**Health surveillance for work with carcinogens and mutagens in research laboratories1**

**Introduction**

The COSHH Regulations require, wherever possible, avoidance of work with carcinogenic or mutagenic substances. Where work with such substances cannot be avoided Regulation 7(5) of COSHH specifies specific engineering & procedural controls to minimise, as far as is reasonably practicable, opportunity for exposure. Additionally, where harmful exposure may still occur, health surveillance of those at risk of exposure may be required.

The need for health surveillance as a control measure for work with a carcinogen or mutagen is specified in Regulation 11. The same criteria apply as for other hazardous materials: (1) an identifiable disease or adverse health effect linked to exposure, (2) a likelihood of hazardous exposure occurring and (3) a valid technique is available to detect early signs of exposure.

As there is a long latency period— typically measured in decades— between exposure to a carcinogen and the development of detectable cancer, for most carcinogens there are no screening tests that are useful at the time of exposure. However, where hazardous exposure may occur, a health record should be maintained in lieu of active monitoring for the effects of exposure2

For most carcinogenic and mutagenic substances there is little evidence available on what constitutes a safe level of exposure. Most carcinogens do not appear to have a 'no-effect' threshold. However, the risk of cancer induction is linked to intensity and duration of exposure to a carcinogen. In a research laboratory environment quantities in use are often very small— grams or millilitres— and often handled for only short periods of time. With appropriate safety controls in place the likelihood of exposure occurring sufficient to cause harm will be very low. Health surveillance will therefore not always be required.

Monitoring to assess exposure against Workplace Exposure Limits (WELs), where these exist, is not always feasible where only small quantities of material are handled. Additionally, WELs are devised on the assumption that exposure occurs for much of the working day and so are of limited applicability to the research laboratory environment. Accordingly, this guidance proposes a pragmatic, staged assessment process based on simple, easily measured criteria which determine the credibility of hazardous exposures occurring within a laboratory environment.

It utilises the precautionary principle so that health surveillance will be required for any work that does not fall within the specified criteria, unless a more detailed risk assessment considering a wider range of factors concludes hazardous levels of exposure are unlikely to occur.

1 <http://www.heops.org.uk/HEOPS_Carcinogen_Guidance_230315.pdf>

2 The Control of Substances Hazardous to Health Regulations 2002 (as amended) Approved Code of Practice and guidance para 239.

It assumes that all work is carried out in accordance with the principles of good laboratory practice, including the use of basic personal protective equipment such as laboratory gloves and protective clothing and no eating or drinking etc.

It does not remove the fundamental requirement under COSHH to avoid work with carcinogens or mutagens or, where this is not possible, to control exposure to any carcinogenic or mutagenic substance to the lowest level reasonably achievable.

**Definitions**

**Carcinogen:** any substance classifiable as a carcinogen (category 1 or 2) under the Classification, Labelling and Packaging of Substances and Mixtures Regulation (CLP Regulation) or novel substances considered to be potentially carcinogenic on the basis of their chemical or physical similarity to a known carcinogen. Commercially supplied carcinogenic substances will be labelled as R45 or H350— *may cause cancer* or R 49 or H350— *may cause cancer by inhalation*

**Mutagen:** any substance classifiable as a mutagen under the Classification, Labelling and Packaging of Substances and Mixtures Regulation (CLP Regulation), or novel substances considered to be potentially mutagenic in humans on the basis of their chemical or physical similarity to a known human mutagen. Commercially supplied mutagenic substances will be labelled as R46 or H340— *may cause heritable genetic damage*

**Exposure:** contact with a substance in any physical form which results in absorption of the substance into the body

**Hazardous exposure:** exposure sufficient to cause some likelihood of cancer induction or lasting genetic damage. In most instances, the total (cumulative) exposure occurring over the expected duration of the work should be considered when evaluating whether or not exposure may be harmful

**Low risk work**

For some work in a research laboratory with carcinogens & mutagens, typical conditions of work are such that exposure sufficient to cause harm will be extremely unlikely. The amount of hazardous material in use is small. The substance is used for only a short period of time. Most manipulations are low energy processes and so unlikely to generate dust or generate aerosols. All handling is carried out inside safety cabinets. Implements are used to transfer material between containers so that no direct handling is necessary. PPE— lab coat and chemically resistant gloves— should guard against inadvertent skin contact.

Where all these conditions are met and the carcinogen or mutagen is in a physical form that will not easily generate dust or vaporise it can be concluded that, in normal use, exposure sufficient to cause harm is exceedingly unlikely and no form health surveillance will be required, unless an accident or spillage resulting in unplanned exposure occurs. (**Figure 1**)

**Figure 1** Work with a carcinogen or mutagen where COSHH Health Surveillance will not be required.

1. The hazardous substance is a non-volatile liquid or a granular or mass solid.

2. The total quantity of substance used over the course of the work does not exceed 1kg or 1 litre

3. The maximum duration of the work is 4 weeks

4. The handling time per day is less 1 hour

5. There is no intentional direct handling of the substance i.e. it is manipulated using implements and containers

6. Manipulations undertaken outside of enclosure are limited to

• weighing out

• pipetting

• dissolving

• transfers between vessels

7. Protective clothing:— laboratory coat, chemically resistant gloves and, if a liquid, safety glasses or face shield— is worn.

Where the above conditions are **not** met, a more detailed risk assessment will be required to determine whether exposure sufficient to cause harm may occur and health surveillance required.

Additional guidance can be found at the HEOPS website <http://www.heops.org.uk/guide.php>

Information regarding health surveillance can be found on the Health [Surveillance](http://www.exeter.ac.uk/staff/wellbeing/safety/guidance/healthsurveillance/) Safety standard

**The threshold for harm**

The likelihood of exposure to a carcinogen being harmful i.e. capable of causing cancer will be determined by the cumulative dose: the quantity absorbed per use and the number of times the substance is used.

This guidance seeks to define in terms of the quantity of carcinogen or mutagen used in the work the circumstances in which health surveillance should not be necessary. It utilises a pragmatic exposure threshold of 10 μg/day. We consider that for periods of work of up to three months, the cumulative exposure will be insufficient to significantly increase the risk of cancer induction or, for mutagens, lasting genetic damage

Where the calculated daily exposure is less than 10 μg/ day health surveillance will be unnecessary for work of less than 3 months duration. Where daily exposure is higher than 10μg or the duration of work exceeds 3 months, health surveillance should be instituted.

**Assessing exposure**

The most important factors determining the level of exposure in a research laboratory setting are:

1. The quantity of material in use.

2. The duration of exposure

3. The physical form of the substance.

4. The type of process

5. The type of ventilation containment used as a control.

**Quantity of material in use**

The chance of a hazardous exposure occurring will increase in line with the quantity of material in use. This guidance considers only the quantity of material being handled or actively used in experimental processes. In a research laboratory environment, no significant exposure to stock quantities is likely, except in the circumstances of a recognised accident e.g. spillage or breaking of a storage container.

**Duration of exposure**

Experimental work in research laboratories typically involves only relatively brief periods of time handling materials, or directly observing a process.

This guidance assumes that the potential daily exposure time i.e. the time spent directly handling the material, or processing the material outside of an enclosed vessel or apparatus does not exceed one hour per day and that the total duration of use of the material will be less than 3 months.

If the daily exposure time will exceed 1 hour, or the duration of use will be longer than 3 months, then the threshold amounts given in this guidance for determining whether COSHH health surveillance should be instituted should be reduced accordingly.

**Physical form**

In a research laboratory environment, the main route by which hazardous exposure could occur is through inhalation of dust or aerosol, fume or gas generated during handling or processing of the material.

Given the typically small quantities of materials used, significant dermal exposure is unlikely to occur: use of implements, flasks and other containers obviate the need to directly handle hazardous substances. Use of laboratory coats and gloves will provide good protection against inadvertent skin contamination in normal use. PPE will also safeguard against gross contamination of personal clothing when only small volumes of hazardous material are being worked with. Accidental ingestion is not a likely circumstance in a laboratory setting.

For solids, the likelihood of hazardous exposure will be determined by the capacity of the material to become airborne during handling. This is largely a function of particle size: the finer the size, the greater the proportion of material than may become airborne.

For liquids the quantity becoming airborne will be chiefly determined by the vapour pressure of the material at the operating temperature of the process(es) in which it is used.

**Type of process**

Processes that impart kinetic energy to a particulate or liquid can generate aerosols and so create opportunity for exposure through inhalation. The risk will be higher for higher energy processes e.g. sieving, grinding or sonication than for lower energy processes such as weighing out, pouring or stirring.

Heating will increase the rate of vaporisation of volatile liquids.

Research suggests that for powdered solids, between 0.01% and 0.9% will become airborne during low energy processes depending on particle size

**Ventilation control.**

Ventilation controls limit inhalational exposure to airborne particulates and gases.

This guidance considers three levels of control, with different levels of effectiveness:

1. Open bench working

2. A performance-regulated safety cabinet i.e. either a chemical safety hood conforming to BS EN14175 and achieving NERC Class 1 performance or a Class I/II biological safety cabinet constructed and maintained in accordance to BS EN 12469:2000 which is externally exhausted or specially designed for the containment of chemicals. NB Other forms of LEV not conforming to these BS standards e.g. positionable exhausts or re-circulating cabinets are not appropriate for work with carcinogens or mutagens which require ventilation control for safe working

3. Isolation i.e. totally contained system, isolator or Class III biological safety cabinet

Open bench provides no control of airborne exposure so is considered to have a protection factor of 1. Open bench work with carcinogens or mutagens will only ever be appropriate where the substance is not capable of becoming airborne in appreciable amounts i.e. a liquid with a boiling point higher than 150°C, or a pelleted solid.

A regulated chemical or biological safety cabinet if properly installed, maintained and used will reliably achieve greater than 99% containment (theoretically you can get higher than this but operator factors can reduce the effectiveness of containment). Dispersal within the laboratory through air movement and the dilution achieved through room ventilation will mean that operators will be exposed to only a fraction of any material escaping the cabinet.

We therefore allocate a nominal protection factor of 1000 to work with powders or liquids undertaken in a safety cabinet.

Isolation or total containment should prevent any exposure occurring during use, although some exposure is credible when the equipment is opened for charging or removing materials. We therefore limit the protection factor for this form of containment to 10000.