PORTACOUNT (facepiece concentration

and external concentration sampling) takes 80 seconds. Therefore, each exercise performed must be carried out for this 80 second period. Each 80 second period is given a fit factor, and at the end of the test, an average fit factor is calculated. The final results can then be saved as a permanent record and then printed.

Various investigations have been undertaken to determine the efficiency of the ambient aerosol method and to compare it to the conventional chamber method. In one such study by Ernstberger et al., (1988), the proposed ambient aerosol method was compared with the intentionally produced oil aerosol method and yielded acceptable results. A Climet Model CI-208 particle counter was used in a normal room atmosphere for the ambient air particle method of respirator fit testing. The results indicated that the CI-208 particle counter performed adequately for these experiments in ambient room air, and that overall the difference in the two methods is not significant at a 95% confidence level. Any particle counter with comparable sensitivity would suffice for this method of respirator fit testing (Ernstberger et al., 1988). The experimental comparison results indicate that use of ambient dust particles in normal room atmospheres is a viable method for quantitative respirator fit testing in that this method provides accuracy comparable to testing with an artificial aerosol (Ernstberger et al., 1988).

Another study performed by Willeke, Ayer & Blanchard (1981), also strove to prove compatibility of the two methods and tested the condensed nuclei counter (CNC) with the photometer while sampling DOP aerosols from the fit testing system. The study found that a CNC used with a variety of aerosols is preferable over a photometer used with DOP aerosols. The study used a very low aerosol number concentrations, detectable by the CNC, but not by the photometer. This research also include a test of the laboratory atmosphere. The aerosol concentration in one of the laboratory rooms was very stable at about 20,000 particles/cm^3. Both studies found that there was good agreement between the two instruments. The photometer-recorded aerosol concentrations in the respirator is on the average 1.64 times higher than the CNC recorded aerosol concentration, that is, the CNC indicates a higher protection factor (Willeke et al., 1981). The difference, however, may be due to the way in which the instruments are calibrated (Willeke et al., 1981). Statistical analysis revealed that the two instruments correlate with each other with a correlation coefficient of 0.967 (Willeke et al., 1981). The authors, therefore, accepted the CNC as an alternative measuring instrument and have investigated various test aerosols to which the conventional photometer will not respond with sufficient scattering intensities.

According to the aforementioned research, the quantitative test chamber and PORTACOUNT have been shown to be equivalent in determining respirator fit, and therefore, the PORTACOUNT is a valid quantitative fit testing instrument.

PROBED CARTRIDGE METHOD

As discussed previously, several factors may cause the leakage measured in a quantitative aerosol fit test to be different from the actual leakage which occurs under working conditions. Factors such as measurement method and aerosol-size distribution into the work environment relative to the laboratory test may have considerable influence on the recorded fit factor (Carpenter et al., 1988). The locations of leak sites and sampling probe may affect significantly the recorded fit factor. In addition, work activity, work rate, minute volume, head and body movements, and air current velocity and turbulence have been suggested as possible sources of variation.

The major disadvantage of every presently available aerosol method is the necessity of an invasive sampling probe. Thus, a surrogate mask is used for fit testing, and the actual mask worn is assumed to have the same shape, pliability and workmanship resulting in the same fit (Carpenter et al., 1988). No accommodation is made for the respirator that is actually used, in regards to change in

shape and pliability during aging, nor for contamination of the respirator during wear (Carpenter et al., 1988).

The respirators used in quantitative fit tests incorporate HEPA filter cartridges, which are 99.97% efficient in removal of particulates of 0.3um aerodynamic diameter (Ernstberger et al., 1988). The ratio of respirator interior to exterior aerosol concentrations is determined by a photometric instrument and expressed as percent inleakage around the facial seal. Particulate penetration through the HEPA filter cartridges is negligible, and inleakage through the exhaust port is prevented by a diaphragm check valve (Ernstberger et al., 1988).

While the above test procedure is used widely, there are several objections to its use, including: the necessity for a special test chamber; the operation of, and maintenance of the aerosol generating equipment; and the uncertainty of the effects of the aerosols on respiratory systems of test subjects and testing personnel. A sequence of maneuvers is necessary for quantitative fit testing because the goodness of fit upon the wearer's face may vary depending upon the wearer's breathing pattern, facial configuration and head position (Willeke et al., 1981).

As discussed previously, a quantitative fit test can underestimate or overestimate the faceseal leakage that will occur under the actual exposure conditions in the workplace.

If the quantitative fit test underestimates the leakage that the resp provides the wearer in the workplace, the wearer's health could be at risk because under actual work conditions the leakage is greater and may exceed safe exposure levels (Holton & Willeke, 1987). A quantitative fit test which overestimates the leakage that a resp provides in the workplace results in additional expenses for the employer if repeated testing is required or when more expensive respirators are provided to the employees (Holton & Willeke, 1987).

Several factors determine the differences between the leakage measured in a quantitative fit test and that which the worker actually receives. Some of these factors include the different head and facial movements and breathing rates that occur during work activities compared to those performed during a resp fit test (Ernstberger et al., 1988). These factors affect the actual leakage into the mask. The measured leakage, however, also can be affected by lung deposition, probe location, probe depth and measurement method. The particle size in an aerosol are known to affect the lung deposition, sampling efficiency, and collection efficiency of that aerosol, therefore, particle size has an effect on aerosol leakage into a resp. In an ambient or industrial environment, the workers are exposed to a variety of aerosols with different size distributions, while in the laboratory fit test, the same workers are exposed to a

specific aerosol with generally a narrow size range. Therefore, the difference in particle sizes between the fit test aerosol and the ambient aerosol could contribute to differences in the measured and the actual resp leakage (Ernstberger et al., 1988).

In view of all the discrepancies and bias associated with quantitative fit testing, it still is the only approved method for detecting respirator fit. By accepting this fact, we can still attempt to develop other techniques and methods which will improve the overall results.

One such technique has been investigated by H.E. Ayer and Jozef Svetlik of the University of Cincinnati Institute of Environmental Health. According to their pilot study, (Ayer & Svetlik, 1987), C.E. Miller, G.J. Foltz and R.P. Mote (cited in Ayer & Svetlik, 1987) proposed that an unprobed respirator could be tested quantitatively by using a probe in a blanked off cartridge. Their pilot study was conducted, therefore, to compare results of such testing with the traditional facepiece probed testing. The fit tests in this study were performed with a TSI PORTACOUNT. A standard HEPA cartridge, of the same make as the respirator to be tested, was cut open, the filter removed, a Lucite piece machined to fit the opening and sealed to the metal or plastic, and a probe inserted in the center. The other high efficiency cartridge was left in place.

The pilot study found that the median fit factors for the probed respirators tend to be slightly higher than those for the probed cartridge, but there was no statistically significant difference found between these two probe locations by the non-parametric signs test. The study did conclude, however, that the use of the probed cartridge results in a lower fit factor due to the increased breathing resistance and therefore higher negative pressure.

CHAPTER 3

METHODS

The only means to ensure proper protection when wearing a respirator is by performing a respirator fit test. The current quantitative fit testing method involves testing the wearer with a specially designed probed facepiece respirator. This results in a fit factor for the probed facepiece respirator, not the respirator which the wearer will actually use. A method which will allow for the actual testing of the wearer's own respirator involves placing a probe in the center of a blanked off cartridge and substituting it for one of the cartridges used on the respirator. The Occupational Safety and Health Association's (OSHA) Standard 29CFR 1910.58, Appendix C, Quantitative Fit Test Procedures 3.f, merely states: "the sampling port on the test specimen respirator shall be placed and constructed so that there is no detectable leak around the port, a free airflow is allowed into the sampling line at all times, and so there is no interference with the fit or performance of the respirator."

Because of the growing use of the probed cartridge method, this study was performed to determine if there is a quantifiable difference between the probed facepiece and the probed cartridge, and if there is, to develop a correlation between the fit factors achieved with both methods. This

correlation will allow for the probed cartridge fit factor to be compared to the probed respirator fit factor, because all current standards are based upon the probed respirator performance at this point. This research was based upon the difference between methods, not the difference between individuals. Personal differences will have an effect upon every test method.

This study involved quantitative fit testing of subjects with both the probed facepiece and probed cartridge, using a ambient aerosol PORTACOUNT Quantitative Fit Tester, and using the ambient room concentration as the test atmosphere.

It is hypothesized that the probed cartridge will result in a lower fit factor due to the increased breathing resistance which results from breathing through only one cartridge. This breathing resistance will cause a higher negative pressure within the facepiece cavity, and therefore, lead to a greater probability of leaks. In actuality, even though the respirator fit test results in a lower fit factor, when compared with the conventional probed facepiece method, it should allow for the same level of protection. If a correlation can be developed between the two methods (e.g. a probed facepiece fit factor of 150 is comparable to a probed cartridge fit factor of 100), this method can be used in industry today by referring to the correlation results. The use of the probed cartridge during

fit testing will negate the use of surrogate respirators during the actual fit testing. This method will allow wearers to be tested in their own respirator, and provide for a less expensive method to perform fit tests without exposing the wearer to any potentially toxic substances.

This method of using an employee's own respirator is the best method because it allows for the use of the respirator under it's actual conditions, the care of the respirator can be examined, and it will provide for a more inclusive part of the respirator program. The probed cartridge method would save industry significant expenses by avoiding the purchase of probed facepiece respirators. But most importantly, the probed cartridge method will give a more representative method of determining the actual fit of the wearers own respirator.

Sample

The sample of subjects used in this study was a sample of convenience. It was composed of two females and two males. All males in this study were clean shaven prior to testing. No one in the sample had worn a respirator for any significant time prior to this study.

Protocol

Materials

*TSI PORTACOUNT with computer software package and attachments (Serial Number - 928 Rev. B, Model 8010, Calibration Date - March, 1990)

*Personal Computer (Compaq Portable II)

*Half-face negative-pressure air-purifying probed respirators (with the right inhalation valve removed) (Brands: MSA Comfo II half face and 3M 7300 Q EASI AIR half face)

*Full-face negative-pressure air-purifying probed respirators (with the right inhalation valve removed) (Brands: MSA Ultra-Twin (small, medium and large), and 3M 7800 EASI AIR full face)

*HEPA filters for each brand of respirator used (MSA Sparkfoe Type "H", TC- 21C-135, and #7255 TC-21C-265)

*Probed cartridge filters made from each type of HEPA filters used (these probed cartridges are modified according to the instructions in Appendix A)

*Probe caps

*Alcohol, syringes, and cotton balls

Test Procedure

1) The testing was performed in one centralized location. At the beginning of each fit test a leak detection test was performed. This involved placing the PORTACOUNT's

HEPA filter onto the inlet tube and determining if there were any leaks within the PORTACOUNT's system. The PORTACOUNT will read 0.00 in the COUNT Mode with the HEPA filter attached. If it does not read 0.00, there is a leak in the system, which would have been found and corrected before beginning the fit test.

2) Each subject was given instructions concerning the fit test, the purpose of the study, and how to wear the respirator properly according to the manufacturer's instructions.

3) The researcher cleaned the chosen respirator (the respirator and method were chosen randomly by the toss of a coin) using the alcohol and cotton balls, ensuring that the respirator dried before donning. Cleaning was performed before and after each fit test. After the respirator dried, the researcher attached the cartridge (either normal or probed depending on the outcome of the coin toss) to the respirator. The same cartridges were used for each fit test (i.e., only one probed cartridge and two normal cartridges for each respirator brand).

4) The subject then donned and adjusted the respirator. The subject was told to obtain a secure fit with reasonable comfort, while the researcher watched and assisted. Once a respirator facepiece-to-face seal was established for each subject and respirator combination, great care was

taken not to alter this fit throughout the test procedure.

5) The subject then performed a positive/negative fit check. If the subject failed any of the fit checks, he/she readjusted the respirator and performed the fit checks again.

6) The PORTACOUNT was controlled through it's computer software and a Portable Computer. The subjects appropriate data was entered in the computer prior to beginning the fit test. This data included the date, subject name, subject number, sex, age, whether they had worn a respirator before, respirator type, manufacturer, HEPA filter and TC approval number, and method.

7) The subject's respirator sample probe was connected to the sample inlet of the PORTACOUNT. If the first test selected was the probed cartridge method, a probe cap was placed over the respirator probe during the test.

8) The subject was then instructed to perform the following exercises for 80 seconds while breathing through the mouth:

   1-breathe normal

   2-breathe deeply

   3-turn the head from side-to-side, and taking a normal breath at the end of each maneuver

   4-move the head up-and-down, and taking a normal breath at the end of each maneuver

5-read the rainbow passage

6-breathe normal

9) At the end of the fit test, the results were saved on the computer for future retrieval. Without breaking the facepiece-to-face seal of the respirator, the PORTACOUNT inlet tube was removed from the probe. If the first test involved was the probed respirator method, a probe cap was placed over the probe, and the right HEPA filter was removed from the respirator and replaced with a probed cartridge. The PORTACOUNT inlet tube was then connected to the cartridge's probe, and the fit test was repeated for this method. If the first test performed was the probed cartridge method, the probed cartridge was replaced with a normal HEPA filter.

10) The subject then repeated the procedure beginning with step seven.

11) At the end of the fit test, another respirator was selected randomly and the test began again with procedure number one.

12) Each subject was fitted by the two methods with each of the two brands (half and full-face respirators) five times each, for a total of 20 fit tests per subject.

Statistical Analysis

The mean, standard deviation, *t*-Test, and *p*-Value was calculated to determine a comparison between the two

methods, the four subjects, the four respirators, the half and full facepieces, and the two brands. A correlation coefficient was calculted for the two probed cartridge and probed respirator methods, the two brands, and the two facepieces. A ratio was calculated for the ratio of the probed respirator method to the probed cartridge method. An ANOVA table was calculated to determine interactions within the subjects, respirators, and the two methods. The statistical analysis was performed using SPSS, and SAS was used to calculate the ANOVA table.

Research Question

The purpose of this study is to determine if there is a quantifiable difference between these two methods, and if there is, to develop a correlation between the fit factors achieved with both methods. This study will involve quantitative fit testing of subjects with both the probed facepiece and probed cartridge, using a ambient aerosol PORTACOUNT Quantitative Fit Tester.

Instrumentation

The instrumentation used in this study involved a condensed nuclei counter which detects ambient particles in the atmosphere. It samples the ambient air and the air inside the facepiece and calculates a fit factor for each exercise performed, and then gives an overall fit factor for

the six exercise. Two brands of respirators (full and half face) with their appropriate HEPA filters (modified and regular) were used in the study.

CHAPTER 4

ANALYSIS OF THE DATA

This study resulted in a large range of fit factors for both the probed cartridge and probed respirator methods. Table 1 and 2 summarize the fit factors obtained during this study. Fit factors for the probed cartridge method ranged from 3 to 1856, and the probed respirator method ranged from 14 to 9274. This resulted in a mean fit factor for the probe cartridge method of 204, and 2,382 for the probed respirator method. An analysis of variance of all the data combined indicated a significant difference ($p = .0001$) between the probed respirator and probed cartridge fit testing methods. A paired comparison test for the combined sample differences was also calculated and the mean differences of the fit factors of the two methods was found to be 2,166 ($p < .001$), which again indicates a significant difference between the two methods.

A correlation coefficient was calculated for the two fit testing methods, and resulted in a correlation coefficient of $r = .16$ ($p < .01$), and a regression equation of $y = 148 + 0.237(x)$. Table 3 summarizes the correlation coefficient data for the two brands of respirators. This indicates a weak correlation between the two methods. However, a correlation coefficient performed on the two brands of respirators used (MSA & 3M) and the two methods

TABLE 1

MSA OVERALL FIT FACTOR RESULTS

SUBJECT #	MSA HALF FACE PROBED RESP	MSA HALF FACE PROBED CART	MSA FULL FACE PROBED RESP	MSA FULL FACE PROBED CART
1	136	61	2576	1284
	9103	347	2581	1089
	4444	1500	1132	357
	115	49.3	816	483
	231	164	7482	1856
MEAN	**2806**	**424**	**2917**	**1014**
ST D	**3979**	**613**	**2677**	**613**
Average % Difference	**74%**		**48%**	
2	110	5.2	775	39
	14	3.4	824	134
	113	21.4	81.4	105
	611	137	107	118
	752	100	88.9	138
MEAN	**320**	**53**	**375**	**107**
ST D	**336**	**61**	**388**	**40**
Average % Difference	**72%**		**56%**	
3	25.3	7.7	1587	207
	231	207	1113	405
	375	208	1988	337
	429	96	1285	375
	197	138	625	333
MEAN	**252**	**131**	**1392**	**331**
ST D	**159**	**84**	**511**	**76**
Average % Difference	**32%**		**62%**	
4	3232	199	6500	1064
	125	41.7	3139	342
	194	128	3015	1277
	612	337	1714	745
	3333	789	2239	364
MEAN	**1499**	**299**	**3321**	**758**
ST D	**1639**	**294**	**1870**	**416**
Average % Difference	**66%**		**63%**	
OVERALL				
MEAN	**1219**	**277**	**3302**	**553**
ST D	**2252**	**349**	**1957**	**499**
Average % Difference	**61%**		**57%**	

TABLE 2

3M OVERALL FIT FACTOR RESULTS

	3M HALF FACE		3M FULL FACE	
SUBJECT #	PROBED RESP	PROBED CART	PROBED RESP	PROBED CART
1	826	12.5	166	3.1
	223	4.3	5000	15.8
	724	5.9	1841	3.2
	2000	11.3	6977	19.4
	2500	19	8451	3.5
MEAN	**1255**	**11**	**4487**	**9**
ST D	**953**	**6**	**3458**	**8**
Average % Difference	**98%**		**100%**	
2	6383	4.8	4688	3.6
	177	56	5172	8.7
	8865	3.1	3158	2.8
	5933	15	2857	38
	3158	4	6186	17.3
MEAN	**4903**	**17**	**4412**	**14**
ST D	**3329**	**23**	**1396**	**14**
Average % Difference	**99%**		**99%**	
3	214	12.6	3058	4.8
	57.7	3.1	498	20
	21.1	3.0	6135	4.1
	78.9	3.8	2707	200
	3774	3.2	5000	41.7
MEAN	**829**	**5**	**3480**	**54**
ST D	**1648**	**4**	**2181**	**83**
Average % Difference	**99%**		**97%**	
4	9274	21.5	3548	68.9
	8165	5.4	382	19.1
	2004	8.0	1171	16.1
	721	6.1	165	4.5
	3871	22.9	412	4.0
MEAN	**4807**	**13**	**1136**	**23**
ST D	**3764**	**9**	**1401**	**27**
Average % Difference	**99%**		**96%**	
OVERALL				
MEAN	**2949**	**13**	**3379**	**25**
ST D	**3151**	**12**	**2505**	**45**
Average % Difference	**99%**		**98%**	

TABLE 3

RESPIRATOR & FIT TEST METHOD COMPARISON SUMMARY

Respirator	p-value	Correlation Coefficient &	p-value
MSA		r = .66	p < .01
Half Face	p < .01		
Full Face	p < .01		
3M		r = .79	p < .01
Half Face	p < .01		
Full Face	p < .01		

resulted in an MSA correlation coefficient of r = .66 (p < .01 and y = 173 + 0.142 (x)), and r = .79 (p < .01 and y = 3395 + 0.163 (x)) for the 3M brand. This indicates a moderate correlation for each brand and the two fit testing methods. The same analysis performed for the two facepiece types (full and half face) and the two fit testing methods resulted in a correlation coefficient of r = .22 (p < .01) for the full face respirators, and r = .34 (p < .01) for the half face respirators. Therefore indicating a slight, but significant, correlation between each of the facepiece types and the two fit testing methods.

A mean difference ratio between the two methods was calculated for the 3M and MSA respirators. This indicated that the probed respirator mean fit factor achieved when using the 3M respirator was 243 times larger than the probed respirator mean fit factor, and the MSA probed respirator mean fit factor was found to be 2.5 times larger than the probed cartridge mean fit factor.

The average fit factor percent difference between the two methods and the MSA respirators is 59%. For the MSA half face respirator, the difference is 61%, and 57% for the MSA full face respirator. These differences are fairly consistent between each subject, except for subject 3 who had a average percent difference of 32% for the MSA half face respirator. These values are listed in Table 1. The average fit factor percent differences for the 3M

respirators, however, were 99% for the 3M half face respirator and 98% for the 3M full face respirator. These differences are constant between each subject. These values are listed in Table 2. This data indicates a significant difference between the two methods when using the 3M respirators. This difference was constant for both the 3M full face and 3M half face respirators.

The analysis of variance performed on this data resulted in no significant differences between the four subjects mean fit factors ($p = .1867$), and the facepiece type mean fit factors ($p = .1736$). Significant differences were found between the different brands of respirators -MSA & 3M ($p = .0354$). These differences may be due to the different materials used in the facepieces of the respirators and the design.

The analysis of variance also indicated significant interaction between the brand of respirator and the fit testing method employed ($p = .0007$). By looking at the data in Table 1 & 2, a large variation exists between these two factors. The two MSA respirators resulted in a smaller difference between the fit factors for the two methods than the 3M respirators. There was a significant difference between the two fit testing methods ($p < .01$) for each of the four respirators. The mean difference ratio also indicated such an interaction between respirator brand and the fit testing method - the 3M mean difference ratio is

significantly higher than the MSA mean difference ratio. Again, this interaction may be attributed to the differences in facepiece material and facepiece design. No significant interactions were indicated by way of the analysis of variance between the other experimental factors.

Another interesting point to mention is the fact that the fit tests resulted in a large variation from test to test for each subject-respirator combination. For example, subject #1 received a fit factor of 136 (probed respirator) during one test, and then received a fit factor of 4444 (probed respirator) for the next test using the same respirator. The analysis of the individual exercises performed during these fit tests revealed no variation between exercises to possibly explain this difference.

Anthropometric measurements of each subject were taken to compare with the Anthropometric test panel used by the Las Alamos Scientific Laboratory (Hack & McConville, 1978). This data is summarized in Table 4. This comparison resulted in a significant difference between all four of the test subjects and the test panel ($p < .001$). Significant differences were also found between the male and female subjects used in this study and the male and female test panel ($p < .001$).

TABLE 4

ANTHROPOMETRIC DATA

Subject	Lip Lenth	Face Length	Face Width
Male			
1	70.5mm	214.7mm	282.1mm
2	54.5mm	217.9mm	301.3mm
Mean	62.5mm	216.3mm	291.7mm
St D	8.02	1.58	9.59
Female			
3	51.3mm	224.4mm	275.6mm
4	64.1mm	208.3mm	269.2mm
Mean	57.7mm	216.4mm	272.4mm
St D	6.4	4.82	6.4

* Significant Difference ($p < .01$) when compared to LASL Anthropometric test panel (Hack & McConville, 1978)

CHAPTER 5

FINDINGS AND INTERPRETATIONS

Due to the high level of variation from fit test to fit test, it is impossible to derive a correlation between the probed respirator and cartridge method independent of the respirator brand used. The variation of correlation between the two respirator brands and the two fit testing methods makes it difficult to relate the fit factor achieved with the probed cartridge to a probed respirator fit factor. The correlation coefficient of 0.16 which was calculated for the two methods is significantly less than 1, therefore, indicating that the two methods do not correlate.

When the two respirator brands were analyzed separately, however, we concluded that there is a correlation. For instance, the correlation coefficient ($r = .66$) for the MSA respirators indicated a moderate correlation at a significant level, and the 3M respirators also indicated a moderate correlation ($r = .79$). The regression equations for the MSA and 3M respirators may be used to predict related probed respirator fit factors. The analysis of variance indicated a significant interaction between the two respirator brands and the two fit testing methods. This is not suprising considering the variability found between each brand and the two fit testing methods.

The analysis of variance also indicates a significant difference between the two brands of respirators. This difference can be attributed to many factors. First, the two brands, MSA and 3M, have different designs. The MSA is more rigid and less contouring to the face, while the 3M is more pliable and seems to contour better. This may explain the higher mean fit factor achieved with the 3M respirators during the probed respirator method. The difference in the probed cartridge method is another story, however. The lower fit factors achieved with the probed cartridge method in the 3M respirators, especially with the half face, may also be due to the pliability of the facepiece. It is hypothesized that the probed cartridge method causes a higher negative pressure, and therefore, leads to the creation of more leaks around the facepiece. This may result to a higher extent in the 3M respirator due to the softness of the material allowing for the creation of more leaks.

The 3M full face, however, has a nose cup to prevent the faceshield from fogging. This nose cup interferes with the in-facepiece sampling of the probed cartridge. The probed cartridge is not able to sample from within the nose cup, and therefore, only samples within the external area of the nose cup. If a leak occurs in this facepiece it will not occur around the nose cup, and therefore, the contaminated air may be more concentrated outside the nose

cup than inside the nose cup. This may yield a lower fit factor than the probed respirator because the probe in the probed respirator penetrates the nose cup, and therefore, samples from within the nose cup.

As determined in previous studies, the full face respirator provides a higher fit factor. In this study, both full face respirators provided a higher fit factor than the half face respirators used. This stands true for both the probed respirator and cartridge methods.

The mean ratio and the mean percent difference both indicated a difference between the MSA respirators and the two methods. However, the mean ratio and the mean percent differences for the 3M respirators were so large that it raises a question as to the occurence of a leak within it's probed cartridge. One could hypothesize that a leak had formed (thereby allowing air to enter the facepiece) when reviewing the fit factors achieved with this method. However, the design of the probed cartridge attempts to avoid this problem by having both ends of the cartridge sealed with silicone.

It is interesting to note the variation of fit factors between tests for each subject. For instance, subject #1, using the MSA half face, had probed respirator fit factors of 136, 9103, 4444, 115, and 231. The corresponding probed cartridge fit factors were 61, 347, 1500, 49, and 164. These differences can only be attributed to the different

donnings. The subject may not have tightened the straps as snuggly as before or the facepiece may have been place on the chin in a different position. Even though a positive/negative fit check was performed for each donning, it obviously did not indicate that the subject had a proper fit. This data indicates that a different fit factor is achieved each time the respirator is used. The fit factors, however, showed the same variation for same day testing and next day testing.

The fact that there was no significant differences between the male and female subject's fit factors is interesting when considering the differences in facial features among the two sexes. Limiting this study to only two of each sex may have limited the generalizability of this fact however. When their anthropometric measurements were compared to the LASL's test panel, significant differences arise. Differences in the anthropometric measurements were expected. Anthropometric measurements are used to aid in the design of respirators which will fit the general population. Again, using such a small subject sample, may have affected this normal distribution.

The lower fit factors achieved with the probed cartridge method may be due to its inability to sample within the breathing zone. Only breathing through one side may lead to incomplete mixing of the air within the facepiece cavity, and therefore, a dead space being created

in the area of the probed cartridge. In addition, breathing through only one cartridge creates a higher negative pressure which may create leaks on the side where the probed cartridge is located. This would result in the probed cartridge sampling a higher quantity of the contaminated air, and therefore, resulting in a lower fit factor. The location of the leak, and the pattern of mixing within the respirator determines whether or not the probe method will affect the fit factor. This study did not measure the leak location or the mixing pattern.

The hypothesis that the probed cartridge method will yield a lower fit factor than the probed respirator method was definitively shown in this study. All but four tests resulted in a lower probed cartridge fit factor. However, there is no way to predict the related probed respirator fit factor with this method for all respirators due to the high variability in fit factors achieved with each donning and the interactions between the two respirator brands. However, individual respirators may be analyized seperately to determine a correlation between the two methods.

There are many variables which exist in this study which may have affected the outcome. These variables include the differences between respirators (brands and facepiece types -full or half face respirators), the inability to control the leak location, the differences associated with different donnings, the breathing

characteristics of the subjects, and the inability of the probed cartridge to sample within the breathing zone.

The general conclusion must be that respirator fit factors are a function of these variations which produce sampling bias. The different magnitudes of sampling bias may be caused by the different probe locations, leak location, and respirator design. Such differences are inherent in intra-subject and inter-subject fit testing. This bias may cause difficulties in the interpretation and use of this type of data. With these biases in mind, the limitations of quantitative fit testing must be considered when interpreting and using this method.

Further research should be conducted using a much larger sample size, a wider range of respirator brands, and a possible means to sample the breathing zone using the probed cartridge method. Every respirator brand would have to be analyzed to determine the correlation between the two methods. It would be valuable to develop a probe cartridge which would not only sample the in-facepiece atmosphere, but which would also function as an operational cartridge. This would alleviate the creation of a higher negative pressure and possibly allow for a better correlation to the probed respirator method. In addition, an insert to the probed cartridge which would extend into the breathing zone of the facepiece would improve the sampling bias associated with probe location, and result in a more representative fit

factor. The probed cartridge method is an appropriate method for the MSA respirators. However, more explanation is needed for the low fit factors obtained using the 3M respirators. This study should be repeated using the 3M respirators to determine if a leak had materialized within the probed cartridge used during this study. Probed cartridge fit factors are lower than the probed respirator fit factors. However, this does not indicate the probed cartridge method is not reliable.

This study indicated a large fit factor variability between each donning. Because of this variability, it is suggested that at least three quantitative fit tests be performed for each wearer, and the average fit factor of the three tests be used to indicate the wearers actual fit. The lowest fit factor achieved during the three tests should not be used due to the variability between the fit tests. However, the average fit factor used must coincide with the appropriate safety value (i.e., for the Asbestos Standard the fit factor must be at least 100 for a half face respirator). A minimum percent variation limit should also be used when calculating the average fit factor. This would apply to any method of quantitative fit testing - probed respirator or probed cartridge.

In conclusion, based on this study the probed cartridge method is an acceptable method for conducting quantitative fit tests. There are many bias associated with it use, but

not significantly more than any other quantitative fit testing method possesses. As hypothesized the probed cartrige method resulted in a lower fit factor than the probed respirator method. This study indicates, in general, that a subject who passes a fit test using the probed cartridge method, will also pass a fit test using the probed respirator method. The probed cartridge method would provide for a much needed testing strategy - using a wearers own respirator to perform the quantitative fit test. This strategy is the best and most crucial because it allows for the use of the respirator under actual conditions, and the condition of the respirator can be examined. The probed cartridge method would also save industry significant expenses by avoiding the purchase of probed facepiece respirators. But most importantly, the probed cartridge method will give a more representative method of determining the actual fit of the wearers own respirator.

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APPENDIX A

PREPARING THE PROBED CARTRIDGE

Preparing The Probed Cartridge according to C. Miller, H. Ayer, and J. Svetlik, University of Cincinnati Institute of Environmental Health:

1) Obtain appropriate HEPA filters.

2) Using a drill press holder and an electric drill fitted with a 17/64" pilot point drill bit, drill vertical holes through the cartridge center.

3) Cut an appropriate length of 1/4" I.D. soft aluminum tubing with a tubing cutter.

4) Place the tubing piece in a flaring tool.

5) Make a longer than normal (1/4") flare.

6) Bend the flare to a flat surface with fine-nose pliers.

7) Insert the tube into the inside of the cartridge hole.

8) Pull the tube through the cartridge, seating the flare against the inside of the filter element.

9) Seal the inside and outside joints of the tube with a gap-filling cyanoacrylate cement.

10) Set the glue with an accelerator.

11) Use a silicone sealer to block all entry into the cartridge except for the tubing.

12) Smooth and surface the sealer.

13) Seal the inside of the cartridge to minimize dead space.

14) Inspect and ensure the hole in the tubing is clear of the sealer.

15) Make sure respirator cartridge attaching fixture is clean of sealer.

16) Dry cartridges overnight before use.

17) Remove the inhalation valve from the side of the respirator in which the cartridge will be used.

18) Attach the probed cartridge to this side of the respirator facepiece.

19) Attach a normal HEPA filter to the other side of the respirator facepiece.

20) The prepared respirator is ready for fit testing.