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Date: October 15, 2020

Dear Valued Customer,

Attached is a document titled "Key Considerations Regarding Respiratory Protection Assigned Protection Factors (APF)". 3M has created this document to provide information relating to APF creation and to assist our customers in their determination of appropriate respiratory protection products for use in countries without specific APFs.

This paper reviews: APF definitions, history of APF in Europe and the United States, definitions of protection factor studies, the basis used for setting APF, and the differences in APF numerical values between geographies. This paper is focused on occupational respirator use in production or laboratory environments and does not address emergency response situations. Following a review of the above topics, the paper provides a suggested approach for considering APFs for air-purifying respirators and atmosphere supplying respirators for occupational use in those countries or regions without specific APF regulations.

This document is current as of October 2020. Subsequent changes to applicable legal requirements, regulations, standards, policies, or new science may result in the need to revisit this document.

In the US, please contact the 3M Personal Safety Division Technical Help Line at 1 (800) 243-4630 for additional questions about our respiratory protection products. In Canada, contact 3M Technical Service at 1 (800) 267-4414.

Sincerely,

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Key Considerations Regarding Respiratory Protection Assigned Protection Factors (APF)

Prepared by the 3M Personal Safety Division, October 2019[1]

Many groups have sought to define Assigned Protection Factors (APF) for specific Respiratory Protection Equipment (RPE). [1-4] Using various RPE performance data and use/application philosophies, regulatory and standards setting organizations have established numerical values they believe meet the intent of their respective definitions. While the definitions are similar, the data used, and its analysis can result in APF values that vary greatly between countries and regions for the same or very similar RPE. Not only can this be confusing for the respirator user, it can make it challenging for occupational health and safety (OHS) professionals in multinational organizations to select appropriate respiratory protection and administer programs consistently across different regions or countries. This paper will review: APF definitions, history of APF in Europe and the United States, definitions of protection factor studies, the basis used for setting APF, and the differences in APF numerical values between geographies. This paper is focused on occupational respirator use in production or laboratory environments and does not address emergency response situations. Following a review of the above topics, this paper provides a suggested approach for considering APFs for air-purifying respirators and atmosphere supplying respirators for occupational use in those countries or regions without specific APF regulations.

Definitions of APF

US Occupational Safety and Health Administration (OSHA) definition: "Assigned Protection Factor (APF) means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section" [meaning 29 CFR 1910.134]. [1]

American Industrial Hygiene Association (AIHA) Respiratory Protection Committee (RPC) definition: "The expected workplace level of respiratory protection that would be provided by a properly functioning and used respirator or class of respirators to properly fitted and trained wearers when all elements of an effective respirator program are established and are being implemented". [2]
The American National Standards Institute (ANSI) definition is similar to the AIHA definition but adds that the respirator is "properly used." [3]

EN 529:2005 (European definition): "Level of respiratory protection that can realistically be expected to be achieved in the workplace by 95 % of adequately trained and supervised wearers using a properly functioning and correctly fitted respiratory protective device and is based on the 5th percentile of the Workplace Protection Factor (WPF) data". [4]

[1] The information in this document is intended for people with knowledge and technical skills sufficient to assess and apply their own informed judgment to the information. No license under any 3M or third-party intellectual property rights is granted or implied with this information.

History of APF in the United States and Europe

United States

In 1976, E. C. Hyatt, published results of laboratory tests on human subjects wearing different classes of RPE. [5] Hyatt called these values protection factors (PF). His resulting PF recommendations were based on quantitative fit factors (QNFF) determined by a quantitative fit test (QNFT). [5]

In 1980, the American National Standards Institute (ANSI) established a table of protection factors for various respirator classes and published them in ANSI Z88.2-1980. [6] Many of the ANSI protection factors were based on Hyatt's work. [5] Following the publication of the ANSI standard, various RPE workplace studies demonstrated that the ratio of outside to inside concentrations (C_o/C_i) measured in connection with workplace RPE use could be significantly different than the ANSI published PFs. [7-12] However, these studies were not consistent in their method of determining C_o/C_i and were performed using a variety of test conditions, including:

- quantitative fit testing (QNFT);
- laboratory tests using different test subject exercises than those used in QNFT;
- testing in actual workplaces with good respiratory protection practices; and
- testing in actual workplaces with poor respiratory protection practices such as wearing RPE over facial hair, no fit testing, poor respirator maintenance, and removing the respirator to talk while in the contaminated area.

Subsequently, there was a push to develop protection factor terminology that more effectively described the test conditions. Many of these terms will be discussed below. During this time, the United States National Institute for Occupational Safety and Health (NIOSH) performed workplace protection factor (WPF) studies on powered air purifying respirators (PAPR). [13] Based on this work, NIOSH established protection factors for the PAPRs tested and by analogy to other forms of RPE. NIOSH's work sparked an increase in WPF studies in the US. Ultimately, the data collected through these workplace studies identified the need for adjusting the NIOSH protection factors. In the ensuing years, WPF studies were conducted on various types of respirators by NIOSH, academia, industry, respirator manufacturers, and OSHA. The largest review of the WPF study data was published by OSHA in 2003. [14] In 2006, OSHA issued a Final Rule establishing APF for the United States based on this data.

Europe

The development of APF in Europe has been based on different approaches by individual country health and safety regulators and standards institutes. As part of the European CE certification process, RPE are tested to relevant EN standards. This testing includes a laboratory Inward Leakage (IL) or Total Inward Leakage (TIL) test – depending on the relevant EN standard. The IL and TIL test are performed on a panel of test subjects (usually n=10) wearing the RPE. The RPE must meet the prescribed maximum leakage limits listed in the applicable standards (ILmax or TILmax) for its respective type and class. The IL test measures face seal leakage and exhalation valve leakage. The TIL test measures filter penetration, face seal leakage, and exhalation valve leakage. For negative pressure tight fitting full facepieces (EN 136) and tight fitting half facepieces (EN 140) only IL is measured. [15,16]; for loose fitting and tight fitting powered air-purifying respirators, TIL is measured [49,50].

The inverse of the TILmax is the nominal protection factor (NPF). To obtain TILmax when only IL has been measured, the maximum allowable filter penetration (PENmax) is added to maximum allowable penetration inward leakage (ILmax). For example, a full facepiece without filter TILmax is 0.05%. The PENmax for a P3 filter is 0.05%. When added to the value obtained from the full facepiece the total is 0.10%. Taking the inverse of 0.10% results in an NPF of 1000. Nominal protection factors were established by the relevant European Standard's Committee for each RPE class as listed in Table 1. The values for the NPF are based on laboratory testing using an aerosol with a particle size range of 0.02µm to 2µm, with a mass median diameter (MMD) of 0.6 µm. This test aerosol includes particles in the size range that, according to filtration theory, are the most penetrating to filter media. [18] Therefore, the NPF is highly dependent on filter penetration and the NPF for RPE with P1 and P2 filters are lower than the actual protection that would be expected in the workplace where particle sizes are generally much larger. This is supported by filter theory. [18] On the other hand, for highly efficient filters, such as a P3, the NPF may be a closer representation of a quantitative fit factor[2].

Historically the NPF has been used to indicate the RPE potential effectiveness in the workplace and NPF were published in BS 4275. [17] However, as mentioned above, various organizations, recognizing the limitations of NPF, began developing and publishing APF.

Protection Factor Studies – Definitions

Workplace protection factor (WPF)

EN 529:2005 definition: The WPF is a measure of the protection provided in the workplace, under the conditions of that workplace, by a properly selected, fit tested and functioning respirator while it is correctly worn and used.

AIHA RPC definition: "A measure of the protection provided in the workplace, under the conditions of that workplace, by a properly selected, fit tested [for a tight-fitting respirator, otherwise properly fitted], and functioning respirator while it is correctly worn and used". [2]

A WPF study consists of collecting and measuring the workplace contaminant concentration both outside the respirator (C_o) and inside the respirator (C_i) simultaneously while the respirator is properly worn during normal or typical work activities. This means the WPF is a direct measurement of respirator performance in a specific work environment. To be considered a WPF, the conditions of the test require that there has been proper training, proper selection, the respirator is in good operating condition, including proper airflow for PAPRs and that the user has passed a fit test following a validated fit test protocol, has performed user seal checks after each donning, and there are no conditions that may interfere with the respirator fit such as facial hair.

Simulated workplace protection factor (SWPF)

The AIHA RPC defines the SWPF as "A measure of respirator performance that is conducted in a laboratory using test exercises designed to simulate work. The respirator must be properly selected, fit tested, worn, and used." [2] Reviewing this definition reveals that the SWPF should essentially be a WPF study conducted in the laboratory. How closely the results represent workplace performance depends

[2] The AIHA RPC defines a fit factor as "A numeric expression of how well a tight-fitting respirator fits a wearer during a fit test." [2]

on how well the investigators simulate the workplace conditions during the test. This includes simulating variables such as:

- work tasks/movements;
- work duration;
- work rate;
- workplace temperature and relative humidity;
- contaminant – particle size and particle size distribution; and
- measurement method – mass vs. count determination.

There are several reasons to conduct SWPF studies and consider them in setting RPE APFs. Many workplaces are difficult to conduct WPF studies in due to factors such as highly hazardous materials, confidentiality considerations, physical space, low ambient concentrations of aerosols, gas/vapors, and willingness of employers to participate. Additionally, laboratory settings may accommodate more challenging conditions to be created with regard to high concentrations (C_o), particle size(s), and variety of worker movements. Also, workplace aerosols are typically not monodispersed and often many times larger than the most penetrating particle size that can be used in SWPF studies. Further, one challenge in WPF studies is that many C_i sample results are "non-detected" due to a combination of the ambient concentration and the RPE's protectiveness; SWPF studies can more closely control the particle concentration to address this situation.

Effective protection factor (EPF)

The AIHA RPC defines effective protection factors as "A measure of the protection provided by a properly selected, fit tested and functioning respirator when it is worn for only some fraction of the total exposure period in the workplace." [2]

EPF is the ratio of the contaminant concentration in the environment (i.e., outside the respirator) to the contaminant concentration inhaled. It is determined by sampling outside the respirator and in the breathing zone during the total exposure period, regardless of whether the respirator is being worn. EPF is therefore strongly influenced by non-wear time. While the respirator is worn, breathing zone sampling is done from within the respirator.

AIHA RPC states that EPF may also be estimated by correcting appropriately measured workplace protection factors (WPF) for the time that the respirator is not worn during the exposure period. This implies that the EPF study is essentially a WPF study except that it includes the amount of material inhaled while the respirator is not worn. The EPF reflects the culture of occupational health and safety at a worksite and the motivation and enforcement of wearing RPE during all times of exposure. When the respirator is worn during all times (100%) of exposure, the EPF is equivalent to the WPF (Figure 1). Removal of the respirators in the workplace has a negative impact on the worker's protection as shown by the EPF compared to the WPF in figure 1.

Program protection factor (PPF)

AIHA RPC defines PPF as "An estimate of the respiratory protection provided to a worker in the context of a specific respirator program." [2] PPF represents the contaminant concentration which the wearer would inhale if the respirator were not worn (C_o) divided by the contaminant concentration inside the respirator as the respirator is used in the context of the existing respirator program (C_i). The PPF is a measure of the effectiveness of the site's respirator program and basically an "as is" workplace study. Factors which may affect the program protection factor are: the activity of the wearer in that setting, the motivation of the

wearer, the fit of the respirator, respirator selection, the respirator design, training, maintenance, storage, supervision, program administration and monitoring, and any other variable, such as communication needs, or user discomfort, that affects program effectiveness. [2] If any of these program elements are deficient, the program protection factor will be reduced.

SWPF and WPF as the Basis for Setting APF

As discussed before, the APF seeks to represent the level of respiratory protection expected when the respirator is properly selected, fit tested, and functioning while it is correctly worn and used. In other words, when the respirator is being used in a continuing, effective respiratory protection program. Comparing the terms used to define the conditions under which the (S)WPF is measured to those stated in the APF definition, it is easy to understand why the (S)WPF has significant advantages when selected as the basis for setting the APF. Conducting Program Protection Factor studies to establish APF could result in generating a low APF due to the workplace having a less robust respiratory protection program, which may penalize workplaces with high performing safety and health professionals and a strong safety culture.

The most comprehensive, rigorous, and recent evaluation of (S)WPF studies was conducted by US OSHA – the resulting APF are listed in Table 2. How these APF values were reached by OSHA is summarized below. More details can be obtained from the OSHA proposed rule and final rule references. [14,33] The majority of the WPF and SWPF studies evaluated by OSHA were conducted by four organizations: NIOSH, DuPont, University of West Virginia, and 3M. All the studies used very similar, if not identical, protocols based on the recommendations of the American Industrial Hygiene Association (AIHA) Respiratory Protection Committee WPF Test Protocol Subcommittee. [23] All respirators in the studies were NIOSH approved.

Key points on WPF experimental design

Both Europe and the US have used WPF data as a basis to establish APF. However, many of the WPF studies differed because of different RPE practices such as performing fit testing, degree of facial hair allowed, and experimental design philosophy.

Field Blanks. One big difference in WPF experimental protocol is the use of field blanks or working blanks. A field blank is a blank sample cassette (a cassette is a housing that contains a filter on which the contaminant is collected) in which no air is drawn through but is handled by the investigator in the same way as the actual sample cassettes. They are open and closed by the investigators and then clipped to the worker's lapel and worn into the work environment. The cassette is then opened and closed at the end of the sampling period after it is removed from the lapel. If any contamination on the outside surfaces of the cassette is picked up by the investigator's hands from the cassette walls and subsequently transferred to the inside of the cassette, the field blanks include this contamination. [23] This quantity of contaminant should not be included in the WPF measurement, however, because it does not result from respirator performance. Several WPF studies with low RPE performance results have not included field blanks in the protocol. [24-26] While this quantity of contaminant is not expected to be large it can be significant for high performing respirators (e.g., APF > 100) where small amounts of contamination have very significant effects on the measured WPF. As an example, a study performed by Myers, *et al*., had to subtract the field blank value for zinc from WPF samples to account for contamination from handling. [27]

Sampling probes. Sampling probes used in WPF studies should be designed to capture large particles and are different than the probes used for quantitative fit testing. [28] Studies have shown large workplace particles with physical diameters greater than 10 µm can penetrate to the inside of a respirator. [29-31] Nevertheless, some WPF studies have used probes designed for small particle testing as in a quantitative fit test. Probe placement is also important. Early studies sometimes used probes that were flush with the wall of the facepiece. In the late 1980s probes projected into the facepiece by a centimeter. [23] In the early 1990s deep probes were used to get as close to the mouth and nose as possible to help reduce sampling bias without touching the wearer. [27] Deep probes are recommended for WPF/SWPF studies today. [61]

Fit testing. Some European WPF studies of tight-fitting RPE did not require fit testing. [24,26,32] Other WPF studies of tight-fitting respirators have not required the workers to have shaved their facial hair within the last 24 hours prior to the WPF study. [24] These "as is" results may explain why some APF in Europe are lower than US OSHA APF for identical respirators.

WPF data analysis. Differences in evaluation methods of WPF studies by different agencies or organizations can also result in different conclusions. BS4275 Annex D provides an explanation for the UK derivation of APF (including a discussion on in-mask sampling bias), but unfortunately, no publicly available, comprehensive explanation of how the other various European APF were established exists. [17]

Differences in Current Assigned Protection Factors (APF)

Background

How an APF is determined depends in part on its definition. US OSHA states: "assigned protection factor means the workplace level of respiratory protection that a respirator or class of respirator is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section [29 CFR 1910.134]".[1] AIHA RPC stresses that APF are the level of respiratory protection provided by a "properly functioning respirator" to "properly fitted and trained wearers." "Properly fitted" meaning that the wearer has been fit tested for the tight-fitting respirator with one of the OSHA validated fit testing protocols. The AIHA RPC points out that the APF considers all potential sources of facepiece penetration (e.g., face seal leakage, filter penetration, valve leakage).[2] It does not, however, account for user-related factors that degrade protection such as poor maintenance, failure to follow manufacturer's instructions, and failure to wear the respirator during the entire exposure period. A notable difference is that the EN definition states that the APF is based on WPF data. The other APF definitions do not indicate the type of data to be used and none of these definitions describe ***how*** the APF is to be determined. They do, however, describe the function of an APF and the conditions of use for the APF to be applicable. These include "a continuing effective respiratory protection program," "properly functioning respirator," "properly used respirator," "properly fitted respirators" and so on. This implies these conditions for how the respirator is to be used must be considered when the WPF data are gathered and interpretation and implementation of these "conditions" is in part responsible for the differences in the numbers.

In EN 529:2005 "correctly fitted" is not clearly defined. "Correctly fitting" could mean that the individual has undergone a "fit test" that meets the ANSI criteria for fit testing, that they have performed a seal check (e.g., wearer seal check, user seal check, fit check), or that they have received professional guidance on selecting a respirator that is best suited to their face. Understanding if someone has

undergone any of these protocols is important to understanding the results of a WPF study. Poor fitting RPE will significantly affect the outcome of a workplace, simulated, or program protection factor study. Some studies considered in the derivation of APF in Europe were conducted at a time, and in countries, where fit testing was not mandated nor regularly conducted as part of a respiratory protection program. Protection factors measured in a workplace that does not fit test or train workers are likely to be lower than one incorporating fit testing and that trains the RPE wearer in correct donning.

An additional important point related to setting and understanding APF is the type of data and the method used to establish the APF. EN 529:2005 defines the APF as the 5th percentile of workplace protection factor data. This implies data from workplace protection factor studies will be used. The US OSHA definition states the APF is the "workplace" level of protection and by the conditions of use implies the data would be derived from a workplace protection factor study. However, in the absence of WPF data, OSHA established the current APF by expert consensus using SWPF studies or other information.

Although EN 529:2005 provides a definition for the Assigned Protection Factor, each EU member state is free to choose whether to adopt this system and can determine the basis for and studies included in their assessment. Consequently, APF vary by country for the same type and class of respirator. Some countries may only reference NPF. Others may use a mix of NPF (laboratory based) and APF (workplace based). (See Table 1).

To illustrate this point, it may be helpful to explain some of the key differences between the UK APF and the US APF.

To summarize:

- Many of the UK BSI/HSE APF were based on data from "As Is" studies that included both "compliant" and "non-compliant" RPE programs. As a result:
    - Not all studies included fit tested wearers as fit testing was not a requirement at the time many of the studies were conducted;
    - No additional training or supervision was provided by the investigators; and
    - Essentially the "As Is" studies were very similar to program protection factor studies, which can result in the employer not being able to utilize the full performance of the RPE.

- Many of the US OSHA APF were based on data from studies that were conducted on "compliant'' RPE programs, for which:
    - A continuing, effective respiratory protection program was in place including training, fit testing, and a clean-shaven worker wearing a properly maintained respirator;
    - The employer followed best practices or legal standards; and
    - The employer was allowed to utilize the full performance of the RPE based on the ability of competent safety and health personnel to run and enforce respiratory protection programs.

It is also worth noting that in both the above cases WPF and SWPF studies were included plus analogy across RPE types where there was a lack of data.

NOTE: The US requires the use of respiratory fit test protocols allowed by OSHA. [1] These protocols have been validated to a reference quantitative fit test (QNFT) method. This reference method has been called the photometric aerosol measurement method, which historically used either forward light scattering photometry or flame photometry. [19] In 1998 OSHA named this refence method the Generated Aerosol Quantitative Fit Testing Protocol. [20] The qualitative fit test protocols were validated against this refence method as well. The saccharin, Bitrex™, and isoamyl acetate protocols have been published in ISO 16975, Part 3. [21]

The US OSHA APF

The following is a summary of the data relied upon and the decision reached by US OSHA in establishing its APF. OSHA developed the APF using a multi-faceted approach described earlier. [14, 33] The Agency reviewed the various analyses of respirator authorities, available WPF and SWPF studies, and other APF literature.

Air-Purifying Respirators

Quarter facepieces – APF 5 - OSHA initially proposed an APF of 10 for quarter mask air-purifying respirators (i.e., quarter masks/quarter mask respirators), including them in the same category as filtering facepieces and half mask air-purifying respirators. No WPF or SWPF studies conducted on quarter mask respirators were submitted to the rulemaking record. The Hyatt Study referenced above, which consisted of testing quarter masks using a fit testing protocol, provided the only data available for quarter mask respirators, and it supported an APF of 5. [5] Therefore, OSHA decided to separate quarter mask respirators into their own category and assign them an APF of 5.

Note: 3M does not manufacture quarter mask respirators.

Half facepieces – APF 10 - OSHA proposed an APF of 10 for both elastomeric and filtering facepiece half mask respirators. According to OSHA, two divergent views existed on this proposed APF. The healthcare industry, NIOSH, and other commenters agreed to an APF of 10 for both types of respirators, while some commenters stated that filtering facepieces should be assigned a protection factor of 5.

OSHA's data analyses supported an APF of 10 for these half mask respirators. The database contained 917 data points from 16 WPF studies for half mask respirators conducted in a variety of American workplaces. Four additional WPF studies of half masks were submitted during the public comment period following publication of the notice of proposed rulemaking. OSHA's expert added these data points to the half mask database and reanalyzed the resulting 1,339 data points for half mask respirators.

OSHA also had a second quantitative analysis performed in which the 1,339 accepted data points (from the original NPRM [Notice of Proposed Rule Making]) database that was updated with data from the four additional studies) for half mask respirators were combined with 403 data points from 12 studies that OSHA originally excluded from the analysis. This second analysis corroborated the original findings according to OSHA. The results of both analyses provide significant support for OSHA's conclusions regarding the selection of 10 as the appropriate APF for half mask respirators.

Finally, OSHA conducted a meta-analysis of the data collected from these numerous studies and concluded that the best available data support an APF of 10 for half mask elastomeric and filtering facepieces. OSHA stated the full data set indicates:

a) The precise APF for filtering facepieces is 18.1, with a 90% confidence interval between 15 and 22;
b) The precise APF for elastomeric half mask facepieces is 12.0, with a 90% confidence interval between 7 and 14; and
c) That a greater percentage of elastomeric half mask facepieces failed to achieve an APF of 10 (4.5%) than filtering facepieces (1.6%). In both cases, fewer than 5% of the respirators failed to achieve an APF of 10, which is the maximum failure rate historically allowed by both OSHA and other standards-setting bodies.

The results demonstrate that no statistical justification exists for assigning an APF of less than 10 to either of these two types of half facepiece respirators. Additionally, OSHA stated that an APF of 10 determined by this rulemaking is an underestimation of the true protection provided by both types of respirators and provides employees who use these respirators with an extra margin of protection against airborne contaminants.

Full facepieces – APF 50 **-** In the proposed rule, OSHA discussed a WPF study conducted in a lead smelter. The respirator used in this study was a full facepiece air-purifying respirator equipped with HEPA [high efficiency particulate air] filters. OSHA stated the authors found a 5th percentile protection factor of 95 for the sample and concluded that the results supported a protection factor of 50. In addition, a Los Alamos National Laboratory SWPF study by Skaggs, Loibell, Carter, and Hyatt measured the protection afforded by another full facepiece air-purifying respirator with HEPA filters. [59] OSHA stated the authors reported fit factors with geometric means ranging from 1,000 to 5,300. However, 23 of the 60 measurements reported were less than 1,000, seven were less than 100, and three were less than 50. Based on a careful review of these studies, OSHA proposed and settled on an APF of 50 for full facepiece air-purifying respirators.

Since the rulemaking, 3M has conducted a WPF study on a full facepiece air-purifying respirator with P100 filters. [34] The study, conducted in a lead smelter, reported the inside concentrations as “below the detection limit” on all samples except for one. The WPF sample for the one value was 297. For the other samples the detection limit was used as the inside concentration and then the investigators used a rank and percentile function to establish a 5^{th} percentile of 900. [34]

Filters. OSHA assigned the same protection factor to all half (10) and all full (50) facepiece air-purifying respirators regardless of the filter being used. In the discussion of the final rule, OSHA stated: “Any effect of filter penetration on respiratory protection is best addressed during respirator selection, which is also the case for half facepiece respirators... ”[33] OSHA believes that if proper respirator selection, as required by the respiratory protection rule (29 CFR 1910.134), is made the filter penetration will not affect the respirator to achieve the APF. If gas and vapor cartridges are properly selected, they will be effective in reducing exposure to the contaminant until breakthrough. Proper use of gas and vapor cartridges requires establishing a change schedule to replace the cartridge before this occurs. In other parts of the world odor detection of the contaminant is used. If changed properly no significant exposure occurs. Particle filters vary based on filter efficiency as established during certification testing. OSHA mentions several reasons as to why it is not necessary to have a different APF for a respirator with a 95-level filter versus a 100-level filter. OSHA pointed out that:

(1) NIOSH stated that for N, R, and P 95 filters, the filters are tested at the most penetrating particle size and therefore filter efficiency in the workplace should exceed the certification filter class; and
(2) the record stated that while 5% (for a 95-level filter) is the worst case, such leakage does not actually occur in the workplace.

Compared to the aerosols used in certification testing, workplace aerosols are typically not monodispersed, made up of particles that are many times larger, and flow through the filters at a lower flow rate. Nelson evaluated WPF studies of half facepiece respirators with dust/mist (DM), dust/fume/mist (DFM), and high efficiency particulate air (HEPA) filters. Nelson concluded the performance of DM, DFM, and HEPA filters when comparing the 5th percentiles [WPF] was not significantly different and was not inconsistent with an assigned protection factor of 10. [35] In addition, OSHA cited studies performed by Janssen and Janssen *et al*., that compared the performance of N95 and P100 filters made by two manufacturers and used during grinding operations in a steel plant. Workplace performance of both filters was equivalent statistically, and the study showed that N95 filter performance was adequate under these conditions. [36,37]

Powered Air-Purifying Respirators (PAPR)

Half Facepiece PAPR – APF 50 - OSHA relied heavily on the WPF study conducted by Lenhart and Campbell, instead of the WPF study performed by Myers and Peach and the SWPF studies of Skaggs, *et al*., and da Roza, *et al*. [11, 7, 59, 60] OSHA believes that the existing WPF and SWPF studies on this class of respirators provided adequate support for its conclusion that an APF of 50 is an appropriate level to predict the protection capabilities of this class of respirators.

Full facepiece PAPR – APF 1,000 - OSHA cited a WPF study in its record by Colton and Mullins that found a corrected 5th percentile protection factor of 1,335 for these respirators. [38] OSHA received no substantive comments or other information regarding the proposed APF of 1,000 for these respirators. However, the ANSI Z88.2–1992 respirator standard and the 2004 draft revision to the ANSI standard submitted to OSHA both assigned an APF of 1,000 to this respirator class. Based on its review of these consensus standards and the existing WPF research literature, as well as the SWPF research studies, OSHA concluded that this respirator class warrants an APF of 1,000.

Loose Fitting Hood or Helmet PAPR – APF 25/1,000 - In proposing an APF of 1,000 for PAPRs with helmets or hoods, OSHA proposed the following limitation on the APF, ‘‘only helmet/hood respirators that ensure the maintenance of a positive pressure inside the facepiece during use, consistent with performance at a level of protection of 1,000 or greater, receive an APF of 1,000’’ and that ‘‘[a]ll other helmet/hood respirators are treated as loose-fitting facepiece respirators and receive an APF of 25.’’[33] OSHA proposed this condition based on available WPF and SWPF studies that found that some of these hood/helmet respirators achieved protection factors well below 1,000. (NOTE: helmet/hood PAPRs have a loose neck seal and a shroud that covers the neck and shoulders.)

One of the studies OSHA evaluated was an SWPF study conducted on several loose-fitting PAPRs and supplied-air respirators. In this study Cohen, *et al*., monitored the pressure inside the respiratory inlet coverings (hoods, helmets, loose-fitting facepieces) throughout the test. They measured several negative pressure spikes in well-performing devices (5th percentile SWPFs greater than 86,000) as well as negative pressure spikes in a device with 5th percentile SWPFs in the 13-18 range. They concluded there was no consistent pattern among the relationship of pressure measurements taken inside the respiratory inlet coverings and the corresponding SWPFs recorded. [39] (NOTE: loose-fitting PAPRs have a loose seal around the jaw-line).

After reviewing the comments on proposed limitations, OSHA concluded that:

- No single parameter (e.g., positive pressure inside the facepiece) will identify respirators that consistently perform at a high APF level;
- No agreement exists on how to determine APF for these respirators based on design characteristics alone;
- No uniform testing criteria are available to use in determining APF for these respirators; and
- Ample evidence demonstrates that WPF or SWPF studies conducted under a variety of conditions determine reliable and safe protection factors for these respirators.[33]

Therefore, OSHA revised the limitation in the final standard for APF for PAPRs (and SARs see below) with hoods/helmets to read as follows: "The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose fitting facepiece respirators and receive an APF of 25. OSHA is setting an APF of 1,000 for PAPRs with hoods and helmets when the manufacturers of these respirators conduct testing that demonstrates that the respirators provide a level of protection of at least 1,000." [14, 33]

NOTE: 3M has tested its respirators with hoods or helmets in either a WPF or SWPF study and published technical data bulletins (TDB) for NIOSH (TDB #175) and CE (TDB #251) approved respirators listing those having evidence that demonstrates performance at a level of 1,000. [40,41]

Loose-fitting facepiece PAPR – APF 25 **-** OSHA concluded that several WPF studies in the record substantiated a study performed by Myers, *et al*. [8,9] On that basis, OSHA concluded that an APF of 25 is appropriate for loose-fitting facepiece PAPRs.

Supplied-Air Respirators (SARs)

Supplied-air respirators (SAR) use compressed air either from a compressor or air cylinder(s) that is controlled by a regulator, valve, or orifice for admitting air into the respiratory inlet covering. SARs are classified by the way air is admitted to the respiratory inlet covering and the type of respiratory inlet covering. Air can be supplied in three modes: demand (negative pressure), pressure demand (positive pressure), and continuous flow. Demand mode is essentially non-existent in the US today. With regard to respiratory inlet covering, SARs fall into two: loose-fitting or tight-fitting. All pressure demand devices use tight-fitting facepieces (half or full). Continuous flow SARs can have either tight-fitting or loose-fitting respiratory inlet coverings.

Half mask SARs - APF depends on 'Mode' see below - For demand-mode half mask SARs, OSHA based its proposed APF of 10 on the analogous performance between these respirators and negative pressure half mask air purifying respirators tested in WPF and SWPF studies. Furthermore, OSHA proposed to give half mask SARs that function in continuous flow or pressure-demand modes an APF of 50, consistent with the analogous performance between these respirators and half mask PAPRs operated in a continuous flow mode during WPF and SWPF studies.

Additional support for the proposed APF came from the Z88.2–1992 ANSI respirator standard that assigned an APF of 10 to half mask airline SARs operated in the demand mode, and an APF of 50 to these respirators when operated in the continuous flow or pressure-demand modes. [42]

NOTE: 3M does not make half mask SARs that operate in the demand mode.

Full facepiece SARs - APF depends on 'Mode' see below - OSHA stated in the proposal that ''[n]o WPF or SWPF studies were available involving tight fitting full facepiece SARs operated in the demand mode. Therefore, in the absence of any such quantitative data, they assigned this respirator class an APF of 50.'' OSHA based the proposed APF on the analogous operational characteristics of these respirators and negative pressure full facepiece air-purifying respirators tested under WPF conditions in the demand mode. Also, the proposed APF was the same as the APF recommended for this respirator class by the 1987 NIOSH RDL [Respirator Decision Logic]. [13, 42]

OSHA proposed an APF of 1,000 for full facepiece SARs operated in continuous flow, pressure-demand, or "other positive-pressure" mode. It based the proposed APF on a SWPF study in which the results for these respirators showed geometric mean protection factors ranging from 8,500 to 20,000. Further justification for the proposed APF came from the similarity in operational characteristics between these respirators and tight-fitting full facepiece continuous flow PAPRs, which had a proposed APF of 1,000. The proposed APF for these respirators also was consistent with the APF of 1,000 assigned to them under the Z88.2–1992 ANSI respirator standard and was substantially lower than the APF of 2,000 recommended for these respirators by the 1987 NIOSH RDL. [13, 42] OSHA received no comments on full facepiece SARs operated in a demand, pressure-demand, or other positive pressure mode. OSHA set an APF of 50 for these respirators when operated in the demand mode, and an APF of 1,000 when the respirators function in a continuous flow, pressure-demand, or other positive pressure mode.

SARs with hoods or helmets – APF 25/1000 - Based on several WPF studies, OSHA proposed an APF of 1,000 for continuous flow SARs with hoods or helmets, contingent upon the manufacturer's demonstration that the respirator meets the criteria specified for PAPRs with hoods and helmets. OSHA assigned these respirators an APF of 1,000 in the final rule only when the employer can provide evidence from the respirator manufacturer that demonstrates the respirator performs at that level; absent such testing, these respirators must receive an APF of 25.

NOTE: See 3M TDB #175 and #251 for those SARs with evidence to support an APF of 1,000. [40,41]

Loose-fitting facepiece SARs – APF 25 - OSHA proposed an APF of 25 for this class of respirators based on analogous performance between these respirators and loose-fitting facepiece PAPRs. Additional support cited in the proposal included data from NIOSH showing that the two types of respirators (i.e., loose-fitting facepiece SARs and PAPRs) have the same minimum airflow rates when evaluated under 42 CFR part 84. The proposed APF also was consistent with the APF specified for respirators in the 1987 NIOSH RDL and the Z88.2–1992 ANSI respirator standard. [13, 42] OSHA maintained the APF of 25 for these respirators in the final rule.

Self-Contained Breathing Apparatus (SCBAs)

OSHA set APF of 10 and 50, respectively, for half mask SCBAs and full facepiece SCBAs operated in the demand mode. In the absence of any new WPF and SWPF studies on these respirators, OSHA based the final APF on analogous operational characteristics between these respirators and half mask facepiece and full facepiece air purifying respirators that have APF values of 10 and 50, respectively. In addition, the final APF are consistent with the APF recommended by the 1987 NIOSH RDL for these respirators. [13]

For tight-fitting full facepiece SCBAs used in the pressure-demand or other positive pressure modes, OSHA set an APF of 10,000 in the final standard, which is consistent with the 1987 NIOSH RDL and the 1992 ANSI respirator standard. [33, 13, 42] Empirical data supporting the final APF comes from the WPF study conducted by Campbell, Noonan, Merinar, and Stobbe. [43] This study showed that protection factors for these respirators, when operating at NFPA-compliant air flows, far exceed 10,000. While four respirator wearers experienced momentary negative pressure spikes inside their facepieces, which indicates possible leakage into the facepiece under some workplace conditions, these spikes did not impair overall respirator performance. OSHA concluded that these study results justify an unrestricted APF of 10,000 for tight-fitting full facepiece SCBAs operating under positive pressure demand.

The OSHA standard also addressed SCBAs with tight fitting hoods and helmets, a relatively new respirator classification. For the class of respirators designated as pressure-demand SCBAs with tight fitting hoods or helmets, such as the Survivair Puma, OSHA set an APF of 10,000. The basis for this final APF is the analogous operational characteristics between these respirators and tight-fitting full facepiece pressure-demand SCBAs.

For a listing of the complete set of respirator performance studies evaluated by OSHA, consult both the proposed and final OSHA APF rule. [14,33] Table 2 lists the APF promulgated by OSHA.

EN 529:2005 Protection Factors

EN 529:2005 is a European standard that provides guidance on the best practice for establishing and implementing a suitable respiratory protective device program. It is published to provide a Europe-wide baseline for the selection, use, care, and maintenance of respiratory protective devices. [4] One goal is to aid compliance with national legislation where it exists or with European legislation. It lists NPF and examples of APF used in select European countries (See Table 1).

As reviewed earlier, NPF are laboratory derived values for a given type and class of respirator. They are written into the performance standards for respirators approved in Europe. They set forth the maximum allowable leakage into the respirator during the certification testing. They are set for a type and class of respirator and are not a measure of performance for a specific model. For example, during the certification test for PAPRs with a TH3 classification, the maximum total inward leakage allowed is 0.2%. The inverse of the maximum allowable TIL % gives you the NPF. Therefore, the NPF for a TH3 PAPR is 500 (100/0.2). If the TIL is less than 0.2%, then the system is assigned an NPF of 500. The NPF does not indicate the performance in the workplace.

According to the European definition of assigned protection factor, APF are based on the 5^{th} percentile WPF. Members of the European Union are free to choose whether to adopt this system or use an alternative. As demonstrated in Table 1, different EU countries have set different APF for the same respirator type. For a thorough understanding of how country APF were set it is recommended that the relevant regulatory organization be consulted.

It is further recommended that employers in countries where APF have been set as a part of national regulation use those APF. Additionally, employers may choose to set internal APF that are lower than the regulated ones for standardization purposes across their locations, or if they do not feel that their respiratory protection program is robust. Below is a summary of the European NPF and APF by respirator type.

Air-Purifying Respirators

Half facepieces (including filtering facepieces). The half facepiece NPF vary based on the filter or cartridge used with the respirator and range from 4 to 50. The different NPF are due primarily to filter penetration in the laboratory test to achieve the CE mark. Important considerations with the use of laboratory aerosol from "certification tests" have already been discussed above. P1 and FFP1 filters are allowed to have up to 20% penetration in the laboratory test. The maximum penetration (ILmax) for a half facepiece respirator is 2% resulting in an NPF of 4 (1/.20 +.02) for a half facepiece with P1 filter. When a P1 or FFP1 filter is properly selected for the workplace aerosol it is reasonable to expect filter efficiency greater than or equal to 95%. [37] If fit tested using an US ANSI validated (or equivalent approved method) fit test method, one would expect less than 1% face seal leakage (equivalent to a fit factor of 100). This would provide a protection factor of greater than 16. Half facepiece respirators with a P3 filters have an NPF of 50. The P3 filter is extremely efficient against the laboratory test aerosol and therefore the majority of the NPF of 50 relates to the allowed face seal leakage (2%). As mentioned earlier, the ratio of outside concentration to inside concentration measured in the workplace could be significantly different than the PF determined using quantitative fit testing. [3-7] In the case of half facepiece respirators with P3 filters one would expect the NPF to be much higher than the resulting WPF and corresponding APF. APF set for half-facepiece respirators in Europe range from 4 for a respirator equipped with a P1 filter to 20-30 for a respirator with a P3 filter.

Full facepieces. The NPF for full facepiece respirators are also set based upon filter type and range from 5 for a P1 filter to 2000 with a GasX cartridge (which assumes 'zero' penetration). The NPF for full facepiece respirators with P1 and P2 filters are like those set for half facepiece respirators with equivalent filters. However, due to the assumed reduced face seal leakage allowed by a full facepiece, the NPF are set significantly higher for P3 filters and GasX cartridges than those for the half facepieces. NPF for a full facepiece with P1 filters is similar to the NPF for a half facepiece with P1 filter. This is due to filter penetration as described above in the half facepiece section. No published WPF study on full facepiece respirators has found a 5^{th} percentile WPF greater than 1,000, which is the NPF given to the full facepiece with a P3 filter. [24, 34, 58] Review of Table 1 indicates that if a gas and vapor cartridge is used, the NPF is even greater. Research has demonstrated that WPF testing of half facepiece respirators with gas and vapor cartridges do not yield significantly different results than those with particle filters. [44] The APF set by certain European countries for full facepiece respirators range from 4 (with P1 filters) to 500 (with a P3 or GasX cartridge). These countries have set APF for both half and full facepieces with P1 and P2 filters similarly and APF for full facepieces with P3 filters higher than those for half facepieces.

Powered Air-Purifying Respirators (Power assisted devices) PAPRs approved to European standards differ from US certified PAPRs in one key aspect – operating flow. In the US, the minimal operating flow is set by the standard. In Europe, the manufacturer sets the flow for each device. This makes it challenging to compare the results of WPF and SWPF studies without knowledge of the flow rates of the devices. This also makes it challenging to compare NPF and APF between the European and US certification schemes.

Tight-fitting facepiece PAPRs. EN 529 combines half facepiece and full facepiece PAPRs together with the filter type being the determining factor of the NPF or APF. In the US, PAPRs are only available with gas and vapor cartridges or HEPA (similar to P3) filters or a combination of the two, and half and full facepieces are considered separately. Only one US WPF study has been performed on a PAPR with lower efficiency filters. (Regulatory changes eliminated these PAPR filters in the US in 1998.) Therefore, it is difficult to compare European NPF or APF to US data. NPF for PAPRs with tight fitting facepieces range

from 20 for a class TM1 PAPR to 2,000 for a class TM3 PAPR. APF set by European countries align on a 10 for a PAPR with a TM1 facepiece. Four European countries (Finland, Germany, Italy, Sweden) set the APF for class TM2 PAPRs at 100, while the UK has set this value at 20. The APF for PAPRs with TM3 facepieces vary among countries ranging from 40 to 1,000.

PAPRs with Loose-fitting helmets and hoods. NPF for PAPRs with hoods or helmets are 10 for class TH1, 50 for a class TH2, and 500 for a class TH3. These are lower than the NPF for PAPRs with tightfitting facepieces. As with the APF for PAPRs with tight fitting facepieces, there is much variation in the European APF and lack of similarity with the US APF. In addition to the differences mentioned earlier regarding airflow requirements in certification, this category of helmets and hoods also includes a wide variety of designs. The design of the hood or helmet has been shown (in US research) to be an important factor affecting PAPR performance. In fact, because of the variety in styles, the US APF separate out the helmet and hood category into hoods/helmets and loose-fitting facepieces. In the US, these loose-fitting facepiece devices are required to have the same minimum airflow to gain certification as PAPRs with hoods and helmets. When US WPF studies indicated performance much lower than what had been expected of a PAPR based on laboratory tests, NIOSH lowered the APF of all loose-fitting devices to 25. NIOSH reasoned that airflow was the single most important parameter affecting performance, however subsequent testing on other styles of helmets and hoods demonstrated that PAPRs with hoods/helmets could perform at an APF level of 1,000. The important parameter identified was the respiratory inlet covering design, not the airflow. Therefore, the US has an APF of 25 for respirators with a loose-fitting facepiece and a default of 25 to helmets and hoods unless the manufacturer has evidence that it performs at the 1,000 APF level.

Several European countries have set the APF for class TH3 PAPRs at either 100 or 200, however, the APF used by the UK for TH3 level PAPRs is 40. In British standard BS 4275:1997 – Annex D (Derivation of assigned protection factors) it is noted that this value was based on 72 data points from “Semi-blouses” (e.g. loose fitting facepieces covering head and shoulders) and “no data” from hoods or helmets. As the UK has set APF for all PAPRs regardless of respiratory inlet covering design, the UK’s APF of 40 is in the range of the US APF of 25 for PAPRs with loose-fitting headtops and that of PAPRs with hoods/helmets without additional data to prove a higher APF.

Considerations for European Countries where APF are Not Nationally Regulated

With such diverse APF for the same or similar devices (Table 3), standardizing RPE selection requirements in a multinational company is challenging. **Follow all national regulations regarding respiratory protection selection and use.** Employers can always voluntarily set an internal company APF at a lower number than what is specified by the national regulations.

For operations in locations **where national regulations do not exis**t, review of existing APF and NPF and the data used to set them is recommended. The discussion above is aimed at assisting occupational safety and health professionals with this type of review. If the workers are in a country where APF have not been set, the employer should consider reviewing the APF of those countries that are using RPE approved under the same regulations (e.g., EN) and that specify similar respiratory protection programs as the employer has implemented.

Half facepiece Air Purifying Respirator (APR)

Except for P1 filter half facepieces, where laboratory filter penetration is the predominant factor affecting achievement of the NPF, APF are lower or equal in all cases. Further review of Table 3 shows for all filtering facepieces and elastomeric half facepieces with either a P2 (or N95 level) filter or better, an APF of 10 or great is assigned. For FFP1 respirators or respirators using a P1 filter, European countries with a set APF agree upon a 4.

Full facepiece APR

European negative-pressure, full facepiece respirators have similar APF for P1 and P2 filters as negative-pressure half facepiece respirators, and higher APF for full facepiece respirators with P3 filters. The type of fit testing performed is a determining factor for the APF. When ANSI compliant qualitative fit tests (QLFT) are used for negative-pressure full facepiece respirators, the APF is limited to 10. This is because the qualitative fit test methods were only validated to ensure face seal leakage of one percent (1%) or less. To achieve the higher APF of 50, face seal leakage of 0.2% or less is required. This can only be accomplished by performing quantitative fit tests (QNFT). Please note that for European countries that have adopted respiratory fit testing, QNFT is the default method for full facepieces. The US APF for a full facepiece respirator is lower than European APF listed in Table 3, except for the UK APF. Closer examination of the UK APF shows a lower APF when gas and vapor cartridges are used than when a P3 filter is used. A US WPF study conducted on a respirator with a combination gas/vapor and particulate filter showed similar fifth percentile WPFs as for a respirator with the same facepiece and high efficiency filters (similar to a P3). These are common challenges with gas and vapor WPF studies. [44]. Where national regulations do not exist, and employers choose to set an internal APF, the APF of 50 may be considered when the particle or gas and vapor cartridges are properly selected and QNFT is performed.

Powered APR (PAPR)

Powered-air purifying respirators (powered filtering or power assisted devices) fall into two categories: loose-fitting or tight-fitting. There are several important design considerations that can affect performance. Air flow and the respiratory inlet covering are two major considerations. US WPF studies have shown the performance of the loose-fitting PAPR varies based on the respiratory inlet covering when air flow is the same. While NIOSH-approved PAPRs have a different air flow requirement than CE-marked PAPRs, the actual air flows of the European systems may be very similar to NIOSH-approved systems. [45] When comparing APF, the air flow and respiratory inlet covering (headtop) should be taken into consideration.

Two different approaches are used in assigning APF to PAPRs. European PAPRs are divided into two groups: loose-fitting (TH) and tight-fitting (TM) PAPR. Within each of these categories there are three possibilities based on the TILmax. In the US the different APF are based on the respiratory inlet covering.

PAPR with loose-fitting facepieces
PAPR with helmet or hood

PAPRs (TH3) can have one of three designs of respiratory inlet coverings: loose-fitting facepiece; hood; or helmet. WPF studies have shown these can have very different performance characteristics with similar or identical airflow. [46] For loose-fitting facepieces the OSHA APF is 25. For NIOSH-approved PAPRs with hoods or helmets the default APF is 25 because some hoods and helmets were determined

not to perform at the level of 1,000. [39] Many hoods and helmets, however, did demonstrate high performance. In this case OSHA allows an APF of 1,000 to be assigned provided the respirator manufacturer has evidence that the PAPR performs at 1,000. Most European national regulations do not make this allowance; however, the Health and Safety Authority (HSA) Ireland follows the US OSHA approach and allows an APF of 1,000 with evidence. [57] The UK HSE may accept a duty holder using 1,000 if they have "robust" evidence. This practice could also be acceptable **where national regulations do not exist**. Definitions and pictures of helmets and hoods can be found in standards [1,42] and other publications. [47]

NOTE: For 3M respirators with hoods and helmets see Technical Data Bulletin #175 and #251 (for CE certified RPE) for which models perform at 1,000. [40,41]

The European APF for loose-fitting PAPRs (class TH3) is in the range 40 to 200 compared with 25 in the US. An APF of 25 may be considered for all PAPRs with all types of loose-fitting headtops (loose-fitting facepieces, hoods, and helmets) except where testing allows the use of a higher APF for PAPRs with hoods or helmets as allowed by OSHA and HSA.

Tight-fitting PAPR

Tight-fitting PAPRs (e.g. with European TM3 class) have one of two types of respiratory inlet coverings: half facepiece and full facepieces. The US OSHA APF is 50 for PAPRs with half facepieces and 1,000 for PAPRs with full facepieces. The EN standard groups all tight-fitting PAPRs together. The UK APF is 40 for all tight-fitting PAPRs (TM3 only). A recent "WPF" study was performed in France on a full facepiece PAPR resulting in an APF of 100. [48] This result was a lower value than the US results, but higher than the UK APF. Due to new asbestos removal techniques and new, lower exposure limits, it was necessary to [re]determine the WPFs for the most frequently used respirators in the French asbestos removal sector concentrating on PAPRs delivering air flow rates in excess of 160 l/min. [48] The authors of that study state that the APF values used prior to this study were determined following several INRS (Institut National de Recherche et de Securite) campaigns in the 1990s and were equal to 60 for PAPRs [45] based on an "as is" WPF. [48] In these earlier studies fit testing was not performed, modified PAPRs were tested with limited air sampling, and no verification was offered that the area for placing and removing cassettes was an asbestos-free area. This points out one problem with using "as is" WPF studies. Using WPF studies that look at respirator performance issues and not program management or respirator user issues eliminates these issues from impacting the respirator performance and the need to "chase" APFs.

Employers with robust respiratory protection programs who wish to set an internal APF in countries that do not have regulated APF may consider that 50 be used for all PAPRs with half facepieces and 1,000 be considered for all PAPRs (Class TM3) with full facepieces.

Supplied-Air Respirators (SAR)

Table 2 and Table 4 show the US OSHA APF for the listed SARs based on mode of operation and respiratory inlet covering. The continuous flow SAR APF are identical to those of PAPRs.

Three European standards address the analogous SARs. [51, 52 53] For the pressure demand SAR, the NPF with a half facepiece is 200 and with a full facepiece is 2,000. [51,52] For continuous flow devices the NPF ranges from 10 to 2,000 depending on the respirator inlet covering and device class (class 1-4).

[53] EN529 does not list APF for most SARs but some European countries publish national guidance on APF for SARs. [54,55,56] These typically range from 5 to 1,000 depending on the respirator inlet covering and device class (class 1-4). An APF of 50 for pressure demand SARs with half facepieces and an APF of 1,000 for pressure demand full facepiece SARs may be considered when setting internal values. These are more conservative values than the respective European NPF.

European standards established a NPF of 200 for class 3 SARs with half mask. The NPF for Class 4 SARs with full facepiece, helmet, hood, or suit is 2,000. In comparison the US APF for continuous flow SARs with a half facepiece and full facepiece is 50 and 1,000, respectively.

For US NIOSH-approved loose-fitting SARs the default APF is 25 because some hoods and helmets were determined not to perform at the level of 1,000. [29] Many SARs with hoods and helmets, however, did demonstrate high performance. In this case OSHA allows an APF of 1,000 for SARs using either hoods or helmets provided the respirator manufacturer has evidence that the SAR performs at 1,000. Table 4 shows the OSHA APF and the European NPF and APF for SARs. Most European national regulations do not make this allowance except for the HSA in Ireland which follows the US OSHA approach and allows an APF of 1,000 with validated data. The UK HSE may accept a duty holder using 1,000 if they have "robust" evidence. This practice may also be acceptable **where national regulations do not exist**.

NOTE: For 3M SARs with hoods and helmets see Technical Data Bulletin #175 and #251 (for CE certified RPE) for those with evidence of supporting an APF of 1,000. [40,41]

Summary

Employers with operations in countries that have regulated APF should follow local regulations and use the regulated APF or set internal APF that are equivalent to or lower than applicable regulations. If the employer is in a country where APF have not been set and they wish to use APF, they should consider reviewing the APF of those countries that are using RPE approved under the same regulations (e.g. EN) and that specify similar respiratory protection programs as the employer has implemented.

Employers should consider that current APF values apply only when:

- The respirator has been properly selected;
- The potential wearer has been medically cleared to wear the selected respirator;
- The wearer has been trained regarding the respiratory hazard(s), proper use of the respirator including how to put the respirator on and take it off, any limitations on its use, and its maintenance including verifying adequate air flow for PAPRs not equipped with an alarm prior to entering the contaminated area each time;
- The respirator is not worn when conditions such as facial hair interfere with the face seal;
- The wearer is properly fit tested using a validated fit-test protocol prior to the use of tight-fitting respirators; and
- The wearer knows the proper procedures and schedule for cleaning, disinfecting, inspecting, repairing, discarding, and otherwise maintaining the respirator.

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Table 1. Nominal protection factors and assigned protection factors used in different countries‡

Standard	Description	Class	NPF	Assigned Protection Factors used in some countries				
				FIN	D	I	S	UK
EN 149	Filtering half mask	FF P1	4	4	4	4	4	4
		FF P2	12	10	10	10	10	10
		FF P3	50	20	30	30	20	20
EN 405	Valved filtering half mask	FFGasX P1	4		4	- -		4
		FFGasX	50		30	- -		10
		FFGasX P2	12		10	- -		10
		FFGasX P3	33		30	- -		10
EN 140 (Mask)	Half mask and quarter mask with filter	P1	4	4	4	4	4	4
		P2	12	10	10	10	10	10
Filters EN 141 *) EN 143 EN 371 *) EN 372 *) EN 14387 EN 12083		P3	48		30	30		20
		GasX	50	20	30	30	20	10
		GasX P1	4					
		GasX P2	12					
		GasX P3	48		30	-.-		10
EN 1827	Filtering half mask without inhalation valves	FM P1	4		4	- -		4
		FM P2	12		10	- -		10
		FM P3	48		30	- -		20
		FM GasX	50		30	- -		10
		FM GasX P1	4					
		FM GasX P2	12					
		FM GasX P3	48					
EN 136 (Mask)	Full face mask (all classes)	P1	5	4	4	4	4	4
		P2	16	15	15	15	15	10
Filters EN 141 *) EN 143 EN 371 *) EN 372 *) EN 14387 EN 12083		P3	1000	500	400	400	500	40
		GasX	2 000	500	400	400	500	20
		GasX P1	5					
		GasX P2	16					
		GasX P3	1 000		400	-.-		20

Table 1. (Continued)

Standard	Description	Class	NPF	Assigned Protection Factors used in some countries				
				FIN	D	I	S	UK
EN 12941	Powered filtering device incorporating a hood or a helmet	TH1 TH2 TH3	10 50 500	5 20 200	5 20 100	5 [b] 20 [b] 200 [b]	5 20 200	10 20 40
EN 12942	Powered assisted filtering device incorporating full face mask, half mask or quarter mask	TM1 TM2 TM3	20 200 2 000	10 100 1 000	10 100 500	10 [b] 100 [b] 400 [b]	10 100 1 000	10 20 40
EN 14593-1	Compressed air line breathing apparatus with demand valve - Part 1: Apparatus with a full face mask		2 000	1 000	1 000	400	1 000	40
EN 14593-2	Compressed air line breathing apparatus with demand valve – Part 2: Apparatus with half mask at positive pressure		200					
EN 14594	Continuous flow compressed airline breathing apparatus	1A / 1B 2A / 2B 3A / 3B 4A / 4B	10 50 200 2000					
EN 138	Fresh air hose breathing apparatus	Half mask Full face mask	50 2 000	500	100 1 000	- - 400	500	10 40
EN 269	Powered fresh air hose breathing apparatus incorporating a hood	Hood	200		100			
EN 137	Self-contained open circuit compressed air breathing apparatus	Negative pressure demand Positive pressure demand	2 000 2000		> 1000[a] > 1000[a]	400 1 000		40 2 000
EN 145	Self-contained closed-circuit compressed oxygen/nitrogen breathing apparatus		2 000	500	> 1000[a]	400	500	
EN 402	Self-contained open circuit compressed air breathing apparatus with full face mask or mouth piece assembly for escape		2000		> 1000[a]	- -		

*) superseded by EN 14387.

[a] Comment from BGR 190 (2004) "Rules for the use of respiratory protective devices":
These devices can be used generally, particularly when filtering devices cannot provide sufficient protection. A restriction of the field of use due to high concentrations of harmful substances cannot be derived from the use of these types of devices as far is known until now. This applies to devices with normal and positive pressure.

[b] Value based on old EN 146 for apparatus THP1/THP2/THP3 and TMP1/TMP2/TMP3.

‡Taken from EN 529:2005. Respiratory protective devices - Recommendations for selection, use, care and maintenance - Guidance document; FIN = Finland, D = Germany, I = Italy, S = Sweden, UK = United Kingdom.

Table 2. OSHA Assigned Protection Factors**

Type of Respirator [1,2]	Quarter Mask	Half Mask	Full Facepiece	Helmet/Hood	Loose-Fitting Facepiece
1. Air-Purifying Respirator	5	10[3]	50	—	—
2. Powered Air-Purifying Respirator (PAPR)	—	50	1,000	25/1,000[4]	25
3. Supplied-Air Respirator (SAR) or Airline Respirator					
• Demand mode	—	10	50	—	—
• Continuous flow mode	—	50	1,000	25/1,000[4]	25
• Pressure-demand or other positive pressure mode	—	50	1,000	—	—
4. Self-Contained Breathing Apparatus (SCBA)					
• Demand mode	—	10	50	50	—
• Pressure-demand or other positive pressure mode (e.g., open/closed circuit)	—	—	10,000	10,000	—

Notes:

[1] Employers may select respirators assigned for use in higher workplace concentrations of a hazardous substance for use at lower concentrations of that substance, or when required respirator use is independent of concentration.

[2] The assigned protection factors in Table I are only effective when the employer implements a continuing, effective respirator program as required by this section (29 CFR 1910.134), including training, fit testing, maintenance, and use requirements.

[3] This APF category includes filtering facepieces, and half masks with elastomeric facepieces.

[4] The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

[5] These APFs do not apply to respirators used solely for escape. For escape respirators used in association with specific substances covered by 29 CFR 1910 subpart Z, employers must refer to the appropriate substance-specific standards in that subpart. Escape respirators for other IDLH atmospheres are specified by 29 CFR 1910.134(d)(2)(ii).

** Taken from 29 CFR 1910.134.

Table 3. Comparison of Respirator Protection Factors from the US and Europe – Air-purifying respirators

Description European/US	Type EN529/NIOSH	APF	NPF	APF				
		OSHA	Non-APF Countries	Germany	Italy	Finland Sweden	France	UK
EN 149 Filtering half mask/ Filtering facepiece	**FFP1**	NA	4	4	4	4		4
	FFP2/95	10	12	10	10	10		10
	FFP3 /100	10	50	30	30	20	10	20
EN 140 Half mask (HM) and quarter mask with filter/Half facepiece	**P1**	NA	4	4	4	4		4
	P2 / 95	10	12	10	10	10		10
	P3 / 100	10	48	30	30	--		20
	GasX/G&V	10	50	30	30	20	10	10
EN 136 Full face mask (FF) (all classes)/Full facepiece	**P1**	NA	5		4			
	P2 / 95	10/50[1]	16	15	15	15		10
	P3 / 100	10/50[1]	1000	400	400	500		40
	GasX/G&V	10/50[1]	2000	400	400	500	30	20
EN 12941 Powered filtering device incorporating a hood or a helmet/Loose-fitting PAPR	**TH1**	NA	10	5	5	5		10
	TH2	NA	50	20	20	20		20
	TH3/HE, G&V	25/1000[2]	500	100	200	200	40	40
EN 12942 Powered assisted filtering device incorporating full face mask, half mask	**TM1**	NA	20	10	10	10		10
	TM2	NA	200	100	100	100		20
	TM3/HE, G&V	50/1000[3]	2000	500	400	1000	60 100[4]	40

Table 4. Comparison of Respirator Protection Factors from the US and Europe – Supplied air respirators

Description European/US	Type EN529/NIOSH	APF	NPF	APF				
		OSHA	Non-APF Countries	Germany	Italy	Finland Sweden	France	UK
EN 14593-1 Compressed air line breathing apparatus (SAR) with full facepiece (pressure demand)	**Full facepiece**	1000	2000	1000	400 (negative pressure) 2000 (positive pressure)	1000		40[6] 2000
EN-14593-2 Compressed air line breathing apparatus (SAR) with half facepiece (pressure demand)	**Half facepiece**	50	200					-
EN 14594 Continuous flow compressed airline breathing apparatus (SAR)	**Half facepiece**	50	Class 1[5] 10 Class 2[5] 50 Class 3[5] 200	5 20 100				10 20 20
	Full facepiece	1000	Class 1[5] 10 Class 2[5] 50 Class 3[5] 200 Class 4[5] 2000	5 20 100 1000			- - - 250	10 20 20 40
	Loose fitting facepiece	25	Class 1[5] 10 Class 2[5] 50 Class 3[5] 200 Class 4[5] 2000	5 20 100 100			- - - 250	10 20 40 40
	Helmet/hood	25/1000 [2]	Class 1[5] 10 Class 2[5] 50 Class 3[5] 200 Class 4[5] 2000	5 20 100 100	5 20 100 1000		- - - 250	10 20 20 40
EN 137 Self-contained	**Full facepiece**	10,000	2000	>1000	400 (negative pressure)			2000

open circuit compressed air breathing apparatus (SCBA) [7]					2000 (positive pressure)			

1. The US OSHA APF varies depending on type of fit testing performed. When negative-pressure, full facepiece respirators are qualitatively fit tested an APF of 10 applies. When quantitative fit testing is performed an APF of 50 applies.
2. APF of 25 applies to powered air-purifying respirators (PAPR) and supplied air respirators with a loose-fitting facepiece. PAPR and supplied air respirators with hoods and helmets with evidence that demonstrates performance at a level of protection of 1,000 or greater receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. See 3M Technical Data Bulletin # 175 [40]. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators and receive an APF of 25.
3. APF of 50 applies to all PAPRs with a half facepiece. APF of 1000 applies to all PAPRs with a full facepiece.
4. Min flow rate 160l/min
5. Refers to the class of continuous flow compressed airline breathing apparatus (SAR). The NPF is based on the class of the device. It is not related to the type of respiratory inlet covering on the device with the exception that half facepieces are not permitted in class 4 devices. This means (with the exception for class 4 devices) the APF is the same whether there is a half facepiece, full facepiece, helmet, hood or loose fitting facepiece on it. 3M does not recommend using an APF greater than 25 for devices using a loose-fitting facepiece.
6. EN14593-1 APF of 40 applies to devices without positive pressure.

7 SCBA regardless of the APF or NPF are the preferred device for entry into atmospheres that are unknown or immediately dangerous to life (IDLH).

Figure 1. Effective Protection Factor