Guidelines on the Selection, Use and Maintenance of Respiratory Protective Equipment in the Pharmaceutical Industry

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Introduction

The preferred strategies for the control of exposure to hazardous substances are ones which do not impose additional burdens, such as the wearing of personal protective equipment (PPE), on the workforce. These strategies include the elimination or substitution of hazardous substances, the use of engineering controls, and systems of work which minimise potential exposure. This approach has been reinforced by the Control of Substances Hazardous to Health Regulations 1994 (COSHH) and its associated Approved Codes of Practice (Reference 1). However, many situations remain in which the use of PPE is necessary, and in those cases suitable and adequate equipment must be selected which must also be properly maintained. The PPE used must also comply with the Personal Protective Equipment at Work Regulations 1992 (Reference 2); respiratory protective equipment (RPE) must either be CE marked, of a type approved by, or must conform to a standard approved by, the Health and Safety Executive (HSE). From 1st July 1995 all RPE purchased must be CE marked.

These guidelines, which have been prepared by the ABPI Occupational Health and Hygiene Sub-Committee, build on the general guidance on the use of RPE which has been published by the HSE (Reference 3), and are intended to give practical help to managers who need to select RPE and ensure that it is correctly used and maintained. They provide more detailed guidance on some areas of work which are of particular concern to the pharmaceutical industry, and also cover the practical aspects of the testing of compressed breathing air. The guidelines should be used in conjunction with HS(G) 53, which also provides details of the respirator classifications used.

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1 The Selection of Respiratory Protective Equipment

1.1 Introduction

1.1.1 This section gives an introduction to the selection of suitable RPE in the pharmaceutical industry. It is recommended that HS(G)53 (Reference 3) and equipment suppliers or manufacturers are consulted before finalising the selection of suitable equipment.

1.1.2 These guidelines do not include consideration of equipment for use in atmospheres which are liable to be oxygen deficient (<18 per cent oxygen by volume) or otherwise immediately dangerous to life or health. Immediately dangerous to life or health includes situations where acute respiratory exposure poses an immediate threat or loss of life, immediate or delayed very serious irreversible adverse effects on health or any exposure that would prevent escape from a hazardous atmosphere. In such circumstances, breathing apparatus will be required and this is not discussed further in these guidelines.

1.2 Selection of Equipment

1.2.1 Figure 1 gives a simplified decision tree for the selection of suitable RPE. It can be seen that all types of equipment offer limited protection e.g. FFP2 disposable ori-nasal respirators have a maximum recommended use concentration factor (MRUCF) of 12 times any applicable exposure limit. If a higher standard of protection is required, then an alternative type of respirator will be required. Examples of the application of the selection procedure are given.

Various types of respiratory protective equipment have a full face mask. This type of equipment is not included in Figure 1. In practice, this type of equipment is frequently rejected by operators on ergonomic grounds and for most purposes more acceptable designs are available (see section 1.2.4). However, RPE which utilises a full face mask may be appropriate in some situations.

Many factors affect the practical performance of RPE in the workplace. These include standards of information, instruction, training and supervision. The guidance in the flow diagram (Figure 1) is based on maximum usage concentrations derived from CEN standards. It should be borne in mind, however, that numerous studies of the performance of RPE in the workplace have indicated that levels of protection may be very much lower than those achieved in testing laboratories. Guidance given in HS(G)53 (Reference 3) reflects this situation. The table below (Table 1) compares maximum recommended use concentration factors derived from CEN standards with those recommended for use against radioactive dusts for equivalent devices (from EH53, Reference 4) and with some measured 'workplace protection factors' (WPFs).

1.2.2 When airsuits are used with well designed equipment and the stringent application of good procedures, it has been found possible to achieve protection factors of over 2,000. However, where high protection factors are required, e.g. over 100, their attainment should be regularly validated and not merely assumed.

1.2.3 There is an overriding requirement that a user should be satisfied of the suitability of a particular item of RPE taking into account the particular circumstances of the company's application. The figures quoted in Table 1 may be of use in assessing the suitability of items of RPE for particular applications in the absence of more specific data.

1.2.4 A number of other factors need to be taken into account when selecting RPE, in addition to those presented in Figure 1. These are highlighted below and some are discussed in detail in HS(G)53 (Reference 3).

Use of equipment in flameproof areas: Powered equipment for use in such areas will need to be intrinsically safe and approved by BASEEFA or an alternative certification body. Alternatively non-powered (negative pressure) equipment or compressed air-fed equipment providing an equivalent standard of protection will be required.

Addendum:

prEN 943 Part 1, released on 5 September 1995, specifies an inward leakage not greater than 0.05% for full airsuits. This is equivalent to a protection factor of 2000

FIGURE 1

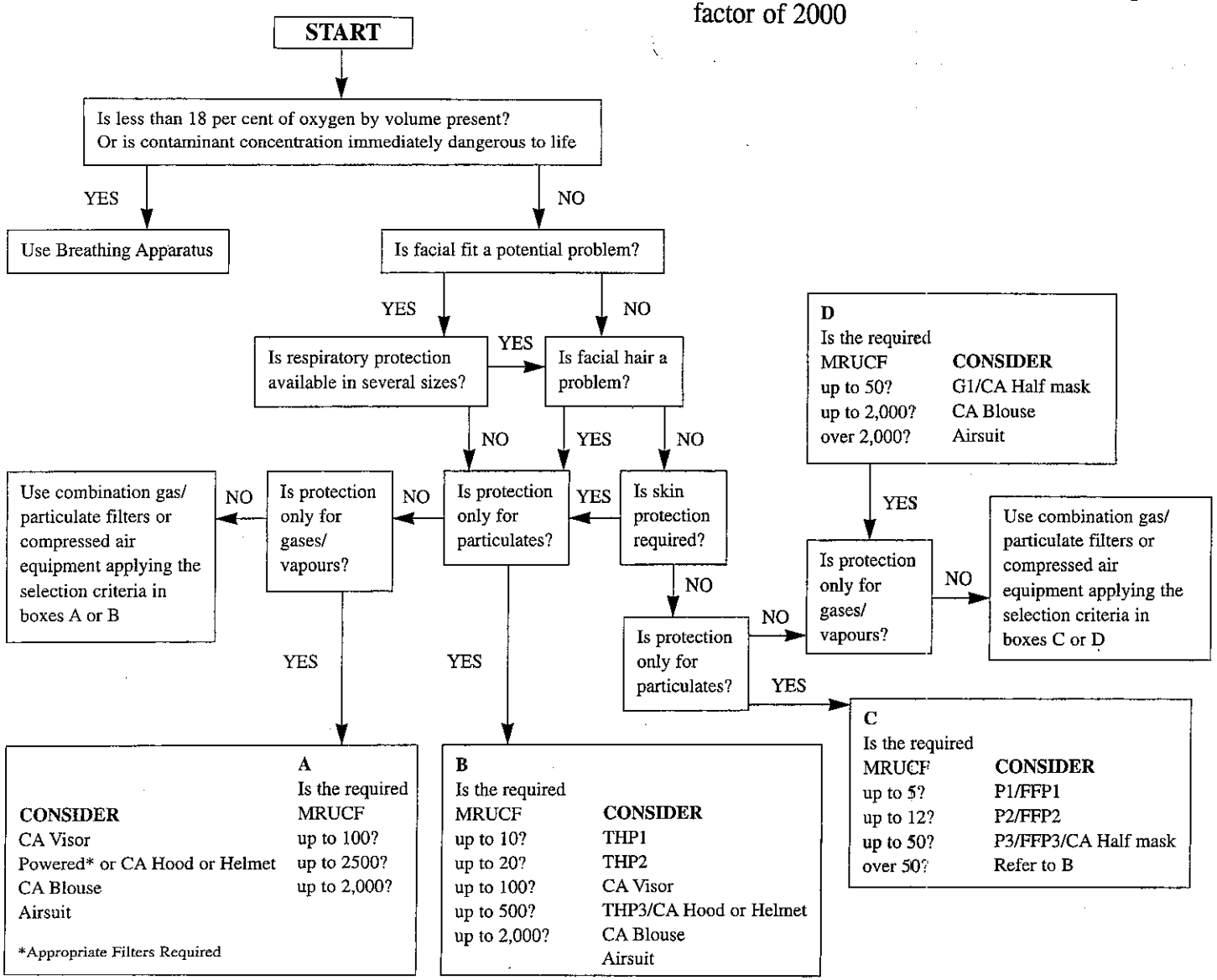

TABLE 1 **Protection Factors**

*Respirator Type/Classification**	*CEN*[1]	*EH53*[2]	*WPF*[3]
Filtering Facepiece			
FFP2	12	3	5-25
FFP3	50	5	
Half Mask			
P2	12	3	5-20
P3	50	5	
Powered Helmet			
THP2	20	5	4-90
Powered Helmet/hood			
THP3	500	50	20-40
Airfed hood	500	up to 500	8-233
Full Airsuit	2,000	up to 1000	100-2000#

*Classifications in European (CEN) standards

1. MRUCFs derived from CEN standards.
2. Protection factors (recommended maximum airborne contamination level expressed as a multiple of the control level for normal continuous use) taken from EH53 'Respiratory protective equipment for use against airborne radioactivity'. The guidance in EH53 attempts to quantify the uncertainty in performance.
3. The WPFs quoted are based on limited data obtained using a variety of study protocols. The results from protection factor studies carried out in the workplace are dependant on the study protocol and a precise definition of a WPF is therefore not given here. Nevertheless, the data does indicate that MRUCFs are not a reliable guide to respirator performance in the workplace and that appropriate allowances should be made. RPE should not be selected if it is required to perform close to its upper performance limits, and due allowance should be made when using Figure 1 (see examples).

Use of airsuits include periods of disconnection to transit the work area.

Use of equipment in aseptic areas: for GMP reasons, special considerations apply to equipment used in these areas and Section 3 of these guidelines should be consulted.

Duration of wearing: When properly fitted, many face masks become uncomfortable over a period of time. For periods in excess of one hour, alternative types of equipment should be considered, as operators will tend to loosen straps or harnesses to ease any discomfort.

For respirators used to protect against particulate exposure, the filters also have finite lifetimes. Glass fibre or similar filters may become clogged with dust, leading to increased breathing resistance or reduced air supply (powered respirators). Electrostatic filters may lose their electrostatic charge with some particulates.

Ergonomic considerations. Physical work rate, mobility, visibility, communications, access to plant/equipment, use of other personal protective equipment or wearing of spectacles etc. will all affect the suitability of a particular item of RPE. The selection of a particular item of RPE must not unduly increase other risks to health and safety e.g. from slips, trips and falls or by reducing the effectiveness of other items of personal protective equipment.

The size and shape of faces vary considerably. Particularly for negative pressure respirators, where facial fit is an important factor affecting respirator performance, it may be necessary to consider whether different sizes of respirator need to be made available in the workplace.

Medical fitness to use any RPE should be considered when selecting any item of equipment. In particular, use of negative pressure respirators, which rely on lung power to draw air through the respirator filters may cause problems for people with respiratory disorders.

Examples of Respirator Selection using Figure 1

Example 1

Workforce – 100 per cent clean-shaven males
Personal exposures to airborne dust up to 10 x 8h TWA OEL have been recorded (exposure occurs throughout the shift).
No particular concerns about skin contact

Initial selection:
Following the Figure 1 flowchart

Facial fit – No	Skin protection – No
Facial hair – No	Particulate only – Yes

Protection factor required is 10+

Therefore select an FFP2/FFP3 disposable face piece respirator (or equivalent non-disposable), provided staff are medically fit, e.g. do not have impaired lung function.

The protection factor required is very close to the MRUCF for FFP2, therefore, to provide a margin of safety, select an FFP3.

Secondary review:
As respirator usage will be for most of the shift, the use of a disposable respirator could be problematical due to operator discomfort, e.g. due to irritation around face seal, heat gain (could be tested in user trials). Therefore, consider THP2 respirator as an alternative.

THP2 – likely to be the final choice (powered helmet or hood) provided it is compatible with other personal protective equipment that may be required and the operation of the RPE programme is to a good standard. Proceed to user trials.

Example 2

The substance in use is a powder which is a skin and respiratory sensitiser which has a 15 min TWA OEL and 8h TWA OEL. Recorded personal exposures are up to 20 times the 15 min OEL and twice the 8h OEL. Exposure occurs at 2 discrete periods of 15-20 minutes during the day.

Workforce is 100 per cent clean-shaven males.
Initial selection:
Following the Figure 1 flowchart:

Facial fit – No	Skin protection – Yes
Facial hair – No	Particulate only – Yes

Protection factor required 20+
THP2 should not be selected as the protection factor required is the same as the MRUCF.
Initially consider Compressed Air Visor.

Second Review:
Final selection will depend on:

Operator acceptability
Potency as a skin sensitiser
Operational considerations e.g. mobility of operators, ease of decontamination of equipment
Compatibility with other personal protective equipment that may be required.

As RPE may only be required for 40 minutes per day, this is a situation where a powered full face mask may be tolerable, provided vision is acceptable. However, visors and full face masks leave skin and hair unprotected. Depending on the potency of the substance as a skin sensitiser, an overall with a hood may be required or alternatively, an air-fed hood or helmet, etc. may be selected to provide improved skin protection. This is one situation where an airsuit could be selected to ensure whole body skin protection and for ease of decontamination.

2 The Use of Airsuits

2.1 Introduction

2.1.1 This section provides practical guidance on the operation of facilities where airfed suits are required for operator protection. It takes a hierarchical approach to the development of a suitable system of work.

The guidelines apply to the use of a single piece suit which is supplied with breathing air from a compressor via an air hose connected to air supply points in the work area. Much of the guidance will also be of value where two-piece suits, air-supplied blouses or air-supplied hoods are used.

The guidelines do not apply to situations where an oxygen-deficient atmosphere may occur, e.g. confined spaces or any other situation where breathing apparatus would be required.

The use of airsuits is only suitable provided that appropriate changing and showering facilities are available. Furthermore, staff must be adequately trained and supervised in the relevant procedures.

2.1.2 Development of an acceptable system of work has implications for the design of the airsuit facility, which are discussed. Details such as the selection of suitable compressors for breathing air systems, selection of suitable materials for pipework, etc. are not considered.

Quality of breathing air is discussed in Section 5.

2.1.3 The selection of an airsuit as a means of personal protection may reflect the need for a high standard of respiratory protection alone, or alternatively a good standard of both skin and respiratory protection. In the latter situation, the levels of respiratory protection required may not warrant the use of an airsuit but the operational advantages of using a single piece suit for ease of decontamination could favour such equipment.

2.2 Suit Performance and Selection

2.2.1 The range of hazardous substances that airsuits may be used for is very wide. The hazards range from highly unpleasant but reversible effects to irreversible effects of an acute or chronic nature. There may be the potential for skin absorption or direct effects on the skin or mucous membranes and the substances may be present as dusts, gases or vapours. These factors together with the potential airborne contaminant levels will determine the design of suit selected, the system of work adopted and any emergency procedures. The properties of a substance may also be a factor in determining the materials of construction for a suit.

2.2.2 Airsuits may have a front or rear entry with the zips protected by a flap. Choice of zip location may be dependent on the risk of heavy contamination occurring to the front of a suit. However, choice of a rear entry suit will inevitably require the presence of a dresser which may in turn affect the size and location of the changing area.

2.2.3 Suits can be fitted with a variety of zips which may or may not be gas tight. Depending upon the type of zip fitted, the difficulty in zip operation will vary, and the risk of a zip jamming, particularly when unzipping a suit, needs to be considered. Again, a dresser may be necessary in some circumstances, even for front entry suits.

2.2.4 New airsuits are fitted with 'low flow' alarms which should give a warning when air flows are too low. Some devices are actually pressure sensors. The equipment will therefore need to be assessed together with the proposed system of work to determine the potential for the device to fail to danger e.g. simple pressure sensors will continue to indicate an adequate supply pressure even though the supply pipe is blocked downstream from the sensor.

2.2.5 Use of an airsuit will modify the thermal environment in which an operator works and will pose some restrictions on movement, touch-sensitivity and visibility. These factors may affect the choice of suit; for example, air distribution systems vary between suits, affecting thermal comfort, or there may be a need to choose between a rigid or flexible visor. As with any other personal protective equipment, it is essential that user trials are undertaken as part of the selection process.

2.2.6 Suits may be fitted with communications systems, either radio-links or hard-wired systems. Whilst they may be installed primarily to improve communications during normal working, they offer benefits in the development of emergency and rescue procedures. It is important to ensure that radio links do not have any blind spots in the work area. Also, see paragraph 2.4.3. Suits fitted with communications equipment may have to be 'flame-free'.

2.2.7 As with all other forms of respiratory protection, the level of protection afforded in the workplace may be significantly different from that determined under laboratory test conditions (see Section 1). In the workplace, operating procedures can significantly affect the actual protection provided by any respiratory protection. Whilst the data is limited, studies have shown that suits may not achieve the performance required for compliance with the CEN standard, protection factors in the range of 100-2000 may be observed in practice. These suits were being used to protect against airborne dusts and were fitted with heavy-duty plastic zips. There were several potential sources of contaminant ingress into the suits including:

decontamination and changing procedures allowing residues on suits, particularly around zips, to be drawn into the breathing zone (in most cases, this is the most likely source of contamination);

through zips, undetected pinholes in the fabric, or elasticated leg terminations due to a bellows effect, particularly but not exclusively when disconnected from the air supply;

contamination of breathing air supplies (recirculation of contaminated air via the compressors was discounted in these studies). Airline connections contaminated by contact with contaminated gloves or equipment or by airborne dust deposition were possible, and dust was found to be deposited inside the flexible airhoses.

2.3 Safe Systems of Work

2.3.1 Any system of work which requires an operator to be deprived of a fresh air supply for any period of time cannot be described as an intrinsically safe system. In the absence of a second person, collapse of an operator whilst disconnected from the air supply could have serious and potentially fatal consequences. Any hard wired communications systems would be disconnected at this time. The use of personal alarms (motion detectors) is not an adequate substitute for a safe system of work. Most motion detectors have a delay period to prevent false alarms and this is unacceptable where rapid rescue is required.

2.3.2 Carbon dioxide concentrations inside the suits should be maintained below 1 per cent by volume (10,000 ppm). (NB: This is not the same as the carbon dioxide concentration in the air supply; which should not exceed 500 ppm). Physiological effects due to elevated carbon dioxide concentrations can be expected to occur in some individuals at exposures to 1.5 per cent carbon dioxide in air. Carbon dioxide concentrations could rise above this level on cessation of the air supply, possibly within thirty seconds.

Limited experimental data and simple calculation indicate that oxygen levels inside suits will fall rapidly on interruption of the air supply. Under simulated heavy working conditions, an oxygen deficient atmosphere (i.e. less than 18 per cent oxygen by volume) can be produced in less than one minute.

The consequences of oxygen depletion or carbon dioxide elevation following either accidental or planned interruption of the air supply to a suit should therefore, be very carefully considered. This should include procedures for normal working and any foreseeable emergencies e.g. evacuation in case of the collapse of an operator whilst disconnected from the air supply.

Loss of the air supply presents a potential risk for a conscious operator unless suitable self rescue facilities exist. One rapid way of restoring a supply of fresh air would be to unzip the suit. This has two limitations:

It would expose the individual to the hazardous substances. This may be tolerable for some substances in an emergency situation but would not be an acceptable risk in many situations;

Suit zips are more likely to jam if operators are working under stressful conditions.

Operators will require clear instructions and adequate training on what actions to take in the event of an air supply failure or other emergency, e.g. the fire alarm sounding.

Evacuation procedures in case of fire/air supply failure, etc. should be established. These should maintain an adequate air supply and minimise exposure to hazardous substances.

The following alternatives should be considered:

use of suits fitted with self-rescue breather tubes (suitable for airborne dusts);

provision of portable compressed air cylinders (5/10 minutes supply);

evacuate to safe area and unzip to ventilate suit;

unzip suit prior to evacuation;

provide 'safe' means of cutting open suits at appropriate points in the work area.

2.3.3 Thermal discomfort and the effects of low humidity can occur when airsuits are used for a long period; e.g. up to a full work shift. These should be controlled by ensuring that the air supplied is of an adequate specification, that work rates are not excessive and adequate rest periods are taken. The type of clothing worn inside an airsuit will also affect levels of comfort.

The physical restrictions placed on an operator (paragraph 2.2.5) will need to be borne in mind when considering manning levels. Work rates in airsuits will inevitably be lower than those in an equivalent non-airsuit area.

2.3.4 **Lone Working**

If disconnection from the air supply is not required, lone working may be permissible provided that a communications link or lone worker alarm system is available and manned. If disconnection from the air supply is necessary, operators should not work alone and should remain in visual contact with another operator. Alternatively provided adequate arrangements for rescue can be made, continuous observation by another operator in a non-airsuit area may be acceptable. Lone worker alarms/communication links may be provided as a back up system.

Effective decontamination of airsuits is likely to be more difficult for lone workers.

2.4 Facility Design

The following paragraphs relate to the design of any new facility. Existing facilities should be reviewed against these guidelines and, where reasonably practicable, appropriate changes made.

2.4.1 **General Considerations**

All facilities should be designed to achieve control by engineering means so far as is reasonably practicable. Where the use of airsuits cannot be eliminated, the objective should be to minimise their use, e.g. for maintenance, clean down or specific operations such as controlled re-entry to a contaminated area.

An airsuit facility should be designed so that an operator can remain connected to a single air supply point from the time when the suit is zipped up, until work is completed and the suit decontaminated and unzipped. In the event that this is not possible, the number of disconnections from the air supply points should be minimised with minimal transfer times between supply points. Disconnections may be necessary for GMP purposes, especially in secondary manufacturing facilities, where changing areas and shower units may have to be separated from the manufacturing area. However, decontamination facilities should always be contiguous with the working area. Entry into the changing area from the work area should always be via a shower. Showers should be of a 'car-wash' design to ensure proper cleansing of a suit. For some substances a detergent may be required to assist removal and hand brushes provided to assist in decontamination of inaccessible parts of the suit e.g. boot soles. The detergent should be compatible with the suit fabric.

Decontamination procedures should be validated e.g. by swab sampling both the inside and outside of suits.

2.4.2 Specific Detailed Considerations

All facilities:

Medical assessments should be considered for airsuit operators before starting work in a suit, and following any medical problem which may render them unfit for further work with the equipment. Such problems could include for example, impaired lung functioning, epilepsy, diabetes or impaired hearing.

All airsuit work should be undertaken with at least one compressor operational. There should be no reliance on air receiver contents alone. Air receivers should be sized as a ~~minimum to provide a sufficient air supply (at the designated supply rate) for the maximum~~ number of suits in use at any one time, to allow for safe evacuation of the area.

Air outlets should be installed so that they will not become contaminated by dust.

In facilities supplied with compressed gases, breathing air connectors must be different from those used for other compressed gas supplies.

Breathing air should be supplied from a dedicated compressor and should not routinely be supplied from instrument air. The air should not be dried to unnecessarily low relative humidity levels. Discrete water droplets must be removed and any further drying should only be sufficient to prevent condensation in the air supply system. In the event of the air supply running low, an alarm must sound at a manned location. If it is essential that the operator remains fully protected at all times, then an alternative air supply should be provided. This should be a second compressor, diesel generator (for emergency power supply) as appropriate or, less desirably, manual or automatic transfer to instrument air.

A system must be available for warning and, if necessary, rescuing personnel working in airsuits in the event of other emergencies e.g. the fire alarm sounding (see also paragraph 2.4.3).

If the air supply rate is adjustable by airsuited operators, this should only be within the range specified by the airsuit manufacturer. The low flow warning device fitted to a suit should not be used as a means of setting a minimum airflow.

All suits should be thoroughly decontaminated after use by showering or washing using a validated procedure. Suits in routine usage, e.g. daily, should be issued to individuals on a personal basis. The inside of suits should be cleaned and sanitised at least once a week and each time before the suit is used by a different operator.

In general, approved heavy-duty medium pressure flexible airlines which comply with CEN standards should be used. In the past, the custom in the industry was to use a wide variety of airlines, a number of which are not able to pass the test procedures applicable to heavy duty use. This does not necessarily preclude their use. The primary requirement for the airline is that it should be suitable for the purpose. 'Light duty' airlines e.g. spiral coiled lines, may still be acceptable in some situations, but this will need to be assessed on a case-by-case basis. Factors which would militate against their use include:

the risk of damage from trucks or movement of heavy objects;

the potential for tension around corners which could cause the airline to collapse;

the full weight of the operator being put on the airline e.g. a fall downstairs which could cause a coupling to be pulled off.

Airlines are also a potential source of slips, trips and falls, and multiple lines are potentially prone to entanglement. This should be considered in the design of the facility, staffing levels and selection of airline type. A variety of airline management systems are available, for example, inertia reels or sliding tracks.

2.4.3 Facilities Requiring Airline Disconnection

Where practicable, use air hose Y-piece connectors on airsuit tail pipes to maintain constant air supply when changing supply points. (NB: The 'spare' connector should be protected from contamination). Where practicable, use in-line filters for airsuit tail pipes to minimise dust ingress into suits via the breathing air supply.

During periods of disconnection oxygen depletion inside suits should be kept below 1 per cent. Disconnection periods should not exceed 15 seconds. When disconnection from the air supply occurs, any hard-wired communication system would also be disconnected.

3 The Selection of Respiratory Protective Equipment for Aseptic (Sterile) Areas

3.1 Introduction

The use of RPE in the pharmaceutical industry needs to follow the guidelines on Good Manufacturing Practice (GMP) to ensure that it does not cause contamination of the product (Reference 6). In Grade B environments of aseptic areas, in order to maintain low bacterial and particulate airborne concentrations, the requirements include that a non-linting facemask should be worn which prevents the exhalation of droplets. In addition, under the COSHH Regulations, RPE must be suitable for its purpose and be CE marked, type approved or conform to an approved standard. From July 1st 1995, all RPE purchased must be CE marked. Any treatment which the RPE undergoes to allow it to be used in aseptic areas must not negate these requirements.

This section provides guidance on the selection of suitable RPE for use in aseptic areas where there is a need to protect the workforce from hazards associated with the work as well as to protect the product. The user should also refer to the general guidance on the selection of RPE in Section 1.

3.2 Validation

Before any new equipment, including RPE, is introduced into an aseptic area, the user should demonstrate that its use will not adversely affect the sterile conditions. Before final selection, samples of the RPE should be tested for microbial bioburden and particle shedding using suitable procedures. The samples tested should be in the same condition as they would be when introduced, i.e. unsterilised, or sterilised by the intended sterilisation method. Then airborne bacteria and particulate levels should be monitored during a trial run. A company's GMP criteria for acceptance of RPE in aseptic areas should be the same as for other equipment such as surgical-type facemasks.

3.3 Suitability of Different Types of RPE

3.3.1 Respirators; General Considerations

Although respirators should be sterilised if it is possible to do so without increasing the risk to the wearers' health, the performance of filters is usually adversely affected by radiation or heat sterilisation. Sterilisation by chemical means may leave residues which affect the skin or the respiratory system. It has been found possible to use unsterilised masks in aseptic areas and to confirm that their use does not compromise the aseptic environment by applying appropriate validation techniques.

If it is decided to sterilise filters, the user should confirm that their performance remains adequate, e.g. whether the filter material still passes the appropriate penetration requirements of BS EN 149 (Reference 7).

3.3.2 Negative Pressure Respirators

Single-shift disposable respirators are preferred to re-usable (e.g. rubber) ones for the following reasons:

Re-usable respirators would require frequent cleaning by a method which does not leave harmful residues, and would cause the problems associated with having to clean equipment for re-use in aseptic areas;

Re-usable respirators invariably contain an exhalation valve.

Disposable respirators which do not contain an exhalation valve are preferred.

The respirators should be supplied singly in individual hygiene packs. They should be stored with the other clean room clothing, so that they are donned before entering the aseptic area. They should be disposed of after each period of use.

Before the validation tests, in addition to the general considerations applying to respirator selection (Section 1.2), the person selecting disposable respirators should give adequate consideration to the following points:

the filter material and construction, (e.g. the filter surface should not contain loose fibres);

shape and size, (e.g. to what extent they cover the exposed part of the face);

wearer comfort, (so that the wearers do not continually readjust the RPE or rub their faces);

whether it is manufactured under clean room condition or may require cleaning before use;

whether a surgical-type mask can be worn over the RPE, (this should not normally be necessary, but such an option may facilitate the validation).

3.3.3 Other Types of Filtering RPE

Other types of filtering RPE, e.g. powered helmet respirators, may also be suitable in certain circumstances. A surgical-type facemask may have to be worn with them, unless it can be shown to be unnecessary. Again, before final selection, the equipment should be validated for its effect on the aseptic environment.

3.3.4 Compressed Air Fed RPE

Any particulates which are present in the supplied air, or which may be generated by the passage of air over the wearer of the RPE, should be prevented from entering the aseptic area. Therefore, airsuits are preferred to hoods or blouses because the exhaust air can be filtered by fitting air filters over the exhaust valves. Such filters may be fitted as original equipment by the airsuit supplier. No alteration should be made to airsuits without first checking with the suppliers that the modification is safe and that it would not breach any regulatory requirements.

Because the exhaust air is filtered, a face mask is not required to be worn inside the airsuit.

Users of airsuits in aseptic areas will need to give adequate consideration to the following points:

- the means of sterilisation/sanitisation of the airsuit prior to each occasion of use;
- the supply of breathing air for the wearers when they transfer between the changing area and the aseptic area. If the transfer could involve disconnection from the air supply for more than 15 seconds, portable compressed air cylinders should be provided for the disconnection periods;
- the facilities for decontamination of the airsuit after each occasion of use. Decontamination normally involves washing the outside of the airsuit before its removal. If the washing facilities are not immediately contiguous with the aseptic area, a method of minimising the spread of contamination and preventing the exposure of persons not wearing airsuits needs to be considered. For example, the outside of the suit could be wiped with a damp cloth before the wearer leaves the aseptic area prior to the final decontamination;
- integrity testing of the exhaust valve filters on the airsuits;
- validation for its effect on the aseptic environment.

The use should also refer to the general guidance on the use of airsuits which is given in Section 2.

3.4 Maintenance Work

Where RPE is required to be worn during the maintenance of production equipment etc. carried out in an aseptic area under sterile production conditions, the considerations described above apply. Where maintenance work is being carried out under non-sterile conditions and the area will be fumigated/sanitised before being used again for production, the above considerations do not apply.

4 Storage and Maintenance of Respiratory Protective Equipment

4.1 Introduction

Provision of effective maintenance and adequate storage facilities is essential to ensure that RPE continues to meet its performance specification. The COSHH Regulations require that RPE other than one-shift disposable types should be maintained on at least a monthly basis; there being some relaxation to 3 monthly intervals for ori-nasal equipment used infrequently for protection against low hazard materials. In addition, records of all maintenance carried out on RPE must be kept for not less than 5 years.

Storage facilities are important to prevent contamination of the RPE or conversely contamination of non-working clothing etc. by the equipment. The Personal Protective Equipment (PPE) at Work Regulations 1992 requires employers to provide adequate accommodation for all PPE.

To meet the above legislative requirements in pharmaceutical manufacturing facilities, employers should provide suitable systems of work with nominated individuals responsible for the various aspects of RPE storage and maintenance. In addition, provision will need to be made in terms of facilities, equipment and training.

All maintenance procedures should be fully documented and should contain the following information:

i) The nature of the procedures;
ii) The frequency with which the above procedures are carried out;
iii) Those responsible for carrying out the procedures and keeping records.

4.2 Maintenance

4.2.1 Introduction

In these guidelines, maintenance includes cleaning, disinfecting, examination, repair, testing and record keeping. The nature of these procedures, and the frequency with which they are carried out, should be determined by the responsible manager taking into account:

- the requirements of the COSHH Regulations;
- the manufacturers' recommendations;
- the hazard of the materials;
- the frequency and severity of use;
- the workplace conditions

The Approved Code of Practice accompanying the COSHH Regulations outlines the maintenance requirements for the various types of RPE in common use. Guidance is also available in Health and Safety Executive publications Guidance Notes HS(G)53 and EH53. (References 3 and 4).

The following paragraphs give guidance on maintenance procedures applicable to the main types of RPE used in the pharmaceutical industry. These recommendations are intended as guidance only. In all cases, responsible managers must determine what procedures are appropriate for the individual types of equipment taking into account the conditions listed above.

4.2.2 Cleaning and Disinfecting

RPE used for long periods during a shift or working day should be cleaned and disinfected at the end of the working period to remove chemical contamination and to ensure it is maintained in a hygienic condition. Heavily contaminated equipment may need cleaning on a more frequent basis. Where equipment is shared between a number of users, cleaning/disinfecting should be carried out before use by each new user.

Suitable procedures for cleaning/disinfecting should be available from the suppliers of the equipment, but they must in all cases take into account the physical properties of the materials being removed, e.g. whether they are water soluble. If it is necessary to use detergent or mild caustic cleaners these should be removed by thorough rinsing, as residues may cause skin problems.

4.2.3 Dry Decontamination of Powders

Dry decontamination using brushes or similar equipment is not recommended. Vacuum cleaners can be used as a primary method of decontamination e.g. before leaving the immediate work area, provided adequate filtration of the exhaust air is provided.

Vacuum cleaning is not as effective as wet decontamination methods and should only be regarded as a means of reducing rather than totally removing dust contamination.

4.2.4 Wet Decontamination of Powders

Cleaning with a suitable liquid is the most effective method of decontaminating RPE. Water is adequate for most water soluble compounds, but for compounds with poor water solubility the mechanical action of water washing may not be sufficient to remove dust deposits. For these compounds, detergents or alkaline cleaning agents should be used, as organic solvents may adversely affect the material of the equipment. In all cases where liquids are used for decontamination, the environmental consequences of the method of disposal of the washings should be given adequate consideration. Care should also be taken not to wet any filters.

4.2.5 Facilities for Decontamination

RPE contaminated with hazardous substances should be thoroughly cleaned after use to ensure employees are not exposed during handling and re-use. The cleaning procedure should not give rise to additional exposures to users or others responsible for decontaminating equipment. Consequently, special facilities may be needed to control emissions arising from the decontamination procedure, e.g. ventilated enclosures.

The requirement for trained staff and special facilities means a central facility for maintaining large numbers of equipment may be the most effective way of ensuring procedures are carried out to an acceptable standard.

Where air suits are in use, facilities for decontamination require special consideration. The design of such facilities are covered in detail in Section 2, but should in all cases take into account the requirements for showering, drying etc.

4.3 Examination, Inspection and Test

All RPE should be examined, inspected and, in many cases, tested before use. The nature of these procedures will depend on the type of equipment, details of which should be obtained from the manufacturer or supplier. Each thorough examination should check:

1. The condition of critical parts such as straps, face seals, exhalation valves, breathing tubes, filters, material integrity etc.
2. The performance of the equipment where appropriate e.g. the air supply rate in battery powered equipment.

With the exception of battery powered equipment, equipment in routine use can be left in a 'ready-for use' state for a period of up to one month after it has been examined.

4.3.1 Air Supplied Equipment

Maintenance procedures should ensure that air supplied equipment (either battery powered or compressed air) is capable of delivering the required air flow before each use.

4.3.2 Compressed Air Line Equipment

In the case of compressed air line equipment, the only acceptable method for testing the adequacy of the air flow is to connect the equipment to the compressed air supply and

measure the flow rate using a calibrated rotameter. This test must be carried out as specified by the manufacturer, as the rotameter must be connected at the appropriate point to obtain a valid result.

Where low flow alarms are fitted, it should be checked that these operate at the air flow specified by the manufacturer. It should be noted that some air-line equipment may be fitted with a low pressure alarm rather than a low flow alarm. Blockage of internal filters or silencers can result in seriously impaired flow, but no reduction in pressure at the alarm. In such cases the alarm will not operate. The provision of low pressure alarms will not therefore obviate the need for testing that the equipment can deliver an adequate air flow. For further details of testing of air supply rates at breathing air points see Section 5.

4.3.3 Battery Operated Equipment

Manufacturers of battery operated equipment should provide details of the method used to test the air flow. In all cases, after testing, the rechargeable nickel-cadmium (Ni-Cd) battery pack should be maintained in a fully charged condition before issue of the equipment for use. This will ensure the equipment delivers an adequate air flow for the manufacturers stated design duration. This will normally be the duration of the working shift but may be as little as 4 hours. Care should be taken to avoid 'memory' effects in Ni-Cd batteries. These may occur when the battery is left in a semi-charged state for a period of time, and cannot be fully recharged. These 'memory' effects can be avoided by fully discharging the battery pack before recharging, and this facility is fitted to some types of chargers. However, it is worth checking with the manufacturers or their technical representatives what regime of charging is best suited for the battery packs under their conditions of use.

4.4 Repairs, Replacements etc.

Replacement of consumable parts e.g. batteries, filters etc. can be carried out by users after suitable instruction. However, more complex procedures, e.g. performance testing, carrying out repairs of material in air supplied clothing etc. will require adequate provisions both in training and workshop facilities. Any parts used should be genuine components supplied from the manufacturer, and should not differ significantly from those in the original equipment. Employees should not, however, attempt repairs on more complex parts which should be renewed or returned to the manufacturer for repair. The manufacturers should give guidance on these matters and should also advise when to consider complete replacement of the equipment.

4.4.1 Respirator Filters, Cartridges, Canisters etc.

As part of the risk assessment required by the COSHH Regulations, the length of filter life will need to be estimated. The manufacturers may be able to advise on the frequency of filter changing, but in many instances it will not be possible to predict the length of filter life for protection against particular substances in various applications. In these cases, a conservative estimate of filter life should be made. For example, a filter change might be required after each shift, though more frequent filter changes may be necessary to protect against exposure to highly toxic materials or high concentrations of gases, vapours or particulates. Whilst it is not a legal requirement, it is recommended that changing frequencies are included in written procedures.

4.5 Training

Employers should ensure that training is given by a competent person not only to RPE users, but also to those involved with its storage and maintenance. The contents of the training programme will depend on the requirements of the job, and should also take into account the complexity of the equipment and the reliance on the equipment in relation to the risks. In all cases, records of training given should be kept (see paragraph 4.6.2).

The programme should include training for new equipment and refresher training, particularly where equipment is only used intermittently. Training in the replacement of

consumable parts in relatively simple RPE, such as negative pressure respirators, only need consist of instruction and practice. More complex equipment will require longer training and include the theoretical and practical aspects of the procedures. For this type of equipment, on initial purchase, on site training may be available for relevant employees from the technical representatives of the manufacturers. However, employers should satisfy themselves that the training will be of an adequate standard.

For RPE which relies on a face seal to achieve an effective performance, a fit test should be performed each time the RPE is put on. Manufacturers should provide instructions on fitting equipment and employees must be trained in the appropriate technique.

4.6 Records

4.6.1 Maintenance of RPE

Paragraphs 68-69 of the COSHH Approved Code of Practice specify the details to be recorded when equipment is maintained. The exact details recorded will depend on the type of equipment, but in all cases records should include details of:

- identification of the equipment;
- condition of all critical parts;
- any repairs/replacements carried out;
- performance tests where appropriate;
- identity and signature of the person carrying out the maintenance.

Records of maintenance can be kept in any form, but must comply with the COSHH. Regulations must be readily available to HSE inspectors, employees or their representatives.

4.6.2 Civil Liability Claims

The COSHH Regulations require that all records relating to the maintenance of control measures be kept for a minimum of 5 years. However, in cases of employees' claims of ill-health arising from exposure to hazardous substances, documented evidence may be required by the courts that employers had fulfilled all their statutory duties. It is prudent therefore, to keep relevant records (e.g. maintenance, training) for the same time as that required for health records, i.e. 40 years.

4.7 Storage of RPE

Where RPE other than one-shift disposable types is used on a day-to-day basis, or even where one shift disposable respirators are used intermittently during a working shift, facilities for storage should be provided. These facilities should be separate from:

1) Production areas that are likely to be contaminated with hazardous substances;

2) Lockers used for the storage of non work clothing.

Taking into account these factors and the varying requirements for storage of different types of equipment, managers will need to assess on a case by case basis what facilities are needed. The assessment will need to take into account not only the requirements for when the equipment is not in use, but also during decontamination/drying procedures.

Consideration should also be given to storage of equipment during transport to and from the workplace where necessary, e.g. when equipment is issued from a central facility. Simple provision such as a plastic bag will be adequate in most instances, but this should not be used as the means of storing equipment in a contaminated environment. All storage facilities provided should be maintained in a clean and hygienic condition.

5 Testing of Low Pressure Compressed Air Supplied as Breathing Air

5.1 Introduction

5.1.1 The COSHH Regulations require regular examination and, where appropriate, testing of all respiratory protective equipment other than one-shift disposables. In the case of airline-fed equipment, volume flow and quality of the supplied air require to be tested. Some criteria for assessing the suitability of compressed air for breathing are contained in British Standard 4275: 1974 (Reference 8) and in a draft standard for public comment published in 1989 by the British Standards Institution (BSI). The following recommendations for concentration limits for potential contaminants in breathing air are made with reference to the above BSI publications.

Carbon monoxide:	5 ppm
Carbon dioxide:	500 ppm
Oil mist:	0.3 mg/m^3

Breathing air should also be free from all odour and contamination by dust, dirt, bacteria or metallic particles and should not contain any other toxic or irritating ingredients. The supplied air temperature should be between 15 and 25°C and its relative humidity should not exceed 85 per cent. In addition there should be no free water in the air supply.

5.1.2 The existence of a published concentration limit for any contaminant is not of itself a ~~justification for regular testing of breathing air supplies against that limit. A suitable protocol~~ defining the parameters to be tested and the frequency with which such testing is to be carried out should be drawn up on the basis of an assessment carried out for any individual air supply system.

5.1.3 In general, some testing of breathing air supplies should be undertaken at intervals not exceeding one month. However, the assessment and the test record history of particular breathing air systems may indicate that testing at less frequent intervals does not compromise safety standards. In such cases, the test intervals should not exceed three months. Where large numbers of breathing air points are in use from a centralised compressed air supply, testing of all points for all parameters at the set interval may be neither practical nor justified. For gaseous contaminants there is limited scope for variability between points for an established air supply system, therefore it is reasonable to test at a number of representative points. For particulates or aerosols which do not pose an acute health risk, a rolling system of tests covering all points in the course of a year is suggested. Where results of routine testing indicate that satisfactory air quality is not being maintained, appropriate corrective maintenance will need to be undertaken. The frequency of subsequent routine maintenance and testing would then need to be increased.

5.1.4 The establishment of a programme of routine testing of breathing air quality is not an alternative to ensuring that the design, location and maintenance of any breathing air installation is suitable and satisfactory. General duties under the COSHH Regulations require that breathing air systems are designed and air inlet points are sited such that possible risks arising through introduction of air contaminants are eliminated or minimised.

5.2 Assessment

The aims of the assessment carried out on any particular system for the supply of compressed breathing air should include the following:

5.2.1 Identification of potential air contaminants which might be present or be introduced into the air supply.

This includes potential contaminants which might be drawn into air compressor inlet points (e.g. carbon monoxide from internal combustion engines or from combustion plant) and contaminants which might arise through operation or failure of the system (e.g. oil mist from oil-lubricated compressors, carbon monoxide from thermal decomposition of lubricating oils, etc. particulates from deterioration of system components, bacterial growth in condensates). The presence and effectiveness of any safety devices should be taken into account. For example, an effective thermal cut-out mechanism will help to minimise the possible risks from thermal decomposition of oil or PTFE seals through system overheating.

5.2.2 Establishment of criteria (usually concentration limits and/or supply flow rates) against which results of testing for contaminants can be compared.

Reference should be made to the standards referred to in paragraph 5.1.1. In addition, it is recommended that a figure corresponding to 10 per cent of any relevant occupational exposure limit be taken as a guideline when considering the acceptability of other contaminants. In the absence of more specific data, the effects of multiple contaminants with similar modes of toxicity should be considered as additive and concentration limits should be reduced accordingly.

5.2.3 Establishment of suitable and reasonably practicable methods for testing against the criteria identified.

Guidance on methods for testing is provided in Section 5.4 and by the British Occupational Hygiene Society (Reference 9).

5.2.4 Establishment of suitable test locations.

Where criteria are achieved through point-of-use filter sets, testing for those criteria will necessarily be at individual points of use.

5.2.5 Establishment of the frequency with which testing for the various air quality parameters should be carried out.

This will depend both upon the likelihood of occurrence and the severity of the hazard. Routine testing may be supplemented by a more extensive battery of tests at less frequent intervals.

5.2.6 All newly installed or newly connected breathing air points must be comprehensively tested for air supply rate and air quality before first use, and after any repair involving a break in the line.

5.2.7 Where breathing air is supplied from mobile compressors, supply rate and quality of breathing air should be tested immediately prior to first use at any new location.

5.3 Testing Parameters

5.3.1 Oxygen

All newly installed breathing air point should be tested to ensure that the oxygen content of the air is normal (20.9 per cent by volume) prior to being used, particularly when breathing air systems are installed in places where other piped gases or services may be present. Testing for oxygen content should also be undertaken following either an extended period of disuse of a system or following any maintenance operations which have required breaking and remaking of breathing air lines. Testing for oxygen content of the air on a regular basis is not normally necessary.

5.3.2 Carbon Monoxide

Unless it can be reliably established that there is no means by which carbon monoxide might be introduced into the system (Section 5.1.4 outlines design requirements), representative points in the breathing air system should be tested for the presence of a carbon monoxide at intervals not exceeding three months. It is recommended that such representative points should include as a minimum points closest to and most remote from the main compressed

air reservoir supplying the system. If there is considered to be a particular risk of carbon monoxide being drawn into the system, owing to the proximity of combustion plant exhausts, for example, consideration should be given to installation of a continuous monitoring (alarm system) for the presence of carbon monoxide.

5.3.3 Carbon Dioxide

Where there is a residual risk that carbon dioxide might be introduced into the breathing air system (Section 5.1.4 outlines design requirements), testing for the presence of excessive carbon dioxide should be undertaken at intervals not exceeding three months. Where testing for carbon dioxide is required, representative points as for carbon monoxide above should be tested as a minimum. If the initial assessment of the breathing air system indicates that there is a particular possibility that stale air may remain in the system over prolonged periods, owing to infrequency of use and/or lack of a controlled air bleed system for example, testing for carbon dioxide should be undertaken at points immediately downstream from any secondary compressed air reservoirs supplying individual parts of a system in addition to the stated minimum.

5.3.4 Oil Mist

Where breathing air is supplied from oil-lubricated compressors or there are other reasons to believe that oil is a potential contaminant of the system, breathing air supply points should be tested for the presence of oil mist at intervals not exceeding three months.

- Where point-of-use filters are used to achieve compliance with limits set for oil mist, testing should be carried out downstream of the individual filters at each point of use.
- Otherwise testing should be carried out at a point immediately downstream from each compressed air reservoir or immediately after any in-line filter if fitted. A representative selection of the individual breathing air points should be tested on a rolling basis, such that the whole system is tested in the course of a year.

5.3.5 Particulates

Particulate contamination arising through degradation of components of the supply system can generally be assessed through inspection of in-line particulate filters where these are fitted at individual breathing air points or within individual air supply hoses. In-line filters should in any case be subject to routine inspection and replacement as part of the RPE maintenance programme required under COSHH. Where there is an identifiable residual risk that particulate contaminants of particular concern might be introduced into the system (see Section 5.1.4 for design requirements), consideration should be given to undertaking more specific assays.

In many circumstances it may be feasible to measure total particulate concentrations as an indirect measurement of quality with respect to oil mist, thus avoiding the need for a specific assay for oil mist. If this approach is taken however, the limit specified for oil mist should be taken as the criterion for acceptability with respect to total particulate including oil mist, unless there is reason for applying a lower limit.

5.3.6 Organic Vapours

It may be appropriate to test newly installed breathing air points for the presence of organic vapour contaminants. Provided that compressor air intake points have been sited away from foreseeable sources of organic vapour contamination (Section 5.1.4), routine testing for the presence of organic vapours should not be necessary. Consideration should be given to the possible need for continuous monitoring of breathing air quality if air intakes cannot reasonably practicably be located away from potentially significant sources of organic vapour or any other volatile/gaseous contaminants. Consideration would need to be given to the nature of the potential contaminant(s) with respect to toxicity and to warning properties (e.g. detectability by smell), when considering the case for continuous monitoring.

5.3.7 Humidity and Temperature

Since the acceptability of temperature and humidity can generally be readily judged on a subjective basis, there is generally no advantage to be gained from any routine measurement. Consideration may need to be given to some investigative measurement in response to subjective complaints of discomfort reported by airline-fed equipment users.

It should be noted that air humidity is an important parameter to be controlled where compressors are used for filling of high pressure cylinders for use with breathing apparatus etc. Such applications are beyond the scope of these guidelines, but BS 4275 includes criteria for such circumstances.

5.3.8 Supply Rate

Individual breathing air points should be checked at intervals not exceeding three months to ensure that they are capable of supplying air at the rate specified for the types of airline-fed RPE in use. The test conditions should simulate the most onerous conditions of use, flow rates being measured in line with the airline-fed equipment and with the maximum anticipated number of breathing air points being in use, or simulated use at the time of the test.

Many airline-fed items of RPE incorporate low flow alarms which effectively continuously monitor the air supply rate to the user. These alarms usually trigger at a flow rate which is below the specified minimum flow rate for the equipment. Ensuring that the low flow alarms are working correctly on all items of equipment is therefore not a substitute for checking that the air supply rate is within the specified range.

5.4 Test Methods

5.4.1 Oxygen Content

Direct reading, electrochemical type oxygen sensors are readily available. Testing may be undertaken directly in-line from the air supply point through use of a suitable sampling port/chamber or using a sample of air collected into a suitable gas-tight bag or similar.

5.4.2 Carbon Monoxide

As for oxygen content, electrochemical type sensors are readily available, therefore similar methods can be used and the two tests can be easily combined. Alternatively gas detection tubes may be used either sampling from a suitable gas bag/container or in conjunction with purpose designed systems for in-line testing. Systems based on infra-red absorption may be more suitable for continuous monitoring applications.

5.4.3 Carbon Dioxide

Direct reading instruments usually based on either infra-red absorption or electrochemical detection are available. Alternatively, gas detection tubes may again be used.

5.4.4 Oil Mist

Oil mist may be quantified spectrophotometrically following collection onto a glass fibre filter placed in-line with the metered air supply. Principal disadvantages of this approach are the time required to sample a sufficient volume of air and the possibility that sampling at a flow rate considerably reduced from normal may not be representative.

Detector tube methods are again available but suffer from similar disadvantages to those for filter collection and frequently provide only a semi-quantitative result based on subjective interpretation of colour stains. In many circumstances it is more practical to consider oil mist simply as part of a total particulate determination.

5.4.5 Particulates

Particulate concentrations may be determined gravimetrically following collection onto a suitable glass fibre filter placed in-line as for oil mists. This method has similar disadvantages with respect to sample collection as for oil mist, but the time required for sample analysis is largely eliminated. In some circumstances it may be appropriate to subject samples of particulate collected onto filters to further analysis if, for example, it is suspected that an airline system is contaminated with a pharmacologically active dust.

An alternative approach is to use a portable light-scattering type, direct reading, dust monitoring instrument. By use of a suitably designed sampling chamber, the particulate concentration can be measured directly in air supplied at the rate specified for the RPE. As the response of light scattering instruments varies according to the nature of the particulate being assessed, it is recommended that a large margin for error should be allowed. For example an indicated level of no more than 0.1 mg/m^3 could be taken as indicating that the breathing air quality is acceptable with respect to particulates which might include oil mist. If use of an instrument of this type is being contemplated, it is recommended that the method is evaluated against a gravimetric method in order to establish the range of readings which might be obtained under normal conditions. The light scattering instrument can then be used to quickly give an indication of any deviation from the norm which might require further investigation.

5.4.6 Organic Vapours

A general test for organic vapours may be made based upon the response of a flame-ionisation detector sampling either from an in-line chamber or from a collected sample of air. Where identification and quantification of specific organic compounds or other vapours/ gases is required, a variety of more selective instrumental or detector tube based techniques are available (See reference 9).

5.4.7 Temperature and Humidity

Instruments and techniques used for assessment of ambient temperature and humidity conditions can be adapted to assess breathing air supplies through use of suitably designed sampling chambers/ports. In general, however, subjective assessment of comfort conditions by equipment users will be greater determinants of the need for system changes than will measured levels.

5.4.8 Air Supply Rate

Air supply rates can be measured using a suitably calibrated rotameter. In order to be meaningful, the air supply rate should be measured with the air-line fed RPE connected in series. It should be ensured that the reading from the rotameter is corrected for any significant deviation from normal atmospheric pressure if it is not practical to connect the flow meter last in the series (i.e. open to ambient pressure air). Individual points should be tested with the maximum number of other points in simulated use at the same time (e.g. if a maximum of three air suits might be in use at any one time in a particular area, each point in that area should be tested with two suits connected to adjacent points on the system). Alternatively, the flow meter should be used to check the efficiency of low flow alarms when fitted, which will then in effect provide a continuous indication of a satisfactory flow rate.

Where air supply points are fitted with supply pressure gauges, maintenance of an adequate supply pressure when connected to a correctly functioning item of RPE may be taken as an indirect demonstration of an adequate supply rate. The item of RPE used for such a test should first be demonstrated to be functioning correctly by validation against an externally connected flow meter as above.

5.5 Summary of Minimum Recommended Test Protocol

5.5.1 Commissioning

- Each breathing air point should be tested for all parameters of possible concern (for example, air supply rate, oxygen, carbon monoxide, oil mist, carbon dioxide, particulates, organic vapours) prior to use for newly installed systems or newly connected supply points.

5.5.2 Monthly or Three Monthly

- Test air supply rate at each point or alternatively check correct functioning of low flow alarms on air-line equipment when fitted;
- Test representative points for presence of carbon monoxide unless it can be demonstrated that CO is not a potential contaminant;
- Test representative points for carbon dioxide where CO_2 is identified as a potential contaminant of concern;
- Test each individual supply point for oil mist and/or particulate content where air quality is achieved through point of use filters. Otherwise, test supply at points nearest and furthest from the supply and at a representative sample of points (~ 25 per cent) such that all points will be tested in the course of a year.

NOTES:

i) Additional testing may be necessary where there are concerns over the potential for introduction of specific contaminants into the breathing air supply e.g. organic vapours, active intermediates or products – see main text.

ii) Where testing is carried out in conjunction with routine maintenance, testing should be carried out immediately prior to, rather than immediately after, maintenance (e.g. filter changing). The frequency of subsequent maintenance and testing will need to be increased if air quality is not being maintained.

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