

Performance Studies on Respiratory Protective Devices in the Workplace – Part I: Variation in Measures of Performance

MP Clayton^{1*}, B Rajan-Sithamparanadarajah² and NP Vaughan¹

¹ Health and Safety Laboratory, Harpur Hill, Buxton SK17 9JN, England

² Health and Safety Executive, Redgrave Court, Merton Road, Bootle, L20 7HS, England.

* Corresponding author & E-mail: mike.clayton@hsl.gov.uk

ABSTRACT

Results gathered from workplace performance studies have provided the basis for many of the assigned protection factors (APFs) for respiratory protective devices (RPDs) that we have today. The lack of a harmonised approach to workplace performance studies has partly been responsible for the huge differences in APFs that can be seen across the world. This variance in APFs has both operational and economic implications for the employers, RPD users, manufacturers and suppliers. APFs play a vital role in the correct selection of RPD and therefore must stand up to scrutiny. With a new suite of ISO RPD Standards on the horizon there is a need and the opportunity to revisit the topic of APFs to ensure that they are fit for purpose. This first paper discusses the issues surrounding workplace performance studies, how APFs were derived and the need for a harmonised approach to future workplace studies. A second paper discusses the key elements of workplace performance studies and makes recommendations with the aim of taking the harmonisation of APFs forward.

Keywords: Respiratory protective devices, assigned protection factors, workplace protection factors, performance

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INTRODUCTION

Exposure to hazardous substances can cause significant damage to health, shortening of life-span and, in extreme cases, death. A significant exposure route is the inhalation of harmful substances that are present in the air at the workplace. Health and safety regulators such as the UK Health and safety Executive (HSE) and the U.S. Occupational Safety and Health Administration (OSHA) require employers to prevent, so far as is reasonably practical, the exposure of employees to hazardous substances. Where prevention is not reasonably practicable, employers must put control measures in place so that hazardous substances do not enter the atmosphere in the first place, or stay below safe levels. If control measures at source are not reasonably practicable or are found to be inadequate then respiratory protective devices (RPDs) may be used as a last resort to control inhalation exposure. In practice, RPDs are an extensively used control measure.

One aspect that contributes to RPD selection criteria is the performance of the RPD; this is usually indicated by the general term *protection factor* (PF). The PF is expressed as the ratio of the concentration of the contaminant (C_o) in the air surrounding the RPD to that in the wearer's breathing zone inside the facepiece cavity (C_i).

$$PF=(C_o)/(C_i)$$

This property can be evaluated in different ways, as described by Guy (1985) and Brown (1992). One such evaluation is the Nominal Protection Factor (NPF). NPFs are derived from the maximum total inward leakage (TIL) or inward leakage (IL) allowed in the relevant laboratory performance standards. During the 1980s and early 1990s, NPFs were used in the UK as a guide for selecting adequate RPD for a given situation; NPFs were published in guidance documents such as BS 4275 (BSI 1974). However, since then workplace performance studies, (Moore and Smith, 1976, Myers and Peach, 1983, Que Hee and Lawrence, 1983, Wallis *et al.*, 1993, Howie *et al.*, 1996), have shown that the laboratory derived performance benchmark is not a satisfactory measure for selecting adequate RPD for use in the workplace. (Note: For the purpose of this paper the term *workplace performance* is used to refer to any study where the protection afforded by the RPD has been measured in the workplace.)

This led to an increased interest in evaluating the performance of RPDs in the workplace. Johnston *et al.* (1992) and Myers *et al.* (1995) reviewed workplace performance studies and made a number of proposals for consideration when developing protocols for workplace performance studies. Although many papers on the results of workplace performance studies have been published there is as yet no common international protocol for conducting, analyzing and reporting the results of these studies. According to Johnston *et al.*, (1992), American Industrial Hygiene Association (AIHA, 1996), Capon (1996), Rajan (1997), Brown (2002) and Bien (2008) there is recognition that efforts should be made to establish a common guideline for best practice when both conducting and reporting workplace performance studies.

One of the main reasons for conducting performance studies is for the derivation of Assigned Protection Factors (APFs) which are fundamental to the selection of adequate RPD. The lack of a harmonised approach to workplace performance studies has partly been responsible for the differences in APF that exist across the globe today. Not only do the values of APFs impact on the decision of which type and class of RPD is adequate for a given situation, but it also subsequently has a bearing on initial outlay and running costs, how the task is undertaken and the supporting regime needed to implement an effective RPD programme. Thus it is important that the APF is neither too optimistic and so put wearers at risk of exposure, nor too pessimistic and so place unnecessary burden on industry.

DEFINITIONS OF WORKPLACE PERFORMANCE STUDIES

Even though many studies referenced in this paper may be termed as '*workplace performance studies*', they used a variety of protocols depending on the type of protection factor of interest. The protocol adopted will determine the usability and comparability of the data. Therefore, there is a need to clearly define the different terms and suggest appropriate protocols so that future studies can be performed and reported with improved clarity; this will help to increase the usage of the published data. Guy (1985) recommended a set of definitions to cover various protection factor terms. These were subsequently updated and published by the AIHA Respiratory Protection Committee (Janssen, 2002) with the aim of consistent application. They are presented here for ease of reference.

Workplace Protection Factor (WPF) as Defined in the JAIHA (63) 2002

'A measure of the protection provided in the workplace, under the conditions of that workplace, by a properly selected, fit tested and functioning respirator when correctly worn and used. WPF is a direct measurement of respirator performance capabilities in a specific work environment. It represents the workplace contaminant concentration which the user would inhale if he were not wearing the respirator (C_o) divided by the contaminant concentration inside the respirator facepiece (C_i). C_o and C_i are measured simultaneously only while the respirator is properly worn and used during normal work activities. C_i measurements made using respirators that are poorly maintained, improperly used, or not worn during the entire exposure period are inappropriate for WPF determination. (See definitions for Effective Protection Factor and Program Protection Factor).'

To obtain workplace performance data that can be classified as WPF data the protocol requires that the study is undertaken within an effective RPD programme. In this protocol, and depending upon the RPD programme present at the study site, the investigators may play a significant role to ensure that the programme is effective. They may be required to carry out facepiece fit testing and provide training prior to conducting the performance study (Myers *et al.*, 1995). While fit testing is established as part of a RPD programme in the US and the UK, it is not a universal RPD programme requirement. During the study, wearers will be closely observed by the investigators to ensure that the sampling equipment does not interfere with wearer safety and verify that the RPD is used correctly in accordance with the manufacturer's instructions and that wearers do not remove the RPD or interfere with its performance during the measurement period.

Programme Protection Factor (PPF) as Defined in the JAIHA (63) 2002

'A measure of the respiratory protection provided to a worker in the context of a specific respirator program. It is defined as the contaminant concentration that the user would inhale if the respirator were not worn (C_o) divided by the workplace contaminant concentration inside the respirator facepiece as it is actually used (C_i). C_i may be estimated from biological monitoring as the airborne concentration expected to produce the measured biological index. PPF is an estimate of the effectiveness of the complete respirator programme rather than the performance capabilities of the respirator itself. It is affected by such factors as the following:

- *Wearers' activities;*
- *User training and motivation;*
- *Proper respirator selection, maintenance, and storage;*
- *User training and fit testing;*
- *Facial hair or other conditions that interfere with proper fit; and*
- *Supervision, administration and monitoring of the program.*

If any of these or other program elements are deficient, the program protection factor will be adversely affected. The best respirators available cannot perform effectively if the RPD programme is badly deficient.'

Because the specific RPD programme in situ at the study site affects the results, a PPF study must be accompanied by the description of the prevailing RPD programme.

Effective Protection Factor (EPF) as Defined in the JAIHA (63) 2002

'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. It is the ratio of the contaminant concentration outside the respirator to that in the air actually 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. While the respirator is worn, breathing zone sampling is done from within the respirator. EPF is strongly influenced by non-wear time, regardless of the respirator's WPF.'

EPF reflects bad practice which cannot be related to RPD performance. This type of study will be greatly influenced by the non-wear time and will generate a highly pessimistic protection factor. This protocol is unsuitable for assessing the performance or extent of protection afforded by the RPD in the workplace but it does give the protection factor which workers have actually experienced, which may be of interest for example if their health or exposure is being monitored at the same time. However, if exposures are high enough to cause health risks it would be unethical to conduct an EPF study.

Simulated Workplace Protection Factor (SWPF) as Defined in the JAIHA (63) 2002

'A measure of respirator performance that is done in a laboratory using test exercises designed to simulate work. SWPF is determined by measuring a test atmosphere concentration outside (C_o) and inside (C_i) a properly functioning respirator that is properly worn. The validity of SWPF as a surrogate for WPF depends on how well the test exercises represent the work to be done.'

SWPF studies have often been criticised for not being representative of workplace conditions on the grounds that the activities performed by the wearers are not representative of the true nature of the activities in the workplace. However, during actual workplace studies the activities performed by workers at their workplace on one site may not be at all representative of activities performed at another site (even though the process involved may be similar). This needs to be considered in all studies and not just in SWPF studies. Cohen *et al.*, (2001) applied a safety factor of 25 to the lower fifth percentile of the SWPF data in the estimations of APFs to account for possible difference between actual workplace and simulated use, though the authors considered this number to be a very conservative value.

While WPF studies should be the first choice when aiming to measure RPD performance in the workplace, there are a number of situations where it is not practical to conduct performance studies in the workplace, therefore there may be a case for simulation studies as an alternative to workplace protection factor studies. Examples of such situations are:

1. Where the study is to be carried out for RPDs used in areas of highly toxic contamination, e.g. nuclear, pharmaceutical and asbestos industries, where ethical or local decontamination rules may prevent WPF studies;
2. When C_o is too low to allow the necessary PF to be measured; and
3. Where observation by the investigators is not possible in real working environments.

Because of these difficulties, investigators have used SWPF studies as a method for assessing the performance of RPDs (Bancroft *et al.*, 2000, Johnston *et al.*, 2000, Cohen *et al.*, 2001, Clayton *et al.*, 2002). In this protocol, workplace activities are simulated under controlled conditions, such as in a purpose built work enclosure. In such work enclosures, surrogate test agents such as sodium chloride aerosol, vegetable oil aerosol or sulphur hexafluoride gas act as the air contaminant in place of the real contaminants. In some applications, e.g. in nuclear decommissioning work, RPD wearers are trained in special training enclosures in which they can simulate specific work activities in an uncontaminated environment. These facilities may be suitable for performing SWPF studies and can improve the realism of the test exercises. Additionally, using actual wearers in SWPF studies will improve the realism of the simulation. The wearers will carry out their normal work tasks, whilst the performance of the RPD is measured. The investigators ensure that the RPD is fully functioning and fitted correctly (fit tested where appropriate) but otherwise restrict their intervention to a minimum and allow the wearers to perform the task and use the RPD as they would in the normal workplace (excluding misuse).

Derivation of Assigned Protection Factors

For RPDs to be brought to the market requires an assessment of its performance for compliance with the regulations in force in the country or area in which the RPD is to be marketed. For example, within Europe compliance with the European Directive (89/686/EEC) is required, and in the U.S. RPDs must meet the certification tests (42 CFR Part 84) established by the National Institute for Occupational Safety and Health (NIOSH). These assessments are carried out in the laboratory under controlled conditions. The assessment covers parameters such as filtration efficiency, breathing resistance, the measurement of re-breathed carbon dioxide and in some regions inward leakage. In the past, the results of the inward leakage test have been used as an indication of the RPD's potential effectiveness in the workplace, for example those published in BS4275 (BSI 1974).

However, the laboratory test for the measurement of inward leakage is very different from the conditions under which actual wearers use the RPD. In short, the exercises carried out by the test subjects during the inward leakage test – while in some way simulating work – do not reflect the actual conditions of use. This therefore leads to laboratory performance measures that are more optimistic than those which may actually be achieved in the workplace.

To assist in the selection of adequate respiratory protection, APFs for given types and classes of RPDs have been derived and published by both health and safety regulators and standards institutes (BSI, 1997; CEN, 2005; HSE, 2005; OSHA, 2006, 2009). The APF, while having a common purpose, is defined slightly differently by various organisations. EN 529:2005 (CEN, 2005) defines the APF as the *'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.'*

EN529 lists APFs for various types and classes of RPDs for three European countries. As can be seen from the examples shown in Table I, these can vary considerably. The reason for these variations within Europe, stems from the different approaches taken to derive the APFs. These different approaches include a mix of workplace performance studies, laboratory studies, the application of safety factors to NPFs, and professional judgement.

Table I. Examples of European Assigned Protection Factors

RPD type	RPD class	APF	APF	APF
		Sweden	Germany	UK
Filtering facepiece	FFP2	10	10	10
Filtering facepiece	FFP3	20	30	20
Full face mask & P3	[FFM] P3	500	400	40
Powered hood	TH3	200	100	40
Powered Full face mask	TM3	1000	500	40

ANSI Z88.2 (1992) standard defines the APF as *'the minimum expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users'*.

OSHA in its review of APFs (OSHA, 2006, 2009) defines the APF as *'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 (29 CFR 1910.134).'*

During the review, OSHA did not use Effective Protection Factor (EPF) and Programme Protection Factor (PPF) studies in its APF determination since these measure deficiencies in the RPD Programme. EPFs were not used because these results include the time spent in contaminated atmospheres both with and without respiratory protection. PPFs are affected by any shortcomings in the RPD programme, including, for example, inadequate selection, poor maintenance, poor user training and inadequate programme supervision. Therefore, OSHA relied on WPF and SWPF studies, since the focus was on the performance characteristics of the RPD only and not the programme.

BSI defined the APF as the '*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*'.

BSI considered that WPF studies in which the investigators carried out fit tests, trained and observed the wearers and assisted with donning (e.g. Myers *et al.*, 1984; Myers *et al.*, 1985; Zhuang *et al.*, 2003) were likely to generate optimistic indications of performance and therefore instead selected the 'As-is' protocol. This approach was considered to be the most suitable type of study on which to base an APF, since it most accurately reflects actual workplace practice. In such 'As-is' studies, no additional training or supervision is provided by the investigators, unless that in place is deemed to be inadequate, and instead relies upon the training and supervision provided by the employer. Intervention is limited to correction of any shortcomings in the RPD programme which could expose the wearers to significant health risks. It should also be noted that at the time BSI derived its APFs, RPD fit testing was not required by HSE and therefore fit testing was not routinely performed.

Additionally, BSI considered that the presence of the investigators, especially on a one-to-one basis, during any workplace or simulated study may have caused behavioural changes in the wearers – this is known as the *Hawthorne effect* (Roethlisberger and Dickenson, 1939) - which could result in optimistic WPFs. Howie *et al.*, (1996) reported that during a human factors survey, as part of the workplace performance study, examples of asbestos removal workers modifying their working practices in the presence of the investigators were noted. However, whether this had an effect on the protection factor could not be determined because no protection factor measurements were being taken at the time of the observations. Any such effect is difficult, if not impossible to prove, let alone quantify, and has not been conclusively substantiated.

However, due to the small number of published studies that could be identified that followed the 'As-is' protocol, studies whose protocols complied with the AIHA WPF definition were included by BSI in its derivation of APFs. Recent WPF studies (Janssen and Bidwell, 2007; Janssen *et al.*, 2007; Janssen and McCullough, 2010) suggests that BSI's concerns over the optimism of such studies relating to training provided by the investigators rather than the employer appears to be unsupported.

For both the OSHA and BSI APF analysis there was little or no suitable workplace data available for some types and classes of RPDs on which to base an APF. Therefore for some devices an APF was ascribed partly on the basis that there was equivalence between its operation and that of a device for which an APF was derived from workplace performance data (Nelson, 1996; BSI, 1997). This 'professional judgement' approach, while the product of many years experience, has little or no technical data to support the decisions taken. Where no workplace data was available and the equivalence route was not an option, laboratory tests and reference to the nominal protection factors were included in the analysis. This was not an ideal situation - however, it was considered the best route to take when faced with a shortage of data.

More recently the development of RPD Standards under the umbrella of the International Standards Organisation (ISO) includes a selection, use and maintenance standard (ISO 16975-1, 2010). One very important task the responsible ISO committee had to tackle was how to develop a harmonised selection process when the current APFs across the globe are so diverse; a new approach for assigning

a performance measure was required. The committee reviewed current values of APFs and NPFs and, with the application of a 'risk based' safety factor, derived 'Protection Levels' (PLs) allocated to laboratory performance classes (ISO, 2011). While this allowed for a harmonised approach to be included in the developing selection, use and maintenance standard, the Standard committee acknowledged that thorough validation of these proposed PLs will be required.

Many questions have been asked, and quite rightly so, as to why there exist such vast differences in the APF for the same type and class of RPD; the current situation is not helpful to international industries when implementing an RPD programme or to RPD manufacturers and suppliers who operate in a number of regulatory environments. These difficulties further support the need for workplace performance studies following an internationally agreed protocol. However, until RPDs meeting the new ISO performance standard become available, it is not possible to conduct such WPF studies to generate data for the determination of the corresponding APFs. Therefore, for the time being, efforts should be focused on developing improved and uniform protocols.

Running in parallel with the development of ISO RPD standards, and to start this much needed work, is a European project under the *Partnership for European Research in Occupational Safety and Health* (PEROSH, 2010). The aim of this project is to determine European wide accepted assigned protection factors for a small range of RPD (PEROSH, 2010). Additionally, the project will aim to investigate the effectiveness of RPD training on the protection afforded by comparing PPFs (though interventions will be made in the case of serious health risk) with those subsequently measured under an effective programme. Therefore a crucial step in this project is to decide which is the most appropriate study protocol to adopt for the follow-up study. This work is currently ongoing.

Problems Arising from the Variation in Assigned Protection Factors

As can be seen in Table I, which shows just a few examples of European APFs, there is a large difference in APFs – up to a factor of 10 for some types and classes of RPDs. When the OSHA derived APFs are also considered the variation is even larger for certain types and classes. This variation in APFs can lead to both operational and economic implications for the RPD users. Take for example a multinational manufacturing company who use RPDs for a common task within the company. For efficiency, they may wish to establish a common RPD programme and deploy the same type and class of RPD across their manufacturing sites residing in different countries. The variance of APFs is a barrier to this approach forcing a more localised based RPD programme and different types and classes of RPDs to be deployed thus being unable to realise efficiency savings. This is also true when considering a harmonised approach to RPD selection.

As can be seen from Table I, the UK APFs are significantly lower for some types and classes of RPDs than many of the APFs derived by other countries. The approach taken by BSI has led to conservative, some would say overly pessimistic, values of APFs. The attraction of these values is that if they are in error, the error will tend to be on the side of safety, and should result in reduced exposures for RPD users. However, the need to adopt more complex RPD programmes has operational and economic implications, so while conservative APFs are on the safe side this needs to be balanced with the additional costs. Additionally the higher APF values of other countries could be considered to be optimistic and, unless these are supported by valid data, could be putting end users at risk

DISCUSSION

Studies on the effectiveness of the RPD programmes in the workplace (Alston *et al.*, 1997; Graveling *et al.*, 2009; Bell *et al.*, 2010, 2011) have shown that, more often than not, RPD programmes are not perfect examples of good practice - lacking in areas such as selection, maintenance, training and use.

Some of these shortcomings will have a minor influence on the RPD performance whilst others can have a major influence. Therefore in many cases the current workplace RPD programmes do not meet the requirements implicit in the current definition of the APF.

This obviously raises two questions. The first is “Are the different current APF definitions (which although slightly differently worded are essentially the same) are correct?” Is an APF definition that refers to an effective RPD programme, (i.e. correctly selected, correctly fitted, correctly maintained, etc) - a *standard that many workplaces do not achieve* - suitable for its purpose?

BSI recognised this dilemma to some extent in its setting of APFs in BS 4275:1997 (now superseded by BS EN 529:2005). They had considered rejecting data from studies whose protocols complied with the AIHA WPF definition and where the investigators played a significant role, because these were “*likely to generate optimistic indications of performance*” (BS4275:1997 Annex D.2.2 b). Therefore, this gave rise to the situation where WPF studies that really were carried out under conditions that conform to the BS 4275 definition of APF (*adequately trained and supervised wearers using a properly functioning and correctly fitted respiratory protective device*) were actually rejected. However, due to lack of any alternative data, data from such studies were included in the UK’s APF setting.

The problem is, however, whether there is a better alternative definition, for example one that more accurately reflects shortcomings in the RPD programme. This is probably not possible due to the variation in RPD programme deficiencies.

The second question is “What is the most appropriate workplace performance study protocol to adopt in future studies – studies whose protocols comply with the AIHA WPF definition or the ‘As-is’ protocol?”

The first would generate protection factors that are steered towards the optimum workplace performance potential of a given type and class of RPD, while the latter would be steered towards protection factors more representative of what is actually achieved in the workplace given the findings by Bell *et al.*, (2010, 2011). However, in order to generate sufficient data for the derivation of APFs, data from several studies at different workplaces have to be combined – a process that would be difficult with an ‘As-is’ study protocol because the prevailing conditions will vary from workplace to workplace.

Neither should the study include additional rigorous input by the investigation team over and above that required to ensure that the RPD programme in situ during the study is in compliance with the appropriate local or national regulatory requirements (Myers *et al.*, 1984; Myers *et al.*, 1985; Zhuang *et al.*, 2003). For example, during the BSI deliberation on APF, the use of fit testing by the investigators was considered to be an additional step that may have resulted in higher WPFs, however, fit testing is now a national regulatory requirement in a number of countries and therefore should be considered to be within an effective RPD programme. However at what stage does additional involvement by the investigators start to skew the data? Consider two situations recently encountered during the study reported by Bell *et al.*, (2010, 2011). In the first, a full face mask respirator was being used to protect against silica dust and was missing a gasket between the face mask and the filter creating a real possibility of significant leakage into the mask via this connection. In the second a powered air-purifying respirator (PAPR) was being used to protect against metal dust/fume. The wearer had received some training however he was not fully aware of the need to check that the flow rate being delivered by the PAPR was sufficient prior to using the device. The device was found not to be delivering the manufacturers minimum flow rate, thus creating the possibility of increased leakage into the device. These are ‘As-is’ situations but were clearly deficiencies in the RPD programme and not the RPD.

CONCLUSIONS

It is clear that different workplace performance study protocols can noticeably affect the results measured in the workplace thus contributing to the variance in the values of APFs that exist today. The study protocol for the development of APFs should be based on the requirements for an effective RPD programme - as this is what is deemed to be 'good practice' - which should be in place in the workplace as required by regional or national regulations. Where it is considered necessary for the investigators to improve the RPD programme in place at the study site, the improvement should be restricted to bringing the RPD programme into compliance. APFs, as the definitions imply, relate to adequately trained and supervised wearers using properly functioning and correctly fitted RPD, i.e. in compliance, and are therefore not intended to take poor programme performance into account.

Improving the RPD programme at a study site beyond that of bringing it into compliance may lead to an over estimation of RPD performance thus potentially putting wearers at risk. While some current APF may be considered conservative any increases should only be made if justified by workplace or simulated workplace protection factor data. Because the quality of the RPD programme is essential for adequate control of wearer exposure, future effort for the determination of APFs or ISO PLs should be backed with an educational programme to improve the quality of workplace RPD programmes up to the standard as required by relevant regulations.

APFs are fundamental to wearer protection. Universally accepted APFs will play a vital role in improving the correct selection of RPDs and the realisation of economic savings. Part II of this paper takes a closer look at some of the important elements of a workplace study and makes recommendations for considerations in future workplace protection factor studies. The International Society for Respiratory Protection started the debate on assigned protection factors back in 1996 (Capon, 1996) and with a new suite of ISO RPD standards on the horizon there is a need and the opportunity to revisit the topic of assigned protection factors to ensure that they are fit for purpose.

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