Health and Safety (Sharp Instruments in Healthcare) Regulations 2013

Guidance for employers and employees

HSE information sheet

Health Services Information Sheet 7

This information sheet is for healthcare employers and employees. It will help you understand your legal obligations under the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 (the Sharps Regulations).

The Regulations implement aspects of the European Council Directive 2010/32/EU (the Sharps Directive) that are not specifically addressed in existing GB legislation. They will apply from 11 May 2013.

All employers are required under existing health and safety law to ensure that risks from sharps injuries are adequately assessed and appropriate control measures are in place. The Sharps Regulations build on the existing law and provide specific detail on requirements that must be taken by healthcare employers and their contractors.

This information sheet should be read in conjunction with other information on managing the risks of sharps injuries, and the associated risks of infection from blood-borne viruses. HSE guidance and links to other relevant guidance can be found on HSE's website.

Which employers must take action on the Sharps Regulations? - regulations 3 and 4

The employer's duties in the Sharps Regulations only apply if you are either:

- an employer whose primary work activity is the management, organisation or provision of healthcare (a healthcare employer); or
- a contractor working for a healthcare employer and your staff may be at risk of a sharps injury while on the premises of or working under the management and supervision of the healthcare employer (for example laundry workers, caretakers, cleaners, waste disposal workers, bank nurses and locum doctors). However, a contractor's duties will only apply to the extent of their control of work involving medical sharps.

The main healthcare employer and their contractors must co-operate and share information to ensure that risks of sharps injuries are adequately controlled and that they have the appropriate arrangements to comply with the Sharps Regulations, as required by the Management of Health and Safety at Work Regulations 1999.

For most healthcare employers and their contractors it will be clear that the Regulations apply to them. The Annex at the end of this information sheet provides examples where further clarification is likely to be helpful.

How do the Sharps Regulations change my responsibilities for managing the risks from the use of sharps?

Effective safe management of sharps, across all sectors, flows from the existing health and safety legislation. In particular, the needs to assess the risks, provide appropriate information and training, and consult with employees. The Sharps Regulations build on the existing law and provide specific detail on requirements that must be taken by healthcare employers and their contractors. These are:

Use and disposal of medical sharps
The Sharps Regulations follow the principles of the hierarchy of preventative control measures, set out in the Control of Substances Hazardous to Health Regulations (COSHH). However, they require that employers consider the additional risk control measures below:

Avoid the unnecessary use of sharps – regulation 5(1)(a)
Needles, scalpels etc will remain essential tools for effective medical care. However, the employer should ensure that sharps are only used where they are required. For example, organisations that have reviewed the use of sharps have identified staff using needles to carry out tasks for which they are not required (for example collection of urine samples from catheter bags). Needle-free equipment is available for certain procedures and should be used, where it is reasonably practicable to do so.

Where it is not reasonably practicable to avoid the use of medical sharps, the Sharps Regulations require employers to:

Use safer sharps (incorporating protection mechanisms) – regulation 5(1)(b)
The employer must substitute traditional, unprotected medical sharps with a 'safer sharp' where it reasonably practicable to do so. The term 'safer sharp' means medical sharps that incorporate features or mechanisms to prevent or minimise the risk of accidental injury. For example, a range of syringes and needles are now available with a shield or cover that slides or pivots to cover the needle after use. The following factors should be considered:

- the device must not compromise patient care;
- the reliability of the device;
- the care-giver should be able to maintain appropriate control over the procedure;
- other safety hazards or sources of blood exposure that use of the device may introduce;
- ease of use (taking into account the existing clinical practices commonly in use by the relevant health professionals – but not assuming custom and practice is safest);
- is the safety mechanism design suitable for the application? The following are relevant:
  - if activation of the safety mechanism is straightforward, it is more likely to be used;
  - if the safety mechanism is integral to the device (ie not a separate accessory) it cannot be lost or misplaced;
  - for many uses a single-handed or automatic activation will be preferable;
  - an audible, tactile or visual signal that the safety mechanism has correctly activated is helpful to the user; and
  - the safety mechanism is not effective if it is easily reversible.

'Safer sharps' do not necessarily remove all risks associated with the use of a sharp. For example, a needle shield is activated after a procedure is completed, but a sharps injury to the healthcare worker can occur during the procedure (eg when a patient moves unexpectedly) and a 'safer sharp' will not prevent this.

For some procedures, there may be more than one person involved in handling, sterilising or otherwise dealing with the sharps. The employer's COSHH risk assessment should consider all these aspects, and identify the appropriate equipment, safe procedures, personal protective equipment (PPE) and immunisation required at each stage.

Involving the end users of the equipment and their representatives in the selection of safer sharps will help ensure that they use the new equipment safely, and any reduction in the number of sharps injuries is maintained for longer.

If a suitable safer sharp is not available to reduce the risk of injury, the employer should ensure that safe procedures for working with and disposal of the sharp are in place.

In some circumstances, patients may provide needles (for example, for administration of insulin) which they expect a healthcare worker to use and the employer has not had an opportunity to ensure that it is a suitable 'safer sharp'. The employer's risk assessment should identify if their employees may be faced with such a request, and make arrangements to ensure that employees have safe systems of work and the appropriate information, training and equipment to deal with this situation.

Prevent the recapping of needles – regulation 5(1)(c)
Injuries can occur after a needle has been used if the healthcare worker holds the needle in one hand and attempts to place a cap on the needle with the other hand (so-called two-handed recapping).

Needles must not be recapped after use unless the employer's risk assessment has identified that recapping is itself required to prevent a risk (eg to reduce the risk of contamination of sterile preparations). In these limited cases, appropriate devices to control the risk of injury to employees must be provided. For example, needle-blocks can be used to remove and hold the needle cap and so allow safe one-handed recapping.

Place secure containers and instructions for safe disposal of medical sharps close to the work area – regulation 5(1)(d)
Regulation 7(6)(c) of COSHH requires systems to dispose of contaminated waste safely. The Sharps Regulations supplement this by requiring that clearly marked and secure containers be placed close to the areas where medical sharps are used. Instructions for staff on safe disposal of sharps must also be placed in those areas.

In many healthcare facilities sharps bins can be placed next to the healthcare worker so they can drop the used sharp straight into it. For example, in wards this can be achieved by placing the sharps container on the dispensing trolley.

However, some healthcare workers do not operate in premises in which they have control, for example paramedics or healthcare workers working in a patient's home. In these cases, the employer's risk assessment should select appropriate sharps, specify safe working procedures and provide suitable portable

sharps containers and means for collection and replacement of those.

Information and training

The Sharps Regulations supplement existing requirements to provide health and safety information and training for staff by requiring that it includes those matters listed below (from Schedule 1 and 2 of the Sharps Regulations), to the extent that they are relevant to the employee's work.

The information provided to employee – regulation 6
Information may be provided in many forms, including safe operating systems, safety guides, posters, information on internal staff websites. The employer must work with any appointed safety representatives in developing and promoting the information to be given to workers (regulation 6(2) and (3)). This provision recognises the role of union and other safety representatives in helping to raise awareness of the risks from medical sharps.

The information provided to employees must cover:

- the risks from injuries involving medical sharps;
- relevant legal duties on employers and workers;
- good practice in preventing injury;
- the benefits and drawbacks of vaccination; and
- the support available to an injured person from their employer (see requirements on accident follow-up below).

Employee training – regulation 6(4)
Training should be in an appropriate form to ensure that your employees know how to work safely and without risks to health with the specific sharps equipment and procedures that they will use. Guidance on ensuring that employees receive appropriate health and safety training is available in *Health and safety training: A brief guide* INDG345 (www.hse.gov.uk/pubns/indg345.htm).

Under the Sharps Regulations, the training provided to employees must cover:

- the correct use of safer sharps;
- safe use and disposal of medical sharps; and
- what to do in the event of a sharps injury (see requirements on accident follow-up below);
- the employer's arrangements for health surveillance and other procedures.

Arrangements in the event of injury

The Sharps Regulations require employers to take specific actions in the event of a sharps injury. This means they need to have procedures in place to ensure that they can respond effectively and in a timely manner when an injury occurs.

Injured employee's duty to notify their employer of a sharps accident – regulation 8
An employee who receives a sharps injury at work must notify their employer as soon as practicable. The employer will need to ensure they have sufficiently robust arrangements to allow employees to notify them in a timely manner, including where the employee works out-of-office hours or away from the employer's premises.

As set out above, an employee's training must be clear about the requirements for notifying and on the employer's procedures for follow-up. This will include who and how they should notify and what information is likely to be useful.

Recording and investigating the incident – regulation 7(1)
Employers must make a record of the sharps injury when they are notified of it, whoever provides that notification. They must investigate the circumstances and causes of the incident and take any action required. The injured person is required to provide sufficient information to their employer to allow them to carry out this investigation.

The record of the injury should include who was injured, and when and where the incident occurred. If possible, the summary record should contain sufficient detail to identify what type of sharp was involved, at what stage of a procedure or post-procedure/disposal of the sharp the injury occurred, and the severity of the injury. If the employer has an existing accident book or other recording system, it will be appropriate to use this for the record of sharps injuries.

The extent of the accident investigation should be proportionate to the potential severity of the incident. For example, where an employee has injured themselves with a clean needle as they take it out of the packet it will usually be sufficient to record the details and ensure they receive any first aid required. Injuries involving a used needle will involve more analysis and an appropriate record should be kept of the findings of the investigation.

The purpose of the investigation should be to establish whether the employer's existing risk control measures are adequate. It should look at underlying and root causes as well as the immediate factors that led to the individual incident. Investigations should be conducted with accident prevention in mind, not placing blame. An investigation of a significant sharps injury may involve expertise from health and safety, occupational

health and infection control teams (where available). Any lessons to be learned should be applied across an organisation (if appropriate), not just in the location or department where the accident occurred.

In the case of an injury where there may have been exposure to a blood-borne virus or other significant infection, the investigation may also involve establishing the infection status of the source patient (where it is possible to identify the individual). If this information is known, it should be handled in accordance with appropriate requirements for patient confidentiality. If it is promptly shared with the medical professional who is treating the injured person, it can greatly assist with ensuring they receive the right treatment or that they do not take unnecessary prophylaxis or anti-viral treatments.

Treatment and follow-up of a sharp injury – regulation 7(2)
The employer must ensure that, when notified of any incident in which an employee has been injured by a sharp that has or may have exposed them to a blood-borne virus, the employee:

- has immediate access to medical advice;
- has been offered post-exposure prophylaxis and any other medical treatment, as advised by a doctor; and
- the employer has considered whether counselling would be appropriate for the employee.

Advice for doctors on the appropriate treatment and follow-up for an exposure to blood-borne viruses, including current post-exposure prophylaxis regimes, is provided by the Department of Health.

In some circumstances, an occupational health nurse or other suitably qualified and supervised practitioner may provide the assessment and treatment for an employee injured by a sharp. This service will be adequate to comply with the requirement for the advice to be provided by a doctor if:

- it is provided within a practice supervised by a registered medical practitioner; and
- it is carried out in accordance with the appropriate established operating procedure of that practice.

If staff work out-of-hours and/or on premises where there is not an occupational health service available to them, the employer must ensure they have sufficiently robust arrangements that will allow employees to access treatment in a timely manner. The training they provide staff should be clear as to where they should go for treatment.

Review procedures regularly – regulation 5(2)
The Sharps Regulations follow the same principles as any successful health and safety management regime, including reviewing procedures to ensure their continuing effectiveness. However, the Regulations specifically require employers to review, at suitable intervals, the procedures that are in place to implement the following risk control measures:

- use of medical sharps at work is avoided so far as is reasonably practicable;
- when medical sharps are used at work, safer sharps are used so far as is reasonably practicable;
- needles that are medical sharps are not capped after use at work unless the risk of injury to employees is effectively controlled by use of a suitable appliance, tool or other equipment;
- in relation to the safe disposal of medical sharps that are not designed for re-use:
  - written instructions are available for employees; and
  - clearly marked and secure containers are located close to areas where medical sharps are used at work.

A suitable review would involve gathering information on:

- the degree of compliance with the relevant procedures (if the procedures are not being followed there is usually a reason why, such as lack of training, or a genuine practical problem with the procedure itself);
- any areas where procedures are absent or inadequate. New ‘safer sharps’ may have become available for certain applications or guidance may have been issued from a relevant authoritative body;
- consultation with the relevant staff and their representatives; and
- injury and incident data.

Annex: Further clarification on when the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 apply

The following have been raised as examples where some further clarification of the application of the Sharps Regulations would be helpful. However, it is important to remember that existing legal requirements still apply, whether or not the Sharps Regulations apply. For example, the need to follow the COSHH hierarchy.

Contractors

A contractor whose employees work at different times at healthcare premises and non-healthcare premises (for example, a cleaning firm) is not required to comply with the Sharps Regulations when their staff are working at a non-healthcare premises (eg an office). However, the existing requirements to ensure risks from sharps injuries are controlled apply. This means that if cleaners at non-healthcare premises may encounter drug litter or other unsafely disposed of used needles, the employer should assess the risk and provide the appropriate controls.

Healthcare workers providing care to people at their homes

The Regulations apply to employers whose primary activity is to organise, manage and provide healthcare, including where their employees provides care for people in their own homes. They do not place any duties on the person receiving care, their family members/cohabitees or their appointed attorney. The employer's risk assessments and arrangements to comply with the Regulations will need to take account of the circumstances that their employees work in, including arrangements for any lone workers.

Residential care homes

Whether the Regulations apply will depend on the nature of the care provided by the home. They will apply if the primary purpose of the home is to provide healthcare. They will not apply if the main purpose of the home is limited to only providing residential care. The residents of either type of home will not have any duties under the Regulations.

Bank nurses and other agency workers contracted to work in healthcare

The employment status of an individual bank nurse or agency worker will depend on their exact circumstances. However, if they are employed by an employer whose main activity is the provision of healthcare or they are employed by an agency that provides services to that main healthcare employer, the Regulations will apply to risks of sharps injuries that arise from their work.

Clinical placement, student assistantship, elective, internship or other workplace training

The employment status of an individual student or trainee while they are on placement in a hospital or other healthcare premises will depend on their exact circumstances. The Regulations will apply to the healthcare employer who is responsible for providing their training. If there is no employment the student is deemed to be an employee of the employer providing the training by virtue of the Health and Safety (Training for Employment) Regulations 1990.

Employers and the medical school/academic institution will need to exchange information to ensure that the risks to the students are adequately controlled. The academic institution is not required to comply with the Regulations at the premises of the school or other academic institution itself.

Clinical trials in the pharmaceutical sector

Clinical trials cover a wide range of studies, some of which involve sharps, for example injections of a trial pharmaceutical or collection of blood samples.

Where employees of a healthcare employer (whether in a hospital or other premises) carry out trials involving sharps on behalf of a clinical research organisation/ pharmaceutical company the Regulations will apply.

Where employees of a pharmaceutical company or research organisation carry out trials, the main activity of their employer is not the management, organisation or provision of healthcare and therefore the Regulations will not apply. However, if they enter healthcare premises to carry out the trial, especially if they make use of the host's facilities (eg sharps waste disposal), the requirements of the existing legislation to co-operate and exchange information will apply.

Pharmacies

High-street pharmacies are primarily retail businesses so the Regulations do not apply. However, if the primary activity of a community pharmacy is to provide healthcare then the Regulations will apply. Pharmacies that are part of a hospital and/or an NHS-run service will be employed by a healthcare employer and the Regulations will apply to them.

Medical staff working in prisons, schools or other non-healthcare workplaces

If an employer's primary activity is the management, organisation or provision of healthcare it does not matter where their staff work, these Regulations will apply. For example, the Regulations will apply:

- in Scotland, to medical staff providing care in prisons employed by NHS Scotland;

- medical staff employed by an independent medical service who provide primary and occupational healthcare to workers on offshore platforms;
- a healthcare business supplies an occupational health nurse to attend a non-healthcare company's premises to administer vaccinations for the company's employees, the healthcare business will be subject to the Regulations, but the company will not;

while the Regulations **will not** apply to the following:

- school nurses employed directly by the school;
- medical staff providing care in prisons, employed by the prison itself.

Non-healthcare contractors to a healthcare employer
Businesses that are contracted to provide non-healthcare services to healthcare employers, such as catering and building or plant maintenance, will only be required to act if those who work for them on the healthcare employer's premises may be exposed to medical sharps while they are working there.

Such a risk should have been identified in a risk assessment. The term 'medical sharps' does not include kitchen knives or utility knives, as these are not used to carry out specific healthcare.

Further information

For further information on managing the risks from sharps injuries, general health and safety advice, or to report inconsistencies or inaccuracies in this guidance, visit www.hse.gov.uk/. You can view HSE guidance online and order priced publications from the website. HSE priced publications are also available from bookshops.

This guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.

This publication is available at:
www.hse.gov.uk/pubns/hsis7.htm.

You can find more advice at:
www.hse.gov.uk/healthservices/index.htm.

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