

Performance Studies on Respiratory Protective Devices in the Workplace – Part II: Towards a unified approach

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ABSTRACT

The assigned protection factor (APF) is a fundamental parameter used when selecting adequate respiratory protective devices (RPD). Various methods have been used to arrive at current APFs, including workplace protection factor (WPF) studies. Many published papers report these results but as yet there is no common international protocol for conducting, analysing and reporting workplace performance studies. The protocols adopted vary according to the objectives of the study, and the protocol and objectives are not always clearly defined. The lack of a harmonised approach to workplace performance studies has partly been responsible for the huge differences in assigned protection factors that can be seen across the world. Part I of this paper discussed the issues surrounding the derivation of APFs and the need for a harmonised approach to future workplace studies. Part II discusses the key elements of workplace performance studies and makes recommendations for consideration with the aim of achieving a harmonised approach to WPF studies.

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

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INTRODUCTION

It is generally, though not universally the case that RPD performance measured in the workplace is lower than that typically achieved when measured in the laboratory. This is due to the interaction of many different factors that are not present when conducting laboratory tests - such as the care with which the RPD has been correctly selected, its suitability for the wearer, the task and the environment, the degree of training received by the wearer, the care with which the device has been donned and how the device is used. APFs are designed to more accurately reflect the likely workplace performance so that improved RPD selection and thus improved wearer protection is achieved.

APFs have been derived by various organisations using different approaches. These different approaches include a mix of workplace performance studies, laboratory studies, the application of safety (or correction) factors to the nominal protection factors (NPFs), and professional judgement (OSHA 2009; BSI 1997; DGUV 2004). As a result the current APFs vary considerably across the world.

With a new suite of ISO RPD performance Standards under development (ISO/TC94, Personal safety - Protective clothing and equipment, Subcommittee SC15, Respiratory protective devices), current and future RPD meeting these standards will have a different classification to that which exists today and therefore it may not be possible to apply the existing APFs to these new classes of RPD. Consequently further workplace performance studies to generate new APFs may be required.

Part I of this paper (Clayton *et al.* 2012) discussed the issues surrounding the derivation of APFs and the need for a harmonised approach to future workplace studies. This paper discusses the key elements of workplace performance studies and makes recommendations for consideration with the aim of achieving a harmonised approach to WPF studies.

Workplace performance studies and the associated data are subject to many influences and variables. These variables include for example, study protocol (Johnston *et al.* 1992; Brown 1992; Nelson and Meagher, 1996; Nelson, 1995, 1996), wearers (Clayton *et al.* 2002), worksite (Howie *et al.* 1996), work process (Johnston *et al.* 1992), the contaminant measured (Zhuang and Myers, 1996), sampling methods (Myers *et al.* 1986; Bostock, 1988), data analysis methodology (Cherrie, 1996; Vaughan and Rajan-Sithamparanadarajah, 2005). This paper following discusses the key elements of workplace performance studies and recommendations are made for consideration by researchers and regulators with the aim of achieving a harmonised approach.

METHODS AND MATERIALS

RPD programme. A fundamental parameter of any workplace performance study is the quality of the RPD programme in operation at the study site. When the objective of the study is to measure the performance that can be provided by the RPD, i.e. a WPF study, then the minimum requirement for the RPD programme is that it is in compliance. It is worth noting that Bell *et al.* (2011) identified that less than half of the workplaces examined had anything approaching an effective RPD programme - lacking in areas such as selection, maintenance, training and use. While some of these shortcomings will have a minor influence on the RPD performance others, such as the lack of fit testing, can have a major influence. Therefore it is essential that the RPD programme be reviewed for compliance.

Because the employer is responsible for the RPD programme it is preferred that RPD selection, use (including training) and maintenance are carried out by the employer. Where it is necessary for the investigators to improve the RPD programme, e.g. where training in correct donning is weak, then the improvement should be restricted to bringing the RPD programme into compliance. Actions beyond that, such as the investigators assisting in the donning process or training (Myers *et al.* 1984; Zhuang *et al.* 2003) could result in optimistic indications of performance.

RPD Selected for the study

Condition of the RPD. Prior to commencing the study it should be established that the RPD selected is adequate for the specific contaminant and level of contamination, and is suitable for each of the individual wearers and for the intended tasks that will be undertaken in the study.

In addition the RPD used in WPF studies should be:

- Certified in accordance with national regulations, correctly assembled and maintained in good working order;
- Compliant with the manufacturers' specification verified prior to and on completion of the study measurement period, e.g. operating at the correct air supply flow rate, supply pressure, battery condition, etc.

RPD filters. New filters should be fitted at the start of each WPF study measurement period. Where the contaminant assessed in the study is a vapour or gas, the filters used should be suitable for the given conditions e.g. concentration, ambient temperature and humidity, work rate etc. and have a service life adequate for the intended duration of the task.

Wearer parameters

RPD training and wearing experience. Wearers should be selected from workers who wear RPD as part of their routine work activity and who have received adequate training, (preferably by the employer), in the use of the RPD under study. Well-trained wearers will be more likely to work with less interference on the performance of the RPD. Although WPF studies should take into account the effect of work on RPD performance, it would be wrong to include in the determination of APFs data resulting from work activities where insufficient training has been given on how to perform the task while wearing the RPD.

Willingness. Co-operation between wearer and investigator is vital for a successful workplace performance study. A willing wearer is more likely to report facts that may have an effect on the performance of the RPD or the reliability of the sample, such as inadvertently switching off a powered air purifying respirator or the sampling system, or knocking the respirator filter, the facepiece or the sampling train.

The study will require the wearer to strictly adhere to the respiratory use policies in operation in the workplace and also to the study protocol. The wearers should be instructed not to remove the RPD or lift the facepiece off their face (e.g. to speak) while in the work area and during the sampling period. Adjustment for comfort, as would be normal wearer practice, should be allowed.

Observation of the wearer throughout the sampling period is crucial to ascertaining the validity of the data collected. However, the presence of the investigators, especially on a one-to-one basis, during the study may possibly cause behavioural changes by the wearers leading to them adopting a different, perhaps safer, style of working (Myers *et al.* 1984; Howie *et al.* 1996). Although no evidence of 'observer effect' was found during the OSHA APF rulemaking process (OSHA, 2006) it would seem sensible to consider the possibility of 'observer effect' during WPF studies.

Facial dimensions. Ideally, the facial dimensions of the wearers should be measured. This would provide useful data which can be used to determine whether the facial dimensions of the study population is comparable to other similar workplaces or other groups of wearers. This data could also be related back to laboratory evaluation of RPD (for 'certification' purposes) where facial dimensions have been recorded (e.g. CEN and AS/NZS standards) or where the facial dimension of the TIL test panel are specified (NIOSH and ISO standards).

ISO has recently published a draft Technical Standard ISO/TS 16976-2 (ISO 2009^a) on anthropometrics which contains information on facial sizes and provides guidance on the measurements to be taken.

Facial hair. Wearers with facial hair should be checked to ensure that the facial hair does not interfere with the face seal of the facepiece. Many studies on tight-fitting RPD have demonstrated that facial hair in this region is detrimental to respiratory protective performance (Stobbe, 1988; Bolsover, 1992). Few studies provide sufficient detail on whether facial hair is present or not, for example in a WPF study by Janssen *et al.* (2007^a) it was reported that the male wearers '*were generally clean shaven... although several did not shave each day before work*'. When conducting studies every effort should be made to encourage wearers to be clean shaven, where appropriate, at the beginning of each sample period.

Fit testing. The definition of the APF refers to 'correctly fitting devices' (EN 529, CEN, 2005), or a 'properly fitted wearer' (ANSI), therefore wearers of RPD incorporating tight-fitting face/neck seals should be fit tested. When Stacey (1998) reviewed the study by Howie *et al.* (1996) in which fit testing was not carried out (not a national mandated requirement at that time), and rejected data based upon the likelihood that the RPD employed in the study did not fit two wearers, the 5th percentile of the remaining data increased from 40 to 198.

All wearers participating in the WPF study should have passed a fit test in the make, model and size of RPD they will be wearing in the study. The fit testing methods, protocols and pass criteria should follow established national procedures (ANSI/OSHA/HSE). It is worth noting that the criteria vary between countries and may also vary between the various types of legislation that exist within the same country. For example, in the UK the recommended level for a full face mask is 2000, whereas OSHA recommends a level of 500.

Workplace site selection

Representative workplace site. APFs are related to specific types and classes of RPD and are not related to specified workplaces. Therefore for an APF to be applicable across a range of workplace settings the WPF data on which it is based should be obtained from, or representative of, the range of workplace settings in which the RPD is typically used.

Job/task and work rate. Increasing the wearer's work rate will lead to an increase in the wearer's breathing rate. This can lead to the possibility of over-breathing air supplied devices such as air fed hoods and powered air purifying respirators resulting in increased inward leakage (Da Roza *et al.* 1990, Bostock, 1985^a). Gijp *et al.* (2004) reported a reduction in protection factors during a simulated workplace protection factor (SWPF) study due to increased breathing rate. Therefore the work rate associated with the task performed during the study may be another variable that can lead to a different performance measurement. Steps should be taken to determine the (metabolic) work rate of the wearers involved in the study. Observations of their work/task can be compared with descriptors on work, such as in ISO 8996:2004 (ISO 2004) to obtain an estimate of the work rate.

The use of video-exposure monitoring (VEM) which involves the combination of real-time monitoring instruments, usually for gases/vapours or dust, with video of the worker's activities, has proved a useful occupational hygiene tool (Rosen *et al.* 2005, Martin *et al.* 1999). Adaptation of this technique to associate real-time in-facepiece sampling with wearer movement can be a useful tool to identify wearer actions that result in increased inward leakage.

Workplace contaminant. A number of authors (Wallis *et al.* 1993; Tannahill *et al.* 1990; Howie *et al.* 1996) have reported that there is an apparent relationship between contaminant concentration and the measured protection factor. A high contaminant concentration tends to lead to higher WPFs. Various reasons for this relationship have been suggested including mechanical effects relating to particle size (Holton and Willeke, 1987; Myers *et al.* 1991), wearer behavioural effects (Moore and Smith, 1976; Campbell and Lenhart, 1985; Howie *et al.* 1996) and analytical detection limits (Stacey, 1998; Johnston *et al.* 2000; Vaughan and Rajan-Sithamparanadarajah, 2005).

Holton and Willeke (1987) and Myers *et al.* (1991) suggested that the reason that RPD are more efficient in higher dust concentrations might be due to the differences in particle size distribution on the assumption that higher concentrations contain a higher percentage of larger particles which do not penetrate the RPD to the same degree as smaller particles.

Myers *et al.* (1991) investigated the effect of particle size and challenge substance (gas/vapour vs particulate) through capillary face seal leaks on a manikin. They found that a gas challenge was more penetrating than an aerosol challenge and also concluded that increasing particle size was associated with a decrease in penetration through the capillary leaks. Similarly, Cho *et al.* (2010) in tests using manikins found that face seal penetration decreased with increasing particle size.

However, the degree of particle size-selectivity of face seal leaks in real workplace conditions is unclear. Whilst the WPF study by Lee *et al.* (2005) also demonstrated a particle size-selective effect, particle shape may have an influence on the penetration through face seal leaks.

Other workplace studies have also questioned the relationship between particle size and WPF. In studies performed by Myers *et al.* (1995), and Janssen *et al.* (2007^{ab}, 2010) large particles (i.e. $>10\mu\text{m}$) were found inside the respirator facepiece. It was proposed that in actual use, face seal leaks, due to a momentary break in the seal, are dynamic and do not act like fixed leaks that are often used in laboratory investigations, concluding that small face seal leaks may exhibit particle size selectivity whereas larger leaks would tend not to.

Depending upon the analytical methods employed and whether respirable or total inhalable dust fractions are relevant, large particles will have a proportionally greater influence on the calculation of mass-based protection factors. In studies conducted by Myers *et al.* (1996, 1998) the respirable fraction (RF) of the challenge was measured and was found to be associated with the WPF – the lowest geometric mean (GM) WPF value was associated with the highest RF and the highest GM WPF value was associated with the lowest RF. It is essential that both C_o and C_i must be based on measurement of the same (respirable or inhalable) dust fraction.

Moore and Smith (1976) and Howie *et al.* (1996) suggested that wearer behavioural effects may explain the apparent relationship between C_o and WPF. They proposed that wearers exercise more care in donning and use of RPD when the contaminant concentration is known to be higher, as the perceived risk to health is greater. Campbell and Lenhart (1985) suggested a similar reason for low PPF values in workplaces of low exposure.

Often the in-facepiece sample can be relatively low and lie near or below the detection level of the analytical method employed. This can lead to large uncertainty of measurement for concentrations close to the detection limit with possible rejection of unquantifiable results from a data set. Stacey (1998), Johnston *et al.* (2000) and Vaughan and Rajan-Sithamparanadarajah (2005) suggested that analytical detection limits can constrain the values of C_i which may give rise to a spurious apparent relationship between WPF and C_o .

Whatever the reason for this apparent relationship it is important that these factors are considered when calculating WPFs and deriving APFs. It is therefore recommended that the nature and size distribution of the workplace contaminant employed in the study is determined.

Sampling

Data collected from several donnings. WPF studies must consider the statistical validity of data collected from just one donning of the RPD. Some RPD are more prone to fit variation than others, e.g. tight-fitting facepieces as opposed to loose-fitting devices. Measurements should therefore be taken over

a number of donnings with the wearers using the same RPD and following the same pre-use and donning procedures.

Number of samples. The design of the WPF study should provide a sufficient number of paired-samples (C_i & C_o) to enable suitable statistical analysis to be carried out and the APF to be derived with a degree of confidence. Table I below, taken from the *European Commission report: Human Exposure to Biocidal products: Technical Notes for Guidance* (EC 2007), can be used as an indication of the necessary sample sizes based on the spread of data, assuming that the WPF data will have a log-normal distribution.

Table I. Scaling Factors to Obtain 90% Confidence Interval for a 5th Percentile with a Variety of Sample Sizes and GSDs

Sample Size	Geometric standard deviation				
	2	3	4	5	6
5	2.19	3.45	4.78	6.15	7.55
10	1.74	2.4	3.02	3.61	4.18
20	1.48	1.86	2.19	2.38	2.75
50	1.28	1.48	1.64	1.78	1.9
100	1.19	1.32	1.42	1.50	1.57

For example, if the 5th percentile of a WPF data set ($n=20$) is 40, and the GSD is 3, the 90% confidence interval will be between ($40 / 1.86$ to 40×1.86), e.g. 21 to 74; but if the sample number was increased to $n=50$, the 90% confidence interval will be between ($40 / 1.48$ to 40×1.48), e.g. 27 to 59.

Due to the influence of the wearer on the performance of the RPD, e.g. variation in face fit and breathing rate between wearers, no one wearer/RPD data set should form more than 10% of the whole data set in order to reduce individual wearer bias.

Sampling procedures. The sampling method employed will depend on the nature of the contaminant to be sampled i.e. dust, gas, vapour etc. The vast majority of studies have employed a filter sampling technique based on the collection of the workplace contaminant over a period of time. This has the advantage of being a relatively simple and wearer/workplace friendly procedure, but with the disadvantage of not being able to generate WPF results until post-sampling analysis has been conducted.

Sampling system. The sampling system should be designed such that that integrity of the RPD is not affected. Modified facepieces and sample probe should be tested to ensure that no leaks have been created.

Sampling trains including sample probes should be as light as possible, must not prevent the RPD from fitting correctly or interfere with the ability of the wearer to perform their task. They should preferably comprise electrically conducting materials to help minimise particle losses. To reduce variation in sample losses in the sampling trains between C_o and C_i , identical sampling trains should be used where possible.

Sampling trains should be sufficiently robust to withstand the conditions under which they will be used. Factors such as rough usage, environmental conditions, nature of the workplace contaminant, etc. should not have an effect on the sample collected. Where it is known that such factors may be present

and may have an effect on the sample then precautions should be taken to minimise this effect, for example, the employment of coil-heaters to prevent condensation.

The integrity of the sampling system should be verified before the wearers enter the contaminated work area or start the task.

In-facepiece sampling (C). It has long been recognised that face seal leaks do not mix well inside the facepiece (Myers *et al.* 1986, 1988^{ab}; Oestenstad *et al.* 1990), and that in-mask sampling has to be carried out with care to reduce the sampling bias in order to obtain a representative in-mask sample.

Myers *et al.* (1986, 1988^{ab}) and Oestenstad *et al.* (1990) showed that leakage through the face seal may cause streamlining of air flows within the facepiece cavity during inhalation. This lack of mixing within the facepiece cavity can lead to under or over-estimation of the leakage (Bostock, 1985^b, 1988).

Myers and Hornung (1993) concluded that the “CLF sampling procedure” utilising a probe described by Liu *et al.* (1984) and fitted close to the inner surface of the facepiece could result in an underestimation of the in-facepiece concentration by between 7 and 41% for negative-pressure facepieces. If the same degree of sampling bias was present in WPF studies then the measured WPF could be overestimated by a factor of up to 1.7 (BSI, 1997). The same authors also concluded that the sampling bias could be reduced by the utilisation of a deep probe located close to the mouth of the wearer.

The AIHA Respiratory Committee (Nelson and Meagher, 1996) discussed the scientific and technical issues regarding workplace protection factor studies and recommended that the advice given by Johnston *et al.* (1992) in relation to in-mask sampling should be adopted where possible:

- Probe positioned midway between the nose and mouth;
- Probe positioned not flush with the inner surface of the facepiece but as close to the face as possible
- Use of an inlet probe that minimises particle loss (Liu *et al.* 1984).

Bostock (1985^b, 1988) reported that sampling bias relating to probe location (deep cf. flush) can be significantly reduced by the use of a multi-holed sampling probe positioned at a point close to (approximately 5-10mm) and directly in front of, the wearer's lips. This design of probe was later adopted by the European standards (CEN, 2001^a) for the measurement of inward leakage.

It is therefore recommended that the in-facepiece probe should be located as close to the wearer's face as possible and at a position half way between the mouth and the nose. Multi-holed probes, (CEN, 2001^a) or probes designed to minimise particle loss should be used.

Sampling rates from the facepiece. A sample of air must be withdrawn from the breathing-zone of the wearer within the facepiece cavity in order to obtain a measure of the concentration of the contaminant. The method employed in sampling (i.e. the sample flow rate, continuous or pulsed sampling, sample return), must be considered against the type of RPD being investigated, the nature of the contaminant and also the analytical method to be used.

Sample rates of 1-2 l/min have been used in many WPF measurements. This sample rate is low enough to avoid significant pressure changes inside the facepiece. However, such low sample rates, (from experience gained in CEN inward leakage testing and simulated workplace protection factor studies) can lead to moisture build-up in the sampling lines and cassettes, especially on RPD such as filtering half masks, and can have an effect on the measurement. This can be reduced by introducing

drying air into the sample lines. EN149 (CEN, 2001^b) employs such a measure; moisture traps and heating coils have also been successfully used.

In powered and supplied air RPD a higher sample rate e.g. 3 - 5 l/min can be used without any problems associated with increasing the in-facepiece negative pressure. Myers and Hornung (1993) showed that higher flow rates can also reduce the sampling bias.

Nelson and Colton (2000) and Janssen and Weber (2005) found that wearers with acceptable fit (i.e. meeting the OSHA criteria for leak rate for acceptable fit) did not experience an increase in face seal leakage with an increase in pressure drop. However, during WPF studies there is no guarantee that the fit will always be adequate and therefore it is still good practice to employ low sampling rates where possible. Additionally, low sample rates may equate to smaller sampling pumps and thus less interference/burden for the wearer.

Many studies (for example Colton *et al.* 1990; Myers, 1984; Hewson, 1992) have reported that on occasions the in-facepiece contaminant collected was too low to be accurately measured. Increasing sample rates and sampling times may or may not be an option. For RPD with high APFs, obtaining a sufficient quantity of in-facepiece sample C_i to allow for an accurate determination of the in-facepiece concentration can be difficult.

Ambient sampling (C_o). The type and position of the ambient sampling head used and the sampling flow rate is as critical for the measurement of C_o as for the C_i .

The ambient sampling head should be located in the general area of the RPD wearer's breathing zone. Typically this sample probe is attached to the wearer's lapel. However, caution should be exercised to ensure that the position of the sample head is away from the path of the RPD's exhaust wash.

To have sufficient confidence in the WPF measurement, a minimum amount of workplace contaminant concentration is required. Johnston *et al.* (1992) recommended a minimum C_o for mass-based analytical methods that is based on the APF of the RPD involved in the study as follows:

$$\text{Minimum } C_o \text{ analyte mass (e.g. ng)} = 10 \times \text{APF} \times \text{mean field blank analyte mass} \dots(i)$$

Similarly Vaughan and Rajan-Sithamparanadarajah (2005) recommend rejection of data pairs containing values of C_o where $C_o < \text{assumed APF (for the device)} \times \text{detection limit of the analytical method}$, as data in this region are inherently unreliable.

Quality assurance and validation of the sampling method. Equipment requiring calibration such as sample pumps and gas analysers should be calibrated before and verified after each sample. Where 'non-standard' sampling techniques are employed these must be validated and the information on the validation undertaken should be included in the reporting. This validation could be in relation to standard sampling methods and incorporate, where applicable, a series of inter laboratory tests.

A series of sample blanks, for both C_i and C_o (the field blanks in equation (i)), should be taken as controls. This will identify any contamination of the samples from sources other than leakage into the RPD, and help in defining the detection limit of the system.

In principle, any measuring instrumentation that satisfies the necessary requirements for sampling (already described), and for analysis of collected data (see below) can be used, subject to some practical limitations:

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- for filtering collection systems, effects of moisture in exhaled breath and other substances in the challenge environment not related to the specific workplace contaminant to be measured, must be considered and eliminated;
 - for gas/vapour measurement systems, potential interferences from other substances in the challenge environment, or in exhaled breath (e.g. variable oxygen, carbon dioxide or water vapour concentrations), must be considered and eliminated;
 - for direct-reading and logging systems (such as on-line particle counting, vapour detection or light scattering systems), synchronisation of external challenge and in-facepiece samples will be critically important where challenge concentrations vary within the work area and with time;
 - for detection systems where measured response varies with particle size (e.g. for light scattering), correction may be necessary to compensate for size distribution differences outside and inside the facepiece.

The principles of numerous established sampling procedures may assist in the development of WPF measurement procedures (HSE 2000; HSE 2005; ISO 1999; ISO 2009^b; WHO 1997).

Data analysis

Vaughan and Rajan-Sithamparamanadarajah, (2005) proposed various criteria to be met if meaningful measurements are to be made. It is essential that the study design should take account of the conditions to be satisfied for C_o and C_i such that reliable estimates of workplace performance can be calculated, and adopt a method for rejecting unreliable data based on the detection limits of the analytical measurement system.

Nicas and Neuhaus, (2004) proposed an alteration to the way that APFs are calculated from WPFs. Rather than calculating the APF at the 5th percentile of the ranked data set, they suggested the following criteria: "(1) For a given wearer, an acceptable WPF distribution has no more than 5% of WPFs below the APF value; (2) For a wearer population, no more than 5% of wearers have unacceptable WPF distributions." Applying these criteria to the data from seven workplace protection factor studies using half masks, they suggested that the current NIOSH-assigned APF of 10 should be reduced to 5. One possible explanation suggested by the authors for the discrepancy in values is the difference in WPFs measured depending on the contaminant, with gas-phase and small particulates giving lower WPFs than large particulates.

Crump, (2007) showed that the Nicas and Neuhaus criterion is inherently more conservative than that of OSHA, and applied a modified version of their model (including use of the maximum likelihood principle for non-detects) to the data from additional half-mask WPF studies. The results marginally supported an APF of 10 for these devices.

The Nicas and Neuhaus and Crump models require that either multiple measurements of WPFs be made on the same individual or multiple measurements of WPF be made using different contaminants. Therefore while these approaches may be applicable to some WPF studies where these data exist or can be collected, they may not be suitable approaches for all WPF studies. Until the above analysis methods have been verified and adopted by the respirator community, the generally accepted method of basing the APF on the 5th percentile of the ranked data set should continue and the recommended treatments by Vaughan and Rajan-Sithamparamanadarajah (2005) for non-detects should be followed.

RPD grouping

In the setting of the current APFs (BSI 1997; Nelson 1996), various types and classes of RPD were grouped together on the basis that they were likely to perform similarly. APFs were then assigned across these groups based on workplace performance data which was available for the 'benchmark' device. Whilst this is not ideal, it does seem to be a logical and acceptable approach in the absence of workplace data. Workplace performance studies are costly and lengthy therefore, where it is possible, data gathered on 'benchmark' devices from appropriate, well defined and executed WPF studies, should be used to develop APFs for other types of RPD. Table II shows examples of RPD grouping:

Table II. Examples of RPD Grouping

'Benchmark' device		'Equivalent' devices
Air Purifying Respirators (Negative pressure devices)	Half face mask	• Unassisted fresh air hose breathing apparatus with half mask [EU] • Negative demand compressed air line breathing apparatus with half face mask [EU] • Demand supplied-air half face mask [US]
	Full face mask	• Unassisted fresh air hose breathing apparatus with full face mask [EU] • Negative demand compressed air line breathing apparatus with full face mask [EU] • Demand supplied-air full face mask [US]
Powered Air Purifying Respirators (Assisted devices)	Half face mask	• Assisted fresh air hose breathing apparatus with half mask [EU] • Continuous flow compressed air line breathing apparatus with half face mask [EU] • Supplied-air respirator continuous flow mode with half face mask [US] • Pressure-demand supplied-air respirator with half mask [US]
	Full face mask	• Assisted fresh air hose breathing apparatus with full face mask [EU] • Continuous flow compressed air line breathing apparatus with full face mask [EU] • Supplied-air respirator continuous flow mode with full facepiece [US] • Pressure-demand supplied-air respirator with full facepiece [US]
	Loose-fitting facepieces	• Continuous flow compressed air line with loose-fitting facepieces [EU] • Supplied-air respirator continuous flow mode with loose-fitting facepieces [US]
	Hoods/Helmets	• Assisted fresh air hose breathing apparatus with hood [EU] • Supplied-air respirator continuous flow mode with helmet/hood [US]

EU – European terminology

US – USA terminology

REPORTING WORKPLACE PERFORMANCE STUDIES

WPF studies require considerable resources, are costly and the process is time consuming. Therefore every effort must be made to maximise the use of the data.

Johnston *et al.* (1992) suggested that clear and consistent terminology must be used for study results to be meaningful. The International Society for Respiratory Protection (Capon, 1996) endorsed efforts to establish a common set of guidelines for best practice when conducting and reporting workplace protection factor studies. Core information for reporting RPD workplace performance studies may be defined as “*The minimum information required to accompany WPF data to enable its validation and wider use*”. Reporting of core information is essential if the full value of the data is to be realised.

Key categories and data elements. The placing of the data elements and their associated information in discrete key categories will help to harmonise and simplify publications and presentation on workplace performance studies. Following a review of published workplace performance studies the recommended key categories are shown in Table III, together with their descriptors. The proposal for the essential and desirable sets of data elements within each of the key categories is given in Table IV.

Table III. Key Categories and Their Definitions

Key Category	Descriptor
Study objective	The type of study and approach adopted for determining the performance of RPD or the RPD programme – e.g. WPF, SWPF or PPF
RPD	A device designed to be worn in a contaminated atmosphere and to provide its wearer with a supply of breathable air. The device(s) under test.
Wearer	The person who is wearing the RPD under test.
Job/Task	The task undertaken by the worker during the period of sampling.
Workplace	The defined area or areas in which monitored wearers' activities are carried out.
Contaminant (Chemical Agent)	Any chemical or compound, on its own or admixed, which is normally present or is generated in the workplace for the purpose of the study, which is used as a contaminant to determine the workplace performance of the RPD.
Sampling methods	The methodologies (and their descriptions) used to obtain a representative sample for determination of the contaminant concentration inside the RPD and in the air surrounding the RPD.
Analytical method	A method (and its description) which will identify and quantify the contaminant concentration inside the RPD (C_i) and in the air surrounding the RPD (C_o).
Results	The data collected from the study, values of C_i and C_o .
Exposure modifiers	The workplace, wearer, activity and RPD factors that may be likely to influence the performance and effectiveness of the RPD under test.

Presenting the core information

Study objective. It is necessary to clearly indicate which type of protection factor e.g. WPF, PPF etc., is being measured.

RPD. This should be sufficiently detailed to enable the reader to identify and compare product specifications which are applicable in their country. The RPD designation/classification should be given together with other details to give sufficient information about the RPD. For example, when describing a negative pressure tight fitting facepiece details should include for example, full face mask, make, model, material, and information about its condition. Filter specification should include type and class, and whether the filter is new or previously used. Other details such as air supply flow rate, battery charge, and any other data elements which may have an effect on the performance of the RPD, should be included.

Wearer/task. In this category, information about the wearers and their activities should be recorded. The task is the major activity undertaken by the worker during the period of sampling. The worker's level of experience and training (both on the task and on the use of RPD), and who carried out the training should also be reported. Information on facial hair is extremely useful when assessing the results to decide whether the data can be included or excluded for the purposes of assessing the effectiveness and setting APFs. Information on facial sizes and sex will similarly be very useful.

Workplace. The data elements in this category provide specific information about the workplace where the study was conducted. When describing processes it would be sensible to use internationally recognisable terms, such as those published by the International Labour Organisation (ILO 1991). The information on this data element should contain sufficient details about the economic activity undertaken at the study site. This would help those using the data, as well as those proposing to carry out studies in similar environments.

The workplace environment can have an effect on the performance of the RPD. It is recognised that sweating can lead to loss of face seal integrity and hence increased face seal leakage (Gardner, 1999; Caretti 1999; Clayton, 2002; Gijp, 2004). The environmental conditions that exist in the study sites are often not reported. This is an important exposure modifier and details of the temperature, humidity and other factors, like high ambient air movement which can increase leakage into loose fitting facepieces, should be reported. Observations of sweating or shivering should also be reported.

Contaminant (chemical agent). It is common for reports to contain common/trivial names of chemical agents. The inclusion (where applicable) of either the Chemical Abstract Services (CAS) or European Economic Community (EEC) number will help to identify the agent in question with greater certainty. If the challenge is in particulate form, the typical airborne size distribution(s) involved should be reported.

Sampling method. The sampling information should include detailed description about challenge and in-facepiece samplers, their positions, sampling losses, probe designs and locations, sampling flow rates and durations and whether sampling over partial or full breathing cycle. Information on any validation undertaken to assess the performance of in-facepiece samplers should be included.

Analytical method. This section should provide details of all the analytical methods used, including the following: the detection limit applicable to the sampling and analytical methods; the uncertainty of measurement and the response times of any 'real-time' measuring instrumentation.

Results. It is necessary to list individual paired values for C_i and C_o . The lack of individual results can limit the overall usefulness of the paper and the study information contained. The data analysis section should describe how the data was treated, and methods adopted for dealing with systematic errors involved in the sampling and analytical procedures. It should make clear reference to the techniques

used for data analysis. Ideally, the report should present the raw WPF data plus, where appropriate, the arithmetic mean, harmonic mean, geometric mean, geometric standard deviation, WPF range, and percentile values at 50th (median) and 5th (the value corresponding to the APF) and the upper and lower WPF detection limits. If during the analysis it was decided to reject data, a clear explanation should be provided of the rejection criteria and those data points rejected should be identified clearly.

Exposure modifiers. Accurate information on exposure modifiers is vital for assessment of workplace performance data. The major factors that can influence the effectiveness of respiratory protection are listed in this category (see Table IV). There is a need for convergence and better reporting in this area.

Table IV. Recommended Data Elements under Key Categories

Study Information	
Essential	Desirable
Study protocol - Study methodology - Deviations from the protocol	
RPD <i>Type of RPD</i> - Class, make, model and Type - Type of facepiece - Operating specifications (pressure/ flow etc.) - Size and material of facepiece - Type of filter <i>Condition of RPD</i> - Level of maintenance - RPD use (in accordance with manufacturer's instructions)	- Date of RPD manufacture - Pre- and post-test filter penetration
Wearer - Sex - Facial hair condition (if present) - Spectacles - Fit tested/ method /pass criterion - Training (RPD and work task) - Experience wearing RPD - Non-PPE accessories	- Facial characteristics/measurements - Medical fitness
Job - Description of the task - Work rate - Duration of wear/exposure - Other PPE worn - Tools used	
Workplace (site) - Economic Activity - Work area and process - Ambient conditions (e.g. temp. hum.) - Air movement	

Study Information	
Essential	Desirable
Contaminant - Contaminant(s) measured for the determination of the WPF - Particle size distribution - Other contaminants(s) present	Composition of contaminant measured (if not obvious)
Sample collection - Sampling methodology - Sample locations, placement inside and outside facepiece - Probe design - Duration and rate of sampling - Validation	Correlation of WPF sampling methodology with Standard Inward Leakage test methodology
Analytical method(s) - Measurement methodology - Detection Limit for Ci and Co - Method reference	
Results - Paired values of Ci and Co - Range, Harmonic mean of WPF data, 5th and 50th percentiles - Data analysis information - Data rejection criteria	Rejected data
Exposure modifiers - Pre-use fit check - Donning/doffing/decontamination procedures - Non-wear periods - Supervision of the RPD programme - Investigators interventions	

CONCLUSIONS

A great many studies have been conducted yet there is still much to be learnt, e.g. the relationship between contaminant concentration and protection factor and the effect of particle size on protection factor. Workplace performance studies are very expensive and unless they are carried out with consideration to points raised in this and many other papers they will continue to be of only limited value. Consensus is needed in order to set common protocols and means of reporting, which is the aim of this paper.

It is also recommended that future reports adopt key categories of information identified in this paper and include sufficient information on the minimum data elements identified in Table IV.

In recommending the above, it is recognised that much of the currently available data does not follow the recommended format or provide sufficient information on all data elements. Nevertheless, a majority of these data have contributed to our current understanding of RPD performance in the workplace and are usable to give direction to future workplace performance studies.

The authors would like to encourage organisations, which have an interest in RPD and their workplace performance, to study the recommendations in this paper and consider adopting them. If this approach is accepted it would be a major step forward and would have national, European and international implications for improving respiratory protection in the workplace.

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REFERENCES

- Bell N, Vaughan N, Morris L and Griffin P. (2011) An assessment of workplace programmes designed to control inhalation risks using respiratory protective equipment. *Ann. Occup. Hyg.*, pp1-12, doi:10.1093/annhy/mer109
- British Standard Institution (BSI). (1997) Guide to implementing an effective respiratory protective device programme, BS4275:1997, British Standard Institution, London.
- Bolsover SM. (1992) Leakage Measurements on Wearers of Respiratory Protective Equipment with Facial hair/Beards/Spectacles: Summary of a Literature Search. *JISRP*, pp.15-22, Fall 1992.
- Bostock GJ. (1985a) An investigation into the performance of positive pressure powered dust hoods and blouses and low flow rates. *Ann. Occup. Hyg.* Vol. 29, No.3 pp. 415-420.
- Bostock GJ. (1985 b) The effect of probe position and dead space on the measurement of face seal leakage. *ISRP International Conference*, York, UK.
- Bostock GJ. (1988) Further studies on the effects of probe position and dead space on the measurement of face seal leakage. Health and Safety Executive, Research and Laboratories Services Division. Internal report IR/L/RA/88/20. www.hse.gov.uk.
- Brown RC. (1992) Protection Factors of Respirators with Special Reference to Dust Respirators. *JISRP*, Vol. 10, Issue 1, pp. 5-33.
- Capon A. (1996) Protection factors who do they protect? *JISRP*, Vol 13, Issue 3, pp.19-25.
- Campbell DL and Lenhart S.W. (1985) Letter to the Editor. *Am Occ Hyg* 29 pp.114 –116.
- Caretti DM and Gardner PD. (1999) Respirator fit factor performance while sweating. *Am Ind Hyg Assoc J* 60 pp. 84-88.
- Cherrie JW and Maclaren W. (1996) Relations between in-mask and ambient concentration. *Am Ind Hyg Assoc J* 57 pp. 396-397.
- Cho KJ, Reponen T, McKay R, Shukla R et al. (2010) Large particle penetration through N95 respiratory filters and facepiece leaks with cyclic flow, *Ann Occ Hyg* Vol. 54. No.1 pp. 68-77.
- Clayton MP, Bailey AE, Vaughan NP and Rajan B. (2002) Performance of power assisted respirators during simulated asbestos removal. *Ann. Occ. Hyg.* Vol. 46, No.1 pp.49-59.
- Clayton MP, Rajan-Sithamparanadarajah B and Vaughan NP. (2012) Performance studies on respiratory protective devices in the workplace – Part I: Variation in Measures of Performance. *JISRP*, Vol. 29, Issue 1, pp. 30-40.
- Colton CE, Mullins HE and Rhoe CR. (1990) Workplace protection factors study on a half-mask respirator in a brass foundry. *Proceedings American Industrial Hygiene Conference Orlando, FL*.
- Crump KS. (2007) Statistical Issues with Respect to Workplace Protection Factors for Respirators. *J Occ Environ Hyg*, 4: 3, pp. 208 - 214.
- DGUV. (2004) Benutzung von Atemschutzgeräten, BGR/GUV-R190, Deutsche Gesetzliche

- Unfallversicherung.
- European Committee for Standardization (CEN). (2001a) Respiratory protective devices - Methods of test - Part 1: Determination of inward leakage and total inward leakage EN 13274-1:2001. European Committee for Standardization, Brussels.
- European Committee for Standardization (CEN). (2001b) Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking EN 149:2001. European Committee for Standardization, Brussels.
- European Committee for Standardization (CEN). (2005) Respiratory protective devices - Recommendations for selection, use, care and maintenance - Guidance document EN 529:2005. European Committee for Standardization, Brussels.
- European Commission (EC). (2007) Human Exposure to Biocidal products: Technical Notes for Guidance; Annex 5: Confidence intervals for percentiles of exposure distributions, Joint Research Centre Human Exposure to biocidal products.
http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/TNsG/TNsG_ON_HUMAN_EXPOSURE/TNsG%20-Human-Exposure-2007.pdf
- Gardner P and Caretti M. (1999) Assessment of Respirator Fit during Exercise in a Hot Environment. ISRP Conference.
- van der Gijp S and Steenweg L. (2004) Respirator Performance during Military Field Trials. JISRP, Vol. 21, Issues 3 & 4, pp.135 – 141.
- Hewson GS and Ralph MI. (1992) Determination of program protection factors for half-mask respirators used at a mineral sand separation plant. Am Ind Hyg Assoc. J. 53: pp. 713-720.
- Holton PM, Tackett DL and Willeke K. (1987) Particle size dependent leakage and losses of aerosols in respirators. Am Ind Hyg Assoc J. 48: pp. 848–854.
- Howie RM, Johnstone JBG, Weston P, Aitken RJ and Groat S. (1996) Workplace effectiveness of respiratory protective equipment for asbestos removal work. HSE contract research report CRR 112/96. HSE Books.
- Health and Safety Executive (HSE). (2000) Methods for the Determination of Hazardous Substances General methods for sampling and gravimetric analysis of respirable and inhalable dust MDHS14/3. ISBN 0-7176-1749-1, HSE books.
- Health and Safety Executive (HSE). (2005) Asbestos: The analysts' guide for sampling, analysis and clearance HSG248. ISBN 0-7176-2875-2 HSE Books.
- International Labour Organisation (ILO). (1991) International standard classification of occupations - (ISCO-88), 1988 edition, International Labour Organisation. ISBN 922-114-8327.
- International Standards Organisation (ISO). (1999) TC146/SC2/WG1/Doc N228 1999 or revision thereof, Air quality gravimetric analysis of workplace aerosol collection media. International Standards Organisation.
- International Standards Organisation (ISO). (2004) Ergonomics of the thermal environment - Determination of metabolic rate ISO 8996:2004. International Standards Organisation.
- International Standards Organisation (ISO). (2009a) Respiratory protective devices: Human Factors - Part 2: Anthropometrics ISO/TS 16976-2:2009. International Standards Organisation.
- International Standards Organisation (ISO). (2009b) Workplace atmospheres - Controlling and characterizing uncertainty in weighing collected aerosols ISO EN15767:2009. International Standards Organisation.
- Janssen LL, Weber R. (2005) The effect of pressure drop on respirator face seal leakage. J Occ Environ Hyg. 2:335-340
- Janssen LL, Nelson TJ and Cuta KT. (2007a) Workplace protection factors for an N95 filtering facepiece respirator. J Occ Environ Hyg. 4:698-707
- Janssen LL, Bidwell J and McCullough N. (2007b) Performance of an N95 Filtering Facepiece Respirator in a Grinding Operation. JISRP, Vol. 24, Issue 1 & 2, pp. 21-31.
- Janssen LL and McCullough N. (2010) Elastomeric, half-facepiece, air-purifying respirator performance in a lead battery plant. J Occ Environ Hyg. 7:46-53
- Johnston AR, Myers WR, Colton CE, Birkner JS and Campbell CE. (1992) Review of respirator

- performance testing in the workplace: Issues and concerns. *Am Ind Hyg Assoc J* 53 pp. 705-712.
- Johnston AM, Miller BG, George JPK, Lancaster RL, et al. (2000) An investigation of factors affecting the performance of power-assisted full facepiece respirators in use. HSE CRR 282/2000 (IOM research report TM/99/07), HSE Books.
- Lee S-A, Adhikari A, Grinshpun S. , McKay R, Shukla R, Zeigler H-L and Reponen T. (2005) Respiratory Protection Provided by N95 Filtering Facepiece Respirators Against Airborne Dust and Microorganisms in Agricultural Farms. *J Occ and Env Hyg*, 2: 11, 577 - 585,
- Martin P, Brand F and Servais M. (1999) Correlation of the exposure to a pollutant with a task-related action or workplace: the CAPTIV system. *Ann Occup Hyg*; 43: pp. 221–33.
- Moore DE, and Smith TJ. (1976) Measurement of protection factors of chemical cartridge, half-mask respirators under working conditions in a copper smelter, *AM Ind Hyg Assoc J*, 37:8, pp. 453-458.
- Myers WR, Peach MJ, Cutright K and Iskander W. (1984) Workplace Protection Factor Measurements on Powered Air-Purifying Respirators at a Secondary Lead Smelter: Results and Discussion. *Am Ind Hyg Assoc J* 45: 10, 681- 688.
- Myers WR, Allender J, Plummer R and Strobbe T. (1986) Parameters that bias the measurement of airborne concentration within a respirator. *Am Ind Hyg Assoc J* 47, pp. 106-114.
- Myers WR, and Allender J. and Iskander W. (1988a) Causes of in-facepiece sampling bias - I. Half - facepiece respirators. *Am Occup. Hyg.*, Vol. 32, No.3, pp. 345-359.
- Myers WR, and Allender J. (1988b) Causes of in-facepiece sampling bias - II. Full -facepiece respirators. *Am Occup. Hyg.*, Vol. 32, No.3, pp. 361-372.
- Myers WR, Hyunwook K and Kadrichu N. (1991) Effect of Particle Size on Assessment of face seal leakage. *JISRP*, Vol. 9, Issue 3, pp. 6-21.
- Myers WR and Hornung RW. (1993) Evaluation of new in-facepiece sampling procedures for full and half facepieces. *Am Occup. Hyg.*, Vol. 37, No.2, pp. 151-166.
- Myers WR, Zhuang Z, Nelson TR, Sides S and Wilmes D. (1995) Field Performance Measurements of half-facepiece respirators - study protocol. *Am Ind Hyg Assoc J*. 56: pp. 765-775.
- Myers WR, Zhuang Z, Nelson TR, Sides S and Wilmes D. (1996) Field Performance Measurements of half-facepiece respirators – Foundry operations. *Am Ind Hyg Assoc J*. 57: pp. 166-174.
- Myers WR and Zhuang Z. (1998) Field Performance Measurements of half-facepiece respirators – Steel mill operations. *Am Ind Hyg Assoc J*. 59: pp. 789-795.
- Nelson TJ. (1995) The assigned protection factor of 10 for half-mask respirators. *Am Ind Hyg Assoc J*. 56: pp. 717–24.
- Nelson TJ. (1996) The assigned Protection factors According to ANSI. *Am Ind Hyg Assoc J*. 57: pp. 737-740.
- Nelson TJ and Meagher JF. (1996) Workplace Protection factor study protocol, American Industrial Hygiene Association Respirator Protection Committee.
- Nicas M and Newhaus J. (2004) Variability in respiratory protection and the assigned protection factor. *J Occ Environ Hyg*. 1:99-109.
- Oestenstad RK, Dillion HK and Perkins LL. (1990) Distribution of face seal leak sites on a half-mask respirator and their association with facial dimensions. *Am Ind Hyg Assoc J*. 51 (5): pp. 285 – 290.
- Occupational Safety and Health Administration (OSHA). (2006) Federal Register /Vol. 71, No. 164 /Thursday, August 24, 2006, p.50129.
- Occupational Safety and Health Administration (OSHA). (2009) Assigned Protection Factors for the revised respiratory protection standard. OSHA 3352-02/2009. www.osha.gov.
- Occupational Safety and Health Administration (OSHA). (29CFR1910.134) Fit testing procedures Appendix A. www.osha.gov.
- da Roza RA, Cadena-Fix, CA and Kramer JE. (1990) Powered-air purifying respirator study. *JISRP*, Vol. 8, Issue 2, Summer, pp. 15-36.
- Rosen G, Andersson IM, Walsh PT, Clark RPD, Saamanen A, et al. (2005) A Review of Video Exposure Monitoring as an Occupational Hygiene Tool. *Ann. Occup. Hyg.*, Vol. 49, No. 3, pp. 201–217.
- Stacey P. (1998) Evaluation of HSE CRR 112/96 - Workplace effectiveness of respiratory protective equipment for asbestos removal work (IR/MF/98/03), Health and Safety Laboratory, UK.

-
- Stobbe TJ, daRoza RA and Watkins MA. Facial Hair and Respirator Fit: A Review of the Literature. *Am Ind Hyg Assoc J*, 49: 4, 199 — 204.
- Tannahill SN, Willey RJ and Jackson MH. (1990) Workplace protection factors of HSE approved negative pressure full-facepiece dust respirators during asbestos stripping preliminary findings. *Ann. occup. Hyg.*, Vol. 34, No. 6, pp. 547-552.
- Wallis G, Menke R and Chelton C. (1993) Workplace field testing of a disposable negative pressure half-mask dust respirator (3M 8710). *Am Ind Hyg Assoc J*, 54: 10, 576 - 583.
- Vaughan N and Rajan-Sithamparanadarajah. (2005) Meaningful workplace protection factor measurements: experiments protocols and data treatment. *Ann Occup Hyg Vol.* 49, Iss 7, pp. 549-562.
- World Health Organization (WHO). (1997) Determination of airborne fibre number concentrations. A recommended method by phase-contrast optical microscopy. World Health Organization Geneva. ISBN 9241544961.
- Zhuang Z and Myers WR. (1996) Field Performance Measurements of half-facepiece respirators - paint spraying operations, *Am Ind Hyg Assoc J* 57, pp. 50-57.
- Zhuang Z, Coffey CC, Jensen PA, Campbell DL, Lawrence RB and Myers WR. (2003) Correlation between quantitative fit factors and workplace protection factors measured in actual workplace environments at a steel foundry *Am Ind Hyg Assoc J* 64:730–738.

Annex 1- Protocol for conducting a WPF study - list of recommended steps:**A.1 Pre-workplace study measurement**

- 1) Define the type and class of RPD to be investigated;
- 2) Gather information on the range of workplace situations in which the selected type of RPD is used;
- 3) Review any existing WPF studies covering the RPD type and selected industry sector;
- 4) Select representative workplace(s) to conduct the study;
- 5) Gain ethical approval and co-operation of the management and workforce at the chosen sites;
- 6) Recruit wearers for the study (include briefing) and gain their informed written consent to participate; measure facial dimensions of the wearers;
- 7) Develop and administer environmental questionnaire;
- 8) Develop and administer human factors questionnaire (e.g. age, facial dimensions, facial hair, corrective eyewear requirements, degree of training and level of experience);
- 9) Review the work activity undertaken to assess the work rate and its duration and consider the need for sampling at different portions of the shift;
- 10) Measure the chosen workplace contaminant(s) to ensure it is suitable for the proposed method, (i.e. the concentration is sufficiently high);
- 11) If the contaminant is a particle, measure the airborne size distribution;
- 12) Establish the analytical detection limits of the measurement system to be applied to the samples;
- 13) Determine the number of WPF data points required (per RPD type/ per wearer) including repeats on the same wearer, consider inter and intra wearer variations;
- 14) Determine the degree and effectiveness of the RPD programme in operation at the chosen sites;
- 15) Where there are shortcomings in the RPD programme, which could lead to significant health risks, address these through training etc. to ensure the RPD programme is compliant.
- 16) Determine the provision of the test RPD – workplace's own or provided by the investigators;
- 17) Ensure that the RPD are suitable for the study, i.e. properly maintained;
- 18) Ensure wearers are fit tested where appropriate following national recognised procedures. Fit testing can be conducted by the employer or the investigators;
- 19) Ensure 100% observation of wearers during sampling, consider the use of VEM;
- 20) Record other PPE used together with the RPD and ensure that they are compatible;
- 21) Measure the WPF.

A.2 Data analysis

- 1) Identify samples affected by sampling problems – interruption of C_i or C_o sample, wearer removes RPD during the sampling period, etc. - and remove from the data set;
- 2) Apply substitution techniques or reject such samples that are at or near the detection limit of the analytical method.
- 3) Apply and justify any correction required e.g. sampling bias, lung retention, control filter blanks;
- 4) Perform appropriate statistical analyses of the data.
- 5) If desired, test for relationships between various factors etc. degree of training, experience, job, work rate, fit factors.

A.3 Reporting the findings

- 1) Report the data and findings together with detailed key categories and data elements as detailed in Table III and Table IV.