

responsible research

Managing health and safety in research:
guidance for the not-for-profit sector



IOSH regularly commissions research to strengthen the evidence base for health and safety management. We are therefore pleased to support the Universities Safety and Health Association in publishing and hosting this guide to responsible research, developed not just for occupational safety and health researchers, but research teams working in every discipline.

'Responsible research' joins IOSH's range of authoritative, free guidance, available at www.iosh.co.uk/techguide.

Responsible research: managing health and safety in research

This guide aims to help anyone who needs to ensure good health and safety performance in a research environment. It provides heads of department, principal investigators and researchers with:

- examples of responsibilities and management approaches
- advice on safety culture and risk assessment
- case studies showing key issues that need to be considered.

The Universities and Colleges Employers Association and the Universities Safety and Health Association have worked with the Institution of Occupational Safety and Health, the Medical Research Council and others to produce useful guidance that covers a wide range of research fields.

Responsible research is designed primarily for researchers in the UK, but the principle of following the 'Plan-do-check-review' cycle when managing health and safety in a research environment is universal.

This guide can be downloaded at www.iosh.co.uk/ushaguide

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Contents

1	Introduction	03
2	Management and responsibilities	04
3	Using a management system approach to manage health and safety in research	08
4	Safety culture	12
5	Risk assessment	14
6	Case studies	18
7	Glossary	30
8	Further reading and sources of information	33
	Figures	
1	Typical line management structure in a college, university or research organisation	04
2	A health and safety management system based on the 'Plan-do-check-review' framework	08
3	The risk assessment process	17

Forewords

This document is the latest in a series produced by and for people working in the higher education sector. As with previous documents, it is produced in a partnership between the Universities and Colleges Employers Association and the Universities Safety and Health Association. This time, due to the broad nature of the research, allied not-for-profit health and safety associations and the Medical Research Council have also collaborated on the project.

It is important that such guidance should be widely accessible, so we have worked with the Institution of Occupational Safety and Health (IOSH), which has kindly edited and designed this document and is hosting it on its website. These new partnerships are welcomed, and reinforce the high esteem that others place on the guidance produced by the sector.

As always, institutions are free to choose how they apply this guidance. However, we hope it will be of particular use to heads of department and principal investigators.

The case studies are designed to show the key issues that need to be considered in particular fields of research. While it is impossible to cover every eventuality, we hope that the principles will be applicable across a wide range of research fields. Indeed, the authors will welcome additional case studies that can be added to this guidance in the future.

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This guidance updates the Health and Safety Executive (HSE) Education Schools Advisory Committee (ESAC) guidance issued in 2000: *Managing health and safety aspects of research in higher and further education*.

Much has changed since that guidance was introduced, and this is reflected in the approach taken here. A lot of the general health and safety guidance contained in the original HSE–ESAC publication is better covered in other documents, such as *Successful health and safety management* (HSG65). Therefore, this new guidance focuses on the role of the principal investigator and aims to support researchers by providing examples of good practice.

The reviewing panel reflected this change in emphasis, asking representatives of the broader research community not only to contribute to the general document but also to provide up-to-date case studies in each of their specialised research fields (see membership list below).

We hope this document will be used to promote good practice in all areas of research and that more case studies will be added to complement those contained within the guidance.

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Portions of this document were originally produced as part of the HSC document *Managing health and safety aspects of research in higher and further education* and therefore are subject to Crown copyright. The content of *Responsible research* is in line with advice from the HSE – for more details go to www.hse.gov.uk/managing/index.htm.

1 Introduction

Research is about investigating new avenues of knowledge, and this carries an unavoidable element of the unknown. The outcome of research work can be uncertain or can differ from what was originally predicted.

Health and safety legislation applies just as much to research as it does to any other area of industry. Despite the inherent elements of uncertainty, it is possible for research workers to innovate without exposing themselves or others to unnecessary health and safety-related risks. Sensible management systems, together with suitable practical training for those involved, are essential to providing a framework in which people can work safely.

This guidance was written for higher education institutes and research councils engaged in research. However, all organisations involved in research work in the not-for-profit sector, such as further education establishments, research charities and the National Health Service, may find it useful in helping to understand their responsibilities under health and safety law, and providing a basis for good practice.

A typical management structure in a research organisation is outlined in Section 2, which also summarises the health and safety duties and responsibilities for each management level.

Section 3 introduces the concept of using a management system approach to health and safety in research, and Section 4 addresses the importance of a positive safety culture. Section 5 outlines the risk assessment and control process.

Case studies in section 6 illustrate how health and safety can be effectively managed in a range of research disciplines.

A glossary of terms used in this guidance and the sources of reference accessed during its compilation can be found in the final sections.

2 Management and responsibilities

It's important to set out the responsibilities for health and safety in a college, university or research organisation. Health and safety law in the UK places responsibilities on employers, employees and third parties, and everyone in the organisation needs to know who is responsible for what.

All researchers in a research establishment must:

- take responsibility for their own health and safety and ensure that they don't compromise the health and safety of others by the things they do or fail to do
- work safely and efficiently
- follow the organisation's policy, guidance and safe systems of work
- attend training and put it into practice in the workplace
- risk-assess, or assist with the risk assessment of their work
- use protective equipment as recommended
- not change research or other work protocols without first discussing the change with their manager and specialist safety advisers as appropriate
- report incidents that have resulted in, or could have resulted in, injury or damage
- assist in the investigation of accidents with the aim of introducing preventative measures
- report unsafe conditions or actions
- work co-operatively to improve health and safety standards and performance.

The executive structure – the layers of management between the top of the organisation and the people doing the research activities – will vary with each research organisation, as will individual responsibilities for health and safety at each level.

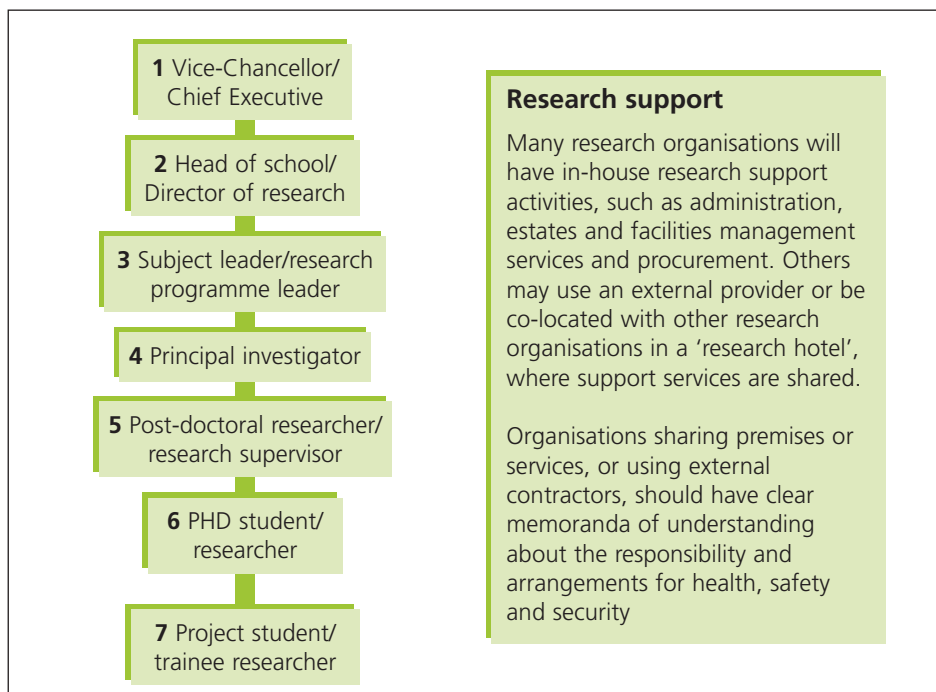


Figure 1: Typical line management structure in a college, university or research organisation

Vice Chancellor (VC), Chief Executive Officer (CEO) or board

The VC/CEO is ultimately responsible for:

- the health, safety and welfare of all those involved in research or providing research support
- the health and safety of visitors to establishments under their control or anyone who may be affected by the organisation's activities
- setting the organisation's health and safety policy, which should:
 - identify the organisation's intentions, responsibilities and arrangements for managing and monitoring health and safety
 - identify how competent health and safety advice will be obtained and show that health and safety will be adequately resourced
 - state how effective methods of consultation, co-operation and assurance of competence will be achieved for researchers, visiting workers, students etc.

Directors of research and heads of school

Directors and heads should ensure that:

- health and safety policies, guidance and arrangements relevant to the expected risks in the research or work area are in place – remember that directors are also employees and are owed the same duty of care as all research staff
- their school or directorate's health and safety objectives are planned
- comprehensive risk management, identification and control programmes are in place, indicating how higher risk activities such as research involving hazardous equipment or substances, lone working or fieldwork will be managed
- reports on health and safety performance are fed back to the VC/CEO at agreed intervals
- individual responsibilities for health and safety are allocated appropriately and performance is reviewed as part of the annual appraisal

- the composition of general or specific health and safety committees or special interest groups is established and trades union representatives are consulted on health and safety matters
 - systems are in place for identifying training needs and providing appropriate training and supervision for research staff and others in the workplace
 - the general and specific health and safety arrangements for contractors, visiting workers and visitors are explicit and communicated effectively
 - appropriate permits and licences are obtained before the research, and records of authorisation, training, incidents and maintenance are kept
 - appropriate planned, preventative maintenance regimes are in place
 - policy and guidance details how health and safety management will be monitored using appraisal, reporting arrangements, inspection, health surveillance, incident and work-related ill health reports, incident type analysis and audit
 - the sanctions for not following organisational and school or directorate policy or codes of practice are made clear to all.
- techniques or situations where there is significant risk (such as the use of lasers or conducting research in the community)
- special permission or licensing arrangements required for the work are in place
 - appropriate supervision is available for researchers and research support workers, depending on the risk of the activity and the age and experience of the individual
 - programmes of work have been risk-assessed and the health and safety of researchers and others will not adversely be affected by known or emerging risks
 - individual responsibilities for health and safety are allocated appropriately and performance is reviewed as part of the annual appraisal. Only principal investigators meeting the required standards are allowed to supervise PhD students
 - consideration is given to the health and safety management, training and communication arrangements for researchers with disabilities or for those whose first language isn't English
 - robust emergency plans are in place for the workplace and research activities which pose high safety risks
 - they are made aware of reported incidents and near misses and will ensure that appropriate actions are taken to prevent a recurrence
 - they are informed about the outcome of safety performance measures such as inspections, safety tours, health surveillance, compliance with risk control systems and safe systems of work, training events attended, work-related injury and ill-health figures
 - they take the appropriate actions recommended by audit findings of non-conformance

- they set an example by their own behaviour and are prepared to take action if health and safety is compromised by the things their researchers do or fail to do.

Principal investigators (PIs)

PIs are generally experts in their field of research and are expected to have up-to-date knowledge about the risks associated with their research area. They are responsible to the programme leader and the director or head of school for the health and safety of their researchers and others who may be affected by the research activities.

PIs should:

- be aware of the legal requirements for their area of research and be able to identify and manage the risks in their field of work
- ensure that all people under their direction have adequate information about the risks and risk controls that apply to their work, and that relevant training and supervision arrangements are in place
- ensure their research supervisors and post-doctoral researchers are trained in risk assessment techniques and are competent to supervise others in their research activity
- monitor workplace safety compliance and draw their manager's attention to deficiencies in health and safety management, such as unsafe acts or conditions, failure to follow safe systems of work, a lack of planned maintenance or inadequate facilities
- enforce health and safety standards and codes of practice and set a good example to their research staff and others in the workplace.

Programme leader/research leader

The programme or research leader is responsible to the head of school or director of research for the safe and legal conduct of research under their remit. This responsibility cannot be delegated. As with all people working in the research environment, the programme leader is responsible for their own safety and the safety of others who may be affected by their unsafe acts or omissions. Programme leaders should ensure that:

- they employ competent researchers, training needs are assessed and training is available, both in general health and safety issues (such as risk assessment) and specific

Post-doctoral researchers/research supervisors

Post-doctoral researchers and research supervisors should be competent in the research area and aware of the risks inherent in the techniques, equipment and methods they use. They should be trained to:

- carry out risk assessments and communicate information on risks and control measures to their researchers and others affected by the research
- understand the institution's policies, procedures and committee structures
- be effective supervisors – supportive, good at coaching and mentoring, excellent role models and take appropriate actions when made aware of health and safety management failures
- contribute to the investigation of accidents and near misses that have affected their research teams

- use safe laboratory and work practices and safe systems of work and reinforce the importance of good housekeeping and occupational hygiene.

Although post-doctoral researchers may be given day-to-day responsibility for ensuring that research is carried out without causing unacceptable risks to health and safety, the overall health and safety responsibility flows through the line management chain and ultimately rests with the VC/CEO of the organisation.

Project students and trainee researchers

Trainee researchers can't be assumed to be aware of the health and safety risks of the research or workplace and must be trained and supervised until they are competent to work without direct supervision.

Research support workers

It's important to establish the risks the research poses to the health and safety of research support staff and others who may be affected in the organisation. As with researchers, responsibility for the health and safety of employees flows up the line management chain to the VC or CEO of the employing organisation. The risks the research activity could present to cleaners, maintenance staff, engineers, technicians and so on must be assessed and adequate risk control measures put in place before the research project starts. Research support workers must be informed about relevant risks, associated risk control measures and their personal responsibility for health and safety. They should also be competent to discharge their duties without causing harm to themselves or others.



Reasonable foreseeability

A reasonably foreseeable risk is one that, if realised, could result in injury or damage, and which could be predicted by a reasonable person with the necessary skills and knowledge.

Legal courts dealing with health and safety cases have to determine whether an unplanned incident was reasonably foreseeable. Employers must seek to identify and evaluate foreseeable risks.

This is not always as easy to judge as it first seems; issues of 'strict liability' can complicate some cases, and case law has evolved to help determine what is reasonably foreseeable. For instance, frivolous acts which result in injury or damage, by employees that have been appropriately trained and provided with the correct equipment, and where the employer has no expectation that the employee would act in this way, would not normally be considered foreseeable.

Health and safety legislation in the UK

The Health and Safety at Work etc Act 1974 (also referred to as HASAW or HSW) is the primary piece of legislation covering occupational health and safety in the United Kingdom.

Statutory instruments (generally regulations) are the secondary type of legislation made under specific Acts of Parliament. These include the requirement to address the risks posed by working with dangerous substances, equipment, noise, ionising radiation and so on. Most of this legislation is 'goal-setting' – it sets out the standard to be achieved and leaves it up to the duty

holder to decide how to do this. Regulations are generally accompanied by codes of practice or guidance, which can be used to help direct the research organisation towards compliance.

The HSW Act and associated regulations are criminal laws. Therefore a breach of health and safety legislation is generally a criminal offence that carries penalties including fines, imprisonment and a range of 'orders' such as community, compensation, remedial action and disqualification.

The HSE is the independent regulator of occupational health and safety

legislation in the UK. It initiates or recommends enforcement action against employers who breach their statutory health and safety duties.

Additionally, an employee who is harmed at work may make a civil claim for compensation against their employer. An employer has a legal duty to protect the health and safety of their employees at work (so far as is reasonably practicable) and to abide by the statutes governing occupational health and safety. If they fail in these duties they may be liable to a claim for damages by the person who has been harmed or suffered loss.



'Absolute', 'so far as is practicable' and 'so far as is reasonably practicable' responsibilities

The HSW Act and other safety legislation impose certain duties and responsibilities on employers and duty holders with respect to the health, safety and welfare of their employees and others who may be affected by their activity.

Some of these duties are 'absolute' and must be complied with, such as the duty of employers to "undertake a suitable and sufficient risk assessment" of work-related risks. But some are qualified by the phrases 'so far as is practicable' and 'so far as is reasonably practicable'. The meanings of these phrases have been established by case law.

To carry out a duty 'so far as is reasonably practicable' means that the degree of risk in a particular environment or activity can be balanced against the time, trouble, cost and physical difficulty of taking measures to avoid the risk. The greater the risk, the greater the rigour that may be expected to control it.

The duty to take reasonably practicable measures is one of

the most widespread requirements in modern UK health and safety law. One example can be seen in Section 13 of the Workplace (Health, Safety and Welfare) Regulations 1992, where it states that reasonably practicable measures should be put in place to stop people falling or being struck by falling objects in the workplace.

'So far as is practicable', without the word 'reasonably', implies a stricter standard. This duty embraces whatever is technically possible in light of the knowledge that the duty holder had, should have had, or had access to at that time (ignorance is no defence). The cost, time and trouble involved must not be taken into account. Again referring to the risks of falls, Section 13 of the Workplace Regulations goes on to stipulate: "So far as is practicable, every tank, pit or structure where there is a risk of a person in the workplace falling into a dangerous substance in the tank, pit or structure, shall be securely covered or fenced."

For most research sectors, the risk control measures required from the employer are 'reasonably practicable'.

3 Using a management system approach to manage health and safety in research

The Management of Health and Safety at Work Regulations 1999 require employers to have suitable arrangements in place for “the effective planning, organisation, control, monitoring and review” of their risk identification and control systems. At the time of publication there is an approved code of practice and guidance supporting the Regulations, which recommends that these arrangements are incorporated into an overall organisational health and safety management system. This is also the approach recommended by

the HSE document *Successful health and safety management* (HSG65).

The case studies in this guidance illustrate how to manage health and safety in various research environments, based on the ‘Plan-do-check-review’ management system framework.

In a system intended to manage the health and safety aspects of a research project, this means putting in place organisational health and safety policy and guidance and:

- Planning the health and safety arrangements for the activity – Plan
- Implementing the planned health and safety controls and carrying out the activity – Do
- Checking that the arrangements and controls put in place to stop injury, damage and ill health are working as planned – Check
- Reviewing the activity to ensure that the health and safety arrangements were adequate and proportionate and then feeding any changes into the next research activity – Review.

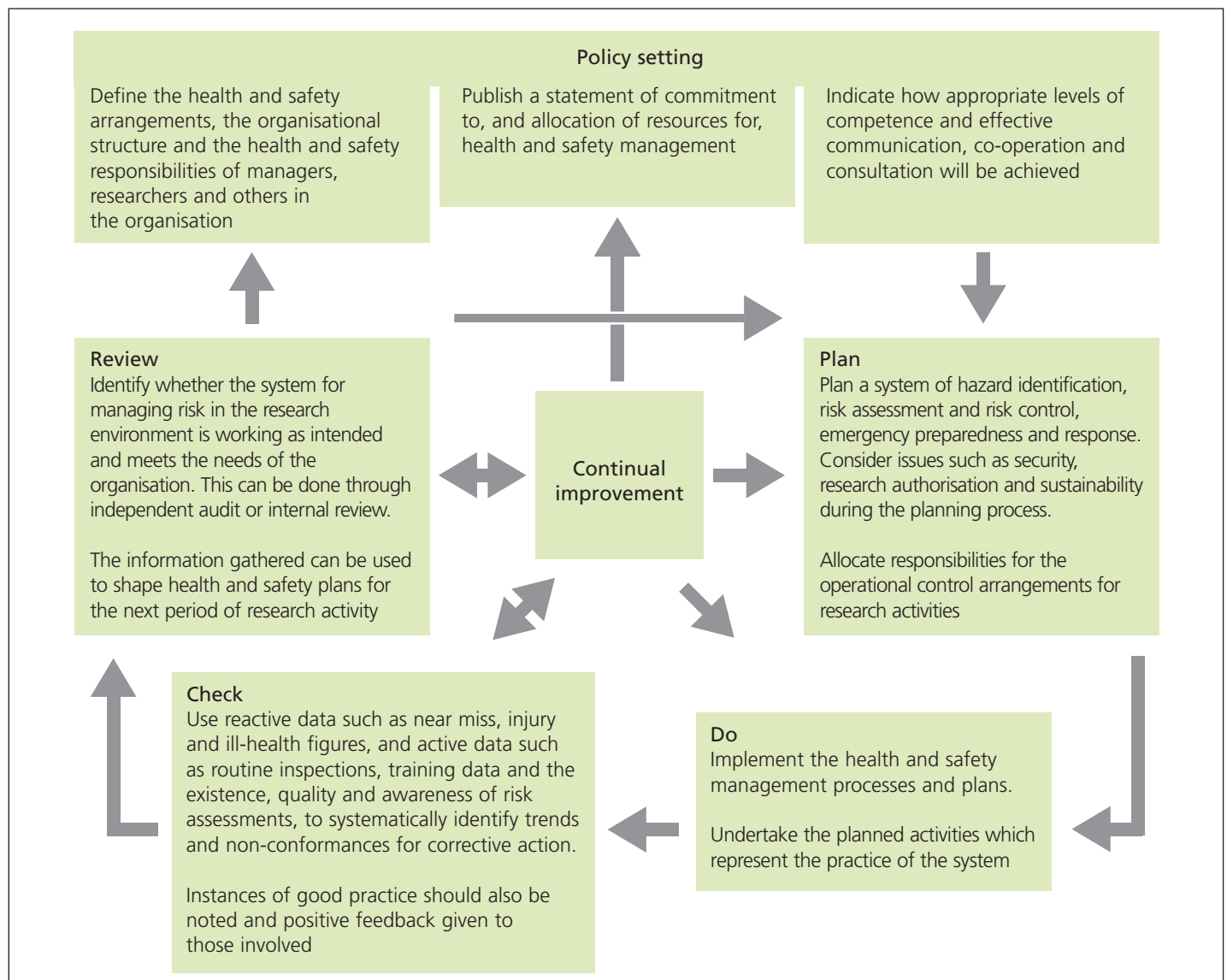


Figure 2: A health and safety management system based on the ‘Plan-do-check-review’ framework



Security

Research often involves the use of materials, equipment, data or processes which could be harmful to people or the environment if access to them was not controlled, or if the organisation did not have measures in place to prevent their escape or loss.

Organisations undertaking research must plan and deploy security arrangements that will prevent accidental access, loss or escape and the deliberate misappropriation of research materials etc.

Safety legislation and guidance may give direction on the security required for specific research activities and some research is governed by notification, authorisation, permitting or licensing schemes. For example, researchers are not allowed to buy drug precursors or chemical weapon precursors unless their organisation has the appropriate Home Office licence; counter-terrorism officers will visit organisations planning work with high risk biological or radioactive materials to make sure security is adequate before the research can proceed.

Security measures and the authorisation or permission required for the research project should be determined at the planning stage. The project risk assessment should consider whether the general security arrangements are enough or if more needs to be done.

The UK environment agencies*, the Department for Environment, Food and Rural Affairs (Defra: www.defra.gov.uk), the Home Office (www.homeoffice.gov.uk), the HSE (www.hse.gov.uk) and the National Counter Terrorism Security Office (NaCTSO: www.nactso.gov.uk) are all involved in various aspects of security in research, and the relevant agency should be contacted if the researcher needs security advice. The HSE's role is limited to advising on matters relating to restricting access to prevent inadvertent exposure or loss of sensitive materials.



Specialist advisors and safety committees

Many research projects need specific permits, approvals or authorisation before they can proceed. Specialist advisers in a range of disciplines can advise on how to meet the requirements of regulators and enforcing authorities, and how to conduct the research with the risks controlled so far as is reasonably practicable.

The requirement to have access to specialist advisers, as well as the responsibilities and duties of these advisers, may be detailed in safety guidance or regulation. For example, the guidance supporting the Genetically Modified Organisms Regulations states that organisations conducting research involving genetically modified organisms (GMOs) should appoint a competent person, such as a 'Biological safety officer' to advise on the notification requirements, containment and safe use of the organisms. Research organisations must consult with a

'Radiation protection adviser' if they need advice on complying with the Ionising Radiation Regulations 1999, or if the activity of the radioactive substances used exceeds certain levels.

In many research organisations, projects involving the use of GMOs or radioactive substances are approved by specialist safety committees, with the specialist adviser giving their expert opinion on the particular risks inherent in the project and what risk controls or authorisation, permits etc are required before the research can proceed.

In addition to radiation protection advisers and biological safety advisers, research organisations may employ or have access to the services of specialist advisers for research involving such things as lasers, chemicals, human tissues or the transport of dangerous goods.

*There are three environment agencies in the UK: the Environment Agency (www.environment-agency.gov.uk), the Northern Ireland Environment Agency (www.doeni.gov.uk/niea) and the Scottish Environment Protection Agency (www.sepa.org.uk).



Emergency planning and business continuity

By law, emergency plans must be put in place for research activities where failures or dangerous incidents present a significant risk to researchers, research support workers, maintenance workers and other building users, if not already addressed by the organisation's general emergency plans.

Some statutes contain an explicit requirement for a contingency plan. For example, the Ionising Radiation Regulations 1999 require the development of a contingency plan to secure, so far as is reasonably practicable, the restriction of exposure to ionising radiation and the health and safety of people who may be affected by such an incident. The plan should be documented within the local rules.

It's also good research practice to make sure contingency plans are in place to prevent emergencies or other unplanned events resulting in research sample or data loss. Several universities have experienced catastrophic events such as major fires and floods that have caused irrecoverable loss of data, samples, artefacts and materials, and signalled the end of particular research projects.

Contingency arrangements such as alarms, emergency generators and off site data and sample storage can help ameliorate potential loss.



Research involving nanotechnology

Nanotechnology is a term for the research, development or use of physical substances with at least one characteristic dimension of 1–100 nm. These can be defined as nanomaterials and their properties may differ from those of the same materials with micron- or mm-scale dimensions. Nanomaterials such as nanotubes, nanodevices, nanowires and nanoparticles can be physically and chemically manipulated for specific applications and are used in a variety of research environments.

Research into the properties of nanomaterials has indicated that some may cause hazardous physical effects when inhaled or ingested. However, the extent of the risk they pose to human health has not been fully established.

The HSE recommends a precautionary approach when working with nanomaterials, meeting the legislative requirements of the Control of Substances Hazardous to Health Regulations (human health risk assessment and control) and, where appropriate, the Dangerous and Explosive Atmospheres Regulations. Many approaches to identifying and controlling nanotechnology risks are presented in the HSE document, *Risk management of carbon nanotubes*, which is available on the HSE website.

The UK Nanotechnology Safety Forum has worked with the HSE, the Environment Agency and the Institute of Occupational Medicine to produce *Working safely with nanomaterials in research and development* (www.safenano.org/UKNanosafetyPartnership.aspx), which offers unified safety guidance.



Working with sources of optical radiation

The Control of Artificial Optical Radiation (AOR) at Work Regulations 2010 require employers to protect the eyes and skin of researchers and others in the research establishment from exposure to hazardous sources of artificial optical radiation.

AOR includes light emitted from all artificial sources in all its forms such as ultraviolet (UV), infrared and laser beams, but excludes sunlight.

Hazardous light sources likely to be present in research environments are UV transilluminators, fluorescence systems and Class 3B and Class 4 lasers, as defined in British Standard BS EN 60825-1. Many other artificial light

sources can cause harm, and some sources which are not normally hazardous can cause eye and skin damage if not used properly.

The law requires that hazardous optical radiation risks to the skin and eyes of researchers is controlled to as low a level as is reasonably practicable.

Further guidance on the regulations, their requirements and practical control measures can be found in the *Guidance for employers on the Control of Artificial Optical Radiation at Work Regulations 2010*, available on the HSE website (www.hse.gov.uk).



Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995

Under these Regulations, specified injuries, diseases and dangerous occurrences must be reported to the HSE within a defined time. The most common reports will be for anyone who is injured in connection with work and is absent from work or can't carry out their normal duties for more than seven days (not including the day of injury).

Certain occupationally-acquired diseases must also be

notified – this does not include minor common infections that circulate in the community.

Dangerous occurrences that require reporting are rare in the research community but would include incidents which have – or could have – resulted in the release or escape of a substance such as a chemical or biological agent likely to cause severe human harm.

4 Safety culture

The safety culture of an organisation depends on the collective output of the health and safety related beliefs, attitudes and behaviours of the people within it. In a research organisation, the attitudes and behaviours of senior managers are particularly influential.

A positive safety culture expects and allows people to behave safely because it is the correct thing to do; it is the normal way of operating within the organisation. Safe behaviour is one visible output of such a culture. This is important in a research environment, since a lot of research is done outside normal working hours when daytime levels of supervision and support are unlikely to be available. Research supervisors need to be able to rely on their researchers to be mindful of their own safety, for example by following research protocols and safe systems of work, wearing personal protective equipment and using safety equipment properly, whether or not their supervisor is present.

A research report and guidance document published by IOSH (*Safety culture, advice and performance* and *Promoting a positive culture – a guide to health and safety culture*) identify some elements that underpin a positive safety culture. In a university or other research organisation, these include:

A comprehensive health and safety policy

This should be drawn up in consultation with staff representatives and endorsed by the executive body of

the organisation, senior management, heads of school and research directors. The policy should include:

- allocated responsibilities and clear arrangements
- a high level of visibility from senior managers with respect to support for health and safety
- a health and safety committee chaired by a member of the executive group
- a 'just' reporting system
- a commitment to learn from incidents, audits and performance reviews and to make any changes required for the ongoing improvement of health and safety management.

Leading by example

- Principal investigators, team leaders and supervisors use safe work practices and take action when health and safety is compromised by researchers' actions or omissions.
- Good safety performance is recognised and rewarded.
- Project proposals consider health, safety and environmental requirements at the planning stage.
- Where necessary, specialist safety advisers are consulted and inform research project proposals.

Practicable guidance and work systems

In a positive culture, guidance and work systems set out how the research should be carried out and how to act in emergencies. In particular:

- researchers have the opportunity to contribute to the development of safe systems of work and appropriate risk control measures
- researchers are made aware of the importance of reporting accidents, near misses and dangerous occurrences
- reporting systems are easy to use and those reporting incidents are not punished for occasional slips and lapses
- it is recognised that accidents and near misses can be used as learning opportunities and can signpost that more training is required or that systems of work should be modified.

Supporting safe research

- Recruitment, selection, training and awareness processes and programmes employ and develop safe researchers.
- Researchers have the knowledge, skills, tools and equipment to work safely.
- Researchers appreciate why safe working is important and understand what sanctions are in place for those who work negligently and compromise health and safety.
- Researchers and their supervisors have access to specialist help and advice.



Researcher Development Framework

The Researcher Development Framework (RDF: www.vitae.ac.uk/CMS/files/upload/Vitae-Researcher-Development-Framework.pdf) is a tool for planning, promoting and supporting the personal, professional and career development of researchers in higher education. It articulates the knowledge, behaviours and attributes of researchers and encourages them to realise their potential.

The RDF is structured in four domains encompassing the knowledge, intellectual abilities, techniques and professional standards needed to do research. It includes the personal qualities, knowledge and skills required to work with others and ensure the research has a wider impact. Each domain contains three sub-domains with associated descriptions of different aspects of being a researcher.

The 'Research governance and organisation' domain details the knowledge of standards and professionalism needed to do effective research, including:

- health and safety
- ethics
- principles and sustainability
- legal requirements
- intellectual property rights and copyright
- respect and confidentiality
- attribution and co-authorship
- appropriate practice
- research strategy
- project planning
- delivery
- risk management.

Recognising the work pressures researchers are exposed to is an important feature of health and safety management in the research environment.

Researchers generally have to work irregular hours, often without the support of colleagues. Programme leaders and principal investigators also have to meet publication and research proposal deadlines and may spend a lot of time looking for funding for their research. Research grants are usually given for a specified amount of time,

and this may cause anxiety to grant-funded researchers as they reach the end of a project. Researchers are more mobile than other staff, as they gain experience and qualifications and move to other research projects and organisations. High-quality research is usually international and this may involve extensive travel and work with researchers for whom English is not their first language. Additionally, research programmes are subject to external quality assessments which can determine future support or funding allocations.

Research organisations should have mechanisms in place to identify and manage cases of work-related stress. The culture of the organisation should also allow researchers who feel they are under too much pressure to access help and support without fearing detriment to their career.

5 Risk assessment

All research tasks and projects should be evaluated for foreseeable health and safety risks before the work starts. The employer must then ensure that significant risks are recorded and that reasonably practicable risk control measures have been put in place. These control measures should be built into systems of work and research protocols. Risk assessments should be carried out by competent people.

The process of risk assessment is no different in research than in any other job. For many social science research projects the risks will not be specialist in nature and general guidance on risk assessment, which can be found in HSE publications, will help identify sensible precautions.

However, in the case of practical research which might involve hazardous substances, equipment or processes, you might need to consider less well-known hazards, especially where new materials and processes are being used. Programme leaders, PIs,

research supervisors and their teams might be the only people who know the work well enough to make valid judgments about risk, and should be prepared to justify their conclusions.

Where risk in a research project is unavoidable, a hierarchy of risk control solutions should be considered:

- Can less hazardous materials, equipment or processes be used?
- Can risks be mitigated at source using engineering controls such as equipment guards and interlocks? What collective protective measures can be put in place?
- Can suitable systems of work be designed, specifying what is required in terms of training, rules, procedures and supervision?
- What individual protective measures are required, such as personal protective equipment, prophylaxis or health surveillance?

Carrying out initial risk assessments before committing to the project will help determine whether existing

resources and facilities are enough to provide any necessary safeguards. If essential systems or facilities such as interlocked access to rooms with lasers or a Class III microbiological safety cabinet are required to control risks, then the project can't start until these are in place. If existing resources can't provide essential safety features, then the project must be altered accordingly.

Risk assessments should also consider the skills and experience of project team members. If some team members are yet to be recruited, the desired skills and competences will help inform the recruitment process and any training needs. The risk assessment will also inform the development of research guidance and safe systems of work, and the risks and controls identified should be incorporated into research work protocols.



Information and training

The HSE defines training as “helping people to learn how to do something, telling people what they should or should not do, or simply giving them information”.

Health and safety law requires that employers provide whatever information and training is needed to ensure, so far as is reasonably practicable, the health and safety of their employees. Research organisations have a duty to ensure that researchers, whether or not they are employees, have sufficient information and training to be able to do their research competently and without increasing risks to their own or others' health and safety.

The skills required for particular tasks or duties should be assessed before recruitment and efforts should be made to employ or contract suitable people. Once researchers have been appointed, their manager or supervisor should assess their capabilities, training, knowledge and experience, and ensure that the demands of the job don't exceed their ability to do their work without creating unacceptable risks to themselves and others.

Training needs analysis should be repeated at regular intervals and when new techniques or equipment are introduced. Refresher training should be provided where appropriate.

Where gaps in knowledge or competence are identified, training and awareness programmes should be put in place and, if training is identified as a risk control measure, it should be compulsory for the researcher to attend. Managers or supervisors should be informed if their researcher fails to attend training, and make sure those who have received training put it into practice in the workplace.

It's important to record all training and information given to researchers. The delivery and receipt of information, formal training and on-the-job training should be signed off by both trainer and trainee. Records of all training should be kept with the researcher's personal file and should be accessible to their manager.

PIs and supervisors need to take responsibility for all assessments associated with their projects, but they may occasionally need to ask research workers to risk-assess some aspects of the work. The research supervisor or PI should check that the researchers doing this have been trained in risk assessment practice and that the assessments have been done to a satisfactory standard.

In some fast-changing research environments, dynamic risk assessment and risk control solutions may be required. Dynamic risk assessment is a continuous process of identifying

hazards and evaluating risks as they come up, taking appropriate actions to eliminate or reduce the risk. The researcher continually monitors and reviews the changing circumstances in the research environment. The actions taken should be documented to improve overall knowledge of risk and risk controls in similar projects.

The risk assessment will also help establish what sort of personal protective equipment is required, and whether specific occupational health arrangements should be in place, for example interventions such as vaccination, or health monitoring and

surveillance, such as regular respiratory function tests.

An important part of risk control in research is that buildings, rooms, equipment etc used during the research should be designed and maintained to ensure they don't compromise health and safety. The planned, preventive maintenance of general plant and specialist equipment is an essential feature of a safe research environment and should be considered at the design and procurement stage of research planning and resourcing.



Occupational health (OH)

OH is about how work and the work environment can affect an employee's health, and how an employee's health can affect their ability to do the job.

An OH service can provide expert advice on the need for specific health controls in work that poses a risk to health – for example work in clinical environments, laboratories, workshops, with research animals or overseas fieldwork. These controls include health screening to assess fitness for work, vaccinations, and periodic health surveillance during work. An OH service will also provide advice on suitable methods for assessment and detection of health risks and can undertake any medical screening or surveillance required.

The OH provider should be able to advise on specific legal requirements for medical certification or health surveillance of staff engaged in certain work activities, such as researchers or other staff who are designated as 'classified workers' under the Ionising Radiation Regulations 1999.

Advice on health precautions for those with pre-existing conditions or disabilities that may make them unusually susceptible to work-related illness or injury can also be obtained from the OH provider.



Occupational hygiene

Occupational hygienists use science and engineering to assist in the prevention of ill health caused by the work environment, specialising in the assessment and control of risks to health from workplace exposure to hazards. Hygienists help employers and employees to understand these risks and minimise or eliminate them.

With good occupational hygiene science and practice, some occupational health risks can be eliminated and others brought under control. In certain instances, some level of exposure will remain and occupational hygiene

techniques can be used to either verify that they are below a safe exposure level (ie that current control measures are adequate) or to indicate the level of exposure experienced.

Occupational hygienists may be able to advise on a range of health risks in the workplace, including chemical hazards, physical hazards such as heat, cold, noise or ergonomics, psychological hazards, and new and emerging technologies such as nano and green technologies.



Hazardous waste

Hazardous waste is defined and listed in the Waste Framework Directive 75/442/EEC, as amended by 91/156/EEC.

The list classifies wastes according to what they are and how they were produced, providing codes for all wastes including hazardous waste. Known as 'EWC codes', they can be found in the European Waste Catalogue, available on the Environment Agency's website. The UK environment agencies produce technical guidance, in a document called WM2, on the interpretation of the definition and classification of hazardous waste. WM2 (www.environment-agency.gov.uk/business/topics/waste/32200.aspx) puts waste into one of three categories:

- Always hazardous – absolute entry (red)
- Never hazardous
- May or may not be hazardous, depending on concentration – mirror entry (blue).

Any waste regarded as 'dangerous' (ie having a risk phrase and possessing any of the hazardous properties H1-H15) should be considered as potentially hazardous and the requirement for special arrangements for its disposal should be assessed.

For most chemical substances used in research, the available disposal routes will depend on the final concentration of the hazardous substance in the waste – which means that most are 'mirror entries' in WM2.

For waste consisting of substances with one or more of the hazardous properties H1-H15, the maximum concentration allowed to be disposed of through normal drains/routes is listed in the guidance document WM2. All waste that contains substances above the threshold concentration for each type of hazard must be disposed of by licensed waste contractors.

Research risk assessments should consider and specify what happens at the end of projects and procedures, such as arrangements for waste disposal and decommissioning equipment or controlled areas.

Once a risk assessment has been completed, its findings, and associated risk control systems, should be communicated to all those involved in the project. Researchers and research support workers should be informed about the hazards and risks they may be exposed to and how they can work safely. It's important to establish that

the proposed control measures are practicable and don't increase risk elsewhere in the research or establishment. Risk assessments should be monitored, reviewed and revised at specified intervals or after an accident or near miss. They should also be revised to capture any new risks after significant changes to the research task, equipment, techniques etc.

The risk assessment process can be used to identify, evaluate and control more than health and safety risks. Research Councils UK has published its *Policy and code of conduct on the*

governance of good research conduct (www.rcuk.ac.uk/documents/reviews/igrc/goodresearchconductcode.pdf), which sets out the safety and other potential research risks that must be addressed such as conduct, ethics, integrity and data management.

Risk assessment records should be kept for at least three years after being superseded or after work has stopped.

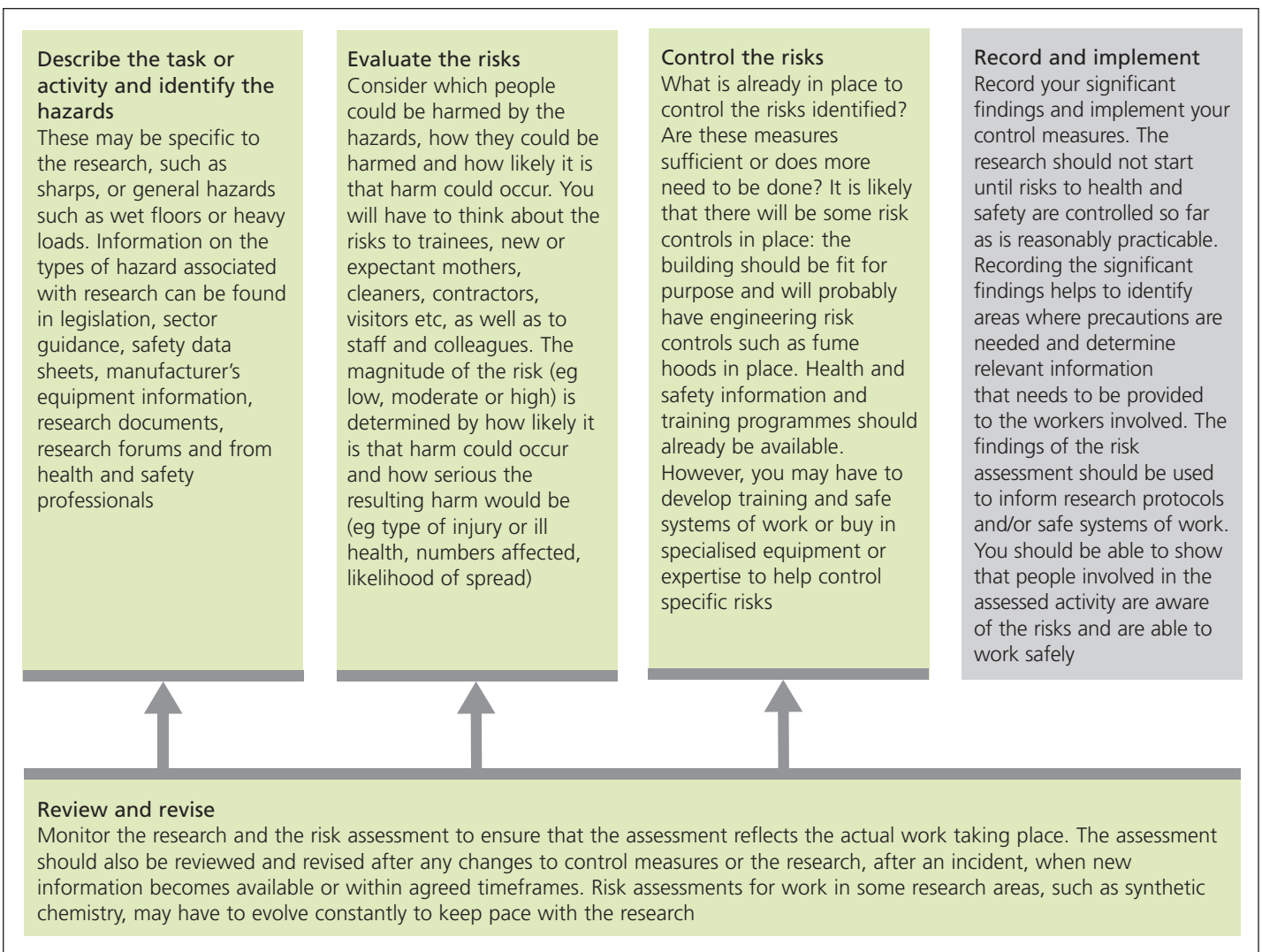


Figure 3: The risk assessment process

6 Case studies

These case studies are examples of 'good practice' currently adopted in research organisations and should help guide you through the management of health and safety and risk in a variety of research areas. For the purpose of the case studies it is assumed that the research organisation has a comprehensive suite of health and safety-related policy and guidance in place.

The first case study is a risk assessment of a social science research project, where researchers are gathering data out in the community. Risk assessments are part of the 'planning' stage of the research project. The rest are set out to follow the health and safety management framework described earlier.



Case study 1

A risk assessment of a social science research project

Research activity

The ALICE (Adolescent Lifestyles in Central England) study is part of a project comparing young people's lifestyles and health behaviours in different counties. Data collection will take place over a three month period and will be repeated after 12 months.

Pupils in S1–S3 in the first year of the study will complete a paper questionnaire in one study period describing their lifestyle and noting which of a random series of 50 films they have seen. Survey assistants will travel by pre-arranged transport to study locations from one of two pick-up points and will assist in taking consent and providing advice about the procedures around completing the questionnaire. In some instances, where the pupils need help, survey assistants will aid in the completion of questionnaires.

The hazards inherent in this research activity are associated with working out in the community, eg exposure to antisocial behaviour and lone working.

What are the risks?

The risks relevant to this research project are:

- travel-related incidents – low risk
- violence or aggression from subjects or others encountered during the data collection process – risk will vary with location and peer group interviewed

- psychological stress through exposure to verbal abuse, working in an unsafe environment, revelation of child protection issues – moderate risk (risk to researchers will be lower if they are experienced)
- fatigue as the result of travel, interview length, numbers interviewed at location – moderate risk
- musculoskeletal disorders from unsafe manual handling practices – low risk.

Who could be harmed?

The persons exposed to the risks are the interviewers and the adolescents interviewed (eg if they reveal child protection issues). With no risk controls in place this project would be moderate risk.

What risk controls are in place?

General controls

Training: defensive driving, lone working safety, dealing with violence and aggression, child protection issues and appropriate response, interview techniques and manual handling.

Emergency procedures are in place (via mobile phones and lone worker alarms and well-practiced procedures for lone-working emergencies) and the researchers will follow the health and safety emergency arrangements of the schools they visit.

Case study 1 continued...

Travel risk controls

Transport is arranged from the research unit but in the event of transport or other problems, assistants must be able to contact the day's team leader and must have a list of telephone numbers and their mobile phone.

Location risk controls

Fieldwork will be conducted in secondary schools during school hours. Out of hours the team members should wait in pairs at designated meeting points. Researchers are identified by uniforms and ID badges.

Study subject risk controls

The questionnaire asks questions about drinking and smoking among an under-age population. These are emotive topics and researchers must refer extremely emotional interviewees to the team leader. Interviewers should not visit schools attended by any subject known to them. Neither can they interview, nor access any information revealed by, such subjects. Researchers working with children and vulnerable adults have been trained in child protection issues and are CRB or equivalent checked.

Trauma risk controls

Instances or threats of violence and aggression will be reported to the team leader and to the head of the school.

Survey assistants are issued with lone worker alarms. Planned, rehearsed response measures are in place.

If any survey assistant has concerns about the child or their handling of the situation then it is their responsibility to discuss this with their team leader. The research group leader runs debrief sessions where researchers who have been exposed to traumatic or upsetting situations or information can discuss these issues with colleagues and the team leader.

Other identified risks

Manual handling risks – researchers are trained and use trolleys for shifting loads. Researchers with musculoskeletal problems are not allowed to lift or shift loads.

Residual risk

With these controls in place the project is assessed as low risk and no further risk controls are required for the research to proceed.

Record and implement controls

The risk assessment is recorded and the researchers are informed of the findings of the assessment. The training needs of the researchers are checked and relevant training is offered before the research study takes place.

Lone worker alarms are issued and researchers are reminded of the procedure for their use and the measures in place for responding to them.

Researchers are given the opportunity to clarify any of the issues raised by the risk assessment and the control measures associated with the research.

Risk assessment review

The risk assessment will be reviewed and revised:

- if the research project changes significantly
- following the occurrence of an unplanned incident during the project
- following the first set of data collection to ensure it has captured and mitigated all the significant risks attached to this project.

If there were any incidents, note what corrective actions were taken – if necessary, amend research protocols accordingly.

Planned review date: _____



Case study 2

Research involving novel chemical substances

Research activity

Synthesis of novel Ergot Alkaloid for use in pharmacology study (subject to licensing under Home Office regulation of precursor chemicals in UK).

Plan

Consider any licence requirements or restrictions on procurement as a result of legislation.

Undertake a comprehensive risk assessment including assessments considering the Control of Substances Hazardous to Health (COSHH) requirements:

- consider the chemistry and apply fundamental chemical properties (eg exothermic acid-base reactions). Also consider mixtures at intermediate steps as well as separately
- assess the planned processes in order to consider safer alternatives or removing steps, eg the procurement of intermediates. Also consider applying administrative constraints, eg restricting lone working and/or access control
- consider the risks to others who may be affected by the research, eg cleaners and maintenance engineers
- consider what equipment and level of local exhaust ventilation (LEV) will be necessary and that the equipment is properly serviced and maintained
- consider whether researchers are appropriately trained in the techniques and safety equipment to be used in the research project and are competent to conduct dynamic risk assessments
- consider storage of materials, particularly to reduce the quantity of hazardous or dangerous materials kept in the laboratory to a minimum, in line with COSHH and regulatory guidance on dangerous substances and explosive atmospheres
- plan the provision of emergency equipment, instruction and training for researchers and others who will work in the local area (eg fire fighting, first aid, spillages).

Do

Ensure that:

- the risk controls identified by the risk assessment are put in place before the work starts
- adequate information and supervision is provided, either through technician level or laboratory manager depending on team
- access to hazardous substances and equipment is controlled
- researchers work in accordance with the experimental protocols and safe systems of work
- new or emerging risks are identified, evaluated and controlled, so far as is reasonably practicable
- adequate provision is made for disposal – consider quantities and concentrations
- any incidents and spillages are reported through the appropriate internal means.

Check

- Ensure that exposure controls are adequate, for example using air sampling (instantaneous/continuous as appropriate) and engaging health surveillance (see EH40).
- Practise emergency procedures. Consider what will happen to LEV used in the event of an emergency – will it continue to operate as normal, or will it shut down, or have a reduced flow, or deploy its fire dampers? Is LEV or other critical safety equipment on an uninterrupted power supply?
- Check waste streams and ensure that necessary arrangements are being followed.
- Review risk assessment periodically, after an unplanned event or before implementation of a new process.

Review

- Were the competencies and resources identified at the outset appropriate or sufficient?
- Were there any incidents? If so, what actions were implemented and will these be required in future? If this is the case, they should be written into the research protocols and standard operating procedures.



The Control of Substances Hazardous to Health Regulations 2002 (as amended)

This legislation, known as the COSHH Regulations (www.hse.gov.uk/coshh/index.htm), requires employers to prevent or otherwise control the exposure of their employees (and others at risk) to hazardous substances used or present in the workplace. There are various sorts of hazardous substances:

- chemicals and products containing chemicals
- fumes and vapours
- dusts and mists
- nanomaterials
- gases and asphyxiating gases
- biological agents.

The employer or responsible person has a duty to identify what substances are involved in work or the workplace and what sort of health hazard they represent. They should then carry out a risk assessment to determine

whether exposure could occur, what the effects of that exposure could be on the people in the workplace and how exposure can be prevented or controlled.

The Regulations also require employers etc to make sure:

- the control measures they've put in place are used and that they continue to be effective
- they provide information, instruction and training for employees and others
- monitoring is carried out for hazardous substances
- health surveillance is provided for employees at risk of exposure to some substances
- there are plans in place to deal with emergencies.

More guidance on COSHH is available on the HSE website (www.hse.gov.uk).



Case study 3

Research involving hazardous biological agents

Research activity

A PhD student, who has never worked with highly infectious agents or at containment level 3, wants to travel to Pakistan to collect blood samples and skin biopsies potentially containing *Mycobacterium leprae* as part of their research into *Mycobacterium* drug resistance. *Mycobacterium leprae* is categorised as Hazard Group 3 in the Advisory Committee on Dangerous Pathogens (ACDP) *Approved list of biological agents* (www.hse.gov.uk/pubns/misc208.pdf).

Plan

- Consider any licence and legislative requirements, such as ethics approval, Human Tissue Authority (HTA: www.hta.gov.uk). The HSE must be informed if this is the first time this biological agent has been used in the organisation. The Home Office must be informed if the biological agent is listed in Schedule 5 of the Anti Terrorism Crime and Security Act 2001. Defra must be informed if the organism is a specified animal pathogen.
- Undertake an overseas risk assessment prior to travel. Guidance on undertaking research activities overseas can be found in the document *Guidance on health and safety in fieldwork* (www.ucea.ac.uk/en/publications/index.cfm/guidance-on-health-and-safety-in-fieldwork).
- Arrange shipping of the biological samples back to the UK via your institute's recognised shipper.
- Consider the potential issues that could come up, eg if foetal calf serum is identified as being present in the sample media, then a Defra import licence may be required.
- Consider the laboratory and storage space requirements for the samples.
- Undertake comprehensive risk assessments for all techniques that are to be used.
- Seek occupational health advice prior to travel and before beginning work on these samples, eg Hepatitis B vaccination may be required.
- If samples are to be retained at the end of the study ensure that this requirement is included in the ethical approval application.
- Consider anonymised coding of samples if they are to be retained at the end of the study.
- Identify the health and safety information and level of training required by researchers involved in this project.

Do

Ensure that:

- the controls identified by the risk assessment are in place before the research project starts
- adequate training and supervision is provided for work in the containment level 2 or 3 laboratory
- clear protocols and/or standard operating procedures are provided for experimental work and that researchers are aware of these and know how to work safely
- samples are packaged according to International Air Travel Association guidelines and are registered under HTA as soon as they arrive
- the names of people working in the containment level 3 laboratory are recorded
- any incidents are reported through the appropriate internal means.

Check

- Practice emergency spill procedures for spills both inside and outside the microbiological safety cabinet (MSC).
- Make sure MSCs and other safety measures are working as planned each time they are used.
- For HTA check that appropriate records of disposal of samples are kept – number of samples disposed, disposal route used and the person responsible for the disposal.
- Check all project workers have appropriate knowledge of the code of practice for working at containment level 2 or 3.
- Check all project workers are aware of the procedures for decontaminating both the MSC and laboratory in the event of an emergency. If this is not contracted out then researchers should be competent to carry out the decontamination.

Review

- Review all risk assessments and codes of practice periodically, before any changes are made to experimental technique or following an unplanned event.
- Were there any incidents? If so, what actions were implemented and will these be required in the future? If this is the case, they should be written into the research protocols and standard operating procedures.



Biological agent hazard groups

The Control of Substances Hazardous to Health Regulations (www.hse.gov.uk/coshh/index.htm) set out the health and safety requirements for working with substances that are hazardous to health. Biological agents are classed as hazardous substances in the Regulations if they are capable of creating a human health risk.

The COSHH Regulations classify biological agents into one of four hazard groups (HGs) based on their ability to infect healthy humans, with HG1 agents being the least harmful and HG4 agents the most harmful.

The classification is based on whether:

- the agent is pathogenic for humans
- the agent is a hazard to employees
- the agent is transmissible to the community
- there is effective treatment or prophylaxis available.

More information on the classification of biological agents can be found in the Advisory Committee on Dangerous Pathogens publication *The approved list of biological agents* (www.hse.gov.uk/pubns/misc208.pdf). The relevant industry standard for managing the risks of work with biological agents is *Biological agents: managing the risks in laboratories and healthcare premises* (www.hse.gov.uk/biosafety/biologagents.pdf).

Guidance on using a management system approach to manage the risks of working with biological agents can be found in the CEN *Workshop agreement laboratory biorisk management standard* (<ftp://ftp.cenorm.be/PUBLIC/CWAs/wokrshop31/CWA15793.pdf>).



Notification of use of biological agents

The HSE expects all research establishments to notify it of their first use of any HG2, HG3 and HG4 biological agent. Notification of subsequent use of a few specific HG2 agents and all HG3 and HG4 biological agents is also required. Further information on notification to the HSE can be found at www.hse.gov.uk/forms/notification/cba1notes.htm.

Sites holding or intending to hold agents listed in Schedule 5 of the Anti Terrorism Crime and Security Act 2001 and the Security of Pathogens and Toxins (Exceptions to Dangerous Substances) Regulations 2002 must notify the Home Office. The Home Office will arrange, via the National Counter Terrorism Security Office (NaCTSO), a site visit by the relevant Counter Terrorism

Security Adviser (CTSA) to conduct a survey and provide commensurate security advice and guidance. Qualifying sites must be able to demonstrate to the CTSA that they are operating securely before they are granted authority by NaCTSO on behalf of the Home Office. Further information on Home Office notification can be found at www.nactso.gov.uk/AreaOfRisks/PathogensToxins.aspx.

Defra must be informed if the organism is a specified animal pathogen. A Defra licence may be required for the importation of some animal-derived materials. Further information on notification and licensing is available at www.defra.gov.uk/animal-diseases/pathogens.



Case study 4

An engineering research project

Research activity

A request is made to investigate satellite propulsion systems using ionised gas. The project will entail working with a high vacuum chamber to simulate the space environment; high voltage equipment for ionisation and ion acceleration; and compressed gases including argon, xenon and hydrogen.

Plan

- Carry out a first pass high-level hazard analysis (preliminary hazard analysis) to identify the major hazard issues, eg:
 - high voltage equipment (if voltage potentials above 5 KV then ionising radiations regulations apply)
 - high vacuum systems (potential for vacuum chamber to become pressurised and become a pressure system)
 - asphyxiant gas
 - explosive gas
 - high noise levels.
- Assemble a team with appropriate cross-functional knowledge to scope an initial design concept and safety system. The safety system should follow the risk control hierarchy of elimination, substitution, engineering controls, procedural controls, PPE (see section 5 for more detail). This is considered good practice and is a requirement of the COSHH Regulations.
- Undertake a detailed hazard analysis on the proposed design – consider using formalised methodologies such as failure mode and effects analysis (see ‘Hazard analysis techniques’ box for more detail). Modify the design accordingly.
- If purchasing new equipment, does it carry the appropriate CE marking?
- If equipment is in-house or a bespoke design, does it meet the essential safety requirements of the relevant legislation (eg directives on machinery, low voltage, pressure equipment, ATEX)? Consider assessment against appropriate harmonised standards, eg EN61010-1.
- Undertake a comprehensive risk assessment as required by regulation and organisational policy and guidance, considering hazardous and dangerous substances, ionising radiations, noise levels, electrical safety, pressure systems, ongoing maintenance requirements etc:
 - consider storage of materials, particularly to reduce the quantity of hazardous or dangerous materials kept in the laboratory to a minimum, in line with COSHH and regulatory guidance on dangerous substances and explosive atmospheres
 - the outcome of risk assessment may indicate that occupational health involvement is required, eg health surveillance, audiometry. (Note: this would be unlikely for this particular research project.)
- Consider what level of training and supervision will be required, taking into account the experience and competency levels of the people involved.
- Ensure that adequate emergency equipment and instruction and training is given to researchers and others that will work in the local area or who will provide support during emergencies (eg fire fighting involving high voltage and pressure systems).

Case study 4 continued...

Do

Ensure that:

- risk controls identified by the risk assessment are in place before the work starts
- equipment is purchased, built, installed and commissioned to appropriate specifications
- adequate provision is made for maintenance
- access to hazardous equipment is controlled
- adequate information and training is given and that appropriate levels of supervision are provided
- any incidents are reported through the appropriate internal means.

Check

- Confirm at appropriate intervals that equipment safety systems operate correctly.
- Check project workers have appropriate knowledge of equipment and safety systems.

- Check work is being carried out in accordance with the risk assessment and agreed protocols.
- Check that required maintenance is being carried out.
- Practise emergency procedures.
- Check risk assessment periodically, after an unplanned event or before implementation of a change to experimental protocol or equipment design.

Review

- Were the competencies and resources identified at the outset appropriate or sufficient?
- Were there any incidents? If so, what actions were implemented and will these be required in future? If this is the case, they should be written into the research protocols and standard operating procedures.



Hazard analysis techniques

There are several available techniques for hazard/risk analysis. These can be complementary and it might be necessary to use more than one of them. The basic principle is that the chain of events is analysed step by step.

Preliminary hazard analysis (PHA) can be used early in the development process to identify the hazards, hazardous situations and events that can cause harm when few of the details of the design are known.

Fault tree analysis (FTA) is especially useful early in the development stages of safety engineering, to identify and prioritise hazards and hazardous situations, and to analyse adverse events.

Failure mode and effects analysis (FMEA) and **failure mode, effects and criticality analysis (FMECA)** are

techniques for systematic identification of an effect or consequence of the failure of individual components. These techniques are more appropriate as the design matures.

Hazard and operability study (HAZOP) is typically used in the later stages of the development phase to verify and then optimise design concepts or changes.

For more detail see (shop.bsigroup.com/en):

- BS 8444-3, IEC 60300-3-9, *Guide to risk analysis of technological systems*
- BS EN 61025, *Fault tree analysis (FTA)*
- BS EN 60812, *Procedure for failure mode and effects analysis (FMEA)*
- BS IEC 61882, *Hazard and operability studies (HAZOP studies) – application guide*.



Case study 5

Research using unsealed radioactive sources

Research activity

In vitro assay for small molecule inhibition of recombinant viral RNA polymerase enzyme activity using a P33-labelled radioactive nucleotide triphosphate.

Plan

- Consider legislative requirements and their impact on how and where the procedure will be conducted.
- Conduct a comprehensive risk assessment – is use of radiation essential? Include COSHH and EA considerations:
 - measure the reaction kinetics including the enzyme K_m in trial experiments; include measurements of waste stream partitioning
 - plan materials required – what format will be used; eg 12 well, 96 well or 384 well plates?
 - what equipment will be needed, eg centrifuge, multichannel pipettes, plate washer? (all have potential for contamination)
 - how many compounds will be tested with how many repeat readings per compound?
 - minimise reaction volumes compatible with reproducibility
 - add the radioisotope once and as the final step to a master reaction mix.
- Minimise exposure to radioactivity using the principles:
 - time
 - distance
 - shielding
 - containment
 - ensure awareness of local rules
 - use of best available techniques (BAT) to minimise waste
 - trial runs using dye label to determine any unexpected potential for spillages, aerosol generation etc
 - frequent monitoring of self and designated work area before, during and after the procedure
 - appropriate personal dosimetry.

Do

Ensure that:

- risk controls identified by the risk assessment are in place before the work starts
- researchers are competent and have had previous theoretical and practical instruction on correct and safe handling of radioisotopes, including minimising exposure, knowledge of waste streams and use of appropriate PPE
- proposed radioisotope usage and waste production is within the limits of the department/institute allowances laid down in the Environmental Permitting Regulations Permit for Open Sources
- radioisotope stock is stored securely in a locked fridge
- any spillages, accidents or incidents are dealt with according to the local rules.

Check

- Ensure that shielding is adequate and work is contained in trays.
- Rehearse emergency procedures in 'scenarios' to make sure contingency measures are adequate to deal with spillages.
- Check records of radioisotope use and contamination monitoring.

Review

- Are the protocols reproducible, can economies of scale be used?
- Do any aspects of the procedure require revision?
- Can the signal-to-noise ratio be maintained using less radioisotope?
- Review the risk assessment frequently, and revise following changes to the experimental protocol.
- If there were any incidents during the project, what actions were implemented? If they will be required in future, they should be written into the research protocols and standard operating procedures.



Radioactive substances: notification, registration and authorisation

If you intend to start work with radioactive substances for the first time, you will need to let the HSE know at least 28 days before you start work. Details on how to notify the HSE using Form IRR6 are on its website (www.hse.gov.uk/radiation/ionising/notification.htm). This is a requirement of the Ionising Radiation Regulations 1999 (IRR99).

Normally you will also need to have been granted certificates or permits of registration and/or authorisation under the Radioactive Substances Act 1993 or the Environmental Permitting (England and Wales) Regulations 2010 by the relevant UK environment agency. Your radiation protection adviser (RPA) will advise you on the planning, risk assessment and authorisation requirements of research involving radioactive substances.

For the purposes of work with ionising radiation, the regulators of radioactive substances are the Environment

Agency (in England and Wales), the Scottish Environment Protection Agency and the Northern Ireland Environment Agency. EPR10 exemption orders apply in England, and in Scotland/Northern Ireland as stand-alone legislation. Otherwise RSA93 still applies in these two countries, where 'permits' are referred to as 'authorisations'.

The loss or theft of, or significant spills or releases of, radioactive materials must be reported to the relevant environment agency (and to the HSE if the amount of radioactive material released or spilled exceeds that in column 4 of Schedule 8 of IRR99). Your RPA will advise on what levels of contamination or escape must be reported and to whom. Emergency response information, as well as other detailed guidance for the safe use of radioactive substances, should be written into your local rules.



Local rules

Under IRR99, radiation employers must carry out a risk assessment before beginning any activity involving work with radioactive substances. For any areas designated as controlled, they must prepare written local rules summarising the arrangements for controlling work with ionising radiations. Local rules may also be considered

appropriate for supervised areas, depending on the nature of the work carried out there. Where local rules apply, a radiation protection supervisor who is trained in the use of ionising radiation must be appointed to ensure that the arrangements set out in the rules are followed.



Case study 6

Research on genetically modified plants

Research activity

This project involves the development and application of transgenic technology to investigate the circadian clock in a cereal. Homologues of the well-characterised *Arabidopsis* circadian clock genes are present in the important cereal crop barley. The researchers propose to study and manipulate the circadian clock function in barley by the construction of transgenic plants with altered clock gene expression.

The project involves:

- transformation of barley embryos with *Agrobacterium* vectors
- tissue culture/regeneration of barley plants
- growth/characterisation/harvesting of plant tissue and seeds
- use of containment laboratories and glasshouse facilities.

Plan

- Conduct a comprehensive risk assessment to address all relevant issues concerning the construction and growth of transgenic plants.
- Consult organisational policies setting out the requirements of the Genetically Modified Organisms (Contained Use) Regulations 2000, as amended, the Environmental Protection Act 1990 and the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996. The first two statutes give guidance on possible hazards, risks and risk control requirements. The last statute requires that a record of the project risk assessment is kept for 10 years.
- Ensure the assessment addresses the safe use of substances hazardous to health and the potential environmental harm from genetically modified (GM) bacteria used to create the GM plants.
- Submit the risk assessment findings to the genetic modification safety committee for review and approval. If the genetically modified plant is likely to be more hazardous than the parent then the HSE must be notified of the project and the notification fee paid.
- Identify suitable laboratory and greenhouse research work areas.
- Identify the knowledge and competences required by researchers to undertake this project safely. Ensure appropriate training is available if required.
- Identify safety-related information and levels of supervision required by researchers.
- Identify GM waste treatment requirements and disposal route.

Do

Ensure that:

- all appropriate controls and containment measures identified by the risk assessment to minimise the accidental release of transgenic seeds to the environment are in place before work starts:
 - the growth, drying and harvest of plants is carried out in the same facility
 - sticky mats are used to trap seeds
 - sealed containers are used to transport plant material and seeds
- supervisors are available if required by the risk assessment, after considering the researchers' experience
- the predicted lower fitness of the transgenic plants is observed in practice.

Check

Ensure that:

- containment measures for all stages of the project are in place and working
- researchers are familiar with the risk assessment, work procedures and incident reporting system, and emergency procedures
- incidents and near-misses are reported, including any accidental releases of plant material outside the greenhouse
- the sticky mats are changed at regular intervals
- the proposed waste disposal routes operate satisfactorily.

Review

- Review the risk assessment frequently and revise it if failures in health and safety management are observed or reported.
- Revise procedures and controls following any changes to the experimental protocols.
- Review contingency arrangements at regular intervals.
- Review the safety management of the project when work is finished and establish whether any lessons can be learned and applied to future projects. If there were any incidents, you may need to amend the research protocols and standard operating procedures.



Genetically modified organisms

The Genetically Modified Organisms (Contained Use) Regulations 2000 require:

- risk assessment of activities involving genetically modified micro-organisms (GMMs) and activities involving organisms other than micro-organisms. All activities must be assessed for risk to humans and those involving GMMs assessed for risk to the environment
 - the establishment of a genetic modification safety committee to advise the researcher or research organisation in relation to GM risk assessments
 - classification of a project based on the risk of the activity, independent of its purpose. The classification is based on the four levels of containment for microbiological laboratories
 - notification of all premises to the HSE before they are used for genetic modification activities for the first time
 - individual activities of Class 2 (low risk) to Class 4 (high risk) to be notified to the competent authority (which the HSE administers). Consents are issued for all Class 3 (medium risk) and Class 4 activities. Class 1 (no or negligible risk) activities don't need to be notified, although they are open to scrutiny by the HSE's specialist inspectors who enforce the regulations. Activities involving GM animals and plants which are more hazardous to humans than the parental non modified organism must also be notified
- fees paid for the notification of premises for:
 - first-time use
 - class 2, 3 and 4 activities
 - notified activities involving GM animals and plants
 - the maintenance of a public register of GM premises and certain activities.

Further advice on research activities involving genetically modified organisms can be found in the SACGM *Compendium of guidance* (www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/index.htm).

7 Glossary

Here, you'll find explanations of some terms, acronyms, agencies and legislation used in research, followed by a list of the sources used in this document (section 8).

ACDP

The Advisory Committee on Dangerous Pathogens advises the Health and Safety Executive and government departments in England, Wales, Scotland and Northern Ireland on all aspects of the hazards and risks to workers and others from exposure to pathogens.

ATEX

ATEX is the name commonly given to the two European directives for controlling explosive atmospheres. The ATEX Workplace Directive specifies minimum requirements for improving the health and safety protection of workers potentially at risk from explosive atmospheres. The ATEX Equipment Directive sets standards for equipment and protective systems intended for use in potentially explosive atmospheres.

AURPO

The Association of University Radiation Protection Officers is a professional organisation. Its members come mainly from universities and similar establishments involved in training undergraduates and graduates in science, engineering and medicine. Its principal aim is to increase knowledge and understanding of radiation protection through the promotion and interchange of information. AURPO is consulted by a number of government and other organisations responsible for drafting new legislation on various matters relating to all aspects of radiation protection.

Best available techniques

Best available techniques (BAT) – known in Scotland and Northern Ireland as best practicable means (BPM) – entails using the best methods possible to reduce discharges of non-radioactive pollutants under Integrated Pollution

Control (IPC) Regulations. Under Environment Agency Radioactive Substances Regulation, the application of BAT is key to the optimisation requirement in the management of the generation and disposal of radioactive waste, in order to keep radiological impacts on people 'as low as reasonably achievable'.

British Occupational Hygiene Society

The BOHS is both a learned society and the only professional society representing qualified occupational hygienists in the UK. Through the Faculty of Occupational Hygiene, it sets professional standards and is the UK examining board for qualifications in occupational hygiene.

CE marking

A CE mark is required for all new products that are subject to one or more of the European product safety directives. It is a visible sign that the product's manufacturer is declaring conformity with all of the directives relating to that product. Second-hand products to which the directives apply brought in from countries outside the EU, and existing products which have been so extensively modified as to seem as new, must also be marked before use.

Competent person

A 'competent person' is someone who has the necessary training, knowledge, experience, expertise and/or other qualities to complete their allotted task safely and effectively.

Containment

The containment of biological agents refers to the sum of the building/laboratory, procedural and management arrangements in place to minimise the risk of infection to people working with the agents or to others (within or outside the workplace) who could become exposed to them.

Containment level

The level of containment selected for working with various biological agents depends on risk, but the minimum should be directly related to the agent's hazard group (HG). For example, Level 2 containment measures would be the minimum requirements selected for work with HG2 biological agents.

COSHH

The Control of Substances Hazardous to Health Regulations 2002 set out the statutory requirements and responsibilities of employers and employees who either work with substances that are, or could be, hazardous to health; or who could be exposed to such substances in a work context. Duties are also placed on employers to ensure that members of the public and third parties are not exposed to harmful substances used in or generated by their work processes.

Criminal Records Bureau

The Criminal Records Bureau helps employers in England and Wales make safer recruitment decisions. A number of roles, especially those involving children or vulnerable adults, require a criminal record check.

CTSA

Counter-Terrorism Security Advisers (CTSAs) are located within police forces and are responsible for providing specialist advice about protective security measures to local organisations. Their work is co-ordinated by the National Security Counter-Terrorism Office (NaCTSO). CTSAs are responsible for undertaking security risk assessments of laboratories holding radioactive sources, precursor chemicals and stocks of specified biological agents and toxins. They have the power to demand improvements to security arrangements in these areas.

Defra

The Department for Environment, Food and Rural Affairs (Defra) is a government department in the UK. It

makes policy and legislation, and works with others to deliver policies in areas such as food, farming and fisheries; animal health and welfare; environmental protection and pollution control. Defra works directly in England and collaborates with the devolved administrations in Wales, Scotland and Northern Ireland.

Disclosure Scotland

Disclosure Scotland is an executive agency of the Scottish Government. A disclosure is a document containing impartial and confidential criminal history information held by the police and government departments which can be used by employers to make safer recruitment decisions. It is the Scottish equivalent of the CRB check. In Northern Ireland the process is called 'Access Northern Ireland'.

DSEAR

The Dangerous Substances and Explosive Atmospheres Regulations 2002 (DSEAR) require employers to control the risks to safety from fire and explosions associated with the use or holdings of certain 'dangerous' substances.

EN61010-1:2001

These are the safety requirements for electrical equipment for measurement, control and laboratory use. EN61010-1:2001 specifies general safety requirements for electrical equipment intended for professional, industrial process and educational use. It applies to four main groups of equipment: electrical test and measurement equipment; electrical control equipment; electrical laboratory equipment; and accessories for use with the above.

Genetic modification

According to the SACGM *Compendium of guidance*, a genetically modified organism is defined as an organism (with the exception of humans) in which "the genetic material has been altered in a way that does not occur naturally by mating and/or natural

recombination" using "recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation".

Hazardous waste

Waste is classified as hazardous if it possesses one or more of the 15 hazardous properties listed in the UK environment agencies' publication *Interpretation of the definition and classification of hazardous waste* (technical guidance WM2). Organisations that produce, transport or receive hazardous waste are regulated by the Hazardous Waste Regulations.

Health and Safety Executive

The HSE is an independent regulator that acts in the public interest to reduce work-related death and serious injury across Great Britain's workplaces.

HTA

The Human Tissue Authority is a watchdog that supports public confidence by licensing organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching and public exhibitions.

IATA

The International Air Transport Association is an international trade body that publishes a range of guidance relating to the transport of dangerous goods, animals and infectious substances.

Ionising radiations

Ionising radiations occur as either electromagnetic rays (such as X-rays and gamma rays) or particles (such as alpha and beta particles). Many areas of research use sealed and unsealed

radioactive sources. The health and safety aspects of working with radioactive substances are addressed by the Ionising Radiations Regulations 1999 (enforced by the HSE). Legal requirements relating to the protection of the environment from radioactive substances are set out under the terms of the Radioactive Substances Act 1993 and in the Environmental Permitting (England and Wales) Regulations 2010. The protection of the environment from radioactive materials is enforced by the various UK environment agencies.

LEV

Local exhaust ventilation, often called dust or fume extraction, is used to protect employees and others from airborne contaminants at work.

Low Voltage Directive

The LVD 2006/95/EC covers electrical equipment between 50 and 1,000 volts for alternating current and equipment between 75 and 1,500 volts for direct current. For most electrical equipment, the health aspects of emissions of electromagnetic fields are also under the domain of the Low Voltage Directive.

Machinery Directive

Directive 2006/42/EC applies to machinery, lifting accessories such as slings and chains, and safety components. A machine is defined as "an assembly of linked parts or components, at least one of which moves". The associated Regulations are enforced by the HSE for machinery used in the workplace, and the Trading Standards Service for machinery used at home. Penalties for non-compliant machinery can be severe.

Microbiological safety cabinet

A microbiological safety cabinet (MSC) is a ventilated enclosure intended to protect the user and the environment from aerosols generated when handling biological agents or material that may contain such agents. MSCs are not

normally designed to contain radioactive, toxic or corrosive substances. There are three types of cabinet:

- class I: a cabinet with a front aperture through which the operator can carry out manipulations inside. It is constructed so that the operator is protected
- class II: a cabinet with a front aperture similar to the class I cabinet, but constructed so that both the worker and product are protected
- class III: a cabinet in which the working area is totally enclosed providing maximum protection for the operator, the work and the environment.

Noise at work

The Control of Noise at Work Regulations 2005 require employers to prevent or reduce risks to health and safety from exposure to noise at work. Employees have duties under the Regulations too.

Non-ionising radiation

Non-ionising radiation (NIR) is the term used to describe the part of the electromagnetic spectrum covering two main regions, namely optical radiation (ultraviolet (UV), visible and infrared) and electromagnetic fields (EMFs – power frequencies, microwaves and radio frequencies). UV lights and lasers can present optical radiation hazards in a research environment and their use is controlled by the Control of Artificial Optical Radiation at Work Regulations 2010.

PPE

Personal protective equipment (PPE) includes safety helmets, gloves, eye protection, high-visibility clothing, safety footwear and safety harnesses. The legal requirements relating to the use and provision of PPE in the workplace are set out in the Personal Protective Equipment at Work Regulations 1992, as amended.

Precursor chemical licensing

The effective control of chemicals used in the illicit manufacture of narcotic drugs and psychotropic substances is an important tool in combating drug trafficking. These chemicals, known as 'precursors', also have legitimate commercial uses as they are legally used in a wide variety of industrial processes and consumer products, such as medicines, flavourings and fragrances. Organisations which use precursor chemicals need to be licensed or registered with the Home Office. Applications are subject to fees. The Home Office produces a wall chart which lists the substances covered by licensing requirements.

Pressure equipment and systems

Pressure systems can range from steam-generating commercial coffee machines to large boilers. Legal requirements relating to the use of pressure systems and pressure equipment are set out in the Pressure Systems Safety Regulations 2000, the Pressure Equipment Regulations 1999 and the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009.

RCUK

Research Councils UK is the strategic partnership of the UK's seven research councils, which invest in research in a range of academic disciplines: medical and biological sciences, astronomy, physics, chemistry and engineering, social sciences, economics, environmental sciences and the arts and humanities.

Strict liability

Strict liability, sometimes called absolute liability, is the legal responsibility for damages or injury, even if the person found strictly liable was not at fault or negligent – ie they had no guilty intent. Strict liability has been applied to holding an employer liable for the wrongful acts of their employees.

UCEA

The Universities and Colleges Employers Association (UCEA) represents UK higher education institutions and provides advice and guidance to them on employment, reward and human resources practice.

UCSF

The University Chemical Safety Forum (UCSF) is a professional group of health and safety practitioners working in the higher education sector who advise on working with chemicals and hazardous materials. They have produced a *UCSF chemical security document*.

USHA

The Universities Safety and Health Association (USHA) is an organisation for the promotion of safety and health in higher education. Membership is primarily open to higher education institutions, both in the UK and from further afield. Membership is also available to research institutions and related organisations on request.

Vitae

Vitae is the UK organisation championing the personal, professional and career development of doctoral researchers and research staff in higher education institutions and research institutes.

WM2

Technical guidance document WM2 is a guide to the interpretation of the definition and classification of hazardous waste and is available on any of the UK's environmental agency websites.

8 Further reading and sources of information

Access Northern Ireland:
www.dojni.gov.uk/accessni

Approved list of biological agents:
www.hse.gov.uk/pubns/misc208.pdf

Biological agents: managing the risks in laboratories and healthcare premises
British Occupational Hygiene Society:
www.bohs.org

CEN workshop agreement – CWA 15793 Laboratory biorisk management standard:
<ftp://ftp.cenorm.be/PUBLIC/CWAs/wokrshop31/CWA15793.pdf>

Control of Substances Hazardous to Health:
www.hse.gov.uk/coshh/index.htm

Defra:
www.defra.gov.uk

Developing a safety culture – business for safety
Confederation of British Industry

Disclosure Scotland:
www.disclosurescotland.co.uk/what-is-disclosure

EH40/2005 Workplace exposure limits
HSE:
www.hse.gov.uk/pubns/priced/eh40.pdf

Environment Agency
www.environment-agency.gov.uk

European Commission:
ec.europa.eu/index_en.htm

European Committee for Electro-technical Standardisation:
www.cenelec.eu/index.html

Guidance for employers on the Control of Artificial Optical Radiation at Work Regulations (AOR) 2010:
www.hse.gov.uk/radiation/nonionising/employers-aor.pdf

Guidance on health and safety in fieldwork:
www.ucea.ac.uk/en/publications/index.cfm/guidance-on-health-and-safety-in-fieldwork

Home Office:
www.homeoffice.gov.uk

HSE:
www.hse.gov.uk

HSE Ionising Radiations Regulations notification page:
www.hse.gov.uk/radiation/ionising/notification.htm

Human Tissue Authority:
www.hta.gov.uk

International Air Transport Association:
www.iata.co.uk

National Counter Terrorism Security Office:
www.nactso.gov.uk/Default.aspx

Northern Ireland Environment Agency:
www.doeni.gov.uk/niea

Policy and code of conduct on the governance of good research conduct
RCUK:
www.rcuk.ac.uk/documents/reviews/gc/goodresearchconductcode.pdf

Promoting a positive culture – a guide to health and safety culture
Institution of Occupational Safety and Health:
www.iosh.co.uk/techguide

Researcher Development Framework Vitae:
www.vitae.ac.uk/CMS/files/upload/Vitae-Researcher-Development-Framework.pdf

Risk management of carbon nanotubes:
www.hse.gov.uk/pubns/web38.pdf

SACGM Compendium of guidance:
www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/index.htm

Safety culture, advice and performance
Institution of Occupational Safety and Health:
www.iosh.co.uk/researchreports

Scottish Environment Protection Agency:
www.sepa.org.uk

Universities and Colleges Employers Association:
www.ucea.ac.uk

Universities Safety and Health Association:
usha.org.uk

University Chemical Safety Forum:
www.ucsf.soton.ac.uk

Working safely with nanomaterials in research and development:
www.safenano.org/UKNanosafetyPartnership.aspx

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IOSH is the Chartered body for health and safety professionals. With more than 40,000 members in 80 countries, we're the world's largest professional health and safety organisation.

We set standards, and support, develop and connect our members with resources, guidance, events and training. We're the voice of the profession, and campaign on issues that affect millions of working people.

IOSH was founded in 1945 and is a registered charity with international NGO status.