Demystifying APFs for RPE: Attempting the impossible

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ABSTRACT

This commentary aims to share international perspectives on respiratory protective equipment (RPE) and the concept of assigned protection factors (APFs). APF is a numerical value established by an organization indicating the level of protection that should be expected for a majority of the population using that respiratory protective equipment (RPE), when used correctly. Different countries and organizations have different approaches to setting AFPs, which can lead to the same exact RPE having different APF values in different countries. After years of navigating multiple country specific rules (or lack thereof), the authors sought to establish which APFs should be applied for companies like theirs that operate globally. In this commentary, the authors do not come to a specific conclusion, rather they share the information they obtained along their journey and provide some discussion of the global situation. The authors are educated in the United States and have international work experience but do not claim to represent all countries' perspectives regarding APFs.

Keywords: respiratory protective equipment, assigned protection factor, nominal protection factor, international standards

COMMENTARY

This commentary aims to share international perspectives on respiratory protective equipment (RPE) and the concept of assigned protection factors (APFs). It is not exhaustive and does not cover all countries' perspectives and requirements regarding APFs. The authors are educated in the United States and have international work experience. The authors and the Journal welcome responses to this commentary that expand this topic. Stephanie Lynch is a respiratory protection specialist (previously employed by the NIOSH National Personal Protective Technology Laboratory and the Department of the Army), currently the Senior Technology and Research Manager at OHD, LLLP. Samantha Connell is a CIH and corporate Industrial Hygienist (IH) working for a multinational corporation that operates across 35 countries worldwide. After years of navigating multiple country specific rules (or lack thereof), the authors sought to establish which APFs should be applied for a company that operates globally. During that search, input from many colleagues and regulatory bodies was sought, and it was quickly realized that this information would be useful for the respiratory protection community at large.

In this commentary, the authors do not come to a specific conclusion, rather they share the information they obtained and provide some distillation of the global situation. Limitations up front: This commentary does not cover all countries' perspectives, regulations or requirements, and only briefly touches on ISO guidance. While the authors do not cover all countries, it is good for readers to consider concepts broader than what is practiced in their own country. As examples, US or UK practitioners might assume that fit-testing is conducted worldwide or that the same set of APFs they apply are used worldwide and may be surprised to find out that it is far from the case; many countries do not require fit-testing at all and have no established APFs.

RPE is a commonly used form of personal protective equipment (PPE) in the workplace. In many places where workplace safety is regulated, whenever inhalation hazards cannot be controlled to safe levels by more effective means, RPE is legally required to protect exposed employees. The protection provided by RPE is dependent on several factors, including filtration efficiency, fit characteristics, proper use, training, and maintenance. One way to ensure the correct RPE is selected for the hazardous exposure is to reference an Assigned Protection Factor (APF) for that type of RPE.

For the purposes of this article, an APF is a numerical value established by an organization indicating the level of protection a properly functioning respirator can be expected to provide to a majority of the population based on performance data and/or theories about RPE use. Several regulatory, standards setting, and research organizations across the globe set APFs, and in many instances these organizations have similar concepts of an APF with somewhat differing definitions and consequently differing values of expected protection. This article aims to highlight how APFs are defined and developed by various organizations, and to provide some insight to the potential future of defining protection provided by RPE.

APFs help practitioners understand and select the appropriate RPE capable of providing the desired level of protection. Use of APFs involves quantifying the workplace exposure level to an inhalation hazard (typically as a measured concentration over an eight-hour work shift), identifying the applicable occupational exposure limit (OEL), using this information to calculate an exposure factor (that is the ratio of the measured exposure level to the OEL), and ultimately selecting RPE that has an APF greater than or equal to the exposure factor – the idea being that an RPE is expected to reduce the wearer's exposure by a factor at least equal to the APF when used properly. Therefore, the wearer could be exposed to an inhalation hazard greater than the OEL and still be adequately protected so long as the APF is greater than the exposure factor for inhalation hazards. In this regard, APFs are also important for determining the maximum use concentration (MUC) of a specific RPE against a specific inhalation hazard. MUC is determined by multiplying the APF of the selected RPE by the OEL for that hazard.

As an example, if a measured exposure to benzene is 6 parts per million (ppm) over an eight-hour period and the referenced OEL is 1 ppm, then the exposure factor is 6 (that is 6 ppm exposure divided by 1 ppm OEL). The RPE used to protect against this exposure would need to have an APF of at least 6. If the RPE selected has an APF of 10, then the MUC for that RPE against benzene is 10 ppm and the exposed employee is adequately protected. Although achieving the established APF is dependent on several other factors, it remains a strong initial indication of the potential protection level achieved by a specific type of RPE.

In the United States (US), the Occupational Safety and Health Administration (OSHA) regulates the selection and use of RPE in the workplace. Employers must select appropriate RPE using the APFs established by OSHA for each RPE type. Although not initially referred to as "APFs", this concept was originally described by the American National Standards Institute (ANSI 1980) and later adapted based on workplace protection factor (WPF) studies conducted by the National Institute of Occupational Safety and Health (NIOSH), academia, industry, respirator manufacturers, and OSHA itself (NIOSH 1987, OSHA 2006).

A WPF study, according to OSHA is "a study, conducted under actual conditions of use in the workplace, that measures the protection provided by a properly selected, fit-tested, and functioning respirator, when the respirator is worn correctly and used as part of a comprehensive respirator program that is in compliance with OSHA's Respiratory Protection standard at 29 CFR 1910.134. Measurements of (concentrations outside) Co and (concentrations inside) Ci are obtained only while the respirator is being worn during performance of normal work tasks (i.e., samples are not collected when the respirator is not being worn). As the degree of protection afforded by the respirator increases, the WPF increases." (OSHA 2009)

For OSHA, where a WPF study was performed, that data was applied to the development of the APF. In the absence of WPF studies data from simulated WPF studies, expert consensus and any other relevant information were applied. OSHA has robust testing protocols and a large body of knowledge that was used to establish their APFs, however this is not fully reflected by the conservative nature of their established APFs. For example, OSHA broadly applies an APF of 10 to all half-mask air purifying respirators, even across several different filtering efficiencies (95, 99, 99.97%) and types such as elastomeric versus filtering facepiece. In their assessment of the data, OSHA calculated a point estimate of the 5th percentile value for all considered studies for each respirator class and found the overall 5th percentile value was 14.5, but as low as 12 and as high as 27. Therefore, they justified their selection of 10 as an adequate APF for all half-mask respirators. Clearly, this represents a conservative approach that assumes all respirator brands and models within a class perform similarly. OSHA selected a value that is highly likely to be attained by 95% of workers that that use any respirator within that class, provided they have been fit-tested and are within a comprehensive respiratory protection program.

In Europe, the development of APFs is based on different approaches by different organizations in different countries. Originally, the only protection factor used to determine potential effectiveness of RPE was the nominal protection factor (NPF), which is the inverse of the total inward leakage of the respirator found in laboratory settings. Since NPF is based on total inward leakage and not just fit, NPF is more representative of RPE protection than a fit-test, but only under controlled laboratory conditions. Where WPF studies are available, an APF is typically set, however which data to consider, how to review it, and which conclusions to draw, can vary across countries. In the absence of WPF studies, SWPF studies may be used to establish an APF. Where neither WPF nor SWPF studies are available, NPFs are recommended to be applied as an estimate for expected protection factor. However, APF values are likely more realistic than NPF values since they are based on real or simulated workplace testing.

In the same way that OSHA's definition of WPF influenced the development of their APFs, the derivation of an APF reported by any group is in some way dependent on its definition of APF. OSHA defines the APF within the context of a compliant respiratory protection program according to their regulations. This means OSHA only applies data from studies where a comprehensive program is in place with fit-testing and training on RPE use. This may not be reflective of broader RPE use and effectiveness.

In European Norm 529 (CEN 2005), the APF is the realistic level of respiratory protection that can be achieved by 95% of adequately trained workers. The definition also states, "using a properly functioning and fitted respiratory protective device". Some of the complexity already begins with this detail from the EN529:2005. The definition contradicts the current requirements by most European countries. For example, Germany and Finland are listed in the norm as having defined APFs, which are derived from WPFs, when neither country actually requires fit-testing.

This inherently creates flaws in the concept of applying APFs in these countries. Currently, the only European country that requires fit-testing for the use of all RPE in the workplace is the United Kingdom (UK). Some other countries require it for substance specific exposures such as silica and asbestos in the workplace. Germany recently mistakenly equated user seal checks, a method of self-checking the seal of a respirator afforded by a donning, with qualitative fit-testing in their regulations (DGUV 2021). It should be noted that the regulatory landscape surrounding RPE use in Europe is actively evolving.

The UK has recommendations that differ from the rest of Europe. In general, the APFs are more conservative, in part, because of a mix of WPF testing with compliant and non-compliant programs. This implies OSHA's APF values could be less conservative than European values because compliant programs are more likely to have consistent RPE use conditions that contribute to better worker protection. Similar to other European countries, the UK APFs were originally based on NPFs and eventually started to consider the WPF and apply a safety factor (BSI 1997).

Because of these different approaches to setting APFs, different organizations can assign APFs to the same RPE. This can be confusing for health and safety professionals working in international settings. In one country, you might only need a filtering facepiece respirator (FFP/FFR), but in another, you might need a full facepiece respirator for the same hazard at the same exposure level. This is exacerbated by the variability in different organization's reported OELs.

Other organizations do not use the term "APF" but do have a protection factor term. Australia and New Zealand' Standard (SA/SNZ 2009) defines protection factors as the ratio between the concentration of an inhalation hazard outside the RPE to the concentration inside the RPE, and further defines a required minimum protection factor (RMPF) as that which will minimize exposure or is necessary to reduce the exposure of a wearer below the OEL. It goes on to reference a table with the RMPF in categories of up to 10, up to 50, up to 100, and 100+ listed with suitable RPE alongside. While it is not a huge leap from the application of APFs, it is still a notable difference and requires a different way of considering the selection of RPE. As comparison, OSHA classifies the RPE based on design and type, while this method takes essentially the inverse, selecting the level of protection needed and identifying an appropriate RPE.

FFP/FFR are a good example to demonstrate the differences of how APFs between organizations were derived for half facepiece respirators. The UK/Europe differentiates between FFP1, FFP2 and FFP3, assigning protection factors of 4, 10 and 20, respectively. However, OSHA does not differentiate between N95 and N99 FFRs, assigning them both an APF of 10 even though they are essentially equivalent to FFP2 and FFP3, respectively. As described above, this may be due in part to differences in methodology and performance requirements when defining APFs.

Table I displays some APFs from the US, UK and Europe. Some of OSHA's APFs are significantly higher, with SCBAs having APFs of up to 10,000. The UK APF is much more conservative at 2,000 for SCBA.

OSHA used approximately 1,700 data points from workplace protection factors and concluded that an APF of 10 for both filtering facepieces and elastomeric half-mask facepieces is adequate. OSHA states that statistically, there is no justification for an APF of less than 10 and is in fact an underestimation of protection for both masks which resulted in 18 and 12 for FFR and elastomeric, respectively (OSHA 2006). The UK (and other countries that have adopted the EN standards), have started with the NPF, which clearly considers filtering efficiency as it is based on total inward leakage that includes filter penetration.

Countries applying EN529:2005 (CEN 2005) either directly use NPFs for half facepieces, which are based on the filter used, or derive an APF from the NPF by using WPF data and/or applying a safety factor. These APF and NPF values range from 4 – 50, with the difference mostly because the data are based on filter penetration in the laboratory tests for CE certification. The UK, Sweden and Finland have adopted APFs of 4, 10 and 20 for FFP1, FFP2 and FFP3 respectively. Germany and Italy have adopted 30 instead of 20 for the FFP3.

Table I: Some international assigned protection factors. Values separated by slashes correspond to different filtration efficiency categories equivalent to FFP1 / FFP2 (N95) / FFP3 (N99).

	Regulatory jurisdiction					
Type of protection	**US-OSHA**	**UK HSE**	**Finland, Sweden**	**Germany, Italy**	**Australia, New Zealand**	**NPF (Non-APF countries)**
Filtering half facepiece	- /10/10	4/10/20	4/10/20	4/10/30	10	4/12/50
Half Facepiece (elastomeric)	10	4/10/20 10 (g/v*)	4/10/ - 20 (g/v)	4/10/30 30 (g/v)	10	4/12/48 50 (g/v)
Full Facepiece (elastomeric)	50	4/10/40 20 (g/v)	4/15/500 500 (g/v)	4/15/400 400 (g/v)	10 – 50 50 - 100 (full-face P3)	5/16/1,000 2,000 (g/v)
Full facepiece SCBA Negative / positive pressure demand	50/10,000	40/2,000	-	1,000+(Germany) 400/1,000 (Italy)	100+	2,000

* g/v = gas/vapour only

As a response to this obvious issue, the International Organization for Standardization (ISO), developed a classification system under ISO 16973 for RPE with protection classes as opposed to APFs (ISO 2016a). The ISO system is based on two performance standards ISO 17420-2 and ISO 17420-4 (ISO 2021a, 2021b) that give requirements for filtering RPD or supplied breathable gas, in addition to the ISO 17420-1 standard providing general requirements (ISO 2021c) and a variety of more specialized applications (ISO 17420-5 through -9, ISO 2021d, 2021e, 2021f, 2021g, 2021h). In the APF systems discussed previously, classification of an RPE is based on design (or type of respirator), not performance. The ISO performance-based classification is a unique approach that allows for the inclusion of any number of novel RPE as it does not restrict them to a set of designated designs.

The basic RPE classification in ISO 16973 starts with assigning a protection class (six classes based on total inward leakage allowed), work rate class (four classes going from light/moderate to maximum), and respiratory interface (10 classes indicating the area of coverage on the wearer and whether it is tight or loose fitting). All RPE gets basic classification. It then goes on to classify the RPE as supplied air or filtering and defines filtration efficiency, and uses the special application classifications, where necessary. This leads to classification codes with a designation for each category (Colton 2017). While the ISO standard aims to standardize the approach, the end-result does not seem like a simplification of the situation for safety professionals in any practical way. It is also dependent on each country voluntarily adopting, implementing, and enforcing this system. Australia is among the first countries to formally adopt this standard, although still in the early days of transition.

The current situation can be summarized as following.

Some countries use APFs. However, as the methodology and performance requirements differ, wearers are left with different designated protection factors for the same equipment. Some countries use NPFs which are laboratory-based and do not reflect realistic working situations. Some (most) countries do not have any established protection factors for RPE. They are left to decide which system they want to follow, if any at all. In the meantime, still other countries' standard setting bodies may have adopted ISO but this leaves them to follow the new system of protection classes and not protection factors.

As it stands, the authors feel that the ease of finding and understanding information and the concepts as currently relayed in the literature are a barrier to achieving the ultimate goal of protecting worker health. There is hope that a standardized approach will eventually be the path forward, but it should remain easily comprehensible and not become a barrier to the effective use of respiratory protection. While ISO has the potential to lead to global harmonization, the basic concept behind the use of an APF seems easier for a practitioner or generalist to apply.

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