**COSHH Risk Assessment Guidance Document**

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# Introduction

## Guidance statement

The Control of Substances Hazardous to Health (COSHH) is a fundamental part of the management of health and safety for all healthcare organisations. The basic principles of COSHH assessments are the same as general risk assessments. However, there are some additional considerations to be taken.

This guidance document is provided to offer those who undertake COSHH risk assessments with a basic understanding of the background to the subject and provide a structure to enable them to complete a suitable and sufficient risk assessment.

Each organisation will have varying risks that are associated with the chemicals, products and substances that they may utilise in the course of their activities. Organisations may already have arrangements in place to manage these risks in context with others.

Whilst this guide contains information and explanations of some of the broader principles and core components of COSHH risk, it is not intended to cover every aspect or circumstance. It must be recognised that some simplifications of explanation and illustrative elements have been provided to assist managers.

Note: The primary source of reference in relation to this subject must be the relevant regulations and any Approved Code of Practice (ACOP) or subsequent information provided by the Health and Safety Executive (HSE)

Many of the key concepts are explained in detail in the [Risk Assessment Guidance Document.](https://practiceindex.co.uk/gp/forum/resources/risk-assessment-guidance-document.1519/)

## Status

The organisation aims to design and implement policies and procedures that meet the diverse needs of our service and workforce, ensuring that none are placed at a disadvantage over others, in accordance with the Equality Act 2010. Consideration has been given to the impact this guidance might have with regard to the individual protected characteristics of those to whom it applies.

This document and any procedures contained within it are non-contractual and may be modified or withdrawn at any time. For the avoidance of doubt, it does not form part of your contract of employment.

## Training and support

The organisation will provide guidance and support to help those to whom it applies to understand their rights and responsibilities under this guidance document. Additional support will be provided to managers and supervisors to enable them to deal more effectively with matters arising from this document.

# Scope

## Who it applies to

This document applies to all staff at Sheerwater Health Centre. Other individuals performing functions in relation to the organisation, such as agency workers, locums and contractors, are encouraged to use it.

## Why and how it applies to them

This document has been produced to provide staff at Sheerwater Health Centre with an overview of how the organisation can undertake a suitable and sufficient COSHH risk assessment whilst giving the necessary level of information to understand how the process is undertaken and the benefits that can be gained for both the organisation and its patients.

# Definition of terms

## Control of Substances Hazardous to Health (COSHH)

COSHH is the law that requires employers to control substances that are hazardous to health.[[1]](#footnote-1)

## Task

An activity performed that sets the context for the risk assessment

## Hazard

Something with the potential to cause harm (hazardous substance)

## Consequence

An outcome that is reasonably foreseeable

## Reasonably foreseeable accident

A reasoned prediction of what and why an accident may occur

## Reasonably foreseeable injury

An injury (or level of harm) that could reasonably be anticipated as an outcome

## Likelihood

The likelihood of an accident (or exposure) occurring

## Risk

Hazard consequence (multiplied by) likelihood

## Risk matrix

A numerical scale of consequence and likelihood

**3.9 Accreditation**

The action or process of officially recognising someone or an organisation as having a particular status or being qualified to perform a particular activity

**3.10 Health and Safety Executive**

The Health and Safety Executive (HSE) is Britain’s national regulator for workplace health and safety. It prevents work-related death, injury and ill health.[[2]](#footnote-2)

**3.11 Substances hazardous to health**

COSHH covers substances that are hazardous to health, including but not limited to:[[3]](#footnote-3)

* Chemicals
* Products containing chemicals
* Fumes
* Dusts
* Vapours
* Mists
* Nanotechnology
* Gases and asphyxiating gases
* Biological agents (germs)
* Germs that cause diseases

# Basic COSHH risk assessment principles and components

## Overview

It will be of huge benefit to have a systematic approach to the identification, assessment and management of risk which would enable a much better understanding of what needs to be managed and to what extent.

Employers’ duties and responsibilities are set out in the Control of Substances Hazardous to Health Regulations (2002) as amended and its Approved Code of Practice (ACOP). All ACOPs, as well as supporting information, can be searched for and downloaded free of charge from the Health and Safety Executive website.

## Duties and responsibilities (summary)

As an employer, there is a requirement for the organisation to assess the risks associated with hazardous substances at work and to control them.

The [HSE website](https://www.hse.gov.uk/coshh/basics/index.htm)provides many sources of useful information to help organisations to comply with the law and to control exposure to hazardous substances in the workplace.

If the organisation uses or generates chemicals or other hazardous substances at work that could put people’s health at risk, then COSHH risk assessments and adequate controls will be required.

An employer’s duties under COSHH ([Regulation 3](https://www.hse.gov.uk/pubns/priced/l5.pdf)) towards employees and other people on the premises, or those likely to be affected by these risks such as contractors, visitors and patients (public), are set out in tabular form on page 15 of the hyperlinked document.

This table (in summary) includes the following requirements:

* To undertake risk assessment with prevention and control of exposure, the use of control measures (including their testing and maintenance), monitoring exposure, health surveillance, the provision of information, training and arrangements for emergencies.

It must be noted that the term ‘so far as is reasonably practicable’ (SFAIRP) is often an interchangeable term with ‘as low as is reasonably practicable’ (ALARP)[[4]](#footnote-4); this is the measure of control to fulfil these employer duties as detailed by the HSE.

The primary duties of the employer and employee are detailed in the Health and Safety at Work etc. Act 1974 (HASAWA). These are also described in the Health and Safety Law poster.

## What is a substance hazardous to health?

The term, hazardous substance, is wide ranging. The COSHH ACOP contains a full list and description of potentially hazardous substances as well as guidance, references and specific linked regulations. It applies to a wide range of substances and preparations (mixtures of two or more substances) which have the potential to cause harm.

Hazardous substances can occur in many forms including those that are both naturally occurring materials as well as manufactured products. This includes solids, liquids, vapours, gases, dusts and fumes as well as asphyxiants, biological agents, mixtures of compounds, micro-organisms or natural materials such as flour, stone, plaster or wood dust.

Employers should regard a substance as being hazardous to health if it is hazardous in the form in which it may occur in the work activity.

A substance hazardous to health need not be just a chemical compound, it can also include any substance that has chemical, biological or toxicological properties and the way it is used or is present at the workplace that creates a risk to health. It is important to appreciate that, under COSHH regulations, the following are also relevant:

* Carcinogens
* Mutagens

##  Routes of entry to the human body

The potential routes of entry for hazardous substances to the human body are:

* Ingestion (by swallowing)
* Injection
* Absorption (through the skin or body membranes)
* Inhalation (through nose or mouth into lungs)

## General regulatory information (summary)

COSHH is a broad and potentially complex subject with many associated regulations that must be considered in context. It is not intended to repeat the wide range of regulatory requirements and guidance within this document but to provide a simplified summary of key elements and to illustrate relevant points. If there are elements of the process that are not understood, or there are significant concerns identified, competent advice is to be sought.

The following may be of use to organisations:

1. The Management of Health and Safety at Work Regulations (MHSWR) and its ACOP (this is often referred to as the management regulations) that may need to be taken into account when managing, for example, pregnant workers or to ensure the protection of young people at work.

1. Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).[[5]](#footnote-5) This is the system for controlling chemicals in Europe which has adopted some of the older aspects of the chemicals system in Europe including Safety Data Sheets (SDS). This includes the list of contents of a data sheet.
2. The Classification, Labelling and Packaging of Substances and Mixtures Regulations (CLP). This includes updated hazard pictograms which alert to the presence of a hazardous chemical.  These pictograms help us to know that the chemicals we are using might cause harm to people or the environment.
	1. The CLP regulations also introduce two new signal words – ‘Danger’ and ‘Warning’. If the chemical has a more severe hazard, the label includes the signal word, ‘Danger’; in case of less severe hazards, the signal word is ‘Warning’.
	2. The CLP hazard pictograms appear in the shape of a diamond with a distinctive red border and white background.  One or more pictograms might appear on the labelling of a single chemical.

Note: If you buy in a chemical product that is classified as ‘dangerous to supply’, it will come with a Safety Data Sheet (SDS) which will help you to make a risk assessment. An SDS describes the hazards the chemical presents and will give you information regarding, for example, handling, storage and emergency measures in case of accident.

An illustrative selection of pictograms with a basic description are shown overleaf. Further information and examples can be found on the HSE website.[[6]](#footnote-6)



Image source: hse.gov.uk

## Key COSHH regulations

The COSHH regulations are set out within the ACOP which also provides approved guidance covering each regulation. Some of the key regulations to be aware of are:

* Regulation 6 Risk assess and record significant findings
* Regulation 7 Risk reduction (ALARP)
* Regulation 8 Use of control measures
* Regulation 9 Maintenance of control measures
* Regulation 10 Monitoring of exposure
* Regulation 11 Health surveillance
* Regulation 12 Information, training, instruction and supervision

(competency) and consultation with employees

* Regulation 13 Accident, incident and emergency plans

## COSHH reference documents

As the day to day health and safety management responsibility rests with managers, it is important that each manager understands the risks and hazards they face in their domain. There are a number of supporting documents which could be utilised to assist the development of COSHH risk assessments. They include:

**1.** [**Working with substances hazardous to health: A brief guide to COSHH**](https://www.hse.gov.uk/pubns/indg136.htm)

This leaflet is aimed at employers in small businesses. It will also be useful for trade union and employee health and safety representatives. It explains how to control hazardous substances at work and comply with the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended).

**2.** [**EH40/2005**](https://www.hse.gov.uk/pubns/books/eh40.htm)

This latest version of the HSE publication EH40/2005 ‘Workplace exposure limits’ has been updated to include the new and revised workplace exposure limits (WELs). This will guide those responsible for controlling exposure to hazardous substances.

**3. Safety Data Sheets (SDS) also known as Material Safety Data Sheets (MSDS)**

Safety data sheets (SDS) are required by the REACH regulations. They are key documents in the safe supply, handling and use of chemicals. They should help to ensure that those who use chemicals in the workplace do so safely without risk of harm to users or the environment.

A safety data sheet (SDS) will contain the information necessary to allow employers to conduct a risk assessment as required by COSHH regulations. The SDS itself is not a risk assessment. It will, however, describe the hazards and this will help employers to assess the probability of those hazards arising in the workplace, usually in the context of a task.

SDSs are essential if a chemical is dangerous and is being supplied for use at work, whether in packages or not. SDSs are also needed if the chemical is not classified as hazardous but contains small amounts of a hazardous substance(s). SDSs must be provided by the supplier/manufacturer of the hazardous substance. Manufacturers/suppliers often place these documents on their websites for customers to download and every SDS follows the same 16 point content format.

Suppliers are responsible for keeping SDSs up to date. However, if there is a concern that this may not be the case, organisations are to request confirmation in writing from the supplier that it is the most recent issue.

Best practice for SDS includes:

1. Recording the issue date and/or any reference numbers on the SDS on the COSHH risk assessment
2. Making the SDS available for staff to access or refer to as required
3. Ensuring emergency plans for the spillage/release of hazardous substances are available to staff

**Note: During the Brexit transition period, all EU regulatory requirements remain in force. For further information, refer to the HSE website for any updates that may develop as the UK leaves the EU.**

## COSHH risk assessment documentation

The important aspect of any risk assessment is the content. A template has been provided at Appendix 1 to enable assessors to construct a reflective risk assessment at Sheerwater Health Centre. It is the assessor’s responsibility to ensure that the data contained within the risk assessment is reflective of the organisation’s conditions.

## What should be assessed

Hazardous products are potentially present in every workplace. However, context is very important. It is therefore sensible to understand what hazardous substances are on site, as well as being reasonable about the actual potential for harm.

Managers should consider the significant risks that may be posed by hazardous substances in the context of:

* The tasks undertaken with the substance (e.g. how they are applied/used)

The assessment should also consider any significant risks posed by:

* How the hazardous substance is stored
* How the hazardous substance is transported (inbound and outbound)
* How the hazardous substance is disposed of
* Accidental release or spillage of the hazardous substance

There are potentially significant differences between the levels of risk posed by different products (hazardous substances) which, in context, will range from very high to very low.

It can be argued that some domestic type products will be of such little consequence in context with other hazardous substances in use, e.g. formalin, that they are trivial in comparison.

It may be the case that if these domestic products are adequately controlled by being kept in an area that is not accessible to the public, then these control measures may be deemed sufficient.

It is important to understand the potential for significant harm for each product or group of products and prioritise accordingly. It is recommended that an audit of products held on site and those products potentially used for home visits is conducted. The list of hazardous substances the audit shows should then be prioritised for assessment.

To further support managers in determining what substances merit assessment, the HSE has provided a [COSHH FAQ page](https://www.hse.gov.uk/coshh/faq.htm).

In relation to contract cleaning, the cleaning contractor is an employer and they have responsibility for undertaking risk assessments for their activities, including COSHH. However, if their products are stored on site, it is suggested that a basic risk assessment be undertaken with control measures for adequate storage, security and access and/or emergency spillages considered by the risk assessor.

General factors that may be considered in a COSHH risk assessment include:

* The relative security and accessibility of the hazardous substance to unauthorised persons including the public, particularly with regard to children and other vulnerable persons
* The competency of those involved
* How often the hazardous substance is used and for how long people are exposed, inclusive of any potential residual effects

An expanded list of illustrated factors that may be considered is provided at Section 5.6.

When risk assessments are being undertaken, it is important to consider, in context, the benefit of having written safe working practices for hazardous products (or circumstances arising from their use) to ensure that storage, transport, use, safe disposal and any emergency requirements are addressed in a practical sense.

Competent judgement must be exercised in context with hazardous substances to ensure that the arrangements in place for their control are reasonable, including when substances are taken off site.

## Making competency-based judgements

It is important that those involved in the COSHH risk assessment process have an appropriate level of demonstrable competence to undertake the risk assessment and manage the process end to end. There are many opinions as to what is meant by the term competency. However, it is generally accepted to be a blend of the following factors: knowledge, experience, ability, skill and training, underpinned by an individual’s clear understanding of their own limitations.

Before undertaking a risk assessment, it is important to understand what needs to be risk assessed. To achieve this, risk assessors need to consider the products and the tasks arising from their use.

## Task listing

Most risk assessments are task based. COSHH related risk assessments are no different. Risk assessors need to ensure they are assessing the tasks that staff and/or patients may undertake or risks they are potentially exposed to from other tasks being performed by staff or others whilst on the premises.

To help generate this list of activities, it is often useful to view this from different perspectives.

Consider the following questions to help to develop a list of activities that may be performed by staff with hazardous substances:

* Do we have a list of hazardous substances on site?
	+ What key tasks do our staff undertake with these hazardous substances**?**
* Are hazardous substances used in a particular location, e.g. in a treatment room?
* Are any hazardous substances used by staff in a particular job role, e.g. HCA?
* Are any hazardous substances used in a particular process, e.g. formalin for preserving biopsy samples?

By adopting this approach, a list of significant tasks can be generated.

* To adequately describe a task only requires (typically) six to ten words (there is no need to embellish as any further relevant detail will rest within the risk assessment).
* Task lists can contain general and clinical based activities.

Whilst this process may seem quite onerous, consider the tasks in terms of potential harm. If it is significant, it merits listing. The table below contains illustrative examples of a list of tasks.

|  |
| --- |
| Task description |
| Internal storage of cleaning and domestic chemicals |
| Cleaning up a body fluids spillage |
| Using oxygen to provide treatment support to patients |
| Using Achticlor disinfectant chlorine tablets |
| Placing a biopsy sample into a formalin pot |
| Closing off and sealing a sharps box |
| Cleaning up a large spillage of formalin |
| Disposing of biologically contaminated materials such as dressings |
| Disposing of contaminated sharps |

Using the task listing methodology will identify what risk assessments may be required. Whilst many of these activities may be clinical in nature with established processes undertaken by trained staff, it can often be the case that the initial basic risk assessment has not been recorded.

It may also be the case that each individual patient is risk assessed by the staff member before a procedure is carried out. This is sometimes referred to as a dynamic risk assessment and, invariably, this type of risk assessment is not documented.

Therefore, if a significant event were to occur, such as a spillage resulting in an adverse effect on a patient, i.e. a burn from a corrosive substance, if written evidence of a risk assessment or an appropriate record of considerations made was required by a court or other legal entity, failing to provide such a written document may prove challenging.

A baseline predictive risk assessment, supported by ongoing dynamic risk assessments, undertaken by competent staff where any significant learning points are captured and then updated into the baseline document, may be considered suitable and sufficient.

## Prioritising task listing

In order to prioritise which risk assessments generated by a list of tasks risk assessors should undertake first, prioritise the tasks using a Red, Amber or Green (RAG) status, as illustrated in tabular form below:

|  |  |  |
| --- | --- | --- |
| Task description | Relative priority | Numerical priority |
| Disposing of contaminated sharps | Red | 1 |
| Depositing a biopsy sample into a formalin pot | Red | 2 |
| Using Actichlor disinfectant chlorine tablets | Amber | 3 |
| Using oxygen to provide treatment support to patients | Amber | 4 |
| Cleaning up a body fluids spillage | Amber | 5 |
| Placing a biopsy sample into a formalin pot | Amber | 6 |
| Disposing of biologically contaminated materials such as dressings | Amber | 7 |
| Closing off and sealing a sharps box | Amber | 8 |
| Internal storage of cleaning and domestic chemicals | Green | 9 |

# Conducting a risk assessment

## Aim of a risk assessment

Before understanding how to conduct a risk assessment itself, there is one key learning point to remember and that is the aim of a risk assessment which is:

The core function of a risk assessment is to identify its relative priority.

Please refer to this section that is also contained within the [Risk Assessment Guidance Document](https://practiceindex.co.uk/gp/forum/resources/risk-assessment-guidance-document.1519/) for detailed information.

## Calculating risk(s)

Using the broad principle of risk, supported by the risk matrix, will enable assessors to calculate the level of risk by using the numerical values of both consequence and likelihood. These numerical values, when multiplied together, give a numerical value of risk: consequence x likelihood = risk

 

Image Source: [Risk Management Policy and Procedure](https://www.sth.nhs.uk/clientfiles/File/Enclosure%20K%20-%20RiskManagementPolicyStrategy.pdf)

Risks are graded and given a rating as shown below:

|  |
| --- |
| **Risk rating**  |
| Low 1 - 3  | Moderate 4 - 6 | High 8 - 12 | Extreme 15 - 25 |

Image Source: [Risk Management Policy and Procedure](https://www.sth.nhs.uk/clientfiles/File/Enclosure%20K%20-%20RiskManagementPolicyStrategy.pdf)

## Interpreting the risk matrix

In every element of risk assessment, interpretation as well as judgement is required. Furthermore, rating consequence is usually deemed easier than rating likelihood.

Detailed information relating to interpreting risk matrices is contained within the [Risk Assessment Guidance Document](https://practiceindex.co.uk/gp/forum/resources/risk-assessment-guidance-document.1519/).

## Assessing the level of consequence (hazardous substances)

It is important to recognise that, when predicting the level of consequence, it must be a reasonable prediction, i.e. what the reasonably foreseeable worst-case injury may be.

It is important to articulate the overall consequence description (predictive story) in a meaningful way. Consider the following:

* The task
* The key hazard (hazardous substance)
* An accident prediction
* A level of injury that is the reasonably foreseeable worst-case (not worst- case)

To show development of the risk assessment process, examples one and two below are subsequently developed in stages throughout this document, culminating in a fully detailed illustrative risk assessment for each at Appendix 1.

The basic consequence structure is set out below:

Example 1

|  |  |
| --- | --- |
| Consequence (hazard) | Hazard rating |
| Task – depositing a biopsy sample into a formalin potHazard – formalinAccident – splash to eyesInjury – significant eye damage  | 4 |

Example 2

|  |  |
| --- | --- |
| Consequence (hazard) | Hazard rating |
| Task – cleaning up a large body fluids spillage Hazard – bodily fluidsAccident – cross contamination by failing to wear PPE Injury/illness – BBV | 4 |

Both of the above simplified examples are expanded into risk assessments in example three and four on pages 18/19.

## Assessing the level of likelihood

Likelihood is made up of whatever data and other factors are relevant to the circumstances that may collectively (as well as potentially independently) make ‘something’ more, or less, likely to occur.

When describing likelihood, it is important to recognise that it is the likelihood of an occurrence (an accident) or the likelihood of something going wrong that could then lead to the level of harm predicted. It is not, for example, the likelihood of a death. Therefore, when making a judgement of how likely it is for something to ‘occur’, it must be a data driven rather than an opinion driven judgement. This means taking into account factors such as existing controls (and their relative effectiveness) and other influencing factors. For example:

* People factors including human behaviours, competencies etc.
* Environmental factors such as sufficient space for social distancing, heating, lighting and ventilation etc.

Factors that could form the judgement as to how likely it is for an untoward event occurring are varied and differ from location to location. It is suggested that only the most relevant factors are included and are adequately described which, in turn, can make it relatively simple to identify how likely it is for an accident to occur.

It may be, on occasion, difficult to identify how likely it would be that something may go wrong. There are two options available to the assessor at this point:

1. Identify another relevant factor and, in most circumstances, this will help to identify the correct value.
2. If another factor does not resolve the matter, for example the assessor still cannot decide if it is a rating of 3 or 4, then always err on the side of caution and rate upwards.

## Likelihood considerations (COSHH)

The illustrative table below provides examples of likelihood considerations written as prompts to aid the completion of an assessment whilst also providing examples as to how the response to such questions could be written.

|  |  |
| --- | --- |
| Likelihood factors (questions could include) | How the response to the question could be written in an assessment |
| How many people are typically involved? How often is the task performed and for how long are people exposed? What is the general competency of those involved?Is a safe working practice or guidance provided?Is this a complex activity?Are people under pressure? Is the task repetitive, i.e. task is occasionally repetitive or complex?Is there adequate supervision? Is the environment suitable? Any special groups to consider?Are there any behavioural issues that arise?If a product is potentially hazardous, is it suitable for the task and the process of use being applied appropriately?Are there any engineering controls in use?  | There are typically 4 – 5 people who undertake this task although usually only one at a time The task is usually performed twice a day and takes 20 – 30 minutes Staff are clinically qualified and/or generally experienced in this workAn NHS guide is provided for this activity which staff do followThe activity has no known complexities There are regular small queues of patients, however the bookings process means patient throughput is controlledThe task is relatively simple, practiced several times per day and lasts a few minutes each time. Supervision is provided (team leaders)The area is well ventilated although occasional residual odour is present Public do have access to this area, although members of staff chaperone No recorded issues of poor behaviour in the application of the processStaff are trained in product use, follow the manufacturer’s guidance and use correct PPE each timeThere is an LEV in place for fume extraction which is subject to inspection and maintenance |

## Rating consequence and likelihood

Once the consequence narrative has been written, reasonable judgement can be made regarding the relative level of harm by using the risk matrix.

There is always the potential for both consequence and the likelihood of an event occurring to be misunderstood which can lead to an inaccurate risk rating. To aid assessors in rating risks, examples three and four (below and overleaf) demonstrate how much information is required to make an informed judgement and assist assessors in selecting the most accurate numerical rating. Use the evidence to form the judgement on each rating, rather than opinion.

Examples three and four also show the basic structure of a simple risk assessment in a short paragraph format for consequence with illustrative likelihood data and ratings applied. These examples do not yet contain any additional data that could be taken from an SDS or other source documents.

Example 3

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Consequence(hazard) | Hazard rating | Likelihood of occurrence | Likelihood rating | Risk rating |
| When depositing a biopsy sample into a formalin pot, if the staff member inadvertently splashed formalin into eyes, it may result in significant eye damage | 4 | Formalin is kept in sealed ready to use pre-filled (100 ml) sample pots, limiting potential for large spillagesStorage area is clean, easily accessible and is well ventilatedStaff are competent although there has been one sample pot spillage in the last 12 monthsStaff are not under particular pressure to undertake procedureOne staff member is a known asthmatic and is restricted from this activity  | 3 | 12 |

Example 4

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Consequence(hazard) | Hazard rating | Likelihood of occurrence | Likelihood rating | Risk rating |
| When cleaning up a large bodily fluids spillage, if a staff member did not follow the procedure and failed to wear correct PPE, this may result in cross contamination resulting in a BBV | 4 | Staff use correct equipment and cleaning products, e.g. Actichlor disinfectant chlorine tablets, and follow correct process each time There is no history of skin contamination or resulting illness in last three yearsAppropriate PPE is provided and worn and staff are competentBodily fluid spillages do occur, once per week on average | 2 | 8 |

## Hazard and precautionary statements

The Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008) introduced a helpful list of both hazard and precautionary statements, as well as signal words, for suppliers and manufacturers of hazardous substances to use to inform customers about their products, including the use of SDS.

A hazard statement is a unique numerical code prefixed with an ‘H’ that has an assigned phrase which describes the nature of the hazard in the substance or mixture. A hazard statement will be determined by the application of the classification criteria.

Examples include:

|  |  |
| --- | --- |
| Reference | Description |
| H318 | Causes serious eye damage |
| H301 | Toxic if swallowed |
| H401 | Toxic to aquatic life with long lasting effects |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled |

A precautionary statement is a phrase that describes recommended measures to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use or disposal. A precautionary statement is prefixed with a ‘P’ followed by a unique reference number.

Examples include:

|  |  |
| --- | --- |
| Reference | Description |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection.  |
| P270 | Do not eat, drink or smoke when using this product |
| P273 | Avoid release into the environment |
| P284 | In case of inadequate ventilation, wear respiratory protection |

Suppliers determine the appropriate precautionary statements based on the required hazard statements. These statements replace the ‘safety and risk phrases’ previously used in the CHIP regulations that the CLP has replaced. The CLP regulations also introduced two new signal words – ‘danger’ and ‘warning’.

If the chemical has a more severe hazard, the label on the packaging includes the signal word ‘danger’ or, in the case of less severe hazards, the signal word used is ‘warning’.

## Using hazard and precautionary statements in a risk assessment

When the hazard consequence description has been written, the relevant hazard statements can be referenced underneath. As a mirror to these hazard statements, it may be the case that existing controls relevant to these hazard statements are recorded in the likelihood. If there is not an existing control that mitigates the hazard statement, then action should be taken to rectify this, in context and as appropriate.

The supplier does not know for certain what activities the product they supply will be used for. Therefore, the supplier will provide what they believe to be reasonable measures to consider in terms of hazard, precautionary statements and any supplementary information.

The employer will know what task(s) will be performed with the hazardous substance and must take into account the information provided, its relevance and include said information within the risk assessment. Example 5 overleaf contains selected information (for illustration purposes) taken from an SDS for formalin, buffered, 10% (phosphate buffer/certified). The document is also used in the illustrative risk assessment at Appendix 1.

Example 5

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Consequence(hazard) | Hazard rating | Likelihood of occurrence | Likelihood rating | Risk rating |
| When depositing a biopsy sample into a formalin pot, if the staff member inadvertently splashed formalin into eyes, it may result in significant eye damageWELs as follows:FormaldehydeSTEL: 2 ppm 15 minSTEL: 2.5 mg/m3 15 minTWA: 2 ppm 8 hrsTWA: 2.5 mg/m3 8 hrsMethyl alcoholWEL: TWA: 200 ppmTW: 266 mg/m3 TWA WEL STEL: 250 ppmSTEL: 333 mg/m3 Hazard statementsH315 – Causes skin irritationH318 – Causes serious eye damageH317 – May cause an allergic skin reactionH351 – Suspected of causing cancerH371 – May cause damage to organsH341 – Suspected of causing genetic defectsH350 – May cause cancerSignal Word: Danger | 4 | Formalin is kept sealed in ready to use pre-filled (100 ml) sample pots, limiting potential for large spillagesOpened in a well-ventilated room when ready to deposit biopsy sample, thus limiting exposureStorage area is clean, easily accessible and is well ventilatedPPE is provided and worn and staff are competent although there has been one sample pot spillage in the last 12 monthsStaff are not under particular pressure to undertake task One staff member is a known asthmatic and is restricted from this activity Precautionary statementsP302 + P352 – If on skin, wash with plenty of soap and waterP305 + P351 + P338 – If in eyes, rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsingP309 + P311 – If exposed or if you feel unwell, call a poison centre or doctor/ physicianP280 – Wear protective gloves/ protective clothing/ eye protection/ face protectionP332 + P313 – If skin irritation occurs, seek medical advice/attentionP308 + P313 – If exposed or concerned, seek medical advice/ attention | 3 | 12 |

## Multiple hazards

Hazardous substances are complex as they have the potential to give rise to a number of injury effects simultaneously that reasonably foreseeably, at worst, would cause differing levels of harm.

For example, in relation to a common general task such as using a sharp blade to cut materials, failing to pay attention may result in a deep cut requiring stitches (consequence rating 3). However, for a task involving a hazardous substance, such as decanting a concentrated acid into a smaller container, failing to pay attention may result in the splashing of acid, potentially causing multiple injuries such as burns to hands, permanent facial scarring, irritation to lungs etc. The consequence ratings are potentially different but each outcome has validity.

An illustrative example of a multiple hazard with separate consequence scores (the same likelihood is used) can be found at Appendix 1 (formalin).

These final examples also utilise additional data that is likely to be required for a suitable and sufficient COSHH risk assessment, including use of an illustrative data sheet obtained from a supplier of formalin.

## The principles of risk management

The core function of a risk assessment is to establish its relative priority whereas the core function of risk management is to allocate resources against the relative priorities.

Detailed information on the principles of risk management is contained within the [Risk Assessment Guidance Document](https://practiceindex.co.uk/gp/forum/resources/risk-assessment-guidance-document.1519/).

## Further considerations

It is wise to have a balanced understanding of any potential impacts of health and safety risks on other business risks (and vice versa). Occasionally, a new risk may be deemed to be so significant that it could be referred directly to the most senior manager/partner. In such instances, it is recommended that risk related discussions are held with all due consideration paid to the potential wider business implications of that risk (and others affected). Once there is a clear understanding, effective additional controls measures can be introduced and implemented.

## Additional controls

Existing control measures may require improvement or new controls may be required. Further information on the hierarchy of risk controls[[7]](#footnote-7) is available on the HSE website.

|  |  |
| --- | --- |
|  Principles | Simple explanation |
| *A screenshot of a cell phone  Description automatically generated*The ‘higher up’ the hierarchy, the more effective the controls.It is worth noting that the ‘higher up’ the hierarchy, the less reliance there is on people doing the ‘right thing’. One of the weaknesses of people is that we are human and, therefore, we are fallible and prone to occasional errors whether these errors are made by e.g. tiredness, confusion, forgetfulness or for other reasons. | **Eliminate** –If the task can be eliminated, this is good, however it may not be reasonably practicable **Reduce by using**:**Substitution** –Tends to be used for the management of chemicals by swapping a hazardous chemical for another that is less hazardous **Engineering controls** – This tends to be a physical barrier that separates the hazard from the person – lead screen, a door, a locked cabinet etc.**SWP and safe systems** – For example, a written way of doing a job **Signs and alarms** – For example, audible/visual alarms, notices etc **Information, training, instruction and supervision** – A simplified way of looking at this is ‘the greater the risk, the more I, T, I & S should be provided’**PPE** (Personal Protective Equipment) – Can include, gloves, masks, aprons, hearing protection, goggles etc. (as a last resort)  |

When articulating a new control that is required, it is important to be clear about what controls are being introduced in order to reduce the level of risk (SFAIRP). The most appropriate manner in which this can be achieved is by constructing the control in terms of SMART, that is specific, measurable, achievable, realistic and time bound. SMART is advocated by the Chartered Management Institute (CMI).[[8]](#footnote-8)

When any changes to existing control measures are made, or when new control measures are introduced, it is imperative that they are communicated to the whole team.

## Reviewing risks

Risk assessments are a legal document and by virtue are disclosable to certain third parties. Additionally, they may be required as evidence for either criminal or civil court actions. Therefore, regular reviews are essential. Reviews should be conducted at least annually.

It must be noted that a change of hazardous substance, or significant changes to the SDS such as a new or changed hazard or precautionary statement, or where new potential risks are identified that may reasonably occur from exposure must prompt a review of the risk assessment.

Managers should establish a robust system that ensures the controls that are in place are maintained, remain effective, any amendments that are required are actioned and key information is made available to those who may be affected by the risk(s).

The date of any review must be recorded on the assessment and the subsequent review date annotated. There are specific circumstances that should trigger a risk review, irrespective of whether it is due. These are:

* After an accident or a near miss
* On a significant change of process or change of equipment
* On a significant change of staff or substantive change in the environment or location
* If requested by an enforcement officer

If challenged by the HSE, the CQC or other regulatory bodies, managers and/or the responsible person will have to justify the periodicity for review of documents and the effectiveness of such reviews. If it cannot be evidenced that a review was undertaken, then it did not happen.

## Monitoring risks

It is recommended that risks arising from tasks being performed are monitored in line with their relative priority as you may be required to demonstrate that you are monitoring the risks in addition to carrying out regular reviews.

Monitoring can be included on the risk register (a PLUS risk register will be released soon). If it cannot be evidenced a risk was monitored, then it did not happen.

## Hazardous substance monitoring (a summary)

While there are thousands of substances used at work, only about 500 substances have Workplace Exposure Limits (WELs) listed in EH40/2005.[[9]](#footnote-9)

The most commonly used methods are monitoring the air in the employee’s breathing zone[[10]](#footnote-10), background air monitoring, wipe sampling of the skin, biological monitoring and biological effect monitoring.

A competent consultant[[11]](#footnote-11) can provide this type of monitoring service on request. They will use calibrated equipment and established processes to clearly demonstrate whether there is compliance by means of the current controls in place being adequate.

If a hazardous substance does not have an exposure limit (as identified in EH40/2005) or it is a mixed product, then you can use the HSE publication, COSHH Essentials, to check if you are using the correct controls. In addition, the following guides may prove useful:

* [Biological monitoring in the workplace](https://www.hse.gov.uk/pubns/indg245.htm)
* [Further information about COSHH](https://www.hse.gov.uk/coshh/furtherinfo.htm)

## Health surveillance[[12]](#footnote-12)

Health surveillance is an important aspect of monitoring. There are a number of important questions that can be asked in relation to health surveillance. Note that questions will be dependent on the circumstances at hand.

**Who should be subject to health surveillance?**

Where it is appropriate for the protection of the health of employees who are, or are liable to be, exposed to a substance hazardous to health, the employer shall ensure that such employees are placed under suitable health surveillance.

**How can they be identified?**

Via the risk assessment which may prompt further exposure monitoring that can then show where (and why) there is a need to introduce health surveillance procedures.

**Who should undertake health surveillance?**

A registered medical practitioner. Sometimes another suitably qualified person, e.g. an occupational health nurse or other responsible person, can supervise the procedure. A responsible person is someone appointed by the employer who is competent (see regulation 7 of the MHSW Regulations) to carry out the relevant procedure and who is charged with reporting the conclusions of the procedure to the employer.

There is a wide variety of measures that could be used in health surveillance which may be specific to the type of exposure, for example:

* Health questionnaire
* Lung function tests
* X-rays
* General medicals
* Blood tests
* Hearing/eyesight tests

## The maintenance and use of control measures

Managers should establish procedures to ensure that any control measures, including PPE (provision and use) as well as any other items or facilities, are properly used or applied. These should never be made less effective by other work practices or by improper use. The procedures should include:

* Undertaking visual checks and observations at appropriate intervals
* Ensuring that, where more than one item of PPE is being worn, the different items are compatible
	+ PPE should also be clean, fit for purpose, replaced as required and stored correctly

On site, there may be a range of machinery, plant and other equipment such as specific engineering controls, e.g. local exhaust ventilation (LEV).[[13]](#footnote-13) LEVs are designed to effectively remove dust/fumes by extraction and carry away any airborne contaminants before they can be breathed in.

It is important that any machinery or equipment is subject to regular maintenance (with statutory inspections, as relevant) and that these items are kept in good working order. These items may or may not be under the direct control of the organisation. If they are not, it is advised that reasonable assurance be sought from the landlord that all plant, machinery and other such items are subject to appropriate maintenance and inspection regimes.

To provide the CQC with demonstrable evidence of such checks, copies of maintenance certificates should be retained by the manager.

Managers must ensure that any systems of work and supervision are reviewed at suitable intervals and revised if necessary as outlined in the COSHH ACOP Regulations 8 and 9:

* Providing adequate supervision to employees to ensure that the defined methods of work are being followed
* Monitoring systems and any arrangements for the effectiveness of controls with prompt remedial action where necessary

### 5.19 Accidents, incidents and emergency plans

Risk assessments should, in principle, identify if there is a need for an emergency plan particularly in the event of an accident, incident or emergency that may expose any employee (or other person) to, for example, a substance that may endanger health.

Examples where emergency plans should be considered are as follows:

* Working with biological, carcinogenic, mutagenic or sensitising agents
* Fire, where it could result in release of materials that are a risk to health
* Working with significant quantities of a corrosive agent that could, for example, reasonably make contact with skin
* Working with substances that have a WEL, particularly if a failure of LEV or other controls would result in exposure

The following are a selection of suggested considerations when developing an emergency plan. Please note this list is not exhaustive:

1. Ensure risk assessments have identified reasonably foreseeable incidents with adequate preventative measures put in place.
2. If a spillage or accidental release of any hazardous materials occurs, consider the requirements for access to equipment such as PPE (or as relevant) and spillage control measures such as absorbent materials.
3. For staff training for emergencies, consider key safety actions such as:
	1. Any emergency stop or isolation procedures
	2. Spillage control actions
	3. Raising the alarm
	4. Evacuation requirements (including if a full building evacuation was required)
	5. First aid provision
	6. Control of an adverse event (including in the absence of practice manager)
4. Availability of locally produced procedures and protocols
5. Time to test the plan
6. Inform emergency services of any significant quantities of hazardous substances or materials being stored or of materials that are dangerous (as relevant)

## Provision of information, training and supervision

It is important to consider in context what is meant by providing suitable and sufficient information to enable employees to work safely. This requires striking the right balance – too little can result in incidents occurring whilst too much could be confusing. If, for example, a substance is being used that is not particularly hazardous and exposure is adequately controlled, basic instructions and training may be all that is required. Employers do have a duty to provide information, training, instructions and adequate supervision under the requirements of the MHSWR.

Training can be delivered in a number of ways including, but not limited to, class or group tuition, individual tuition, written instructions, including leaflets, and courses. Employers should also decide how much time is needed to provide suitable and sufficient training. New employees should be provided with relevant induction training which should always cover emergency and evacuation procedures.

To satisfy the CQC at inspection, detailed records of training are to be retained.

## Residual risk

Residual risk is the remaining risk after all the additional control measures have been implemented and are deemed to be working effectively. Until this point, the actual level of risk is managed in terms of its relative priority; this is essentially a competency-based judgement with the aspiration that the risk will reduce numerically.

As another competency-based judgement, assessors must be mindful that, whilst the general objective is to reduce risk numerically, if the control is not suitable, it could increase the risk rather than decrease it.

## Quality assurance and administration

The important aspect of a risk assessment is the content. Using the template at Appendix 1, the following points are to be completed as they are considered to be the principles of good risk assessment administration:

1. Confirm task description
2. Insert organisation name
3. Create/insert local risk assessment reference
4. Insert date risk assessment completed
5. Create/insert relevant documents reference
6. Insert risk assessor’s name and job role
7. Insert the name and job role of any contributors to the risk assessment
8. Insert manager’s name and job role
9. Insert name and job role of who reviewed the risk assessment (see risk review profile – how often the document and content must be reviewed)
10. Check content of risk assessment for relevance and general accuracy
11. Check that the additional control measures required are SMART
12. Check all the ratings are correct and that the risk rating is a result of multiplication
13. Once the controls have been implemented, then revisit the risk assessment and calculate the residual risk
14. Complete your risk register (available soon on PLUS)

**5.23 Audits and review**

It is recommended that all safety management systems (including risk assessments) are subject to review with a periodic audit to enable compliance and thereby provide assurance to all stakeholders.

In order to ensure that risk assessments remain valid and controls remain effective, it is also important to supervise activities proportionally to the level of risk that they present. Other circumstances that would prompt a systems review include, but are not limited to, an accident or near miss or a significant change of staff, location, equipment or process.

# Additional information

## Recommended resources

Additional sources of information are available from a variety of health and safety related organisations, including but not restricted to the following:

[The Health and Safety Executive](http://www.hse.gov.uk/)

[International Institute Risk & Safety Management](http://www.iirsm.org/)

[IOSH (Institution of Occupational Safety & Health)](https://iosh.com/)

[British Safety Council](http://www.britsafe.org/)

[Royal Society for Public Health](http://www.rsph.org.uk/)

[Royal Society for Prevention of Accidents](https://www.rospa.com/)

[Chartered Institute of Environmental Health](https://www.cieh.org/)

[Health and Safety Executive](http://www.hse.gov.uk/)

# Summary

COSHH risk assessments are relatively straightforward to structure and follow the same process used to conduct a general risk assessment. The additional elements to consider are adding in items such as hazard and precautionary statements, noting if the substance has a WEL and, if so, what additional measures may be required.

There is no such thing as a perfect risk assessment. However, any COSHH risk assessment that is to be considered as being suitable and sufficient must reflect local circumstances.

Risk assessors and managers must understand the range of risks that they face and their relative levels (priorities), understand the resources at their disposal and then allocate those resources in a meaningful way.

# Appendix 1

**Risk Assessment and Control Form**

Brief task description: [Insert task description]

Organisation name: [Insert organisation name] Risk assessment reference: [Insert local reference number]

Date completed: [Insert date completed] Relevant documents reference: [Insert SDS/reference numbers and review date]

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **General risk description**(Hazard Consequence) | **Hazard rating** | **Likelihood****(including relevant people, environmental and data factors as well as existing control measures)** | **Likelihood rating** | Risk rating | Additional control measures required | **To be implemented By who?****By when?** | **Residual risk** ***(risk after all additional controls are implemented)*** |
| When depositing a biopsy sample into a formalin pot, if the staff member inadvertently splashed formalin into eyes, it may result in significant eye damageSplash to skin\* causing irritation(Multiple hazard example\*)WELs as follows:FormaldehydeSTEL: 2 ppm 15 minSTEL: 2.5 mg/m3 15 minTWA: 2 ppm 8 hrTWA: 2.5 mg/m3 8 hrMethyl alcoholWEL – TWA: 200 ppmTWA: 266 mg/m3 TWAWEL – STEL: 250 ppmSTEL: 333 mg/m3 Hazard statementsH315 – Causes skin irritationH318 – Causes serious eye damageH317 – May cause an allergic skin reactionH351 – Suspected of causing cancerH371 – May cause damage to organsH341 – Suspected of causing genetic defectsH350 – May cause cancerSignal word: Danger | 43 | Formalin is kept in sealed ready to use pre-filled (100 ml) sample pots, limiting potential for large spillagesOpened in a well-ventilated room when ready to deposit biopsy sample, thus limiting exposurePPE is provided and worn and staff are competent, although there has been one sample pot spillage in the last 12 months, no injury recordedStaff are not under particular pressure to undertake task One staff member is a known asthmatic and is restricted from this activity Precautionary statementsP302 + P352 – If on skin, wash with plenty of soap and waterP305 + P351 + P338 – If in eyes, rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsingP309 + P311 – If exposed or if you feel unwell, call a poison centre or doctor/physicianP280 – Wear protective gloves/ protective clothing/eye protection/ face protectionP332 + P313 – If skin irritation occurs, seek medical advice/ attentionP308 + P313 – If exposed or concerned, seek medical advice/ attention | 33 | 129 | Develop a storage, use, disposal, spillage and emergency procedure and procure any necessary materialsUndertake a review of PPE to ensure that correct equipment is provided, such as:* Safety glasses with side-shields to (European standard – EN 166)
* Gloves to (European Standard – EN 374)
* Disposable apron
* Long sleeved clothing required

Provide adequate training to staff in the above procedure and use of PPE to maintain competencyEnsure that locations where formalin is used are sufficiently well ventilated to limit exposureEnsure where formalin is used that there is sufficient availability of eyewash and hand washing facilitiesProvide adequate supervision to ensure PPE is worn correctly and staff are adequately informed as to the associated risksEnsure that an updated version of the SDS is available to staff | Practice manager by end August 2020Practice manager by end August 2020Practice manager by end Sept 2020Practice manager to confirm by end July 2020Practice manager to confirm by end July 2020Practice manager to implement by the end August 2020 then ongoingPractice manager by end July 2020  |  |
| Cleaning up a large bodily fluids spillage, if a staff member did not follow the procedure and failed to wear correct PPE, this may result in cross contamination resulting in a BBV such as Hep B | 4 | Staff use correct equipment and cleaning products, e.g. Actichlor disinfectant chlorine tablets and follow correct process each time There is no history of skin contamination or resulting illness in last three yearsAppropriate PPE is provided and worn and staff are competentBodily fluid spillages do occur, once per week on average | 2 | 8 | Note: No SDS provided as this is a biological hazardUndertake a review of the cleaning procedure and associated PPE provided, to ensure best practice is followedProvide a refresher training session for staff to ensure best practice techniques are embeddedUndertake a review of Actichlor disinfectant chlorine tablets risk assessment and associated processes  | Practice manager by end August 2020Practice manager by end Sept 2020Practice manager by end August 2020 |  |

**General Administration**

|  |  |  |
| --- | --- | --- |
| **Risk assessor’s name:**   | **Contribution to risk assessment by:**   | **Manager approval** |
| [Insert name of risk assessor] | [Insert name of any contributors] | [Insert name of manager] |
| **Risk assessor’s job role:**  | **Contributor’s job role:** | **Date of approval** |
| [insert job Role] | [insert job role] | [insert date] |

|  |  |  |  |
| --- | --- | --- | --- |
| **This document was reviewed/updated by:**  | **Job role:** | **On date:**  | **Next planned review due:** |
| [Insert name of assessor] | [insert job role] | [insert date] | [insert date] |

|  |  |
| --- | --- |
| **Risk review profile** | **Recommended risk assessment and risk controls review periodicity** ***Guidance note****: The principle of review is that the more significant the risk level, the more often it must be reviewed.***Always review if an incident has occurred:** |
|  | If the risk is 15 – 25 (Very high) Review at least every 1 – 3 months |
|  | If the risk is 8 – 12 (High) Review at least every 6 – 12 months |
|  | If the risk is 4 – 6 (Moderate) Review at least every 12 – 18 months |
|  | If the risk is 1 – 3 (Low) Review at least every 18 – 24 months |

1. [HSE COSHH basics](https://www.hse.gov.uk/coshh/basics/index.htm) [↑](#footnote-ref-1)
2. [Health and Safety Executive – GOV.UK](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwiAiIfT69PqAhUYRhUIHd1sDqYQFjABegQIGBAD&url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Forganisations%2Fhealth-and-safety-executive&usg=AOvVaw2f8KK-LqMOWpRcK_2KhmgO) [↑](#footnote-ref-2)
3. [HSE what is a substance hazardous to health?](https://www.hse.gov.uk/coshh/basics/substance.htm) [↑](#footnote-ref-3)
4. [HSE ALARP and SFAIRP](https://www.hse.gov.uk/risk/theory/alarpglance.htm) [↑](#footnote-ref-4)
5. [REACH and Safety Data Sheets](https://www.hse.gov.uk/reach/resources/reachsds.pdf) [↑](#footnote-ref-5)
6. [HSE hazard pictograms](https://www.hse.gov.uk/chemical-classification/labelling-packaging/hazard-symbols-hazard-pictograms.htm) [↑](#footnote-ref-6)
7. [HSE Hierarchy of Controls](https://www.hse.gov.uk/risk/faq.htm#hierarchy) [↑](#footnote-ref-7)
8. [www.managers.org.uk](http://www.managers.org.uk/) [↑](#footnote-ref-8)
9. [Exposure Limits](https://www.hse.gov.uk/pubns/books/eh40.htm) - HSE [↑](#footnote-ref-9)
10. [HSE Monitoring COSHH](https://www.hse.gov.uk/coshh/basics/monitoring.htm) [↑](#footnote-ref-10)
11. [HSE G409 – Exposure measurement: Air sampling](https://www.hse.gov.uk/PuBns/guidance/g409.pdf) [↑](#footnote-ref-11)
12. [Control of substances hazardous to health (sixth edition)](https://www.hse.gov.uk/pubns/books/l5.htm) [↑](#footnote-ref-12)
13. [Local Exhaust Ventilation (LEV) workplace fume and dust extraction](https://www.hse.gov.uk/lev/) [↑](#footnote-ref-13)