Respiratory Protective Devices – request for workplace and/or laboratory performance data

Purpose of this letter

The purpose of this letter is to draw your attention to an initiative led by the UK Health and Safety Executive (HSE) in support of the validation of new respiratory protective devices (RPD) performance levels which are to be introduced as part of a new suite of International Standards under development in ISO committee ISO/SC15. HSE seeks your support in either providing existing RPD performance data or by contributing to the generation of new performance data. We are interesting in gathering data for a range of different types of RPD.

Background

Since 2003, there has been activity within the International Standards Organization (ISO) to develop a new suite of respiratory protective devices (RPD) standards. A number of the ISO standards relating to RPD have already been published and it is expected that the two main performance standards that will cover filtering RPD and breathing apparatus will be published in the near future.

One of the new standards[1] (published as a technical specification in 2016) covers selection and use of RPD. This technical specification includes reference to the new performance criteria including proposed Protection Levels (PLs) for RPD. The proposed ISO PLs are based on the judgement of the ISO RPD Standards Committee and have been devised to help establish global understanding concerning the adequacy of RPD in the workplace. However, before these values are adopted, they require validation. These PLs may eventually replace the national current Assigned Protection Factors (APF) when they are validated.

Many existing APFs are based on limited data relating to older designs of RPD and so this is also an opportunity to update current knowledge in this area.

A task group was established under ISO/SC15, with HSE taking an active part. In 2014 HSE established a working group, the primary focus of which is to:

a. Review existing workplace/laboratory data which is relevant to investigating and validating the new Protection Class and Protection Levels;
b. Encourage the generate new data to contribute to the validation process;
c. Liaise with regulators and others including UK and international stakeholders to identify potential partners to help generate relevant data;
d. Provide feedback to ISO/SC15.

Making use of current RPD performance data

RPD performance data is generated from either:

i. Workplace protection factor (WPF) studies – these are studies undertaken in the workplace to measure the RPD performance against the respiratory hazards present at the workplace;
ii. Simulated workplace protection factor (SWPF) studies – these are studies undertaken in the laboratory to measure the RPD performance against a challenge agent under laboratory controlled conditions;
iii. Total inward leakage tests – these are standard tests conducted in the laboratory as part of CE certification.

The working group has now met twice - December 2014 and January 2017. An earlier agreed action resulting from the meeting was a request for data relating to the performance of RPD. Ideally, these data would be derived from WPF studies or SWPF studies, however TIL data from certification of RPD held by manufacturers is also a very useful source of data. Since that request HSE has received SWPF and TIL data for some RPD types but there are still gaps in the data and therefore more data would be very welcome.

We therefore would like to issue a renewed call for any workplace, simulated or laboratory TIL data. TIL data could be based on the existing TIL method (BSEN13274-1)[2], or the new proposed ISO TIL method (ISO 16900-1)[3]

All information provided will be treated in the strictest confidence. Information provided will only be used for the purposes of this project and will only be available to members of the HSL PPE team who are working on this project. Any data supplied will be anonymised. Data will only be referenced by RPD type and class and no reference to make/model will be made.

Additionally, should there be a requirement, HSE is happy to negotiate and sign suitable Confidentiality or Non-Disclosure Agreements with individual manufacturers, or others who supply data to support this project. We will seek agreement from participating parties before disclosure of any summary reports. Confidential information will be anonymised and will not be disclosed.

If you have and are willing to share any WPF or TIL data please would you send to Mike Clayton mike.clayton@hsl.gsi.gov.uk.

Generation of new WPF, SWPF and TIL data

In order to conduct a robust validation of the proposed ISO PL, and to gain a better understanding of the true performance of RPD in the workplace, both laboratory TIL data together with either workplace or simulated workplace data is required. There is currently insufficient data available in order to conduct a robust validation. HSE is therefore seeking your support in contributing to the generation of new performance data. This can be by either:

iv. Conducting a WPF study in your workplace;
Providing support for WPF studies, for example by the provision of access to workplaces/devices, provision of RPD volunteers, etc.;

v. As a partner in the funding of shared research projects e.g. collaboration with for example HSL.

vi. Conducting TIL tests according to both the current and new methods for new RPD, or new TIL tests on existing devices.

Appendix 2 provides an overview of what a WPF study may entail.

If you are interested in contributing to this project HSE would very much like to hear from you. If you wish to find out more about this project, or have any concerns about supplying data, then please contact Mike on +44 (0)1298 218332.

Thanking you in anticipation of your support.

[1] ISO/TS 16975-1 Respiratory protective devices - Selection, use and maintenance - Part 1: Establishing and implementing a respiratory protective device programme

[2] BSEN 13974-1 Respiratory protective devices - Methods of test - Part 1: Determination of inward leakage and total inward leakage

[3] ISO 16900-1 Respiratory protective devices: Methods of test and test devices: Determination of inward leakage

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Appendix 1: Comparison of UK APFs and ISO PLs

The table below shows the relationship between the total inward leakage result, the ISO Protection Class (PC) and the ISO Protection Level (PL).

Protection class (PC)	Total inward leakage (max) %	ISO Protection Level (PL)
PC1	20	4
PC2	5	10
PC3	1	30
PC4	0.1	250
PC5	0.01	2000
PC6	0.001	10000

Under the proposed ISO system, apart from RPD falling under special applications e.g. firefighting, RPD can potentially attain any protection class from PC1 to PC6. Potentially RPD types and classes that we are familiar with today could have a wider ranges of protection classes and protection levels in the future.

Appendix 2: Respiratory Protective Devices - Workplace and simulated workplace protection factor studies

Introduction

Workplace protection factor (WPF) and simulated workplace protection factor (SWPF) studies are a means for measuring the performance of RPD under actual or simulated work conditions. They usually take the form of measuring the actual inhaled concentration of an airborne challenge substance and comparing this to the challenge substance concentration outside the RPD, while the RPD is worn under actual or simulated work conditions.

Scope

This document provides a brief overview of the steps involved in conducting a workplace or simulated workplace protection factor study. The references provided at the end of this document provide essential information on conducting studies that should be followed in order to generate valuable performance data. This document should not be considered to be a comprehensive guide to conducting WPF or SWPF studies.

Study workplace

For WPF studies the workplace chosen should contain a detectable and measureable airborne challenge substance. The workplace should have in place an effective and managed RPD programme. The workplace should allow sampling regimes to be installed and permit observation by the 'researcher' of the RPD wearers participating in the study.

For SWPF studies, the airborne challenge is usually purposely generated and retained inside a test chamber of sufficient size to enable an RPD wearer to conduct simulated workplace activities.

RPD wearers

Studies on RPD will inevitably involve the use of volunteers. It is therefore important that studies are conducted ethically and that the health, safety and wellbeing of the volunteers are managed. Studies should not place any volunteers at risk of exposure. Additionally, it is important to consider face fit testing, wearer's RPD training, experience and willingness to participate in the study as these are all contributory factors that may impact on the protection factors measured.

RPD to be used

The RPD used in the study should be in good condition, maintained and used in accordance with the RPD instructions for use.

Modification to RPD

In order to sample from inside of the facepiece a sample line with suitable probe is fitted to the RPD. For tight fitting facepieces it is likely that a modification to the RPD is required. For certain designs of loose fitting facepieces (e.g. hood and visors) it may be possible to achieve this without the need to adapt or modify the RPD. In either case, it is essential that assurance testing is conducted to ensure that the modification or adaption does not affect the integrity of the RPD. This may require

the input of a test laboratory, the Notified Body responsible for the certification of the RPD being used and the national regulator.

Study sampling duration

The duration of the in-mask sampling will depend on a number of factors including the nature and concentration of the airborne challenge substance, the RPD type worn, and should reflect the duration of the workplace tasks undertaken or simulated. Typically sampling durations will be in the order of >1hr.

Data/sample collection

To obtain a measure of RPD performance the concentration of the airborne challenge inside and outside the RPD is simultaneously measured and recorded either continuously in real time (in the case of direct reading instrumentation e.g. particle counters), or in the case of collection of samples, for later analysis.

Data analysis

The protection factor (PF) is expressed as the ratio of the concentration of the contaminant (Co) in the air surrounding the RPD to that in the wearer's breathing zone inside the facepiece cavity (Ci) and is calculated as shown in equation 1.

$$PF=(C_o)/(C_i) \quad \ldots\ldots\ldots (1)$$

Definitions:

Workplace protection factor: '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 (Co) divided by the contaminant concentration inside the respirator facepiece (Ci). Co and Ci are measured simultaneously only while the respirator is properly worn and used during normal work activities. Ci 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).'

Simulated workplace protection factor: '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.'

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