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Quantitative Fit Testing Techniques and Regulations for Tight-Fitting Respirators: Current Methods Measuring Aerosol or Air Leakage, and New Developments

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Quantitative Fit Testing Techniques and Regulations for Tight-Fitting Respirators: Current Methods Measuring Aerosol or Air Leakage, and New Developments

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Until a few years ago, only two quantitative fit testing (QNFT) techniques were available and accepted by U.S. Occupational Safety and Health Administration (OSHA) regulations. In the 1980s and 1990s, several new and fundamentally different QNFT methods were developed. Two of the newer methods are commercially available and are accepted by OSHA as suitable alternatives. In this article the principles of operation of the OSHA-accepted and of some newly developed but not yet approved QNFT techniques are explained, and each technique's major advantages and disadvantages are pointed out. Emphasis is given to negative-pressure air-purifying respirators, as they are in most frequent use today. The requirements and recommendations for fit testing positive-pressure respirators are discussed as well. Finally, the presently available QNFT standards and regulations are summarized to assist the user in making fit testing decisions.

Keywords: aerosol leakage, air leakage, fit testing, respirator, respiratory protection

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.[1] Air-purifying respirators are used most frequently in routine work practices because they are smaller, more easily maintained, and are least restrictive of the wearer's movements. Thus, the focus of this article is on negative-pressure air-purifying respirators. The discussion is then extended to positive-pressure air-purifying and atmosphere-supplying respirators.

Even the best tight-fitting respirator (i.e., quarter, half- or full-facepiece) 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 hazardous work environments to ensure that the respirator worn satisfies a minimum of fit, and that the user knows when the respirator fits properly.[2] The fit of a respirator can be determined by qualitative or quantitative methods. Qualitative fit test (QLFT) methods rely on the subject's voluntary or involuntary response (i.e., taste, smell, or irritation) to a test agent. Quantitative fit test (QNFT) methods provide an objective and numerical basis by measuring a fit factor.[3] Although QLFT methods are of definite value because such tests

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can be carried out quickly at the workplace, they have not been universally accepted because of their dependence on the wearer's subjective response.[4]

The essential steps of the first QNFT method were to generate an aerosol, disperse it in a test enclosure, have the test subject wear a test respirator in that enclosure, and measure the aerosol concentration inside and outside the respirator. In the 1980s and 1990s several new and fundamentally different QNFT methods have been developed. 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.[5–9] The purpose of this article is to explain the operation of each QNFT technique along with the major advantages and disadvantages of each technique and to discuss many of the QNFT standards and regulations.

Description of Qualitative and Quantitative Fit Tests

When a QLFT is performed, the QLFT method requires the introduction of a challenge agent into the area around the respirator while it is worn. A fit determination is then made by the wearer depending on whether the presence of the challenge agent is detected or not through subjective means such as odor, taste or nasal or throat irritation. If the agent is detected, the respirator fit is considered to be inadequate. Three types of QLFT agents are used most frequently: isoamyl acetate, sodium saccharin, and irritant fume.[1,2,10] The QLFT methods have the advantages of being inexpensive, fast, relatively simple, and easy to perform in the workplace. The main disadvantage of the QLFT methods is that the fit determination relies on the subjective response of the wearer as to whether or not the challenge agent has penetrated into the respirator. If the wearer has a disability for detecting the challenge agent that has not been identified, the test result is invalid.

When a QNFT is performed, the respirator is worn in a relatively stable test atmosphere, often containing aerosol particles. The adequacy of the respirator fit is determined by measuring the aerosol concentrations outside and inside the facepiece of the respirator. In the traditional QNFT, the fit test is performed during several head and mouth movements reflecting work situations that may cause leaks. During the test the filters 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 through the respirator face seal, not through the filter material. The ratio of the aerosol concentration outside the respirator to the one inside is referred to as the fit factor; sometimes it is also referred to as the quantitative fit factor.[3,11–13] The fit factor measures the respirator's fit to the wearer's face under the conditions of the test. As such, the fit factor may not predict the degree of protection in the workplace.

When the ratio of contaminant concentration outside the respirator to inside the respirator is measured in the workplace, it is referred to as the workplace protection factor (WPF).[3,11–13] For particulate contaminants in the workplace, the amount of aerosol reaching the wearer's breathing zone from the outside environment depends on the concentration and size distribution of the aerosol surrounding the wearer, the type of filters 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 on the same factors, but instead of filter type and particle size distribution, the adsorption characteristics of the cartridge(s) for the contaminant are important.

The major advantage of the QNFT is that this test yields a numerical and objective FF that is compared with the minimum fit factor required by the standards. Thus, a decision can be made as to whether the respirator has an acceptable fit. However, the fit of the same respirator on an individual may vary from one wearing to the next,[14] because the human facial features are complex and the respirator may not fit 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 including fit test technique.[5–9,15–18] For example, when the QNFT is performed with an aerosol sensor, particles from outside the respirator may streak into the interior space of the respirator through one or more leak sites.[19] Since the wearer's breathing cycle is too short for complete mixing of the aerosol inside the respirator, the measured fit factor can depend 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.[19–25]

Fit Test Dependence on Respirator Type

When performing QNFTs on a respirator with aerosol particles, face seal leak penetration is distinguished from filter penetration by using HEPA filters. The HEPA filters 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, well-maintained respirator.

When testing respirators with replaceable filters, non-HEPA filters and chemical cartridges can easily be replaced by HEPA filters for the fit test. QNFTs of filtering facepiece respirators are more challenging to perform because the filters cannot be interchanged. 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 aerosols be assumed to penetrate to the respirator interior through the face seal leak(s) alone. With filtering facepiece respirators made of non-HEPA filter material, aerosol penetration through the face seal(s) is not easily distinguished from aerosol penetration through the filter material itself. Therefore, a need exists for the development and commercialization of fit testing methods suitable for such devices so that QNFT techniques may be considered for them in the future. Figure 1 categorizes the principal QNFT techniques that have been developed for both HEPA and non-HEPA filter respirators.

QNFT Methods for Air-Purifying Respirators with Replaceable Fitlers

When a face seal 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. Environmental contaminants, particulate or gaseous, may be carried inward with this airflow. Measurement of the aerosol concentration inside the respirator relative to that outside constitutes one type of QNFT in use today. The other type of QNFT is the measurement of the airflow into the respirator interior.

Aerosol Measurement Methods

The first aerosol QNFT method was developed by Burgess et al.[26] in 1961. In 1972 Hyatt et al.[27] reported on the first practical

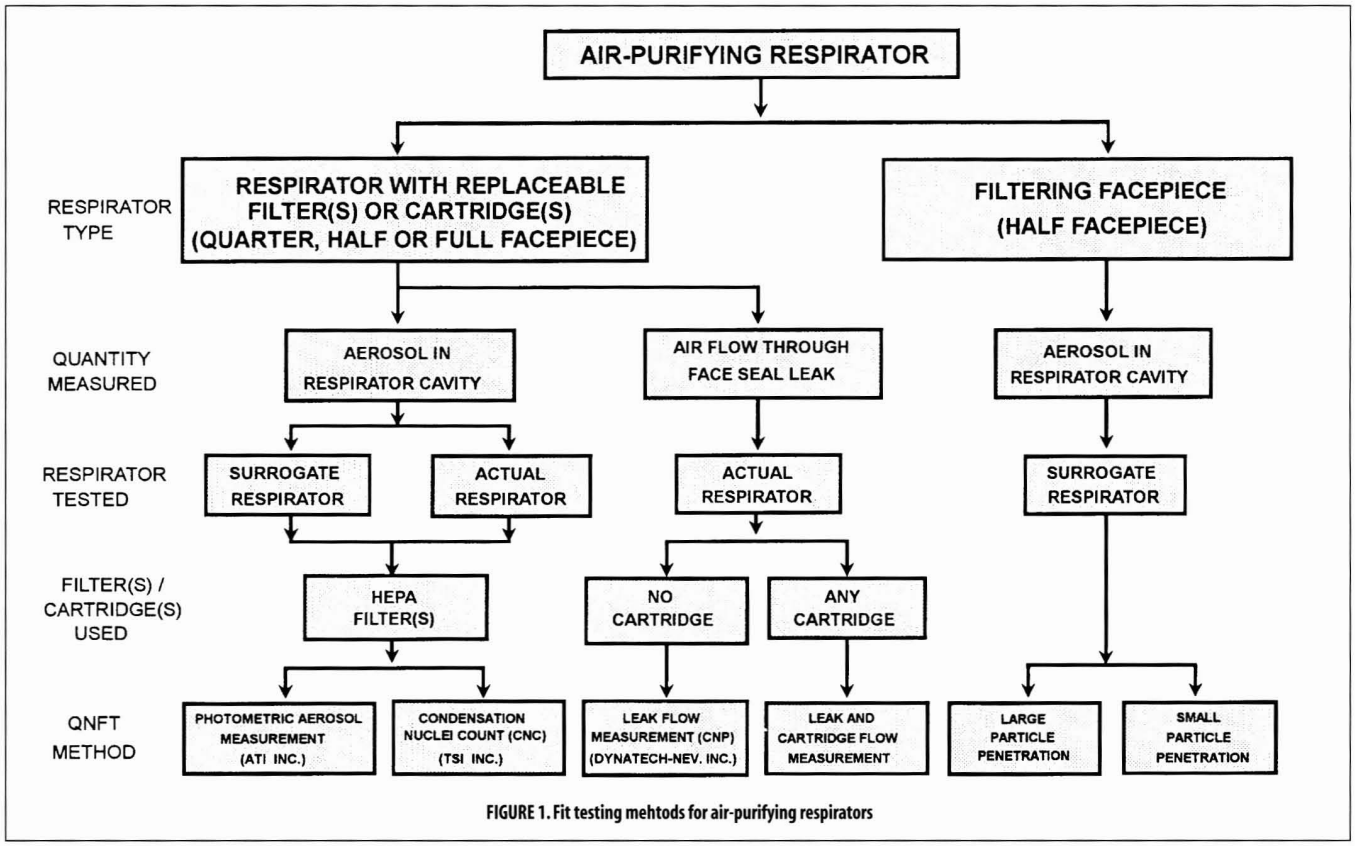

FIGURE 1. Fit testing mehtods for air-purifying respirators

aerosol system for routine use, utilizing dioctylphthalate 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 used as test agents, e.g., sodium chloride, different oils, and ambient air aerosol particles.

During fit testing with an aerosol detector, only HEPA filters are used,[2] and all aerosol particles sampled inside are assumed to have penetrated through face seal leak(s). Since HEPA filters are at least 99.97% efficient at the most penetrating particle size of 0.3 μm aerodynamic diameter,[1] 0.03% penetration of 0.3 μm particles yields a minimum fit factor of 3333, if no face seal leak exists. Thus, high fit factors may have limited meaning, if the aerosol instrument efficiently detects particles that penetrated through the HEPA filters. Most QNFTs, however, use particles that have a particle size distribution with most particles both larger and smaller than 0.3 μm, and HEPA filters are typically 99.997% efficient to meet product certification at 99.97% efficiency. Thus, fit factors above 3000 generally do reflect face seal leakage, but should be used with caution. Since HEPA filters may cause a different pressure drop across the respirator from the actual filter or cartridge to be used in the workplace, the aerosol QNFTs may not predict face fit during actual use. It is generally assumed, however, that the respirator tested with HEPA filters will also have a very good fit to the wearer's face when the respirator filters are made of non-HEPA filter material.

Another problem with 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.[28–30] The degree of aerosol particle removal depends on the subject's breathing rate and lung physiology. The size and dimensional composition of the respiratory tract may differ among individuals as much as externally visible differences of head, arm, and body. The aerosol measurement method thus provides an indicator of face seal leakage, but the measurement may be affected by lung deposition and filter penetrations.

Until recently, all QNFTs with aerosol detection were performed with surrogate respirators with a sampling probe imbedded in the respirator body in the breathing region between nose and mouth.[24] Once a respirator brand and size are chosen as a result of testing with surrogate respirators, it is assumed that the wearer's own respirator has the same pliability and workmanship, thus resulting in a similar face fit. Recently, replaceable sampling probes or ports have been designed that fit between the HEPA filter and the facepiece so that the wearer's own respirator can be tested directly.[31] This method may also be more hygienic. Whether the sampling port is mounted in the respirator body or in one of the replaceable adapters, the aerosol concentrations measured through the sampling port may not truly represent the average aerosol concentration inside.[19–25,32–34] This inherent difficulty with any aerosol measurement method is due to the observation that the aerosol that leaks or streaks into the respirator may not mix sufficiently inside during the short inhalation period. The measured aerosol concentration may, therefore, be highly dependent on the location of the sampling port relative to the leak site(s), which are subject dependent.

While the QNFT is performed with an aerosol detector, the respirator wearer performs 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 are thought to simulate actual wear movements that may affect the respirator's seal to the face.[35] However, these movements are not defined as to the angle of exertion, length of time, and breathing rate.

As seen in Figure 1, the available QNFT methods with aerosol detection can be classified into three types, which will be described next.

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 Figure 2A. In an aerosol photometer the aerosol is continuously drawn through a sensing volume in which a light beam is focused onto the aerosol cloud, and the light scatter from this cloud yields an electronic signal that is proportional to the aerosol concentration.[36] The mass median aerodynamic diameter (MMAD) of the aerosol generated for fit testing with a photometer is usually in the size range of visible light wave lengths (ca. 0.4–0.7 µm) or larger. The aerosol is uniformly distributed in 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 kept rigidly constant. Since it was the first fit testing system developed, this system is frequently used as the benchmark for evaluating other systems.[5–8,15,16] The disadvantages are the size and expense of the entire system and the aforementioned inherent difficulties with particle deposition in the lung and lack of aerosol mixing inside the respirator.

Photometric QNFT systems are commercially available from Air Techniques (Owings Mills, Md.). Until recently, they were also available from Dynatech-Frontier Inc. (Albuquerque, N.M.). The systems sold by the latter company are now serviced by Dynatech-Nevada (Carson City, Nev.). The present OSHA regulations for QNFTs are based on the photometric and flame photometry measurement techniques. All commercially available photometric QNFT systems are therefore accepted by OSHA.

Flame Photometry Measurement

The flame photometry measurement technique is the other QNFT method addressed in OSHA regulations.[10] This QNFT method has many of the same advantages and disadvantages as the photometric aerosol measurement. Schematically it can be represented by Figure 2A also, except the aerosol photometer is replaced with a flame photometer. The test aerosol, sodium chloride (NaCl), is drawn continuously to a propane burner and flame photometer assembly.[37] The NaCl particles are vaporized in the burner and the characteristic yellow light emitted by sodium is detected utilizing a sensitive photomultiplier tube. The light intensity is directly related to the concentration on NaCl aerosol particles. The MMAD of the generated aerosol is around 0.5–0.7 µm. This method uses the same type of fixed booth or portable hood as the photometric technique. Variable relative humidity in the test environment can make controlling the particle size more challenging. Flame photometry QNFT systems are also commercially available from Air Techniques. This aerosol QNFT method is not as popular, and the sampling problems are similar to the photometric technique.

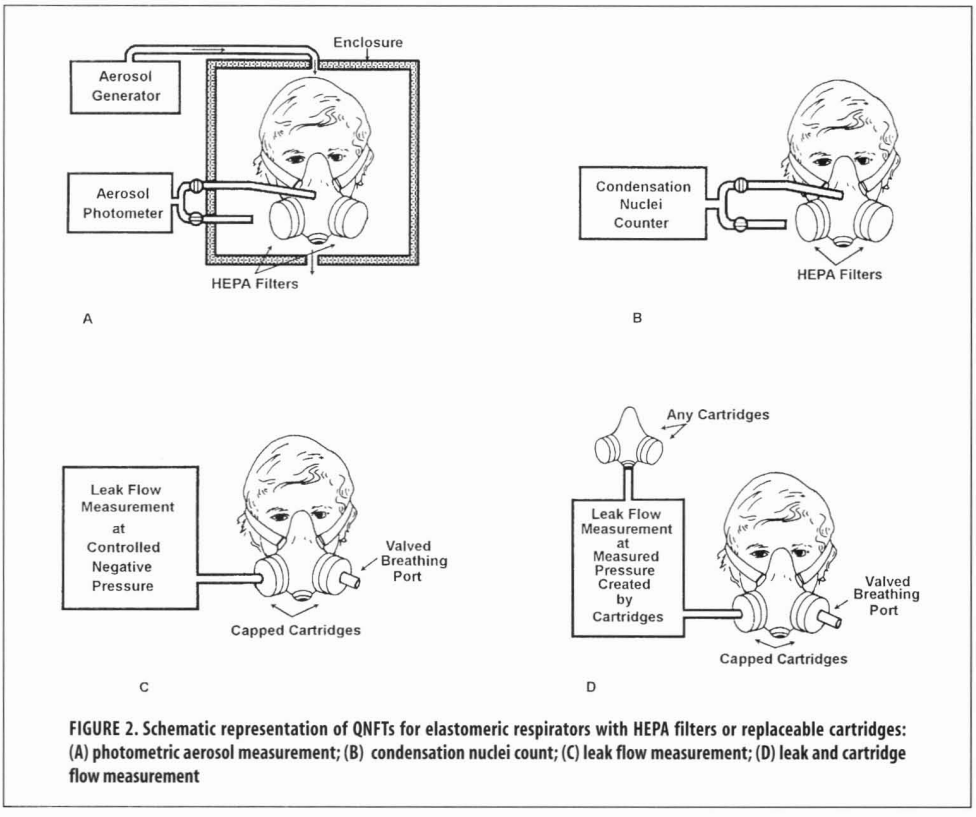

FIGURE 2. Schematic representation of QNFTs for elastomeric respirators with HEPA filters or replaceable cartridges: (A) photometric aerosol measurement; (B) condensation nuclei count; (C) leak flow measurement; (D) leak and cartridge flow measurement

Condensation Nuclei Count

About one to two decades more 0.05 µm than 0.5 µm particles are normally present in indoor air environments.[5] In 1981 this led Willeke et al.[38] to design a QNFT with an aerosol measurement device that detects particles smaller than 0.5 µm. A continuous-flow condensation nuclei counter (CNC) was used instead of the photometer and was found to perform the QNFT quite well. In the CNC, the small particles, invisible to conventional photometric techniques, are first grown to a larger size by vapor condensation and are detected by a photometric light scattering or an optical single-particle counting technique.[39] TSI Inc. (St. Paul, Minn.) developed this technique into a commercial product, the PortaCount™ Respirator Fit Tester, which is currently in wide use. As shown in Figure 2B, it requires neither an aerosol generator nor an enclosure.[40] However, the ambient air concentration must be relatively constant, undisturbed 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 a room may be too low.

The major advantage of this system is its smaller size. The CNC-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 and later released may also increase the particle count inside the respirator.[41] These additional particles lead to a more conservative fit factor, but could result in rejecting acceptably fitting respirators.

Airflow Measurement Methods

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 leaks. Therefore, in the late 1980s Carpenter and Willeke[15,42] and Crutchfield et al.[43–46] independently of each other developed QNFTs that measure face seal leakage directly. The two major techniques are listed in Figure 1 and are schematically represented in Figures 2C and D.

Leak Flow Measurement

The first published leak measurement method by Carpenter and Willeke[15,42] used an indirect method to measure face seal leakage (not shown in Figure 2). The cartridges of an elastomeric respirator were replaced with two capped cartridges. One capped cartridge had a large opening with a valve in it, so that the wearer could breathe normally. The wearer then closed the 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 indicator of the leakage rate. This method, commercialized by Dynatech-Frontier in the late 1980s and early 1990s, worked well with rigid respirator facepieces.[47] However, in the early 1990s, as the respirator facepieces were redesigned, they became more pliable. Thus, 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 became 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 method.

The face seal leak flow is measured more directly in the commercially available FitTester 3000 (Dynatech-Nevada) developed by Crutchfield et al.[43–46] When using this device, the cartridges are also capped, (see Figure 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 representative of inhalation. While maintaining this controlled negative pressure (CNP), a mass flow meter measures the airflow 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 fit factor is then determined by dividing a representative inhalation flow rate by the measured leak flow rate. The test is repeated in several head positions, e.g., with the head turned upward or sideways. When air leaks into the volume between respirator and face, 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.

One disadvantage of the CNP technique is that the leak flow is determined at a predetermined negative pressure. Even the same type cartridges and filters produce different negative pressures inside the respirator cavity, because different manufacturers' filter materials and cartridges have different flow resistances at the same flow rates.[48,49] Another disadvantage is that the test cannot be performed while the wearer exercises and breathes normally. An 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 sophisticated aerosol measurement technology.

Leak and Cartridge Flow Measurement

To fit test with the actual respirator to be worn and with the filters or cartridges that are to be used in the workplace, Krishnan et al.[17,18] and Han et al.[50] have recently developed a new system that measures the face seal leakage at the negative pressure created by the wearer's own breathing (see Figure 2D). The cartridges may be of the HEPA or any other type of filter or cartridge classification. 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 breath-holding the leak flow is thus measured at the negative pressure created by the wearer through the actual filters or cartridges. The ratio of the cartridge flow to the leak flow determines the fit factor. The same fit factor 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" for short. This new system can potentially be used in field situations for determinations of the actual face fit before and after wear in hazardous environments.

Any particles present outside the respirator may be carried inside with the leak flow. 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 leaked into the respirator can be calculated. This may be useful when one wants to estimate the worker's exposure. Thus, an estimate of the workplace protection factor potentially can 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 both 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. Aerosol methods can be used for such training as well, but have a slower response time.

QNFT Methods for Non-HEPA Filtering Facepieces

If the respirator is made of HEPA filter material, all aerosol measurement QNFT methods 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 consist of non-HEPA filters, new methods have been explored especially for filtering facepiece respirators. For a while HEPA filter versions of less efficient filtering facepieces were manufactured for fit testing. However, the QNFT data obtained with the increased rigidity and greater pressure drop of a HEPA filtering facepiece are not valid indications of the performance of a non-HEPA filtering facepiece. Therefore, face seal leakage needs to be detected without making any changes to the filter material.

Large Particle Penetration

The most penetrating particle size for respirator filters is usually at or

near 0.3 μm. A HEPA filter is at least 99.97% efficient at that size. The recent change to respirator certification, 42 *CFR* 84, established three series of filters (N, R, and P), each with three filter efficiency levels: 99.97%, 99%, and 95% at 0.3 μm MMAD.[51] The previous classifications of dust/mist (DM) and dust/fume/mist (DFM) respirators are generally less efficient than 95% at 0.3 μm MMAD. Common to all these respirators is the increasingly efficient aerosol particle removal below and above 0.3 μm MMAD. The filter efficiency is very good for particle sizes above 1 μm.[49,52]

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 QNFT.[53,54] The 3M system uses a monodisperse aerosol generator, an exposure chamber, and an aerosol sensing instrument. While these components are commercially available, the system as a whole is not. 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 fit factor reflects the penetration of the 2.5 μm test particles and no modification of the respirator is necessary. While the fit factor is measured using a different particle size, the results showed these fit factors correlated well with fit factors measured by the traditional fit tests.[53] While developed for fit testing probed filtering facepieces, this method can also be used for fit testing respirators with replaceable cartridges or filters.

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 Myojo et al.[55] to the recent development of the "Small Particle QNFT (SPQNFT).

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 L/min) and a high flow rate (e.g., 100 L/min). 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 the subject is breathing normally or during breath-holding. The latter is preferred, because lung deposition is avoided and the probe samples the entire respirator interior, thus avoiding the aerosol sampling problems pointed out before. The SPQNFT is not yet commercially available.

Other Method Developments

Brown and Vaughn[56] recently developed a technique through which the leakage into a respirator is assessed by monitoring the pressure pulsations caused by a pulsating volume flow into the respirator's interior. This method appears to work best for a respirator with a poor fit. This recent development and the small and large particle QNFTs are not commercially available at this time. However, for those who want to use QNFTs for non-HEPA filtering facepiece respirators, new methods need to become commercially available. Once available, they will be useful for the increased use of filtering facepiece respirators in health-care environments and will avoid the deficiencies of qualitative fit testing with agents such as saccharin, which cannot be detected by all workers.[57–60]

Comparison Studies

Photometric Aerosol Measurement Versus CNC

The principal difference between the photometric and the principal CNC aerosol measurement techniques is the size of the test particles. The photometer responds primarily to particles of a size equal to or larger than the wavelength of light, 0.4–0.7 μm, while the count by the CNC reflects primarily particles below this size. Since particle penetration through a narrow space is particle size dependent, one expects some difference in the measured fit factors. In one of the first studies, the photometer and CNC measurements differed by less than 20%.[61] In a study with a 5% controlled leak in the respirator, the differences between the measured fit factors was very small.[40] In a study with half-mask respirators on 24 subjects exposed to a challenge aerosol with a MMAD 0.5 to 0.7 μm, the range of fit factors obtained by both methods was extremely large and followed a lognormal distribution with a geometric standard deviation of 3.9 for the CNC and 6.7 for the photometric method.[16] Tests with both methods resulted in the same pass or fail results except for one. Biermann et al.,[8] in laboratory experiments on a mannequin with a breathing machine, found that the fit factors agreed well at fit factors below 1000. In tests with human subjects they found a good correlation between the two methods. For fit factors above 1000, the number of particles penetrated into the respirator volume may be quite small. If a comparable number of particles is generated in the lung and exhaled into the same respirator interior, the indicated fit factor will be lower, thus making the fit factor data of 1000 or more questionable.[5] Since the smaller aerosol particles detected by the CNC may have higher diffusion losses in the leak site, the aerosol leakage recorded by the CNC, resulting from a small leak, is expected to be lower than the one recorded by photometric methods, i.e., the CNC-recorded fit factor is higher than the photometer-recorded fit factor.[24]

Aerosol Measurement Versus Airflow Measurement

Comparison tests have shown that most of the fit factors derived from leak flow measurements have lower values and less variability than those derived from photometric aerosol measurements.[6,9,15,44,45,62] If there are no particle losses, and the aerosol mixing is perfect inside, the fit factors determined by the aerosol methods should be the same as those by the airflow measurement methods. However, as the leak size gets smaller, aerosol particle loss in the leak site increases. In addition, there are particle losses to the interior wall of the respirator. Thus, the fit factors are expected to be about the same for low fit factors, but the fit factors from aerosol measurements are expected to be increasingly higher than the fit factors from leak flow measurements, as the fit gets better. In addition, the aerosol measurements are expected to have greater variability because of the uncertainty of the aerosol measurement due to the aforementioned lack of aerosol mixing in the respirator interior.[15,17,18,42]

QNFT for Positive Pressure Respirators

Recently there has been increased interest in the fit testing of tight-fitting, positive-pressure respirators. Positive-pressure respirators include powered air-purifying respirators, continuous-flow and pressure-demand airline respirators, as well as pressure-demand, open-circuit self-contained breathing apparatus (SCBA) and positive-pressure, closed-circuit SCBA with tight-fitting

facepieces. The facepieces on positive-pressure respirators are similar, if not identical, to those on negative-pressure respirators. Hence the concerns about obtaining an adequate fit are similar. The OSHA cadmium standard[63] requires fit testing for these respirator types. The ANSI (American National Standards Institute) standard requires fit testing of positive-pressure, tight-fitting respirators in all situations, not just cadmium exposures, using either QLFT or QNFT methods.[64]

The purpose of the fit test for positive-pressure respirators is to prevent unacceptable respirator fits that might degrade protection through leakage or reduce the service life of an SCBA.[64] If an aerosol monitor were used for fit testing a positive-pressure respirator while air is supplied to the respirator, any particles contained in the air source or generated by a powered air-purifying respirator motor would be indistinguishable from the particles leaked inward through face seal leaks. If a fit test method were to be used that measures the leak flow, the positive pressure air supply would have to be shut off. Therefore, all QNFTs of positive-pressure respirators are performed in the negative-pressure mode.

Conversion to the negative-pressure mode can be accomplished in two ways. One way is to use an adapter, available from the manufacturer, to convert the respirator to the negative-pressure mode with HEPA filters. The other way is to obtain an air-purifying, negative-pressure version of the identical facepiece. Both must be probed for QNFT measurements. Thus, the fit testing of positive-pressure respirators is identical to the fit testing of negative-pressure respirators.

Standards and Regulations

Although fit testing of respirators has become an accepted practice in the United States and Canada, the majority of countries do not require fit testing. At this time respirator use standards and regulations requiring fit testing are limited to the United States, Canada, Australia, and New Zealand. Facial fit is evaluated during respirator certification using a total inward leakage test in Australia, New Zealand and many European countries.[65–67] The total inward leakage of a test aerosol from all sources (e.g., faceseal, filter, exhalation valve) is determined for a panel of people (e.g., 10) wearing the respirator with the filter to be used in the workplace. For non-HEPA filters, filter penetration can be very significant. The test suffers from the same sampling limitations as QNFTs using aerosol methods. These tests do not predict how well a respirator will fit a specific individual.

QLFT Versus QNFT

ANSI Z88.2 and most of the OSHA regulations allow either QLFT or QNFT methods for tight-fitting respirators.[64,68–71] Some of the OSHA substance-specific standards, however, may require one method over the other in certain situations. Table I outlines when quantitative fit testing is required over qualitative fit testing to comply with OSHA regulations. The lead and asbestos standards, as written, only allow QNFTs for full-facepiece, negative-pressure respirators, but OSHA has stated they will allow QLFTs for these respirators for use in concentrations up to 10 times the permissible exposure limit.[72,73] Only the more recent standards have described how QLFTs and QNFTs should be done. The standards with a QNFT protocol (asbestos, benzene, cadmium, formaldehyde, lead in construction, and methylenedianiline) describe the flame photometry and photometric aerosol measurement techniques as discussed earlier, which use an aerosol generator and test chamber.[10] OSHA, however, has stated it will allow QNFT using the CNC and CNP techniques.[74] Unfortunately, specification standards do not allow for new and potentially better techniques to be used as they are developed.

One fit test method has not been shown to provide a greater degree of protection than another. Advantages and disadvantages of QLFT and traditional QNFT methods have been described.[1,2,19–21] While WPF studies on half-facepiece respirators appear to indicate that fit testing, as required by ANSI, is a beneficial practice, it appears one method is not necessarily more protective than another.[75]

Australia, Canada, and New Zealand have developed respirator use standards that also require fit testing[76,77] These standards allow either QLFTs or QNFTs to be used on all "close" fitting respirators. The photometric, flame photometry, and CNC QNFT technologies are allowed.

Fit Test Frequency

The OSHA respiratory protection standard is vague regarding frequency of fit testing and the type of respirators to be fit tested.[70] OSHA issued a directive to clarify that all employees required to wear negative-pressure respirators must be fit tested either qualitatively or quantitatively.[78] This implies that employees must be fit tested with the respirator prior to wearing it in a hazardous atmosphere and must be refitted when a new make or model respirator is used. The directive did not address retesting frequency. Table I identifies some of the substances with specific fit testing frequencies. In addition to those standards listed in Table I, the OSHA standards for benzene, formaldehyde, and 4,4′-methylenedianiline require fit testing to be repeated annually.[68]

While OSHA standards may not always specify the frequency for repeat fit testing, one study has shown that respirator wearers obtained higher fit factors upon refitting.[79] It was thought the wearer's increased experience and familiarity with the respirator led to better fitting by the wearer. This supports repeating fit testing at some specified frequency. The OSHA proposed rule for respiratory protection, if not changed, would require annual fit testing besides the initial fit test.[71]

In addition to initial fit testing, ANSI Z88.2 requires fit testing to be repeated annually or when a different make or model is selected. It also requires the fit test to be repeated when a person has a condition that may interfere with facepiece sealing such as a significant weight change (>10% or 20 pounds)

TABLE I. OSHA Standards Requiring Quantitative Fit Tests

Substance	Number[A]	Condition Requiring QNFT	Required Frequency of Fit Testing
Acrylonitrile	1910.1045(h)(3)(iii)(B)	more than 10 employees wearing negative-pressure respirators	initial and semiannual
Arsenic	1910.1018(h)(3)(iii)	more than 20 employees wearing respirators	initial and semiannual
Asbestos	1910.1001(g)(4)(iii)[B]	exposures >10×PEL[C]	initial and semiannual
Cadmium	1910.1027(g)(4)(iii),(iv)	exposures >10×PEL	initial and annual
Lead	1910.1025(f)(3)(ii)	exposures >10×PEL	initial and semiannual

[A]The same requirements are found in Construction (1926) and Shipyard Employment (1915) regulations.
[B](h)(4)(ii) in 1926.1101 and 1915.1001
[C]Permissible exposure limit

or dental changes.[54] The OSHA asbestos standards have a similar requirement for repeating the fit test immediately when the wearer has a condition that may interfere with facepiece sealing.[10]

The Australian/New Zealand standard recommends fit testing to be performed to assure the choice of a suitable respirator and to be repeated annually or whenever there is a change in the wearer's facial characteristics or other features that may affect the facial seal of the respirator.[76] The Canadian standard states fit tests shall be used to select a specific make or model of respirator to be used by each employee and repeated annually or whenever work conditions necessitate a change in the type of respirator.[77]

Test Exercises

Test exercises have been thought to be important elements of fit test protocols for detecting face seal leakage. OSHA believes a series of test exercises should be conducted, even for some newly developed QNFT techniques that do not use test exercises.[74] Five exercises were chosen at first to simulate head and facial movements by the wearer based on the assumption that they were representative of the workplace.[80] These exercises were normal breathing, deep breathing, turning the head side-to-side, moving the head up and down, and talking. Normal breathing is typically repeated as the sixth exercise. The number and type of test exercises are not consistent, however, in OSHA substance specific standards. OSHA has added other exercises to its QNFT protocols.[68] The benzene, cadmium, formaldehyde, and lead in construction standards require eight exercises in the QNFT protocol. These standards require the addition of a grimace exercise and either jogging in place or bending over to touch the toes. The asbestos and methylenedianiline standards' QNFT protocols require nine exercises: grimace, jogging in place, and bending over to touch the toes in addition to the six basic exercises. This inconsistency not only makes it difficult to run respirator programs, but no data were entered during the standard-setting process to indicate that the change was necessary or that an increase in protection would be provided. The grimace exercise is a facial expression that is difficult to duplicate between test subjects. Facial expressions were recommended not to be used as a standard exercise.[80] Normal breathing was repeated at the end of the fit test to see if the respirator would reseal after the seal had been broken during the facial expression exercise. OSHA protocols require all exercises except grimace to be conducted for 1 minute.[68] The grimace exercise is to be conducted for 15 seconds.

While the Australian/New Zealand standard does not specifically identify exercises for QNFT, it does list normal breathing, deep breathing, side-to-side and up-and-down head movements, talking, and other exercises depending on the situation, to be performed for 30 seconds under the QLFT protocol.[76] The Canadian standard lists the five different basic exercises to be used for QNFT of respirators equipped with a facepiece.[77]

Minimum Fit Factors Required

While QNFTs provide an objective indicator of fit, deciding what value indicates acceptable fit is more challenging. ANSI Z88.2 requires a minimum fit factor of 10 times the assigned protection factor (APF) for negative-pressure respirators.[64] The APF is defined as the minimum expected workplace level of protection provided by a properly functioning class of respirators, to a stated percentage of properly fitted and trained users.[12] The APF is used to select respirators. A respirator with an APF of 10 may be used in concentrations up to 10 times the occupational exposure limit.[64] ANSI used WPF studies to establish its APFs.[81] Since fit testing using a minimum fit factor of 10 times the expected APF was used in the WPF studies evaluated by ANSI, this practice was adopted as the criterion for fit testing.[82] ANSI felt that the same criterion used to establish its APFs should be used in programs utilizing its APFs. Results of workplace testing have shown that quantitative fit testing, using this pass/fail level, selected respirators that provided an appropriate level of protection to workers as long as they wore the respirators.[75,83,84] Since no correlation has been established between fit factor and WPF, the fit factor used to indicate the minimum acceptable fit in standards has been somewhat arbitrarily chosen.

The OSHA substance specific standards are also inconsistent regarding the minimum fit factor needed for a successful QNFT. OSHA has established minimum fit factors in six substance specific standards: asbestos, benzene, cadmium, formaldehyde, lead in construction, and methylenedianiline. Table II summarizes currently required minimum fit factor levels. Generally, the minimum fit factor is 10 times the APF. However, the asbestos and methylenedianiline standards established different pass/fail levels.[10,85] In all of these standards OSHA requires three separate QNFTs to be performed. The lowest fit factor must pass the required minimum fit factor. It is important to note that using identical pass/fail levels for the QNFT methods described earlier could result in an acceptable fit with one QNFT technique and an unacceptable fit with another QNFT technique for the same respirator-person combination. Correction factors are currently not used to relate one technique to another.

TABLE II. Standards or Regulations with Minimum Required Fit Factors

Standard	Negative-Pressure Half	Facepiece Type Full
ANSI Z88.2-1992	100	1000
29 CFR 1910.134 (existing)	—[A]	—
29 CFR 1910.134 (proposed)[B,C]	100	500
Asbestos (29 CFR 1910.1001)[B,C]	100	1000
Benzene (29 CFR 1910.1028)	100	500
Cadmium (29 CFR 1910.1027)[B]	100	500
Formaldehyde (29 CFR 1910.1048)	100	500
Methylenedianiline (29 CFR 1910.1050)[B]	250	1250
Lead in construction (29 CFR 1926.62)	100	500
AS/NZS 1715:1994	—	—
CSA Z94.4-93	>10	<100

[A]Not established in the standard or regulation
[B]The same requirement is found in the construction version of the regulation (29 CFR 1926).
[C]The same requirement is found in the shipyard employment version of the regulation (29 CFR 1915).

Other standards are not as specific in identifying the minimum fit factor. The Australian/New Zealand standard does not establish a minimum fit factor.[76] The Canadian standard defines a successful QNFT when the fit factor measured is equal to or exceeds the corresponding APF identified in their standard.[77] There is limited guidance for the minimum fit factor for positive-pressure respirators. ANSI states that for positive-pressure, tight-fitting respirators, a fit factor of at least 100 must be obtained when tested in the negative-pressure mode.[64]

CONCLUSIONS

The first commercially available and OSHA-approved QNFT technique, utilizing an aerosol generator and either a photometric

aerosol monitor or a flame photometer, provided a great service to the occupational hygiene community in that it gave numerical values for the selection of an acceptable fitting respirator. As the need for fit testing respirators increased, the CNC was developed and became widely accepted because it does not require an aerosol generator. The instrument is small and costs less than the entire photometric test system. It is also accepted by OSHA. A problem common to all aerosol methods, however, is the lack of aerosol mixing in the respirator interior and the subject-dependent removal of aerosol particles by the human lung, which results in the sampling of a reduced aerosol concentration from the respirator interior during the exhalation cycle. Realizing that the aerosol particles that leak into the respirator interior penetrate there with the airflow through the face seal leak(s), one may ask: "Why not measure the airflow through the face seal leak(s) as the relevant parameter indicating goodness of fit?" The CNP system is such a leak flow measurement system and is accepted by OSHA. It has been extensively evaluated and is gaining in popularity. While the leak flow test gives precise and repeatable data on the face seal leakage in whatever position the head is held in, it does not integrate the leakage during movements of the head and breath holding is required during the test.

From the review of the standards it appears that generally the minimum fit factor for pass/fail criterion of negative-pressure respirators is 10 times the respirator APF, at least a six-exercise protocol should be followed, and the fit test should be repeated at least annually.

The authors do not conclude by indicating a preference of one system over another, but wish to emphasize that further QNFT developments are desirable, and that new regulations should preferably be written so that they can accommodate technological improvements. The present regulations are for the purpose of selecting an acceptably fitting respirator. With the existing technologies, the head positions in which facial distortions seriously affect the face seal can also be determined. New emerging technologies may be able to measure the fit of a respirator before and after entering a hazardous air environment.

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