

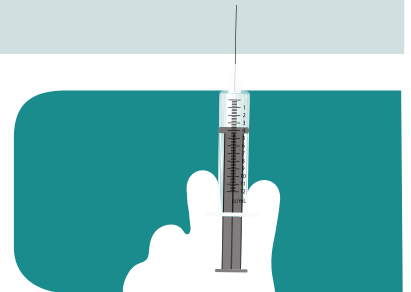


Guide to the European Union
**(Prevention of Sharps Injuries
in the Healthcare Sector)**
Regulations 2014

Our vision:

A country where worker safety, health and welfare and the safe management of chemicals are central to successful enterprise

CONTENTS



INTRODUCTION	2
WHY ARE THE REGULATIONS REQUIRED?	3
WHAT ARE SHARPS?	3
WHO WILL BE AFFECTED BY THE REGULATIONS?	3
WHAT DO THE REGULATIONS REQUIRE OF EMPLOYERS AND EMPLOYEES IN THE HEALTHCARE SECTOR?	4
RISK ASSESSMENT	4
Step 1: Identify the hazard	4
Step 2: Assess the risk	5
Step 3: Select appropriate controls and implement them	6
Eliminate the unnecessary use of sharps	6
Safety-engineered protection mechanisms	6
Prevent recapping of needles	7
Safe disposal of used sharps.	7
Personal protective equipment	8
Vaccination	8
Policies and procedures	8
Information and awareness-raising	9
Training	9
REPORTING	10
RESPONSE AND FOLLOW UP.	10

INTRODUCTION

The purpose of this guide is to provide practical information on the implementation of the European Union (Prevention of Sharps Injuries in the Healthcare Sector) Regulations 2014, hereafter referred to as “the Regulations”. The information is aimed at employers, managers, employees, safety representatives, health and safety practitioners and other interested parties in the healthcare sector.

The Regulations transpose Council Directive 2010/32/EU. The directive implements the Framework Agreement on prevention of sharps injuries in the hospital and healthcare sector concluded by the European Hospital and Healthcare Employers’ Association (HOSPEEM) and the European Federation of Public Services Unions (EPSU).

The Regulations relate to the risks posed by sharps to those working in healthcare. They implement specific control measures to protect employees at risk, and require an appropriate response in the event of an incident occurring.

The Regulations build on the more general duties under the Safety, Health and Welfare at Work Act 2005 and the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 which apply across all industry sectors.



Why are the regulations required?

WHY ARE THE REGULATIONS REQUIRED?

The everyday work of healthcare employees puts them at risk of serious infections, including hepatitis B, hepatitis C and HIV, as a result of sharps injuries. More than one million sharps injuries are estimated to occur in the European Union each year. Sharps injuries pose serious risks to healthcare workers in Ireland and represent a high cost for health systems and society in general. While the risk of infection can be relatively low, the anxiety of having blood tests and possible treatment, which can have unpleasant and debilitating side-effects, can cause an employee a great deal of stress.

WHAT ARE SHARPS?

The Regulations define sharps as 'objects or instruments necessary for the exercise of specific healthcare activities, which are able to cut, prick or cause injury or infection'. This includes equipment such as needles, blades (such as scalpels) and other sharp medical instruments. Sharps are considered to be work equipment within the meaning of Regulation 2 of the Safety, Health and Welfare at Work (General Application) Regulations 2007.

WHO WILL BE AFFECTED BY THE REGULATIONS?

The Regulations apply to all employers and employees in the healthcare sector. This includes nurses, medical practitioners, nursing auxiliaries and assistants, cleaners, dental nurses, paramedics, home carers etc. The Regulations

apply to students working in healthcare, self-employed persons in healthcare and any employees employed by organisations contracted to provide services for healthcare organisations such as cleaners and other ancillary staff.

The employer's duties in these Regulations apply to:

- healthcare employers, a healthcare employer is an employer whose main activity is the management, organisation or provision of healthcare services and
- other employers who provide services to a healthcare employer under the authority of the healthcare employer or in the healthcare employer's place of work. For example a contractor providing services in a hospital such as cleaning or security services. The duties on this employer apply only insofar as this employer has control of the activities involved in providing these services.

Under the Safety, Health and Welfare at Work Act, 2005 employers in the same workplace have a duty to co-operate and co-ordinate activities to ensure that health and safety risks are adequately controlled in the workplace.

Where an employee of a healthcare employer provides healthcare services in another employer's workplace or in the home of a patient, the employer will be required to comply with the Regulations.

What do the regulations require of employers and employees in the healthcare sector?

For example, if a healthcare provider supplies an occupational health nurse to provide a service to a company's employees, the healthcare provider is subject to the Regulations, but the company will not be. The company will, however, remain subject to existing health and safety legislation.

Employers whose main activity is not the provision of healthcare but whose employees may work with sharps will not fall within the scope of the Regulations (unless they are working on the premises of a healthcare employer who is subject to the Regulations). Therefore organisations such as schools and prisons will not be subject to the Regulations even though they might employ medical staff. Those employers will, however, remain subject to existing health and safety legislation.

Although the scope of these Regulations is limited to those working in the healthcare sector, all employers, regardless of industry sector, are obliged under existing legislation to identify and implement reasonably practicable measures to eliminate or control foreseeable workplace hazards. This includes hazards arising from sharps and exposure to potentially harmful biological agents, including blood and body fluids, in the workplace. In this context employers and employees across all industry sectors are advised to consider the measures outlined below as best practice in eliminating or reducing the risk from sharps injuries in their workplace where such a risk exists.

WHAT DO THE REGULATIONS REQUIRE OF EMPLOYERS AND EMPLOYEES IN THE HEALTHCARE SECTOR?

The Regulations place duties on employers and employees with regard to the following:

- Assessing risks of sharps injuries;
- Selecting appropriate controls;
- Implementing those controls through safe working procedures and the provision of information and training; and
- Having in place arrangements for accident reporting, follow-up and the care of the injured employee.

RISK ASSESSMENT

There is a requirement in existing legislation¹ to identify hazards in the workplace and to assess the risks presented by those hazards.

Risk assessments must be documented and brought to the attention of employees.

The Regulations require the employer to ensure that the risk assessment takes account of employees' exposure to a risk of injury and/or infection from sharps.

Risk assessment is essentially a three-step process which involves identifying the hazard, assessing the risk and implementing the appropriate control measures.

Step 1: Identify the hazard

Is there a potential for sharps injuries? If yes ...

¹Section 19, Safety, Health and Welfare at Work Act, 2005 and Regulation 7, Safety, Health and Welfare at Work (Biological Agents) Regulations 2013

Step 2: Assess the risk

Decide who might be harmed and how.

There are many types of work activities which can expose employees in healthcare to the risk of sharps injuries, including:

- Clinical work – clinical procedures such as phlebotomy, cannulation, vaccination, acupuncture and surgical procedures;
- Ancillary services – cleaning, portering, handling hospital laundry and working in a sterile supplies department;
- Diagnostic and laboratory work; and
- Mortuary work.

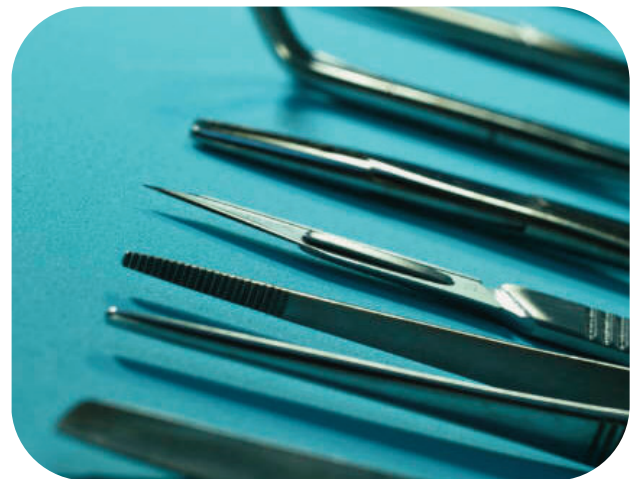
Community based as well as hospital staff may be injured by sharps in the course of their work and by sharps which have not been disposed of correctly.

Assess how likely it is that a sharps injury could occur and the potential for harm, consider:

- The work environment and working conditions and identify factors which could increase the risk of a sharps injury, such as overcrowded conditions, fatigue, stress and emergency situations.
- The nature of the work involved. Does it increase the risk of a sharps injury occurring, e.g. are employees regularly involved in invasive procedures? Are there unpredictable or potentially pressurised situations?

- The experience and knowledge of the employees at risk. Employees who have not received training and information on safe work practices, or new and inexperienced staff, may be at greater risk.
- Whether employees may be working with patients known to be (or likely to be) infected with a blood-borne virus (Hepatitis B, Hepatitis C or HIV).

Decide if existing controls are adequate or whether further controls are necessary.



Existing data on sharps injury reports can help to identify areas of higher risk. However, it should be kept in mind that sharps injuries are not always reported within organisations.

Following the evaluation you may need to consider making improvements to existing controls with priorities for action. A number of control measures may be required to achieve a safe work environment. Consult with employees when deciding on the most appropriate controls.

Step 3: Select appropriate controls and implement them

The Regulations place a duty on the employer to ensure that, where the results of risk assessment reveal a risk of injury and/or infection from sharps, control measures are in place to eliminate or reduce the risk. Compliance with the Principles of Prevention must be ensured. The Principles of Prevention are a hierarchy of control measures set out in descending order of preference. They are contained in Schedule 3 of the Safety, Health and Welfare at Work Act 2005. The control measures in the Regulations are set out below, taking account of the Principles of Prevention.

Eliminate the unnecessary use of sharps:

Where there is a risk of exposure to injury and/or infection from sharps, the Regulations require the employer to eliminate the unnecessary use of sharps. Examples include eliminating unnecessary injections and introducing the use of needle-free systems.

Safety-engineered protection mechanisms:

Eliminating the use of sharps is often not possible. The Regulations require that where there is a risk of exposure to injury and/or infection from sharps, the sharps must incorporate safety-engineered protection mechanisms, referred to here as safer sharps, where these devices are available and appropriate. These safer sharps are designed and constructed to incorporate a feature or mechanism which prevents or minimises the risk of accidental

injury from cutting or piercing the skin.

There are two main types of safety engineered sharps devices: active and passive. Active devices require healthcare employees to activate the mechanism, whereas passive devices deploy automatically. Where these devices are provided, healthcare employees must be trained in their correct use.

Prior to introducing any safer sharp device, the healthcare practitioners should evaluate the effectiveness of the device to ensure its suitability for use and to check that it does not create any additional hazard to the client or the employee.

It is important that those who will use the device are involved in the selection process.

The following criteria² should be taken into consideration when selecting safer sharps:

- The device must not compromise patient care;
- The device must perform reliably;
- The safety mechanism must be an integral part of the safety devices, not a separate accessory;
- The device must be easy to use and require little change of technique on the part of the healthcare professional;
- The activation of the safety mechanism must be convenient and allow the caregiver to maintain appropriate control over the procedure;

²The Safer Needles Network and the Partnership for Occupational Safety and Health in Healthcare (POSHH), 2010

Prevent recapping of needles:

- The device must not create other safety hazards or sources of blood exposure;
- A single-handed or automatic activation is preferable;
- The activation of the safety mechanism must manifest itself by means of an audible, tactile or visual sign to the healthcare professional; and
- The safety mechanism should not be easily reversible once activated.

Prevent recapping of needles:

Manual recapping of needles that are sharps has been identified as a particularly hazardous activity. The practice of recapping needles is banned where there is a risk of injury and/or infection. The risk of injury and infection can be controlled by:

- Not recapping needles after use and disposing of them safely; or
- The use of safety devices designed to prevent a risk from recapping.

Safe disposal of used sharps:

Sharps injuries can occur when used sharps are being transported from place to place and when they are incorrectly disposed of, such as failure to dispose of the sharps into a sharps container or disposing of a sharp into an overfilled container. The Regulations require that suitable sharps disposal containers and written procedures for the

safe disposal of sharps be placed as close as possible to the work area where the sharps are used.

In many healthcare facilities sharps containers can be placed next to the healthcare worker so that the sharp can be disposed of into the sharps container at the point of use, e.g. attached to a dispensing trolley. This may be more difficult where there is no control over the work environment, such as in a client's home.



The risk assessment should identify suitable controls, which may include safe work practices and the provision of portable sharps containers and a means for collection and replacement of these.

Personal protective equipment:

In addition to the above requirement, it should be noted that the Carriage of Dangerous Goods by Road Regulations require that containers for the disposal of used sharps be UN-approved containers designed for this type of waste and that they be properly labelled and puncture resistant. All sharps containers must be tagged with a unique reference number which is traceable to the point of production.

Sharps bins should be easy to close temporarily and permanently. Sharps bins should be marked with a 'fill line' and designed to prevent overfilling and accidental spillage of contents.

Personal protective equipment:

The Regulations require the employer to provide suitable personal protective equipment for the employee at risk where there is a risk of injury and/or infection from the use of sharps. Disposable gloves should be worn for all activities that carry a risk of exposure to blood or body fluids. Although a sharp instrument can easily penetrate a glove, the wearing of a disposable glove greatly reduces the risk of transmission of infection to the injured employee³.



³NHS Employers Health and Safety Essentials Guide, 2011

Vaccination:

The Regulations require that, where the risk assessment indicates that there is a risk of exposure to a biological agent for which an effective vaccine exists, the employer must offer the vaccine (free of charge) to the employee at risk.

Currently a vaccine is available for protection against hepatitis B but not for hepatitis C or HIV. The Immunisation Guidelines for Ireland, Royal College of Physicians of Ireland, list the vaccines recommended for certain categories of workers based on the type of work they carry out.

Employees must be informed of the benefits and drawbacks of both vaccination and non-vaccination. Records of vaccination and follow-up as necessary should be retained and should be kept confidential.

Immunisation is a very effective healthcare intervention; nonetheless, it must be seen as just one part of a wider policy to prevent the transmission of infections. It should never be regarded as a substitute for good infection control practices such as hand-washing and standard precautions.

Policies and procedures:

The employer must have in place policies and procedures which take account of the findings of the risk assessment and the control measures which are in place to prevent or reduce the risk of sharps injuries and/or infections. Policies should be reviewed at regular intervals to ensure that they continue to be effective and up to date.

Information and awareness-raising:

Providing health and safety information is a requirement of Section 9 of the Safety, Health and Welfare at Work Act 2005. The Regulations build on this requirement by ensuring that the information provided to employees includes those matters listed in the Regulations.

These are:

- Potential risks to health;
- Precautions to prevent exposure;
- The steps to be taken by employees in the case of accidents and incidents;
- Guidance on existing legislation relating to the protection of employees at work from the risks to health and safety from sharps;
- Information on any support programme made available by the employer to an employee who has sustained a sharps injury at work. Support programmes may include counselling services and employee assistance programmes; and
- The importance of recording accidents and incidents involving sharps.

Training:

The Regulations require the employer to provide training relating to risks from sharps to employees who are exposed to the risks. Providing health and safety training is a requirement of Section 10 of the Safety, Health and Welfare at Work Act 2005. The Regulations build on this requirement by ensuring that the training provided includes those matters listed in the Regulations. These are:

- The correct use of medical devices incorporating sharps protection mechanisms;
- The risks associated with blood and body fluid exposures;
- Preventive measures in accordance with the procedures in the workplace, including standard precautions, safe systems of work, the correct use of sharps, disposal procedures, the importance of immunisation;
- The employer's policies and procedures with regard to the prevention of sharps injuries and infections, and procedures relating to the monitoring of the safety of work practices relating to sharps;
- Incident reporting and response procedures and their importance; and
- The measures to be taken in the case of injuries. This should include first aid measures to be taken and where to seek any immediate further assistance.

Training must be repeated at regular intervals. When determining when the training should be repeated, the following are to be taken into account:

- The safety of work practices;
- Improvements in the prevention and treatment of sharps injuries and infections; and
- New or changed risks arising from the use of sharps.

It should also be noted that Section 10 of the Safety, Health and Welfare at Work 2005 requires training to be provided:

- On recruitment;
- In the event of a transfer of an employee or change of task assigned;
- On the introduction of new work equipment, systems of work or changes in existing work equipment or systems; and
- On the introduction of new technology.

In keeping with the Safety, Health and Welfare at Work Act 2005 employees are entitled to receive time off from their work without loss of remuneration to receive such training. The training must be provided in such a way as to ensure that it is reasonably likely to be understood by the employee concerned. Employees are required to attend training that is provided for their safety, health and welfare at work.

REPORTING

The Regulations place a duty on employees to report to their employer or immediate supervisor any accident or incident involving an exposure to the risk of injuries and /or infections from sharps. This will ensure that an injured employee can receive the appropriate care and the incident can be investigated with a view to preventing recurrence.

An employer must report certain categories of work-related sharps injuries to the Health and Safety Authority (HSA). Work-related sharps injuries must be reported in the following circumstances:

- Where a work-related sharps injury results in an employee being prevented from carrying out their normal work for more than three consecutive days. This must be reported online at www.hsa.ie or on an IR1 form.
- Where the incident could cause severe human infection/human illness, e.g. a percutaneous injury with a contaminated sharp where the source patient is known or found to be positive for hepatitis B, hepatitis C or HIV. The IR3 form, Report of Dangerous Occurrence, may be used to report the incident to the Health and Safety Authority.

For more information on how to report an injury or dangerous occurrence to the Health and Safety Authority see www.hsa.ie.

Because sharps are considered to be medical devices, it should also be noted that there is a voluntary system of reporting incidents involving medical devices to the Irish Medicines Board at www.imb.ie

RESPONSE AND FOLLOW UP

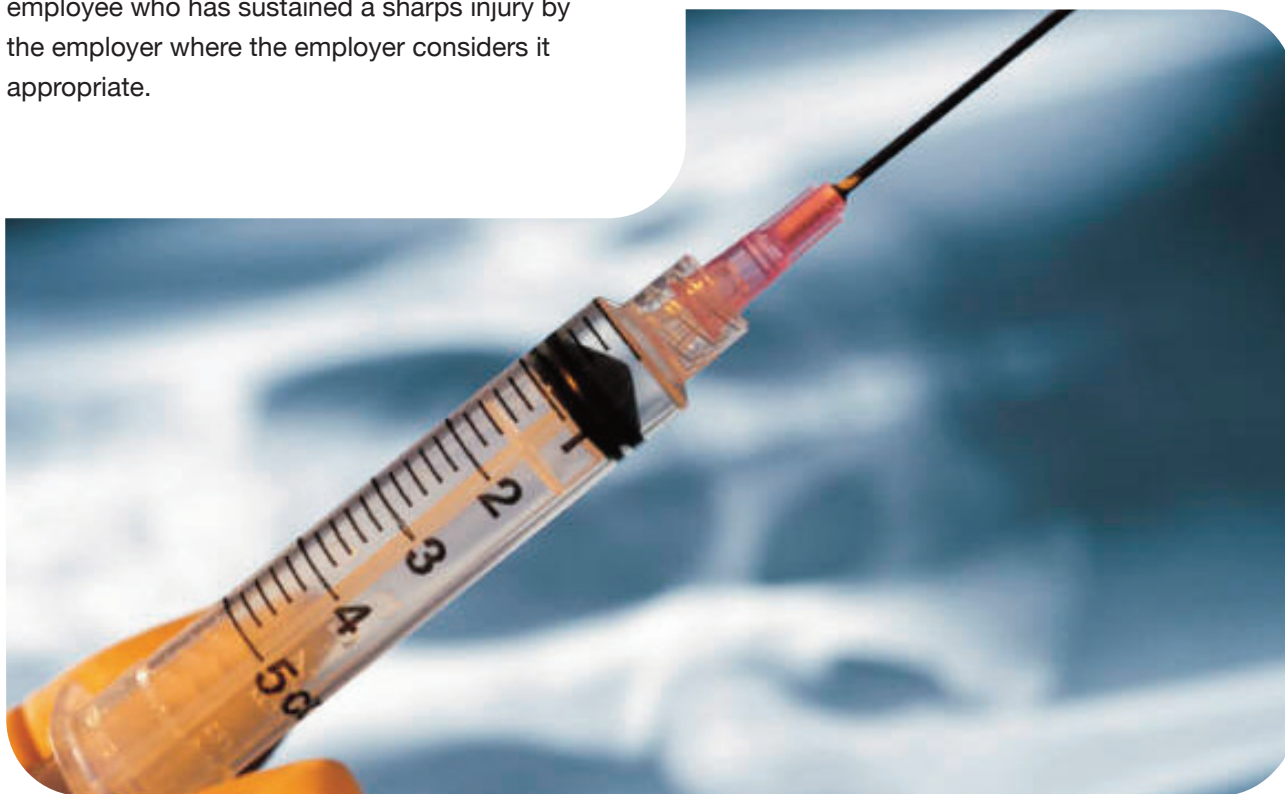
The Regulations require the employer to have in place policies and procedures to be followed in the event of sharps injury at work. They should include the immediate first aid response, the arrangements in place for the care of the injured employee and the reporting and investigation procedures. They must take account of confidentiality issues which may arise for the injured employee.

If staff members work out of hours and/or on premises where there are no appropriate treatment services available to them, the employer must ensure that they have sufficiently robust arrangements to allow employees to access treatment in a timely manner.

The employer must investigate the reported accident or incident and take any necessary remedial action to prevent recurrence. The purpose of the investigation should be to establish whether the employer's existing controls are adequate. It should look at underlying causes as well as the immediate factors that led to the incident.

Post-exposure prophylaxis, any medical tests considered necessary and any health surveillance that is deemed appropriate must be made available by the employer to the injured employee. Counselling must be made available to an employee who has sustained a sharps injury by the employer where the employer considers it appropriate.

The HSE/HPSC have produced Guidelines for the Emergency Management of Injuries (including needle-stick and sharps injuries etc.), these should be taken into account when determining appropriate response and follow-up when a sharps injury occurs in the workplace. These Guidelines cover first aid, assessment of the risk of transmission of infection, testing, treatment (including post-exposure prophylaxis for HBV and HIV), counselling and follow-up, records and documentation.



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