

Quantitative Fit Testing Techniques for Respirators Protecting the Human Respiratory System against Environmental Aerosols

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Introduction

Occupational diseases caused by breathing contaminated air is avoided primarily by engineering control measures that prevent atmospheric contamination. When effective engineering controls are not feasible or while they are being instituted, an appropriate respirator must be used. Respirators can be classified into two types: air-purifying respirators that remove contaminants from the ambient air and atmosphere-supplying respirators that provide air from a source other than the surrounding atmosphere (National Institute for Occupational Safety and Health, 1987a). Except for special cases, air-purifying respirators are used most frequently in routine workpractices because they are smaller, more easily maintained, and restrict the wearer's movements the least. Thus, the focus of this article is on air-purifying respirators.

Even the best respirator may not protect the wearer sufficiently if there is an improper match between the edge of the respirator and the facial skin. Therefore, respirator fit testing is required before entering specific work environments to ensure that the respirator worn satisfies a minimum of fit and that the user knows when the respirator fits properly (American Industrial Hygiene Association, 1991). The fit of a respirator can be determined by qualitative or quantitative methods. The qualitative fit test (QLFT) methods rely on the subject's voluntary or involuntary response, i.e., taste, smell, or irritation to a test agent. The quantitative fit test (QNFT) methods provide an objective and numerical basis by measuring the fit factor (FF) (National Institute for Occupational Safety and Health, 1987b). These factors do not depend on the subject's voluntary or involuntary response. QLFT methods have not been universally accepted because of their dependence on the wearer's subjective response.

Until a few years ago, only one QNFT method was available and accepted by U.S. regulations. When using this method, an aerosol of about 0.5 μm mass median aerodynamic diameter (MMAD) is generated and dispersed in a test enclosure in which the respirator fit is tested on an individual by photometrically measuring the aerosol concentration inside and outside the respirator. In the 1980's and 1990's several new and fundamentally different QNFT methods have been developed. Two of the newer methods are also commercially available and are accepted by the U.S. Occupational Safety and Health Administration (OSHA) as suitable alternatives: the continuous-flow condensation nuclei counting (CNC) method, commercially known as

"PortaCount™", and the controlled negative pressure (CNP) method, commercially known as "FitTester 3000™". Other methods, such as the dichotomous-flow QNFT (Dichot) method, offer new ways to quantitatively assess respirator fit and may become commercially available in the future. Since these various methods have different advantages and disadvantages, and use different techniques to yield a quantitative measure of fit, the numerical values resulting from their use may differ from each other (Biermann and Bergman, 1988; Crutchfield, et. al, 1995). In this article, the principle of operation of each QNFT technique is explained with special focus on the aerosol methods.

QUALITATIVE VERSUS QUANTITATIVE FIT TEST

When a qualitative fit test is performed, the QLFT method requires the introduction of a gas, vapor or aerosol challenge agent into the area around the respirator while it is worn. A determination is then made as to whether the wearer can detect the presence of the challenge agent through subjective means such as odor, taste or nasal irritation. If the presence is detected, the respirator fit is considered to be inadequate. Three types of QLFT agents are currently accepted by OSHA: isoamyl acetate, sodium saccharin, and irritant fume (Asbestos, 1994). The QLFT methods have the advantages of being inexpensive, fast, relatively simple, and easy to perform in the workplace. The disadvantage of the QLFT methods is that their output relies on the subjective response of the wearer as to whether or not the challenge agent has penetrated into the respirator. It is also impossible to rank the degree of fit in order to select the best respirator for an individual. If the wearer has a disability for detecting the challenge agent, the test result is invalid.

When a quantitative fit test is performed, the respirator is worn in a stable test atmosphere containing aerosol particles. The adequacy of the QNFT is determined by measuring the aerosol concentrations outside and inside the facepiece of the respirator. Since talking and head movement may distort the face where the respirator seals against it, the QNFT is performed in several head and mouth positions reflecting work situations. During the test the cartridges of the test respirator are of the high efficiency particulate air (HEPA) filter type so that the aerosol particles measured inside the facepiece can be assumed to have penetrated there through the respirator face seal interface, not through the filter material of the cartridges. The ratio of the aerosol concentration outside the respirator (C_o) to the one inside (C_i) is referred to as the respirator's fit factor (FF). The FF measures the respirator's fit to the wearer's face under the conditions of the test. As such, the FF does not predict the degree of protection during actual wear in an occupational exposure. During actual wear, the amount of aerosol particles reaching the wearer's breathing zone from the outside environment depends on the concentration and size distribution of the aerosol particles surrounding the wearer, the type of cartridges used, the amount of sweat and dirt on the wearer's face, the degree of facial movements, the wearer's care in keeping the respirator well placed on the face, and other factors. In the case of gaseous contaminants, the degree of penetration to the wearer's breathing zone depends also on the adsorption characteristics of the cartridge(s) and the surfaces of the face seal leak. The ratio of contaminant concentration outside the respirator to inside the respirator during actual wear is referred to as the workplace protection factor (WPF).

The major advantage of the QNFT is that this test yields a numerical and objective FF that is compared with the minimum FF required by the standards. Thus, a decision can be made as to whether the respirator has an acceptable fit. The QNFT is therefore recommended when respirator leakage must be minimized for work in a highly toxic workplace. However, the fit of the same respirator on an individual may vary from one wearing to the next, because the human facial features are complex and the respirator may not attach to the face in the same way every time it is worn. The fit factor determination may also be affected by a number of other factors, particularly by the type

of fit test technique used (Rose, et al., 1990; Krishnan, et al., 1994). When the QNFT is performed, aerosol particles from outside the respirator may streak into the interior space of the respirator through one or more leak sites. Since the wearer's breathing cycle is too short for complete mixing of the aerosol inside the respirator, the measured FF depends on the location of the leak site(s) relative to the sampling port leading to the aerosol sensor. Thus, there may be considerable sampling bias in a QNFT utilizing an aerosol sensor (Holton, et al., 1987; Myers, et al., 1988; Willeke and Krishnan, 1990).

ELASTOMERIC VERSUS FILTERING FACEPIECE RESPIRATOR

The only respirator that is legally permitted at this time to be worn in U.S. occupational environments where fit testing is required before its use is the elastomeric kind with one or two cartridges. Due to the flexible material that is mostly used for the respirator body in recent designs, such a respirator generally follows the contours of the wearer's face quite well. When fit testing an elastomeric respirator with aerosol particles, face seal leak penetration is distinguished from cartridge penetration by using HEPA filters in the cartridge(s). The HEPA cartridges are assumed to be 100% efficient so that only face seal leakage causes aerosol transport from the outside to the respirator interior. It is also assumed that there is no leakage through the exhalation valve during fit testing with a clean respirator.

There is currently no fit testing regulation for filtering facepiece respirators. These devices are also referred to as low-maintenance or disposable respirators. In such a device, the filter material and its support structure make up most of the respirator body. Thus, only in a filtering facepiece made of HEPA filter material can environmental aerosols be assumed to penetrate to the respirator interior through the face seal leak(s) alone. With filtering facepiece respirators made of less efficient filter material, aerosol penetration through the face seal(s) is not easily distinguished from aerosol penetration through the filter material itself. The construction of such devices frequently includes now soft material at the facial interface so that the filtering facepiece respirator follows the facial contours better. Therefore, a need exists for the development and commercialization of fit testing methods suitable for fit testing such devices so that fit test regulations may be considered for them in the future. Figure 1 categorizes the principal QNFT techniques that have been developed for both types of respirators.

QNFT METHODS FOR ELASTOMERIC RESPIRATORS WITH CARTRIDGE(S)

Fit testing is performed to minimize face seal leakage. When a leak occurs, air flows through the leak site(s) from the exterior to the respirator interior during inhalation when the pressure in the interior is less than that outside. Therefore, one type of QNFT is the measurement of the air flow into the respirator interior. Environmental contaminants, be they particulate or gaseous, may be carried inward with this air flow. Measurements of the aerosol concentration inside the respirator relative to that outside constitute the other type of QNFT in use today. Methods of the latter type will be discussed first in the order shown in Figure 1.

Aerosol Measurement Methods

The first aerosol QNFT method was developed about 35 years ago (Burgess et al., 1961). The first practical aerosol system for routine use utilized dioctylphthalate (DOP) aerosol as the challenge agent and forward light-scattering photometry as the aerosol detection technique. Since then other aerosol instruments have been used for detection and a variety of other aerosol particles have been utilized as test agents, e.g., sodium chloride, corn oil, and ambient air aerosol particles. During fit

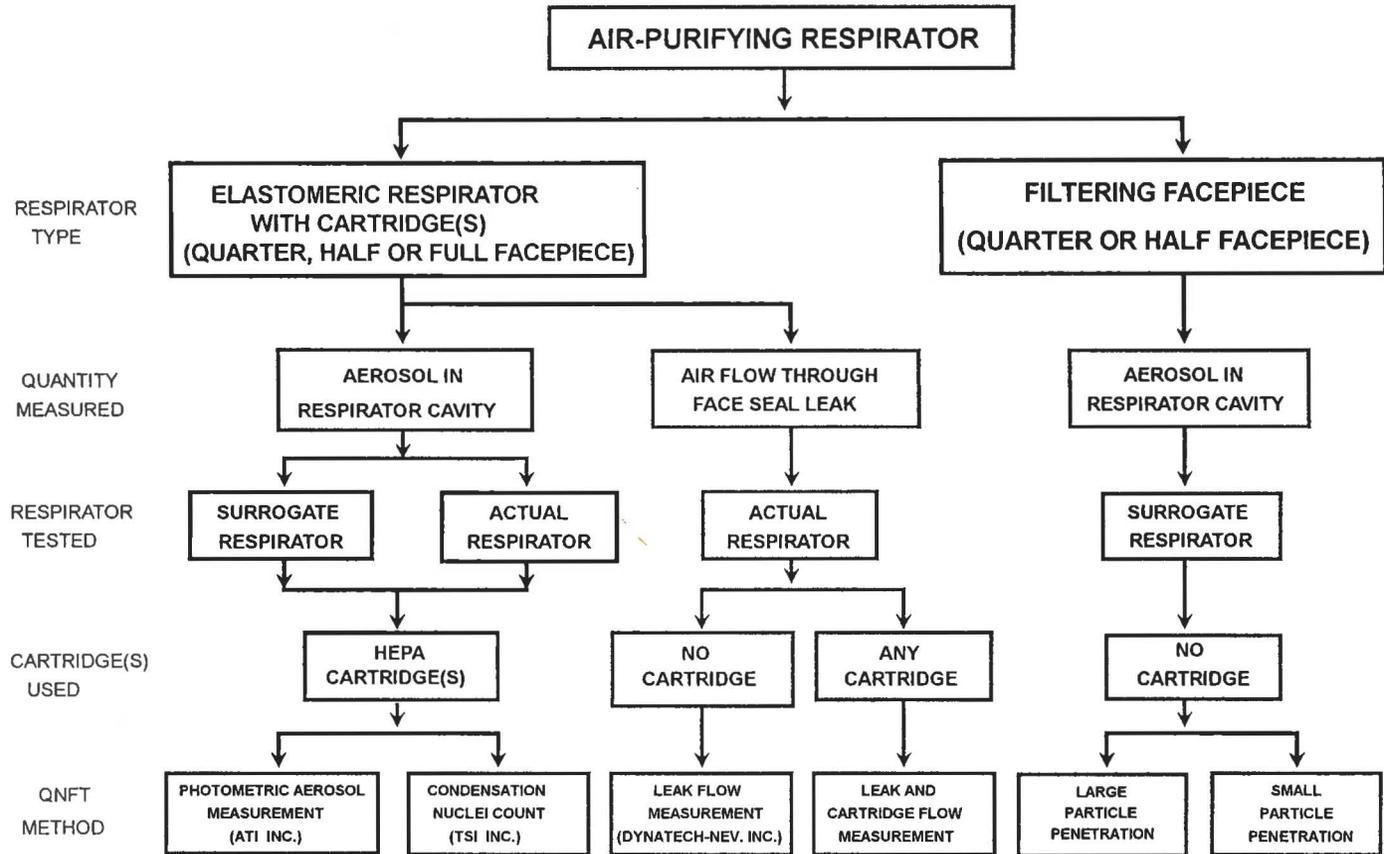


FIGURE 1. Fit testing methods for air-purifying respirators

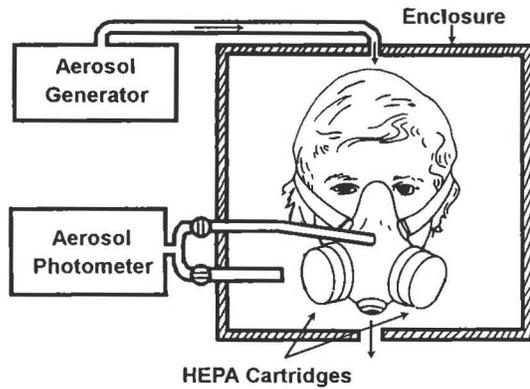
testing with an aerosol detector, the QNFT operator selects one or more respirator brands manufactured by one or more companies and chooses an available respirator size for each brand that will most likely fit the respirator wearer. Since the HEPA filters used in the cartridges are at least 99.97 % efficient measuring the most penetrating particles of about 0.3 μm aerodynamic diameter, 0.03 % penetration of 0.3 μm particles yields a FF of 3,333, if no face seal leak exists. Thus, FFs above 1,000 may have limited meaning, if the aerosol instrument efficiently detects particles penetrated through the HEPA cartridges(s).

During actual wear in an occupational work environment the cartridges may not contain HEPA filters, but filters of lower efficiency which produce a lower pressure drop across them during inhalation. The respirator's fit to the face may be less efficient during inhalation, if the pressure drop to the respirator interior is less. Thus, the aerosol test is useful for selecting a suitable respirator, but may not predict the face fit during actual wear. Another problem in this technique is that the aerosol instrument measures the aerosol concentration continuously inside the respirator during inhalation and exhalation. During exhalation the aerosol concentration in the respirator is reduced by the amount of aerosol particle deposition in the wearer's respiratory tract. The aerosol measurement method thus measures primarily face seal leakage, but the data may be affected by lung deposition and cartridge penetrations.

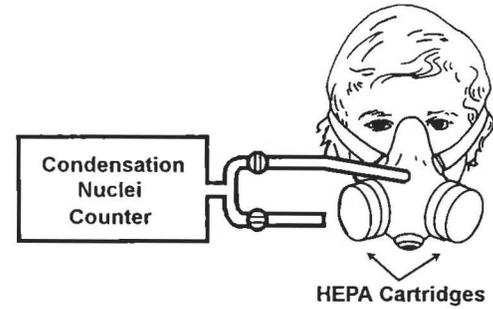
While the QNFT is performed with an aerosol detector, the respirator wearer undertakes several exercises, such as up and down movement or side-to-side movement of the head, or talking while keeping the head in the forward position. These movements simulate actual wear practices, that may affect the respirator's seal to the face. However, these movements are not defined as to the angle of exertion, length of time and breathing rate. As a result, wearers with the same fit are likely to have different fit factors resulting from this activity.

Photometric Aerosol Measurement: The first practical QNFT systems used an aerosol photometer to detect the aerosol inside and outside the respirator, as schematically represented in Fig. 2A. Photometers are most sensitive to aerosol particles of about 0.5 μm in MMAD. As the aerosol concentration inside a well-fitting respirator is much less than that outside, and there are not that many 0.5 μm particles present in normal indoor or outdoor air environments, it is necessary to generate an aerosol in that size range when photometer aerosol detection is used. This leads to the need for an enclosure, either a fixed booth or a portable hood that covers at least the head. The advantage of this system is that the aerosol concentration can be rigidly kept constant. Also, the size of the test particles is in the respirable size range. Therefore, this system is frequently used as the benchmark for evaluating other systems. The disadvantages are the size and expense of the entire system and the aforementioned inherent difficulties with particle deposition in the lung and inhomogeneity in aerosol mixing inside the respirator.

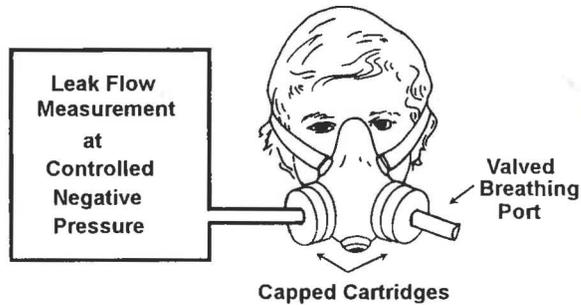
Condensation Nuclei Count: In a natural outdoor environment there are generally 10^3 to 10^4 more 0.05 μm particles present than 0.5 μm ones. In indoor environments that ratio is similar or less. This led to a QNFT with an aerosol measurement device that detects particles smaller than 0.5 μm (Willeke, et al., 1981). A continuous-flow condensation nuclei counter (CNC) was used instead of the photometer and was found to perform the QNFT quite well. TSI Inc. (St. Paul, Minnesota) developed this technique into a commercial product, termed "PortaCount™", which is currently in wide use. As shown in Fig. 2B, it requires neither an aerosol generator nor an enclosure. However, the ambient air concentration must be constant, unperturbed by smoking and other sources, that might vary the external aerosol concentration. A highly filtered room is also not desirable, as the aerosol concentration in such as a room may be too low.



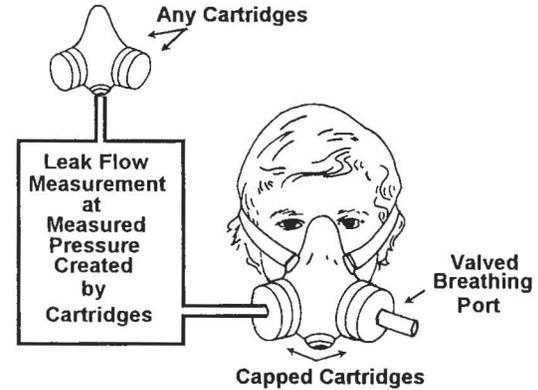
A. PHOTOMETRIC AEROSOL MEASUREMENT



B. CONDENSATION NUCLEI COUNT



C. LEAK FLOW MEASUREMENT



D. LEAK AND CARTRIDGE FLOW MEASUREMENT

Figure 2. Schematic representation of QNFTs for elastomeric respirators with cartridges

The major advantage of this system is its smaller size. The QNFT is relatively simple and economical to administer. It has the same disadvantages of lung deposition and imperfect aerosol mixing in the respirator as the photometric QNFT system. In addition, if small aerosol droplets are generated by the test subject's respiratory system during exhalation, these exhaled particles will be added to the total count attributed to face-seal leakage. If the test subject has smoked within 30 to 45 minutes before the QNFT, smoke particles retained in the respiratory tract may also increase the particle count from inside the respirator. Although the present OSHA regulations are written for QNFTs with photometric measurement, the CNC technique is also accepted as a "de minimus violation".

Air Flow Measurement Methods

Fit testing is performed to select a respirator that minimizes the leakage of external contaminants into the respirator and thus the wearer's breathing zone. The contaminants may be particulate or gaseous. The QNFTs discussed above measure the amount of aerosol present in the respirator wearer's breathing zone. Particulate and gaseous contaminants can be present in the respirator interior only, if they are carried there by air leakage through face seal leakage. This led to QNFT methods that measure the leakage of air into the interior of the respirator. The two major techniques are listed in Fig. 1 and are schematically represented in Figs. 2C and D.

Leak Flow Measurement: The first leak measurement method utilized an indirect method to measure face seal leakage (Carpenter and Willeke, 1988). The cartridges of an elastomeric respirator were replaced with two capped cartridges. One capped cartridge had a large opening in it, so that the wearer could breath normally. The wearer then closed a valve, inflated the chest a little to create a negative pressure in the respirator interior and then held the breath for a few seconds. A pressure sensor attached to the same or to the other capped cartridge monitored the pressure inside. If the pressure remained constant, there was no leakage. If the pressure difference to the outside decayed, the decay rate was an indication of the leakage rate. This method, commercialized for a while by Dynatech-Frontier (Albuquerque, New Mexico) in the late 1980's and early 1990's, worked well with rigid respirator bodies (McGlone, 1988). However, as the respirator bodies become more pliable in the early 1990's, the volume of the respirator interior could no longer be assumed to remain constant, independent of the pressure difference; i.e., with the more pliable respirator material the pressure decay rate become a function of air leakage and change in respirator cavity volume. Although calibration of the volume change could have been entered into the leak flow calculation, use of this method was discontinued in favor of a more direct leak flow measurement.

The face seal leak flow is measured more directly in the commercially available FitTester 3000™ (Dynatech Nevada, Carson City, Nevada) (Crutchfield, et al., 1995). When using this device, the cartridges are also capped, see Fig. 2C, and the wearer holds the breath for a few seconds while the instrument reduces the pressure inside the respirator to a predetermined level that is typical of inhalation. While maintaining this controlled negative pressure (CNP), a mass flow meter measures the air flow rate out of the respirator that is needed to maintain the negative pressure. In the absence of exhalation valve leakage, this flow rate is equal to the face seal leak rate at that pressure. The FF is then determined by dividing the inhalation flow rate, that is typical for that pressure, by the measured leak flow rate. The test is repeated in several head positions, e.g., with the head turned upward or sideways. Such static tests are more repeatable than aerosol measurements during head movements, because aerosol measurements are dependent on the location(s) of the face seal leak(s). When air leaks into a volume at negative pressure, the air molecules virtually instantaneously adjust relative to each other so that the measured pressure is the same anywhere in the volume. In contrast, aerosol particles take time to physically mix throughout the entire volume to the same concentration

level.

One disadvantage of the CNP technique is that the leak flow is determined at a predetermined negative pressure. Cartridges, even of the same classification, produce different negative pressures inside the respirator cavity, because different filter materials and areas in the cartridges have different flow resistances at the same flow rates (Xu, et al., 1991; Chen and Willeke, 1992). A major advantage of the FitTester 3000™ is its lower cost. The pressure and flow sensors in a leak flow measurement system are inherently more inexpensive than the sophisticated aerosol measurement technology. Although the FitTester 3000™ is very different from the photometric aerosol measurement system, it has been granted by OSHA the "de minimus violation" status.

Leak and Cartridge Flow Measurement : In order to fit test with the actual respirator to be worn and with the cartridges that are to be attached to the cartridges, be they of the HEPA or any other classification, a new system has been developed (Willeke and Krishnan, 1994) that measures the face seal leakage at the negative pressure created by the wearer's own breathing, see Fig. 2D. In this method, the cartridges are attached to a reference respirator and the pressure is measured inside at a typical average breathing rate. Through a feedback system the same pressure is created inside the respirator worn by the test subject. During breathing holding the leak flow is thus measured at the negative pressure created by the cartridges. The ratio of the cartridge flow to the leak flow determines the degree of fit. This ratio is also the average dilution factor with which contaminants penetrating through the face seal leak(s) are diluted before entering the respiratory tract. This leak and cartridge flow measurement system is not yet commercially available. Since two flows are measured by this system, it is also referred to as the Dichotomous QNFT system or "Dichot" in short. This new system can potentially also be used in field situations for determinations of the actual face fit before and after wear in hazardous environments. Sweat, dirt and strap tension may seriously affect the face seal during actual wear. If the aerosol penetration is experimentally determined for different face seal leak situations, and the aerosol size distribution is measured or known in the work environment, the amount of aerosol inhaled can be calculated for each FF measurement. Thus, an estimate of the workplace protection factor could be made. Another advantage of this and the CNP method is their fast response time. A break of the face seal is detected virtually instantaneously by any of the leak flow measurement methods, making these methods suitable training tools for workers trying to detect how far they can move their head before serious face seal leakage occurs.

QNFT METHODS FOR FILTERING FACEPIECES

When the air purifying filter is not contained in one or two cartridges, but constitutes the respirator body itself, the respirator is referred to as a filtering facepiece, low maintenance respirator or disposable respirator. If the filter is made of HEPA material, the QNFT aerosol methods for elastomeric respirators with cartridges can be applied to filtering facepieces, because the measured aerosol concentration can be assumed to be primarily due to face seal leak penetration. However, the facepiece must be probed, i.e., a surrogate filtering facepiece must be used. Since most filtering facepieces used today are less efficient than the HEPA ones, new methods have been explored specifically for filtering facepiece. For a while, HEPA versions of less efficient filtering facepieces were manufactured for fit testing. However, the QNFT data obtained with the increased rigidity and pressure drop of a HEPA filtering facepiece are not valid indications of the performance of filtering facepieces made of less efficient filter material. Therefore, face seal leakage needs to be detected without making any changes to the filter material.

Large Particle Penetration : Filter penetration is higher in the submicrometer size range. The most

penetrating particle size is usually at or near 0.3 μm . A HEPA filter is at least 99.97 % efficient at that size. The latest NIOSH rule, 42 CFR part 84 of 1995, categorizes filters into 3 classes: A is at least 99.97 %, B is at least 99 %, and C is at least 95 % efficient at the mask penetration size (Respiratory Protection Devices, 1995). The previous classifications of dust/mist (DM) and dust/fume/mist (DFM) respirators are generally less efficient than class C respirators. Common to all these respirators is increasingly efficient aerosol particle removal for particle sizes above 1 μm , due to increased impaction and interception of the particles (Chen, et al., 1992).

The almost complete collection of 2.5 μm particles on DM and DFM respirators led the 3M company to the development of the "Large Particle Quantitative Fit Test (LPQNFT)" (Iverson, et al., 1992). The 3M system, consisting primarily of commercially available components, utilizes a monodisperse aerosol generator, an exposure chamber and an aerosol sensing instrument. When using this system, the monodisperse "large" particles are assumed to have penetrated to the respirator interior only through face seal leaks. Thus the measured FF reflects the penetration of the 2.5 μm test particles. In the traditional QNFTs with the photometric measurement the MMAD of the test particles is about 0.5 μm . Thus, the FF values are not comparable between these two types of measurement.

Small Particle Penetration: When a small aerosol particle approaches the filter material of a respirator, it faces a potentially tortuous path through the filter, resulting in removal in most cases. When this particle approaches a leak site, however, that opening may be very large relative to the size of the particle. A 1 μm particle may face an opening of 10, 100 or even 1000 times its own size. Its motion through the leak site and its potential removal by the leak site surface is, therefore, quite different from motion through the filter material. This difference led to the recent development of the "Small Particle Quantitative Fit Test (SPQNFT)" (Myojo, et al., 1994).

In this test the filtering facepiece is probed and the combined aerosol penetration through filter and leak(s) is measured at a low flow rate (e.g., 10 Lpm) and a high flow rate (e.g., 100 Lpm). The face seal leak rate and a corresponding measure of fit is then determined from the penetration ratio for the two flow rates. The test can be performed while breathing normally or during breath holding. The latter is performed, because lung deposition is avoided and the probe samples the entire respirator interior, thus avoiding all of the aerosol sampling problems pointed out before.

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