
This consultative document is issued by the Health and Safety Executive in compliance with its duty to consult under section 50(3) of the Health and Safety at Work etc Act 1974.

Comments should be sent to:

Martin Dilworth
Health and Safety Executive
5.S.S Redgrave Court
Merton Road
Bootle
L20 7HS

Tel: 0151 951 4335  Fax: 0151 951 4575

E-mail: sharpsconsultation@hse.gsi.gov.uk

to reach there no later than 8 November 2012

The Executive tries to make its consultation procedure as thorough and open as possible. Responses to this consultation document will be lodged in the Health and Safety Executive's Knowledge Centre after the close of the consultation period where they can be inspected by members of the public.

Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004 (EIR)). Statutory Codes of Practice under the FOIA and EIR also deal with confidentiality obligations, among other things.

If you would like us to treat any of the information you provide, including personal information, as confidential, please explain your reasons for this in your response. If we receive a request under FOIA or EIR for the information you have provided, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will be disregarded for these purposes. Requests for confidentiality should be made explicit within the body of the response.

HSE will process all personal data in accordance with the DPA. This means that personal data will not normally be disclosed to third parties and any such disclosures will only be made in accordance with the Act.
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>How to Respond</td>
<td>2</td>
</tr>
<tr>
<td>Code of Practice on Consultation</td>
<td>3</td>
</tr>
<tr>
<td>Summary</td>
<td>4</td>
</tr>
<tr>
<td>Background</td>
<td>5</td>
</tr>
<tr>
<td>European Directive on Sharp Injuries in Healthcare</td>
<td>5</td>
</tr>
<tr>
<td>What are sharps injuries and can they be prevented?</td>
<td>6</td>
</tr>
<tr>
<td>Why are new Regulations needed?</td>
<td>7</td>
</tr>
<tr>
<td>Guidance and awareness-raising activities</td>
<td>8</td>
</tr>
<tr>
<td>Which employers will be affected by the regulations?</td>
<td>8</td>
</tr>
<tr>
<td>What will healthcare employers and their contractors need to do</td>
<td>10</td>
</tr>
<tr>
<td>Risk control measures</td>
<td>11</td>
</tr>
<tr>
<td>Arrangements in the event of a sharps injury</td>
<td>12</td>
</tr>
<tr>
<td>Guidance on prevention of sharps injuries and infections</td>
<td>13</td>
</tr>
<tr>
<td>Implementation date</td>
<td>15</td>
</tr>
<tr>
<td>Statutory requirement for a review of the Regulations</td>
<td>15</td>
</tr>
<tr>
<td>What is the likely impact of the proposed new Regulations?</td>
<td>15</td>
</tr>
<tr>
<td>Annex A – Draft text of the Regulations – for consultation</td>
<td>19</td>
</tr>
<tr>
<td>Annex B – Impact Assessment</td>
<td>25</td>
</tr>
<tr>
<td>Annex C - List of the consultation questions</td>
<td>53</td>
</tr>
</tbody>
</table>
Consultation by the Health and Safety Executive

The Health and Safety Executive has a statutory duty to consult stakeholders to seek their views on its proposals. It believes that public consultation provides an open and transparent approach to decision-making. Following consultation, the Health and Safety Executive will make a recommendation to the Secretary of State on the best way forward.

How to Respond

A summary of the proposal and the questionnaire can be found at [http://www.hse.gov.uk/consult/condocs/cd244.htm](http://www.hse.gov.uk/consult/condocs/cd244.htm). You do not have to use this questionnaire, and you are welcome to comment on any issue raised by this document. You can:
- Complete the [online questionnaire](http://www.hse.gov.uk/consult/condocs/cd244.htm); or
- Respond by email – to sharpsconsultation@hse.gsi.gov.uk; or
- Respond on paper – you can do this either by:
  - Printing the online questionnaire; or
  - Making a written response in whatever format you wish.

Send your completed response to:

Martin Dilworth  
Health and Safety Executive  
5.S.2 Redgrave Court  
Merton Road  
Bootle  
Merseyside L20 7HS

We would be grateful if you could send an email address when you provide your response, so that we can inform you of when the HSE intends to publish information concerning consultation responses on the HSE website.

**Responses must be received by 8 November 2012.**

What happens next?

We will acknowledge all responses and give full consideration to the substance of arguments in the development of proposals. The Health and Safety Executive will then decide on how best to take the regulations forward based on an interpretation and analysis of the consultation responses. We may contact you again if, for example we have a query in respect of your response.

We will tell you when the HSE will publish information concerning the consultation responses. We will provide a summary of those who responded to this consultation and we will produce a summary of the views expressed to each question; this information will be placed on the HSE’s website.
Code of Practice on Consultation

We are committed to best practice in consultation and to the Government’s Code of Practice on consultation. The Code of Practice sets out seven criteria for consultation. These are:

- **When to consult** - Formal consultation should take place at a stage when there is scope to influence the policy outcome.
- **Duration** - Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.
- **Clarity of scope and impact** - Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.
- **Accessibility** - Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.
- **The burden of consultation** - Keeping the burden of the consultation to a minimum is essential if consultations are to be effective and if consultees’ buy-in to the process is to be obtained.
- **Responsiveness of consultation exercises** - Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.
- **Capacity to consult** - Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

Contacting HSE if you have a query or a complaint

If you do not believe that this document or the consultation on these proposals meet the criteria on consultations set out above, or if you are not satisfied with the way this consultation exercise has been conducted, please either write to:

Teresa Farnan (HSE Consultation coordinator)
Health and Safety Executive
7th Floor, Caxton House
Tothill Street
London
SW1H 9NA

Or send an email to teresa.farnan@hse.gsi.gov.uk

We aim to reply to all complaints within 10 working days. If you are not satisfied with the outcome, you can raise the matter with HSE’s chief executive, Geoffrey Podger, at Health and Safety Executive, Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS. You can also write and ask your MP to take up your case with us or with Ministers. Your MP may also ask the independent Parliamentary Commissioner for Administration (the Ombudsman) to review your complaint.
Summary

1) The Health and Safety Executive (HSE) is proposing new regulations, provisionally titled the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013, to implement the Council Directive 2010/32/EU on the prevention of sharps injuries in the hospital and healthcare sector. The guidance and awareness-raising activities that will accompany the new Regulations will also be important in drawing attention to the new legislation and ensuring that the risks in the workplace are reduced. HSE proposes to work with healthcare stakeholders to promote compliance with existing legislation and the new Regulations.

2) This Consultation Document seeks views on:
   - whether the proposed regulations enable healthcare businesses and workers to identify what they need to do
   - how the regulations should be supported by guidance and who is best placed to provide that guidance
   - the initial assessment of the costs and benefits of the proposed changes

3) The consultation questions are set out together on pages 53-55.

4) This consultation relates to Regulations that will apply in England, Scotland and Wales. Governments in Northern Ireland and Gibraltar will prepare proposals for implementing the Directive in their respective administrations.
**Background**

What are medical sharps?

‘Sharps’ is a word that HSE believes is commonly used by healthcare workers to refer to needles, blades (such as scalpels) and other medical instruments that could cause an injury by cutting or piercing the skin. The term was initially used in the context of waste disposal; where ‘sharps’ waste is collected and kept separately from other waste so that it can be disposed of appropriately.

In this legislation ‘sharps’ refer to medical instruments or other objects that are necessary for carrying out healthcare work and could cause an injury by cutting or pricking the skin.

**Question 1**

a) Is the use of the term ‘medical sharps’ in the regulations consistent with how it is commonly used by employers and workers in the healthcare sector?

b) If you think that this use is not consistent, please provide comments to support your answer.

**European Directive on Sharp Injuries in Healthcare**


6) The aim of the Directive is to contribute to a safe working environment for healthcare workers by introducing measures to protect them from injuries caused by sharp medical instruments. Injuries can include infection from serious blood-borne viruses, such as Hepatitis B and C and HIV. The Directive implements an Agreement between the European Hospital and Healthcare Employers’ Association (HOSPEEM) and the European Federation of Public Services Unions (EPSU). Further information on the Directive can be found on HSE’s [website](https://www.hse.gov.uk):

7) HOSPEEM and EPSU have set out in their Agreement a package of measures for:
a) assessing risks of sharps injuries,
b) selecting appropriate risk controls,
c) implementing those controls through provision of information and training and safe working procedures,
d) arrangements for accident reporting
e) investigation of the circumstances and causes of sharps injuries, and
f) provision for follow up of sharps injuries.

8) HOSPEEM and EPSU produced a Joint Clarification (6179/10, February 2010) in response to questions raised by Member States about the Agreement. The Joint Clarification sets out the intentions behind the requirements of the Directive and has been taken into account in drawing up the proposed regulations.

What are sharps injuries and can they be prevented?

9) Injuries to healthcare workers from needles and other sharp medical instruments are a well known risk. The most significant consequences of such an injury arise from the potential for exposure to blood borne viruses (e.g. hepatitis C). This can occur where the injury involves a sharp that is contaminated with blood or a bodily fluid from a patient. While there are very few UK healthcare workers known to have contracted an infection in this way, such diseases can be very serious. The anxiety and effects of the injury and its potential consequences, including the taking of a post-exposure prophylaxis\(^1\), can have a significant personal impact on an injured worker. There is no reliable source of data on the number of sharps injuries to healthcare workers. Studies estimate that annually there may be as many as 100,000 injuries in the UK, and a 2010 Care Quality Commission survey of NHS staff found that 2% reported that they had suffered a needlestick injury in the previous 12 month period\(^2\).

10) In recent years, alternative medical equipment has become available that does not use a needle, or that incorporates a protection mechanism. These include needles that are fitted with a device that is activated after use to cover the needle. However, a safer version is not necessarily available for all sharp instruments. Studies have shown that where healthcare employers have considered the use of ‘safer sharps’ and selected one appropriate to the work being done, they can reduce the risk of injury. Where staff are trained to use the safer sharps that impact will be more effective and longer lasting. See HSE’s research report *An evaluation of the efficacy of safer sharps devices: Systematic review* RR914 (HSE, 2012)

11) However, the Directive is not just about the introduction of safer sharps. Some healthcare employers have already looked at the use of sharps by

---

\(^1\) Post-exposure prophylaxis assists the person’s immune system to fight the virus. They are usually very strong antibiotics taken for months after potential exposure to the virus and can have unpleasant side-effects.

\(^2\) The survey of NHS staff reported work-related illnesses: 29% work-related stress, 10% manual handling, 3% slips, trips and falls, 2% needlesticks and 1% exposure to a dangerous substance.
their staff and identified procedures that did not require the use of a sharp at all, or where staff were using a system of work which is known to be high risk. In these cases they have successfully reduced the risk of injury by changing to safer practices.

**Why are new Regulations needed?**

12) The Directive must be implemented in all Member States by 11th May 2013. HSE has developed these proposals for implementing the Directive, taking into account the Government’s **Guiding Principles** for EU legislation. These principles are aimed at ensuring that, in implementing EU obligations, burdens on business are minimised and UK businesses are not put at a disadvantage relative to their European competitors. The Principles state that, when transposing EU law, the Government will:

   a) wherever possible, seek to implement EU policy and legal obligations through the use of alternatives to regulation;
   
   b) endeavour to ensure that UK businesses are not put at a competitive disadvantage compared with their European counterparts;
   
   c) always use copy-out for transposition where it is available, except where doing so would adversely affect UK interests e.g. by putting UK businesses at a competitive disadvantage compared with their European counterparts. If departments do not use copy-out, they will need to explain to the Reducing Regulation Committee (RRC) the reasons for their choice;
   
   d) ensure the necessary implementing measures come into force on (rather than before) the transposition deadline specified in a Directive, unless there are compelling reasons for earlier implementation; and
   
   e) include a statutory duty for ministerial review every five years

13) Many of the requirements contained in the Directive already form part of health and safety law in Great Britain. HSE is proposing that the new regulations should only contain those requirements that are not specifically addressed in existing domestic legislation – a draft of the proposed regulations is at **Annex A**. The Directive cannot be effectively implemented by non-legislative means.

14) These regulations will complement more general duties under the Health and Safety at Work Act 1974, the Management of Health and Safety at Work Regulations 1999 and the Control of Substances Hazardous to Health Regulations 2002. They apply to the risks in the healthcare sector posed by medical sharps and implement specific control measures identified in the Directive, both to protect workers at risk and to respond appropriately in the event that an accident occurs. Fuller details of the regulations and how they interact with the existing legislation are set out below.

15) An initial Impact Assessment of the options considered in preparing this proposal has been prepared and included in **Annex B**. The Impact
Assessment has been considered by the Regulatory Policy Committee, an independent body responsible for scrutinising the quality of analysis and evidence of impact assessments. They have given their opinion that this assessment is fit for purpose, but that the final stage Impact Assessment will provide robust estimates of the additional impacts of meeting the Directive’s requirements. The final version of the assessment will reflect revisions to the proposal and take into account the further evidence that will be provided by the consultation process.

Guidance and awareness-raising activities

16) The new regulations will be accompanied by revisions to HSE’s existing guidance on managing the risks from use of sharps and exposure to blood-borne viruses. HSE will provide guidance to help employers to understand what is required by the legislation. However, other authorities also provide guidance that is relevant to the effective control of risks in the healthcare sector and so this consultation asks questions regarding who is best placed to provide guidance and assist HSE in raising awareness of the requirements.

Which employers will be affected by the regulations?

The Regulations apply to:

Employers whose main activity is the managing, organising and provision of healthcare (referred to in this document as ‘healthcare employers’)

and

Employers who provide services to a healthcare employer and whose employees (or other staff who work under their direction and supervision) are exposed to a risk of injury from medical sharps while at work on the healthcare employer’s premises.

(see Regulation 3)

17) The proposed regulations will only apply to employers, contractors and workers in the healthcare sector. NHS Trusts/Boards, independent healthcare businesses and other employers whose main activity is the managing, organising and provision of healthcare will be subject to the regulations.

18) Employers who are not healthcare employers, but who are contracted to work on the premises of a healthcare employer, and whose work activities put their own workers at risk of injury from medical sharps, will also be subject to the same duties. However, a contractor’s duties will only apply to the extent of its control of work involving medical sharps. Such contractors could include those providing laundry, cleaning or waste disposal services.
19) The two categories of employers, described in paragraphs 17 and 18 above, will be required to take specific measures to protect not only those that they employ but also others who work under their supervision and direction. This will, for example, include students who work in a hospital or healthcare premises during a clinical placement, a student assistantship, an elective or an internship (even if they do not otherwise qualify as ‘an employee’).

20) Employers who 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 required by the Management of Health and Safety at Work Regulations 1999 or the Control of Substances Hazardous to Health Regulations 2002. The term ‘medical sharps’ does not include kitchen knives or utility knives as these are not used to carry out specific healthcare activities.

21) Employers whose main activity is not the provision of healthcare but whose staff may nevertheless work with medical 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, as set out in paragraph 18). Therefore, organisations such as independent schools or 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 duties.

22) 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 proposed regulations. For example, if a healthcare provider supplies an occupational health nurse to attend a company’s premises to administer vaccinations for the company’s employees, the healthcare provider will be subject to the new regulations, but the company will not. The company will, however, remain subject to existing health and safety duties. A patient, a person with a disability, a family member, a guardian or an attorney who commissions healthcare services will not be subject to these regulations.
Question 2

a) In addition to the examples provided above (paras 17-22), are there other common circumstances under which people carry out healthcare activities using medical sharps where the application of the proposed regulations could usefully be clarified in guidance?

b) If you think that there are, please provide details to support your answer.

What will healthcare employers and their contractors need to do differently under the Regulations?

23) Existing health and safety legislation requires employers to protect workers from the risks of injury from medical sharps and exposure to biological agents:
   - The Health and Safety at Work etc. Act 1974
   - Control of Substances Hazardous to Health Regulations 2002,
   - Management of Health and Safety at Work Regulations 1999
   - Personal Protective Equipment at Work Regulations 1992
   - Provision and Use of Work Equipment Regulations 1998
These require employers to ensure the safety of employees and others affected by work activities so far as is reasonably practicable. This includes an effective health and safety management system, for example carrying out of risk assessments, implementing control measures and safe systems of work, providing suitable work equipment and personal protective equipment (PPE) and providing training and information to employees. Existing duties include ensuring the safe disposal of waste contaminated by blood or other hazardous substances, and arranging health surveillance and vaccinations where appropriate.

24) The proposed regulations build on these existing requirements. In summary, the regulations:
   - identify a small number of specific risk control measures that must be taken,
   - provide detail on what must be included in the information and training provided to workers;
   - require employers to work with safety representatives in providing information to workers; and
   - set out action to be taken by the employer following an injury caused by a medical sharp, which includes investigating the incident and ensuring in appropriate cases that treatment including post-exposure prophylaxis is made available to the injured person.

25) The regulations will also require injured workers to:
   - report the injury to their employer
- provide their employer with information about the circumstances of the accident.

26) Employers already take many of these measures as they are contained in existing well-established practices, procedures and guidance. The measures required are set out fuller below.

Risk control measures

27) Employers are already required under the Management of Health and Safety at Work Regulations 1999 and Control of Substances Hazardous to Health Regulations 2002 to assess the relevant risks that arise from the exposure at work to sharps. The assessment required under Regulation 3 of the 1999 Regulations requires employers to identify the measures that they need to take under relevant health and safety legislation, which from 11 May 2013 will include the new regulations. Most healthcare employers will, therefore, need to review their existing assessment, to identify what, if any, additional measures they need to take.

28) The new regulations follow the principles of a hierarchy of preventative control measures which appears in existing health and safety legislation. An employer should, in the first instance and where it is reasonably practicable, take steps to avoid the use of medical sharps, for example by introducing blunt suture needles (where clinically appropriate) or needle-free IV equipment. See Regulation 4(1)(a).

29) Where it is not reasonably practicable to avoid the use of medical sharps, the proposed regulations will require employers to do the following:

a) **Use of sharps incorporating protection mechanisms.** The employer should substitute the traditional, unprotected medical sharp with a ‘safer sharp’ where reasonably practicable. In the regulations, the term ‘safer sharp’ means medical sharps that incorporate features or mechanisms to prevent or minimise the risk of accidental injury. See Regulation 4(1)(b).

b) **Prevent the recapping of needles.** 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). The risk of injury can be effectively controlled by:
   - not requiring that needles are recapped (and ensuring they are disposed of safely, see below),
   - the use of devices which are designed to allow recapping in a safe manner, for example needle-blocks, which hold the needle cap and so allow safe one-handed recapping.
See Regulation 4(1)(c).

c) **Place secure containers and instructions for safe disposal of medical sharps close to the work area.** Evidence shows that sharps injuries often occur when the used medical sharp is being transported or when disposed of incorrectly. Sharps injuries to ancillary and
support staff nearly all involve disposable medical sharps that have not been placed in an appropriate sharps container or have been placed in an overfull container. The new regulations will supplement the requirement in regulation 7(6)(c) of COSHH to dispose of contaminated waste safely by requiring that clearly marked and secure containers are 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. See Regulation 4(1)(d).

d) **Review procedures regularly.** Employers will be required to review at suitable intervals the procedures that are in place to implement the above risk control measures. Review of procedures to ensure their continuing effectiveness is a normal part of an effective health and safety management system. See Regulation 4(2).

e) **Provide information and training to staff.** Providing health and safety information and training is an existing legal requirement for employers. The new regulations will build on that requirement by ensuring that the information and training they provide includes those matters listed in the Schedules, to the extent that they are relevant to the employee’s work. The information must cover:
- the risks from medical sharps,
- relevant legal duties on employers and workers,
- good practice in preventing injury,
- support available to an injured person and
- the benefits and drawbacks of vaccination.

Employee training 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 also f and g below).

The employer must work with safety representatives in developing and promoting the information to be given to workers. This provision recognises the role of union and other safety representatives in helping to raise awareness of the risks from medical sharps. The requirement to work with safety representatives will not apply where such representatives have not been appointed in a workplace.

See Regulation 5.

**Arrangements in the event of a sharps injury**

f) **Reporting of sharps injuries and investigation of the circumstances and causes.** An employee, or other person, who works for an employer to whom the new Regulations apply, who receives a sharps injury at work must, as soon as practicable, report it to their employer. As set out above, an employee’s training must include what to do in the event of an injury. The injured person’s priority is likely to be that they treat their wound and seek any further immediate assistance. The training the employer provides to staff
should be clear about the requirements for reporting, such as arrangements for out of office hours and/or staff working in another employer’s premises. See Regulation 6.

Employers must make a record of the reported injury, 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. See Regulation 7(1).

**g) Follow-up of a sharp injury** – The regulations will require the employer to ensure that an injured worker has been offered post-exposure prophylaxis and any other medical treatment, as advised by a doctor. Employers must also consider whether counselling of the injured worker would be appropriate. If staff work out-of-hours and/or on premises where there is not an occupational health service available to them, the training the employer provides to staff should be clear as to where they should go for treatment. See Regulation 7(2).

**Question 3**

a) Is it clear what actions employers and employees will need to take under the proposed regulations (see paragraphs 27 - 29)?

b) Please provide comments to support your answer.

**Guidance on prevention of sharps injuries and infections**

30) HSE’s current guidance on this topic is:

- *Prevention of Blood Borne Viruses* (INDG342),
- Health and Social Care Sharps webpages and
- new Advisory Committee on Dangerous Pathogens’ Blood Borne Viruses webpages (prepared by ACDP and hosted on the HSE website).

These provide guidance on appropriate precautions, including signposts to the relevant NHS and other guidelines. In practice, most NHS healthcare sector managers/workers seek guidance, or work to standards on control of sharps risks, issued by other bodies than HSE. In any case, the issue of sharps injuries to staff needs to be dealt with in accordance with the appropriate standards for wider infection control and safe use and disposal of medical instruments in general.

31) HSE has identified a number of non-HSE codes of practice, standards or guidance that apply to matters relevant to the Directive. National-level guidance includes, but is not limited to the following:

**Employers guidance aimed at prevention and treatment of needlestick or sharps injuries**

- NHS Employers guidance (known as ‘the blue book’) *Needlestick Injury*
- **NHS Staff Council** *Occupational Health and Safety Standards* (p88-90)

**Healthcare Acquired/Clinical infection standards**

- **Department of Health** *The Health and Social Care Act 2008: Code of practice for the NHS on the prevention and control of healthcare associated infections and related guidance* (Dec 2010) – criterion 10 is that staff are protected against infection (p36-37).

- **National Institute for Health and Clinical Excellence** (March 2012)
  
  CG139 *Infection: prevention and control of healthcare associated infections in primary and community care* (section 1.1.4 – Safe use and disposal of sharps, p17-18)

- **Welsh Healthcare Associated Infection Programme** *Infection Prevention Model Policy/Procedure 4: Occupational Exposure Management, including needlestick (or “sharps”) injuries, Policy and Procedure* (October 2009)

**Occupational health guidance and other guidance relating to the testing, treatment or management of staff (or patients) who may be infectious**

- **Immunisation against infectious disease** (known as ‘the green book’) (2006), Department of Health,

- **Department of Health** *Health clearance for tuberculosis, hepatitis B, hepatitis C and HIV: New healthcare workers* (March 2007)


- **HIV Post-Exposure Prophylaxis**: Guidance from the UK Chief Medical Officers’ Expert Advisory Group on AIDS (October 2008), Department of Health.

- **HPA – PHLS** Advisory Committee on Blood Borne Viruses (Feb 1999) *Guidance on the investigation and management of occupational exposure to hepatitis C*

32) HSE proposes to publish a brief guide to the new regulations which will set out the changes required and be available for one year from publication. HSE will also ensure that its existing guidance listed at paragraph 30 is updated to reflect the requirements of the new regulations. HSE is already working with some of the organisations that produce the relevant non-HSE guidance to ensure that such guidance will reflect what the new regulations will require. NHS Employers have already revised their ‘blue book’ guidance. New guidance is also being prepared by a group of stakeholders working under the umbrella of the Partnership for Occupational Safety and Health in Healthcare (POSHH) and by the Scottish Government Health Workforce Directorate.
**Question 4**

a) Do you agree that HSE’s guidance on the new regulations should be built into its existing relevant guidance?

b) In addition to the organisations that produced the guidance listed at paragraph 31 and 32 are there other organisations that HSE should seek to work with to ensure that relevant non-HSE guidance aligns with the requirements of the new regulations.

**Implementation date**

33) The latest date of implementation specified in the Directive is the 11 May 2013 and this is the proposed date for commencement of the new regulations. We will aim to publish HSE’s guidance twelve weeks prior to this on 15th February. This provides plenty of time to raise awareness of the proposed changes amongst those employers who are currently not well-informed of the proposals. See Regulation 1.

**Question 5 – Does the proposed implementation date have any unintended consequences for the UK healthcare sector?**

**Statutory requirement for a review of the Regulations**

34) The proposal is to include a requirement on the Secretary of State to review the impact of the regulations every five years. The focus of the review will be to identify areas where implementation and enforcement could be improved to reduce burdens or increase effectiveness. A report will be published. See Regulation 8.

**What is the likely impact of the proposed new Regulations?**

35) HSE uses an Impact Assessment to assess and understand both the costs and benefits of all new regulations. An important part of the impact assessment is the cost-benefit analysis which identifies the costs and benefits of a proposal and quantifies, in monetary terms, as many of them as is feasible. The initial impact assessment for the proposed regulations is attached in Annex B to this Consultation Document.

36) HSE has obtained the following figures on the numbers of employers in the healthcare sector and how these breakdown within the sector. We are confident that the majority of employees work for employers who are within the NHS. However, in the dentistry and care home sub-sectors we believe independent employers are probably more numerous. We know very little about the number of civil society (including charity) employers.

**Table 1:** Number of employers in the healthcare sector, broken down by type and whether provided by public, private or civil society.
<table>
<thead>
<tr>
<th>Service</th>
<th>Public</th>
<th>Independent</th>
<th>Civil society</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospitals (ES&amp;W)</strong></td>
<td>337</td>
<td>192</td>
<td>Not known</td>
</tr>
<tr>
<td><strong>GPs (ES&amp;W)</strong></td>
<td>9754</td>
<td>Not known</td>
<td>Not known</td>
</tr>
<tr>
<td><strong>Dental Surgeries (E&amp;S)</strong></td>
<td>11,531</td>
<td>– probably mostly independent</td>
<td></td>
</tr>
<tr>
<td><strong>Ambulance Services (E&amp;S)</strong></td>
<td>13</td>
<td>Not known</td>
<td>Some – eg air ambulance</td>
</tr>
<tr>
<td><strong>Care Homes and Hospices (E&amp;S)</strong></td>
<td>6355</td>
<td>– probably mostly independent</td>
<td></td>
</tr>
</tbody>
</table>

ES&W = England, Scotland and Wales
E&S = England and Scotland (figures not available for Wales)

37) The impact assessment considers the costs of implementing the regulations. The regulations primarily clarify existing general health and safety duties. We therefore anticipate that the main costs associated with the regulations will be the time taken to review risk assessments, the introduction of safer sharps and familiarisation costs. Due to the type of evidence available, we were unable to quantify all of these costs, but we were able to rank them relative to one another.

38) HSE is seeking information to help improve the cost/benefit analysis in the impact assessment. For the purposes of the questions below, please consider ‘cost’ in terms of the time it will take to comply with the requirement and / or the financial cost to comply with each requirement.
Question 6
To assist us with the impact assessment please answer the following:

a) Numbers of employers in the healthcare sector
   IA 1. Please provide any information you have which will help us to fill in the gaps in Table 1; with appropriate references to the source of the information.

b) Review of Risk Assessments
   IA 2. Do you agree or disagree with the following assumptions made by HSE in the impact assessment:
   - All risk assessments relevant to sharps injuries will have to reviewed
   - It will take each hospital and ambulance trust between 2 and 3 hours to review the relevant risk assessments.
   - It will take GPs, dental practices and care homes between 0.5 hours and 1 hour to review the relevant risk assessments.
   IA 3. Please provide comments to support your answers to IA2.
   IA 4. Can you estimate how many risk assessments your organisation may need to amend as a result of the proposed regulations?
   IA 5. How long will it take your organisation to make amendments to a risk assessment?

c) Safer Sharps
   IA 6. Does your organisation use any ‘safer sharps’ in its activities now?
   IA 7. Will your organisation use an increased number of ‘safer sharps’ as a result of the proposed regulations?
   IA 8. If you can, please provide an estimate of the % increase in the use of safer sharps by your organisation as a result of the proposed regulations, where 100% is that all possible traditional devices have been replaced by safer sharps?

Continues over page
Question 6 – continued

d) Familiarisation

IA 9. Do you agree or disagree with the following assumptions made by HSE in the impact assessment about familiarisation costs, (in other words the time it will take to read and understand the new regulations).

a) For each hospital and ambulance service between 5 and 10 people will have to spend time familiarising themselves with the proposed regulations.

b) For each GP practice, Dental surgery and care home one person will spend time familiarising themselves with the proposed regulations.

c) Each person will spend between 1 and 3 hours reading and understanding the proposed regulations.

e) Other impacts

IA 10. Please provide information about the cost impacts arising from other requirements in the regulations, specifically in relation to the following areas:

a) Placing of secure containers and instructions for safe disposal of medical sharps close to the work area

b) Not recapping needles where there is a risk of injury

c) Procedures to be reviewed regularly

d) Information and training

e) Reporting of sharps injuries by workers and investigation of the circumstances and causes by employers

f) Follow up of a sharps injury

If your information is:
- Published cost data, please provide the appropriate reference
- A summary of cost data already collated by your organisation – please provide a summary of what it covers and contact details for obtaining a copy

Benefits

IA 11. If you are able to identify any anticipated benefits to you (eg reduced costs of injuries) from implementation of the changes required by the proposed Regulations, please provide a description?
Annex A – Draft text of the Regulations – for consultation

2013 No.

HEALTH AND SAFETY

THE HEALTH AND SAFETY (SHARP INSTRUMENTS IN HEALTHCARE) REGULATIONS 2013

Made - - - - ***
Laid before Parliament ***
Coming into force - - 11th May 2013

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 15(1) and (2) and 82(3)(a) of, and paragraphs 1(1), 8(1), 14, 15(1), 16 and 20 of Schedule 3 to, the Health and Safety at Work etc. Act 1974(1) (“the 1974 Act”).

The Regulations give effect without modifications to proposals submitted to the Secretary of State by the Health and Safety Executive under section 11(3) of the 1974 Act.

Before submitting those proposals to the Secretary of State, the Health and Safety Executive consulted the bodies that appeared to it to be appropriate as required by section 50(3) of the 1974 Act.

Citation and commencement

1. These Regulations may be cited as the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 and come into force on 11th May 2013.

Interpretation

2. In these Regulations—
   “injury” includes infection;
   “medical sharp” means an object or instrument which is used for carrying out activities specific to healthcare and which is able to cause injury by means of cutting or piercing the skin;

(1) 1974 c.37; sections 11(1) and 50(3) were amended by the Legislative Reform (Health and Safety Executive) Order 2008 (S.I. 2008/960), articles 3 and 5 and articles 3 and 16(4) respectively; sections 15(1) and 50(3) were amended by the Employment Protection Act 1975 (c.71), section 15, Schedule 15, paragraphs 6 and 16(3) respectively; section 50(3) was further amended by the Health Protection Agency Act 2004, section 11(1), Schedule 3, paragraph 5(1) and (3).
“safer sharp” means a medical sharp that is designed and constructed to incorporate a feature or mechanism which prevents or minimises the risk of accidental injury from cutting or piercing the skin.

Application of duties

3.—(1) The requirements imposed by these Regulations on an employer apply to—
(a) an employer whose main activity is the managing, organising and provision of healthcare (“A”); and
(b) subject to paragraph (2), an employer—
(i) who provides services under contract to A; and
(ii) whose employees, or other persons who work under the employer’s supervision and direction, are exposed to a risk of injury from medical sharps while at work on A’s premises,
in relation to that work.
(2) The requirements imposed by these Regulations on an employer referred to in sub-paragraph (b) of paragraph (1) apply only to the extent of that employer’s control of—
(a) the activities which are liable to expose that employer’s employees, or other persons who work under that employer’s supervision and direction, to a risk of injury from medical sharps while at work;
(b) a person who uses or supervises or manages the use of medical sharps; or
(c) the way in which medical sharps are used,
on A’s premises.
(3) Where a duty is placed by these Regulations on an employer in respect of employees of that employer, the employer is, so far as is reasonably practicable, under a like duty in respect of any other person who is not an employee of that employer but who works under the supervision and direction of that employer.

Use and disposal of medical sharps

4.—(1) An employer must ensure that—
(a) use of medical sharps at work is avoided so far as is reasonably practicable;
(b) when medical sharps are used at work, safer sharps are used so far as is reasonably practicable;
(c) 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; and
(d) in relation to the safe disposal of medical sharps that are not designed for re-use—
(i) written instructions for employees; and
(ii) clearly marked and secure containers,
are located close to areas where medical sharps are used at work.
(2) An employer must review at suitable intervals the policies and procedures in place to meet the requirements of paragraph (1) so as to ensure that those policies and procedures remain up to date and effective.

Information and training

5.—(1) An employer must provide all employees of that employer who are exposed to a risk of injury at work from medical sharps with information on the matters specified in Schedule 1.
(2) In meeting the requirement under paragraph (1), the employer must cooperate with worker representatives in that employer’s undertaking in developing and promoting the information specified in Schedule 1.

(3) In paragraph (2), “worker representatives” means any—
   (a) safety representatives within the meaning of the Safety Representatives and Safety Committees Regulations 1977(4); or
   (b) representatives of employee safety within the meaning of the Health and Safety (Consultation with Employees) Regulations 1996(5).

(4) An employer must provide all employees of that employer who are exposed to a risk of injury at work from medical sharps with training on the matters specified in Schedule 2 to the extent that those matters are relevant to the type of work carried out by the employees.

Reporting of injuries

6.—(1) An employee of an employer referred to in regulation 3(1)(a) or other person who is working under such an employer’s supervision and direction (the employee or other person being referred to in this paragraph as “B”) must—
   (a) report as soon as practicable to that employer, or to any other employee of that employer with specific responsibility for the health and safety of persons at work, any incident at work in which B has suffered an injury from a medical sharp; and
   (b) provide when requested by that employer sufficient information as to the circumstances of the incident to enable the employer to comply with regulation 7.

(2) An employee of an employer referred to in regulation 3(1)(b) or other person who is working under such an employer’s supervision and direction (the employee or other person being referred to in this paragraph as “C”) must—
   (a) report as soon as practicable to that employer, or to any other employee of that employer with specific responsibility for the health and safety of persons at work, any incident at work in which C has suffered an injury from a medical sharp on the premises of an employer referred to in regulation 3(1)(a); and
   (b) provide when requested by that employer sufficient information as to the circumstances of the incident to enable the employer to comply with regulation 7.

Arrangements in the event of injury

7.—(1) Where an employer is notified of an incident at work pursuant to regulation 6, the employer must—
   (a) record the incident;
   (b) investigate the circumstances and cause of the incident; and
   (c) take any necessary action to prevent a recurrence.

(2) Where an employee suffers an injury at work caused by a medical sharp that exposed, or may have exposed, the employee to a biological agent, the employer must—
   (a) ensure that any treatment advised by a registered medical practitioner, including post-exposure prophylaxis, is made available to the employee;
   (b) consider providing the employee with counselling.

(3) In this regulation—
   (a) “biological agent” means a micro-organism, cell culture or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health;

(4) S.I. 1977/500, amended by S.I. 1996/1513; there are other amending instruments but none is relevant.

(5) S.I. 1996/1513, to which there are amendments not relevant to these Regulations.
(b) “post-exposure prophylaxis” means a course of treatment of medicine administered to a
person after exposure, or suspected exposure, to a biological agent in order to prevent
infection or development of disease caused by that biological agent.

Review

8.—(1) The Secretary of State must from time to time—
(a) carry out a review of these Regulations;
(b) set out the conclusions of the review in a report; and
(c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to
prevention of sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and
EPSU(6) (which is implemented in part by means of these Regulations) is implemented in other
Member States.

(3) The report must in particular—
(a) set out the objectives intended to be achieved by these Regulations;
(b) assess the extent to which those objectives are achieved; and
(c) assess whether those objectives remain appropriate and, if so, the extent to which they
could be achieved with a system that imposes less regulation.

(4) The first report under this regulation must be published before the end of the period of five
years beginning with the day on which these Regulations come into force.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding five
years.

Signed by authority of the Secretary of State

Name
Minister of State
Date

Department for Work and Pensions

(6) OJ No L 134, 1.6.2010, p66.
SCHEDULE 1 Regulation 5(1) and (2)

INFORMATION TO BE PROVIDED TO EMPLOYEES

1. The risk of injury from medical sharps.

2. Legislative requirements relating to the protection of persons at work from the risks to health and safety from medical sharps, including duties on employers and employees.

3. Good practice in preventing injury from medical sharps.

4. The benefits and drawbacks of vaccination and non-vaccination in respect of blood-borne diseases.

5. The support provided by the employer to an employee who is injured at work by a medical sharp.
SCHEDULE 2

TRAINING TO BE PROVIDED TO EMPLOYEES

1. The safe use and disposal of medical sharps.
2. The correct use of safer sharps.
3. What employees should do if they are injured at work by a medical sharp.
### Annex B – Impact Assessment

**Title:**

**IA No:**

**Lead department or agency:**
Health and Safety Executive

**Other departments or agencies:**

**Impact Assessment (IA)**

**Date:** 5/4/2012

**Stage:** Consultation

**Source of intervention:** EU

**Type of measure:** Secondary legislation

**Contact for enquiries:** Anna Bliss
HSE, Redgrave Court 5S.2, Merton Road
Bootle L20 7HS    Tel: 0151 951 3581
anna.bliss@hse.gsi.gov.uk

**Summary: Intervention and Options**

<table>
<thead>
<tr>
<th>Cost of Preferred (or more likely) Option</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Net Present Value</strong></td>
</tr>
<tr>
<td>£14.5m</td>
</tr>
</tbody>
</table>

**What is the problem under consideration? Why is government intervention necessary?**

Council Directive 2010/32/EU of 10 May 2010, implementing the Framework Agreement on Prevention from Sharp Injuries in the Hospital and Healthcare Sector between HOSPEEM and EPSU requires transposition by 11 May 2013. This Directive implements a social partner agreement, which was negotiated at EU level by the representatives of healthcare sector employers (HOSPEEM) and employees (EPSU). It is concerned with the control of risks to healthcare workers of injury and infection from needles, scalpels and other medical sharps (commonly referred to as ‘sharps’).

**What are the policy objectives and the intended effects?**

1. To ensure effective implementation of the Directive by introducing the measures in addition to existing general requirements that must be taken by employers in the healthcare sector.  
2. To minimise burdens on public, private and third sector employers and ensure that businesses in the UK are not placed at a competitive disadvantage relative to their EU counterparts. The intended effect is that healthcare workers are offered a good standard of protection and the number of sharps injuries fall.

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**

The UK’s domestic legal framework does not allow the social partners at Member State level to introduce their own, legally binding measures to implement this Directive. The Directive requires Member States to provide for effective, proportionate and dissuasive penalties in the event of any breach of the Directive, and non-legislative implementation in the UK would not meet this requirement. Therefore, although a ‘do nothing’ option is not a viable option, and so does not have its own analysis, it is the notional baseline against which to compare the three options for implementation.

- **Option 1** - Implement by amending existing health and safety Regulations to add in the substantive clauses of the Directive
- **Option 2** - Implement using a new set of health and safety Regulations to transpose the substantive clauses of the Agreement following the wording of the Directive where possible - PREFERRED OPTION
- **Option 3** - Implement using a new set of health and safety Regulations that entirely copies out the wording of the Directive.

**Will the policy be reviewed?** It will be reviewed. **If applicable, set review date:** 04/2018

**Does implementation go beyond minimum EU requirements?** NO
Impact assessment

<table>
<thead>
<tr>
<th>Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.</th>
<th>Micro Yes</th>
<th>&lt; 20 Yes</th>
<th>Small Yes</th>
<th>Medium Yes</th>
<th>Large Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

What is the CO₂ equivalent change in greenhouse gas emissions? (Million tonnes CO₂ equivalent)

Traded: NA

Non-traded: NA

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:  

Date: ____________________________
Summary: Analysis & Evidence Policy Option 1

Description: Implement by amending existing health and safety regulations to add in the substantive clauses of the directive.

FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year 2012</th>
<th>PV Base Year</th>
<th>Time Period Years</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2012</td>
<td>10</td>
<td>Low: Not quantified</td>
</tr>
</tbody>
</table>

**COSTS (£m)**

<table>
<thead>
<tr>
<th></th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Cost (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>High</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>Not quantified</td>
<td>Not quantified</td>
<td>Not quantified</td>
</tr>
</tbody>
</table>

Description and scale of key monetised costs by ‘main affected groups’

It has not been possible to quantify the costs of option 1, but it is possible to say that the total costs of option 1 will be greater than option 2 or option 3 (see below).

**Other key non-monetised costs by ‘main affected groups’**

It is anticipated that the costs of option 1 will be predominantly the same as option 2, except for familiarisation costs. Option 1 would not make it clear to duty holders that the Directive only applies to the healthcare sector, and so it is expected that a proportion of duty holders and employees who may use sharps in their business activities, but who are not in the healthcare sector, may spend time familiarising themselves with the Directive. One-off familiarisation costs for part of the healthcare sector have been estimated to have a present value in option 2 between £8.7m and £18.7m. It is not possible to quantify how many more duty holders will spend time on familiarisation under option 1, as HSE is not clear which sectors in addition to the healthcare sector might be concerned with the changes. There is also a possibility that if more duty holders familiarise themselves with the Directive then more duty holders may take action to comply with the Directive, increasing compliance costs compared to option 2. HSE intends to gather views during consultation on the different

**BENEFITS (£m)**

<table>
<thead>
<tr>
<th></th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Benefit (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>High</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>Not quantified</td>
<td>Not quantified</td>
<td>Not quantified</td>
</tr>
</tbody>
</table>

Description and scale of key monetised benefits by ‘main affected groups’

It has not been possible to monetise the benefits of the Sharps Directive

Other key non-monetised benefits by ‘main affected groups’

It is estimated that the implementation of the Directive will deliver benefits in terms of reducing the number of sharps injuries, including those where there is a high risk of a blood borne infection arising. However, due to the complex causality between the proposed changes to the regulations and the factors that lead to a sharps injury, it is not possible to quantify the reduction in injuries that might occur as a result. It is possible that the risk reduction benefits of option 1 may be slightly greater than those in option 2 because of the effect whereby it is anticipated that a greater number of duty holders may comply with the Directive. On balance the additional benefits of option 1 compared to option 2 are thought to be relatively insignificant.

Key assumptions/sensitivities/risks

3.5
There is currently insufficient evidence to quantify the baseline situation in the UK and therefore the likely impacts of many of the substantive clauses of the Directive. HSE is planning that the evidence base will be increased to allow further quantification through the public consultation and by targeted evidence gathering from the sector.

**BUSINESS ASSESSMENT (Option 1)**

<table>
<thead>
<tr>
<th>Direct impact on business (Equivalent Annual) £m:</th>
<th>In scope of</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs: Unquantified</td>
<td>NO</td>
<td>IN/OUT/Zero net cost</td>
</tr>
<tr>
<td>Benefits: Unquantified</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net: Unquantified</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Summary: Analysis & Evidence**

**Policy Option 2**

**Description:** Implement using a new set of health and safety Regulations to transpose the substantive clauses of the Agreement following the wording of the Directive where possible

### FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year 2012</th>
<th>PV Base Year 2012</th>
<th>Time Period Years</th>
<th>10</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
</thead>
</table>

#### COSTS (£m)

<table>
<thead>
<tr>
<th></th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition)</th>
<th>Total Cost (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>9.2</td>
<td>Optional</td>
<td>9.2</td>
</tr>
<tr>
<td>High</td>
<td>19.8</td>
<td>Optional</td>
<td>19.8</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>14.5</td>
<td>Not quantified</td>
<td>14.5</td>
</tr>
</tbody>
</table>

**Description and scale of key monetised costs by ‘main affected groups’** (NB total quantified costs are underestimates) The estimated monetised costs are those impacts which it has been possible to quantify with the limited information available pre consultation. The total one-off cost estimated includes the costs of familiarisation for healthcare employers and employees in the public sector and private hospitals. These are the employers for which data has been accessible. The total present value of the familiarisation costs is estimated to be between £8.7 million and £18.7 million. This is expected to be an underestimate of the total familiarisation costs because it does not include costs for private GPs, dentists or care home providers. The one-off cost estimate also includes the cost of all duty holders in the healthcare sector reviewing risk assessments to ascertain whether they already meet the new specific requirements on sharps risks introduced by the Directive. The one-off review cost to public sector healthcare duty holders and private hospitals is estimated to have a present value between £0.6 million and £1.1 million. Again, this is expected to be an underestimate of the total cost of reviewing risk assessments as it does not include any cost estimate for the private healthcare providers listed above. Due to the uncertainty in the number of private sector duty holders it has not been possible to quantify EAC to Business.

**Other key non-monetised costs by ‘main affected groups’** Due to a lack of quantified data on the current level of compliance with current best practice guidance and UK domestic legislation (the baseline), it has been difficult to quantify the effect the Directive will have above this baseline in a number of areas, including the update of risk assessments to be specific about the risk from sharps; elimination, prevention and protection mechanisms to reduce the risk of sharps (e.g. introducing safer sharps); information and awareness raising; training; reporting; and response and follow up procedures following injuries. These areas where impacts are anticipated are discussed in the evidence base below.

<table>
<thead>
<tr>
<th>BENEFITS (£m)</th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Benefit (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>High</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>Not quantified</td>
<td>Not quantified</td>
<td>Not quantified</td>
</tr>
</tbody>
</table>

**Description and scale of key monetised benefits by ‘main affected groups’**

It has not been possible to monetise the benefits of the Sharps Directive.
Other key non-monetised benefits by ‘main affected groups’
It is estimated that the implementation of the Directive will deliver benefits in terms of reducing the number of sharps injuries, including those where there is a high risk of a blood borne infection arising. However, due to the complex causality between the proposed changes to the regulations and the factors that lead to a sharps injury, it is not possible to quantify the reduction in injuries that might occur as a result.

Key assumptions/sensitivities/risks
There is currently insufficient evidence to quantify the baseline situation in the UK and therefore the likely impacts of many of the substantial clauses of the Directive. HSE is planning that the evidence base will be increased to allow further quantification through the public consultation and by targeted evidence gathering from the sector.

BUSINESS ASSESSMENT (Option 2)

<table>
<thead>
<tr>
<th>Direct impact on business (Equivalent Annual) £m:</th>
<th>In scope of</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs: Not</td>
<td>Net: Not</td>
<td>No</td>
</tr>
<tr>
<td>Benefits: Not</td>
<td></td>
<td>NA</td>
</tr>
</tbody>
</table>

Summary: Analysis & Evidence

**Policy Option 3**
**Description:** Implement using a new set of health and safety Regulations that entirely copies out the wording of the Directive.

FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year2012</th>
<th>PV Base Year2012</th>
<th>Time Period Years 10</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Low: Not quantified</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High:Not quantified</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Best Estimate: Not quantified</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COSTS (£m)</th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition)</th>
<th>Total Cost (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>High</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>Not quantified</td>
<td>Not quantified</td>
<td>Not quantified</td>
</tr>
</tbody>
</table>

**Description and scale of key monetised costs by ‘main affected groups’**
It has not been possible to quantify the costs of option 3, but it is assumed that the total costs of option 3 will be greater than option 2 but probably less than option 1.

Other key non-monetised costs by ‘main affected groups’
It is anticipated that the costs of option 3 will be predominantly the same as option 2, except for familiarisation costs. The Directive is written in such a manner that it can be confusing around compliance, and so the Directive is just copied out, it is expected that it will take duty holders in the healthcare sector longer to familiarise themselves and understand their requirements under the Directive. Familiarisation costs in option 2 are estimated for part of the healthcare sector at between £8.7m and £18.7m. It would be arbitrary to estimate how much longer this may take duty holders in the healthcare sector under option 3 without evidence to support it, but HSE believes that without the clarification as proposed in option 2, that this copy out option would make understanding the Directive more onerous for duty holders. Option 3 could also have the potential to lead to over compliance with the Directive due to the clauses of the Directive being confusing. This could further increase the costs of option 3 compared to option 1, but this effect is not possible to quantify ex ante. HSE believes that the additional costs above option 2 caused by option 3 would not be as great as the additional costs above option 2 caused by option 1, because the duty holders concerned with the changes should at least be limited to the healthcare sector, unlike in option 1 where this could be a much wider population of duty holders.

<table>
<thead>
<tr>
<th>BENEFITS (£m)</th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition)</th>
<th>Total Benefit (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
</tbody>
</table>
Impact assessment

<table>
<thead>
<tr>
<th>Impact Assessment</th>
<th>Optional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description and scale of key monetised benefits by ‘main affected groups’</td>
<td>Not quantified</td>
</tr>
</tbody>
</table>

It has not been possible to monetise the benefits of the Sharps Directive.

Other key non-monetised benefits by ‘main affected groups’

It is estimated that the implementation of the Directive will deliver benefits in terms of reducing the number of sharps injuries, including those where there is a high risk of a blood borne infection arising. However, due to the complex causality between the proposed changes to the regulations and the factors that lead to a sharps injury, it is not possible to quantify the reduction in injuries that might occur as a result. If the confusion caused by copy out leads to requirements of the Directive not being implemented appropriately, or in fact to over compliance, then this may reduce the risk reduction achieved compared to option 2 and option 1. However, it is not possible to quantify this effect in advance.

Key assumptions/sensitivities/risks

3.5

There is currently insufficient evidence to quantify the baseline situation in the UK and therefore the likely impacts of many of the substantial clauses of the Directive. HSE is planning that the evidence base will be increased to allow further quantification through the public consultation and by targeted evidence gathering from the sector.

BUSINESS ASSESSMENT (Option 3)

<table>
<thead>
<tr>
<th>Measure qualifies as</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs: Not quantified</td>
</tr>
</tbody>
</table>

Evidence Base

Problem under consideration

1. Injuries from needles and other sharp instruments (commonly referred to as needlestick injuries or sharps injuries) constitute a known risk in the healthcare sector. Sharps injuries to healthcare workers from instruments contaminated with a patient’s blood have the potential to transmit more than 20 infectious diseases; including blood borne viruses (BBV) that can have a serious impact on health. In addition to the health impact, the anxiety and side effects of post-exposure prophylaxis have a significant personal impact on healthcare workers, with an infection having the potential to limit their career in healthcare and possibly their life.

2. Although there is no one reliable source of data on the number of sharps injuries to healthcare workers, studies estimate that the annual incidence rate may be as high as 10,000 in the UK. Costs to healthcare sector employers include amongst other things, lost time (for post incident investigation, treatment etc) and costs of prophylaxis pharmaceuticals. An accurate assessment of the economic burden of sharps injuries is difficult to obtain because of widespread under-reporting and projected costs often do not account for long-term treatment costs resulting from infection, absenteeism, worker’s compensation or emotional repercussions.

3. The Directive, instituted as a self-produced initiative in the European Parliament, was adopted by means of social dialogue procedures, under which representatives of employers and employees may propose legislation (i.e. not the usual procedure for making legislation). The Framework Agreement, which the
Impact assessment

Directive implements by way of an Annex, was drafted by the European social partners in the healthcare sector (HOSPEEM\(^7\) and EPSU\(^8\)) without being negotiated by Member States in the usual way. For the UK, NHS Employers participated in the negotiations for employees and Unison represented UK employees, both of whom support the Directive. In February 2010, the social partners produced a joint clarification\(^2\) in response to questions from working parties about the Directive.

Rationale for intervention

4. The Directive was agreed by EU Council in May 2010 and the deadline for transposition is 11 May 2013. The EU rationale for the Directive is to achieve the safest possible working environment by preventing injuries to workers caused by all medical sharps (including needle-sticks) and protecting workers at risk in the hospital and healthcare sector\(^3\).

Policy objective

5. Sharps injuries constitute a known risk in the healthcare sector. The existing health and safety legislative requirements provide a good standard of protection for healthcare workers. This Directive introduces measures in addition to existing domestic legislation that must be taken by employers in the healthcare sector. The UK policy objectives are to ensure the effective implementation of the Directive, to minimise burdens on public and private sector employers and ensure that businesses in the UK are not placed at a competitive disadvantage relative to their EU counterparts.

Description of options considered

6. Three different options are considered to meet these objectives, being different ways of implementing the requirements of the Directive. The ‘do nothing’ option is not a valid option for the transposition of an EU Directive, and so has not been analysed further. However, the ‘do-nothing’ option is the notional baseline against which the costs and benefits of Options 1 – 3 are calculated.

- **Option 1**: Rely on existing regulatory provisions and amend existing regulations to add in the substantive clauses of the Directive.
- **Option 2**: Introduce a new set of health and safety Regulations to transpose the substantive clauses of the Agreement that go beyond existing UK legal requirements, following the wording of the Directive where possible. – PREFERRED OPTION
- **Option 3**: Introduce a new set of health and safety Regulations that entirely copies out the wording of the Directive.

7. **Option 1** relies on existing legislation to achieve the aims of the Directive to protect healthcare workers from exposure to blood borne viruses (BBV) and sharps injuries. Amendments would need to be made to accommodate those specific measures not already covered in existing domestic law. Incorporating its provisions within the existing regulatory regime (either by amending or revoking and starting afresh) would have a disproportionate impact across all business sectors because it would apply to all industries and not just the hospital and healthcare sector as proposed by the Social Partners. Rather than create a coherent regulatory regime, it is likely the result would be complex, unclear and burdensome on duty holders.

8. **Option 2** proposes to introduce a new set of health and safety regulations aimed at the healthcare sector alone. It represents a more proportionate approach and minimises unnecessary additional burdens by effectively removing non-

---

\(^7\) The European Hospital and Healthcare Employers’ Association.

\(^8\) The European Federation of Public Service Unions.
healthcare businesses from further obligations. The new set of regulations would transpose the substantive clauses of the Directive, referring to existing requirements where they exist and, in respect of the remaining provisions, follow the wording of the Directive where possible. Where further clarification is needed, the Social Partners Clarification document will be consulted and the wording of the Directive will be amended when drafting the regulations. This will reduce the burdens on duty holders when understanding their requirements in the Directive.

9. **Option 3** proposes to introduce a new set of health and safety regulations that would entirely copy out the full wording of the Directive. The option to entirely copy out is not recommended because it would create unnecessary burdens as it repeats requirements in existing legislation (potential double banking; a term used to describe the situation when EU legislation covers the same ground as existing domestic legislation) and the wording in areas is unclear. This may lead to the healthcare sector spending a disproportionate amount of time trying to understand the law and erring on the side of caution - doing more than is necessary or required at an additional cost.

Monetised and non-monetised costs and benefits of each option (including administrative burden)

10. The costs and benefits of the transposed Directive are considered below. The relevant costs and benefits are the *additional* requirements for the UK, compared to the baseline or notion al ‘do nothing’ option (i.e. what is the current practice in the UK), arising from the substantive clauses of the Directive.

11. At this pre-consultation stage, little evidence is available to allow full monetisation of the costs and benefits. In order to collect robust quantifiable evidence of monetised costs, it would have been necessary to undertake significant engagement with the healthcare sector (and other sectors as well), possibly including surveys, which would have put an additional burden on the sector. Given that the healthcare sector is already under considerable pressure of change and the Directive has already been agreed with employers at EU level, HSE did not feel this was a proportionate approach for the impact assessment. HSE therefore intend to use the formal public consultation to question the industry / duty holders in order to gather further evidence around impacts and by targeted evidence gathering from the sector.

12. The approach taken at this stage has been to rely largely on quantitative and qualitative evidence collected from informal consultation with selected representatives from the hospital and healthcare sector. The focus of the newly gathered evidence was to establish the baseline (i.e. what businesses are doing already to comply with existing legislation) and then to compare this relative to the substantive clauses of the Directive (i.e. what additional changes businesses will need to make to comply with the Directive.) The evidence is primarily concerned with the degree of change required in order to comply with the Directive. A bibliography of the quantitative and qualitative evidence used in this analysis can be found in **Annex 1**. Where assumptions are made, but are not cross-referenced to evidence, they are based on HSE’s best knowledge and experience of working with dutyholders and introducing and amending health and safety law.

**Number of employers affected**

13. We do not know exactly how many employers within the hospital and healthcare sector will be affected by the legislation. To construct an estimate we initially identified occupations whose workforce we already know are exposed to sharps and then sourced data from the Care Quality Commission (CQC), British Medical
Impact assessment

Association, NHS Information Centre, NHS National Services Scotland and from internet searches (see Annex 2). Each of these data sources have their own variables and limitations, such as geographical area covered, reporting criteria, voluntary membership and definitions used. For example, the data obtained from the CQC contains a large proportion of registered care homes and we cannot be certain whether these establishments carry out medical provision which includes the likely use of needles. To refine the search, only care homes “with nursing” were included in the data. By including all these numbers, we have probably over-estimated the number of employers in this area. Data on third sector organisations offering healthcare services was not available, but HSE suspects the numbers are small.

14. Following the clarification from the Social Partners, we have not included healthcare professionals employed by the prison service, schools or armed forces as they do not fall “under the managerial authority and supervision of a healthcare employer”.

15. Due to the nature of the data it is not possible to estimate the total number of employers in the healthcare sector, but it is possible to state that, for the purposes of the impact assessment, hospitals, GP practices, dental surgeries, ambulance trusts and care homes and hospices have been included as relevant employers. Numbers of employers in each of these areas have been obtained for the public sector (see Annex 2) but are not so readily available for the private sector and the third sector. Within each of these employers there could also be more than one duty holder who is required to implement elements of the Directive. This is discussed in more detail in the relevant sections below.

Number of employees / workers affected.

16. The Directive defines the scope of those covered by the agreement as being limited to all workers in the hospital and healthcare sector, and all who are under the managerial authority and supervision of the employers.

17. Based on the Annual Population Survey data, HSE has estimated that there are around 1.7 million workers / employees that would be covered by the Directive. This estimate is based on the assumption that the employees affected will be those within Standard Industrial Classification codes 86 and 87, which include nurses, medical practitioners, nursing auxiliaries and assistants, cleaners and domestics, dental nurses, dental practitioners, midwives, medical and dental technicians, healthcare practice managers, paramedics, hospital porters, residential and day care managers, elementary cleaning occupations, care assistants and home carers.

Overview of the Directive

18. The risks from sharps injuries to workers in the healthcare and non-healthcare sector are already addressed by existing legislation and evidence shows this is reasonably well complied with. Many of the requirements within the Directive make reference to this existing legislation, which cover the basics of risk assessment, elimination and control measures, provision of information and training and the reporting and follow-up of an injury or incident. These existing general provisions apply to all businesses and not just those in the healthcare sector, whereas the Directive is restricted to the hospital and healthcare sector.

19. From comparing the Directive to domestic legislation and existing working practices, there appear to be very few new duties being imposed on healthcare employers and workers. The main changes are primarily concerned with clarifying existing duties and improving compliance with those duties. We therefore anticipate that the main costs associated with implementing the
**Impact assessment**

**Directive will be familiarisation costs.** However, the size of the familiarisation cost incurred by the employer will vary depending on which option is chosen, i.e. how the Directive is transposed.

20. Due to the type of evidence available, we are unable to quantify all of these costs, but we are able to rank them relative to one another. The areas of the Directive which we think will involve an extra cost are risk assessment, elimination and control measures, information and awareness raising, training, reporting and response and follow-up. The impacts are discussed in more detail below and a set of tables have been produced (see Table 1, Table 2 and Table 3) to illustrate how the estimated costs and impact compare to one another.

**Costs**

21. Option 2 is the preferred option, and the costs and benefits of the Directive are discussed in detail below with reference to Option 2. The analysis for options 1 and 3 that follows indicates where the costs and/or benefits are expected to differ significantly to those estimated for Option 2.

**Option 2**

**Costs to duty holders**

22. Even though some legal requirements appear to be new under the Directive, they either already exist under current guidance or are established as good practice and are already being implemented by the majority of the healthcare sector. Some requirements that already exist under domestic legislation may require the same legal duty but involve a change to its content only, such as extending its scope or providing further clarification. In these instances, we assume the Directive will increase compliance in these areas. The knowledge of the baseline situation in the UK is based on a number of evidence sources; see the Bibliography in Annex 1.

23. Where it is expected that there will be additional costs linked to the Directive, these are discussed in more detail below, along with the information that would be required in order to quantify the cost. HSE is planning to use the consultation and targeted evidence gathering to find out more information about which healthcare employers already adopt best practice, and which might have to make changes as a result of the directive.

**Familiarisation costs**

24. HSE believes that the one-off familiarisation costs and recurring costs will be kept to a minimum with Option 2 compared to Options 1 and 3. This is because a new set of regulations clearly aimed at the healthcare sector will make it clear which businesses should be complying.

25. Familiarisation costs will fall to both duty holders and to the employees, with the duty holders spending time understanding the regulations and disseminating the information to the appropriate workers/employees, and the workers/employees spending time understanding what will change in their day to day job.

26. **Duty holders:** The costs will depend on how many duty holders need to read and understand the new regulations, and how long it will take them to do this. While HSE is able to provide a best estimate for the length of time involved for duty holders to familiarise themselves with the regulations, there is uncertainty about how many duty holders will fall under the healthcare umbrella.

27. Based on HSE knowledge of the sector, it is assumed that for hospitals and ambulance trusts, there could be between 5 and 10 duty holders who have to
spend time understanding the regulations and what it means for their organisation. For GPs, Dental surgeries and care homes, it is assumed that there is just one person designated to health and safety, and so only one person who is responsible for the main familiarisation with the new regulations and guidance.

28. Using the numbers of these different employers from Annex 2, it is calculated that in total there could be about 30,000 manager grade duty holders in the public sector who familiarise themselves with the changes. It is not known how many could be in the private sector in total, but it is estimated that there could be between 1000 and 2000 in hospitals alone.

29. Based on HSE’s best estimates and experience, it is assumed that it will take each duty holder between 1 and 3 hours to understand the new regulations and what is required of them, then applying the appropriate and adjusted hourly wage rates from ASHE 2011\(^9\), the total cost of the time spent in the public sector (and private hospitals) on familiarisation is estimated to be between £1.1 million and £3.6 million. This is the one off cost estimated for the public sector, and any future familiarisation costs are expected to be minimal as it is not expected there will be substantial numbers of new employers entering the public healthcare sector.

30. It is not possible to quantify the cost of familiarisation for duty holders in the private sector (other than hospitals) as HSE does not have robust estimates of the number of private employers in the dental sector, GPs, or care homes. It is likely that the above estimate for the public sector already includes an element of the private sector, as some dental practitioners registered with the NHS might also undertake private work and care homes may take public and private patients. So as a minimum, undiscounted familiarisation costs for duty holders could be between £1.1 million and £3.6 million one-off costs.

31. **Employees / workers**: As explained in paragraphs 16 and 17, it is estimated that there are around 1.7 million workers in the healthcare sector. This number will include the 31,000 – 32,000 duty holders estimated above. It is assumed that each employee / worker may spend between 15 and 30 minutes finding out what is changing and how it will affect their job. This is a much shorter amount of time than that spent by duty holders because it is assumed that the information will be targeted so that employees / workers only need to understand the bits that are changing that apply to them. The time required for familiarisation does not include any time for actions that will have to be taken as a result of the knowledge about the requirements in the Directive. The costs of these actions are included in the compliance costs sections below.

32. On that basis therefore, there could be around £1.67 million workers / employees required to understand what the changes mean to them and it is estimated the

---

\(^9\) The Annual Survey of Hours and Earnings, Standard Occupation Codes Table 14.5a 2011. It is assumed that the duty holders in hospitals will be ‘Hospital and Health Service Managers’, and will earn approximately £27 per hour according to ASHE. GPs will be earning £37 per hour according to ASHE and dental practitioners will earn just under £37 per hour. Duty holders in ambulance trusts will be classed as ‘hospital and health Service managers’ per ASHE and will earn £27 per hour while duty holders in care homes will be classed as health and social services managers, and will be paid £21 per hour per ASHE. All these hourly wage rates are grossed up by 30% to reflect the true cost of that time to the employer, with the additional costs reflecting the overheads from employing that person (employer tax and NIC, pensions, building costs etc)
time taken could be between 0.25 hours and 0.5 hours. The total time spent by workers / employees on familiarisation is estimated to be between 420,000 hours and 830,000 hours. Applying the average adjusted hourly wage rate from ASHE 2011 in the healthcare sector, the undiscounted cost of this time is estimated to be between £7.9m and £15.8m one off costs.

33. In total the undiscounted cost of familiarisation for the healthcare sector (including duty holders from the public sector and private hospitals only) is estimated to be between £9.0m and £19.3m. As these familiarisation costs will be in year one of the appraisal period, the discounted total cost is estimated to be between £8.7m and £18.7m. N.B. It is assumed that there won’t be any future familiarisation costs for new workers / employees. Although new staff will join the sector, they will be inducted in all health and safety procedures at once, and it is assumed that no distinction would be made around what used to happen for sharps and the current requirements. Thus the time that new staff spend familiarising themselves on health and safety is not expected to change when the Sharps Regulations are introduced. In other words the only costs of familiarisation will be one off costs when the Regulations become law.

34. The approach in Option 2 removes a substantial proportion of the familiarisation costs that would be associated with Option 1 (see further details below). Only those parts of the Directive which go beyond existing legislation will be transposed into the regulations, which removes any duplication and the possibility of some employers thinking they need to comply twice with two separate, yet related, pieces of legislation (a cost associated with Option 3). The wording of the Directive is not always clear and we propose to follow the social partner’s clarification and the Government guidance on transposition to avoid gold-plating. By clarifying certain requirements within the regulations themselves, this will save employers time and money seeking clarification elsewhere. The costs associated with employer ambiguity and the need for further interpretation is a considerable cost associated with Option 3, see below.

35. Within the cost estimate provided for the public sector duty holders is uncertainty around the number of duty holders that will be involved in the familiarisation per employer, and how long the familiarisation process may take. The assumptions made have been based on HSE experts’ best judgement, and the assumptions will be tested with stakeholders at consultation and by targeted evidence gathering.

Risk Assessment:
36. It is already a requirement in UK law to undertake a risk assessment\(^4\). An HSE inspection initiative designed to collect baseline data on current practice around sharps risk\(^4\) points to the fact that the risk assessments currently performed by healthcare employers tend to be generic rather than specific to the use of sharps.

37. The Directive will mean that risk assessments should consider the specific control measures set out in the Directive, and so it is likely that many healthcare employers will have to update their risk assessments.

38. All employers in healthcare will have to review their risk assessments in order to ascertain whether they are in compliance with the Directive.

39. In order to estimate the costs of reviewing and revising risk assessments, data is required on the number of employers and the number of risk assessments already in place.
40. As explained above, HSE has access to data for the estimated number of employers in the public healthcare sector (and private hospitals). Each of these employers may have more than one risk assessment, depending on the size of the organisation. For instance, hospitals may have a risk assessment for each different clinical activity, whereas a GP practice may just have one main risk assessment.

41. Based on HSE’s best estimates, it is assumed that it might take each hospital and ambulance trust between 2 and 3 hours to review all its risk assessments. It is assumed that it would take GPs, dental practices and care homes between 0.5 hours and 1 hour to review all of its risk assessment(s) as these are smaller organisations.

42. Using the cost of time assumptions outlined in footnote 1, the total cost of reviewing the risk assessments for public sector employers (and private hospitals) is estimated to have a present value of between £0.6 and £1.1 million (assuming the review of risk assessment takes place in year 1 of the appraisal period).

43. As with familiarisation costs, it is not possible to estimate the costs of reviewing risk assessments to the private healthcare sector, due to a lack of robust data on the number of employers in this sector. It is likely though that the cost estimates for the public sector include some overlap with the private sector, particularly for the areas of dental and care home provision.

44. Information from 9 responses to HSE questionnaires sent to the hospital and healthcare sector has shown that some risk assessments already in place are not specific to sharps. Any risk assessments that are general in nature would need to be reviewed to ensure they adequately address the risks from sharps.

45. HSE does not have information available to quantify how many additional risk assessments will need to be reviewed in this way in the sector. Thus, it is not possible to quantify the full costs of this clause on risk assessments in the Directive, however HSE intends to gather more information at consultation and via targeted evidence collection about the private healthcare sector and the number of employers that might need to produce a sharp-specific risk assessment.

Elimination, prevention and protection

46. This clause in the Directive specifies how any risks identified in the risk assessment should be eliminated, prevented or protected against.

47. HSE understand that the healthcare sector is already undertaking many of the requirements in the Directive around elimination, prevention and protection as a matter of best practice. The area that will have possibly substantial implications however is around the use of medical devices incorporating safety-engineered protection mechanisms, or safer sharps.

48. **Safer Sharps**: This is just one control measure in the Directive that is intended to be considered alongside others when assessing the risk, such as elimination and prevention through safer working practices. This point had to be clarified in the social partner’s clarification because Member States did not feel it was explicit in the wording of the Directive. HSE propose to amend the wording of the Directive to clarify this point for employers so they do not incorrectly assume that
incorporating safer sharps or that banning recapping are absolute duties without the need to consider the element of risk. Without this clarification, employers may have felt that they need to replace all of their sharps with safer alternatives even though there is no risk of injury (a cost associated with copying out the Directive in Option 3).

49. The rationale for introducing safer sharps is that, together with employee training, they reduce the risk of sharps injuries and so have the potential for long-term health benefits. This is discussed in more detail in the benefits section.

50. Data on the volume of safer sharps sold in the UK, provided by the NHS suppliers on the purchase / supply of safety and non-safety devices shows that to some extent NHS Trusts are already introducing safer sharps into the workplace. Between the years 2003 and 2011 there has been an increase in the proportion of safer sharps purchased compared to standard sharps from 5.5% in 2003 to 13% in 2011, i.e. a 7.5 percentage point increase.

51. The data is less clear for private hospitals. Evidence from questionnaires sent to the hospital and healthcare sector shows that some private hospitals might have introduced safer sharps in some areas, but not in all, but there appears to be awareness that safer sharps are available.

52. An HSE inspection initiative found out that in 18 of the 22 Trusts/Boards inspected, safety devices were in use and in four of these, a wide range of devices were in use. These devices ranged from safety cannulae, retractable lancets, needle-free devices, pre-filled syringes with safer devices, sharp safe butterfly needles etc. Some Trusts were even using cost–benefit analysis to evaluate the use of safer sharps. However in the 14 remaining Trusts/Boards, the use of safer devices was limited; being used for intravenous cannulation, phlebotomy, and in specialised units. In some instances, managers expressed a reluctance to consider the use of safer devices.

53. As already noted, data on the supply of safer sharps shows there has been an increasing trend to use safer sharps across the NHS between 2003 and 2011. This increasing trend to use increased volumes of safer sharps could continue even without the Directive. Thus, it is difficult to quantify what specific effect the Directive will have compared to if the Directive was not introduced. It is also possible that over time, as increased volumes of safer sharps are purchased, the price will begin to drop, which will in turn increase the demand for safer sharps, so uptake in the future could be larger and at a faster rate than the data might seem to predict.

54. Due to the large variability in the cost of different safety devices compared to the standard, it is not possible to estimate the average mark up of safety devices over standard sharps. If looked at on a case by case basis, it would be a very different picture for each hospital, as they will use a different mix of sharps depending on their clinical activities.

55. However, a case study is provided in the literature, of one hospital trust in Scotland. It is estimated that for the trust, purchasing safer sharps would cost £200,000 more per annum than standard sharps. Another report states the estimated total cost of introducing safer devices to prevent needlestick injuries is £136,000 per NHS Trust per annum.

56. As noted, these estimates cannot be extrapolated across all hospitals in England, Wales and Scotland due to the significant variability that is expected between
hospitals. However, it is illustrative of the potential costs for just one hospital if all sharps were replaced with safer sharps. As also explained, many hospitals might already be purchasing these safer sharps anyway and so a move to using more safer sharps would not be as costly as this case study suggests. The Directive also allows for risk to be taken into account, and so for some hospitals on the balance of risk the decision may be to not purchase the safer sharps.

57. Due to the variability that is likely to exist in the healthcare sector, and the uncertainties about what is currently happening and what will happen as a result of the Directive, it is not possible to quantify the impact of the Directive on the use of safer sharps at this time. HSE plan to use the consultation and targeted evidence gathering to gather more data on the current use of safer sharps and views on what might change as a result of the Directive and the cost implications of this.

58. Ban on recapping: This is a new requirement under the Directive. However, evidence from existing NHS policies and stakeholder feedback show that the practice of replacing a cap onto a needle after it has been removed is not currently permitted or is actively discouraged in the workplace. Some procedures in dentistry and radiopharmacy do require a cap to be replaced on the needle, and this will be allowed providing it does not involve a risk of injury. The additional costs incurred by a ban on recapping where a risk exists are likely to felt by those smaller organisations that do not already discourage the practice of recapping or resheathing needles. We will attempt to capture the cost implications from this at the consultation stage and through targeted evidence gathering.

59. Placing sharps containers as close as possible to the work: This is already covered by industry best practice and is included in national healthcare guidance. By introducing it into law, dutyholders may need to introduce an audit or inspection routine to ensure sharps containers are being positioned as close as possible to the work. This will incur an additional cost to the dutyholder and we will attempt to capture this cost at the consultation stage and through targeted evidence gathering.

60. Workers informed about vaccinations and vaccination to be offered free of charge to all workers and students: This requirement is already required under existing legislation. However, further evidence is required to establish whether all workers and students are currently provided with the vaccination and who incurs the cost. Further clarification is needed from stakeholders on how this will affect them in practice. This will be obtained at the consultation stage and through targeted evidence gathering.

Information and awareness raising

61. HSE understands that some degree of information and awareness raising is already taking place and that this is a continuous process. However, HSE expects that when this is made a legal requirement in the Regulations the main healthcare unions will respond and be involved with an awareness raising campaign.

62. Raising awareness by developing promotional material in partnership with representative trade unions and/or workers’ representatives: We need to fully understand more about what is meant by awareness raising and promotional material in order to be able to estimate a cost for this. HSE will be engaging with healthcare unions at the consultation stage to discuss what this will involve.
63. Unionisation is not as common place in the private sector as the public sector. We will consult with employee representatives to establish how this will work in practice in order to quantify this likely cost.

**Training**

64. Training is already a requirement under domestic legislation. However HSE understand that the new Regulations would require that the content of this training be changed for some employers (see below). There is no quantitative evidence of the scale at which current training takes place, and whether it covers sharps injuries specifically. Thus, it is possible to say that HSE expects there to be additional costs as a result of this requirement in the Directive, but cannot quantify now how much it might cost in total to deliver this training. We believe the additional impact of training will include changes to content, such as:

- **Correct use of safer sharps** – specific training for staff on the safe use and disposal of safer sharp devices;
- **Induction training** – training and information for all new and temporary staff before they start work on the risks of sharps injuries and the control measures in place;
- **Reporting procedures** – training on what ‘sharps’ incidents need to be reported and how; and
- **Measures following an injury** – training on what procedures are in place in the event of an injury.

65. HSE plans to use the consultation and targeted evidence gathering to find out further information about what training is currently delivered and whether any update to the content will be required compared to what is currently delivered, and how many employers might be affected.

**Reporting**

66. HSE understands from the HSE questionnaires sent to the healthcare sector that most healthcare employers have their own internal reporting systems in place, as there is already a national reporting system in place that must be adhered to; the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). However, the evidence seems to suggest that not all healthcare employers have a system in place for the reporting of all injuries, but just those which involve a risk of biological fluid transfer. The Directive requires that any accident or incident involving sharps is reported. Thus, a proportion of healthcare employers will have to establish procedures for the reporting of all sharps incidents to their own management teams and communicate this policy to their employees. The Social Partners clarification made it clear that no new reporting requirements under RIDDOR would be needed.

67. With the data that is currently available to HSE it is not possible to quantify how many employers might be affected by this requirement and so will have to update their internal reporting systems. It is not therefore possible to quantify this cost.

68. HSE plan to ask for further information during consultation and through targeted evidence gathering about which healthcare employers might be affected by this, and what impact the changes might have.

**Response and follow up**

69. The Directive requires that policies and procedures are in place for when a sharp injury occurs, and that all workers must be made aware of these policies.
Anecdotal evidence is that policies and procedures are currently in place for the reporting of sharps injuries and these can be sometimes escalated up the chain.

70. HSE understands that although this is a new legislative requirement, it is probably already established in guidance and good practice.

71. **Provision of prophylaxis:** This is currently good practice in the public sector, but further evidence is required as to whether this is the case for the private/third sectors. Additional information will be obtained via targeted evidence gathering and through consultation.

72. **Employer to investigate and record accident/incident:** Evidence shows this is already being carried out, but to what extent may vary between the different sectors.

73. It is not clear if there will be any additional costs to any health care employers as a result, and HSE plan to use the consultation and targeted evidence gathering to test what the impacts may be.

**Overall costs of Option 2**

74. Overall, we propose that by restricting the familiarisation and ongoing costs of the Directive to the healthcare sector alone, and by avoiding duplication and ambiguity, this is a proportionate and transparent way to proceed. Option 2 only affects those dutyholders for whom the Directive was intended and it clearly identifies what additional requirements are necessary above and beyond their existing duties. The costs are therefore targeted at the minimum numbers affected and the clarity of what is involved should ensure greater consistency across the sector.

75. **This makes Option 2 our preferred option.**

76. Table 1 lists the significant additional requirements of the Directive that HSE believes will incur an additional cost. For each requirement, we have tried to indicate the relative size of the overall cost involved (i.e. those over and above the status quo) and to highlight whether it is a one-off or recurring administrative or compliance cost.

**Table 1  Type and size of relative cost for each additional requirement under the Directive**

<table>
<thead>
<tr>
<th>Legal requirement of the Directive where change is anticipated</th>
<th>Changes required</th>
<th>One-off cost</th>
<th>Recurring administrative cost</th>
<th>Recurring compliance cost</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clause 5:</strong> Risk assessment</td>
<td>Ensuring the risk assessment adequately addresses the risks from sharps.</td>
<td>High</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clause 6:</strong> Elimination, prevention and protection</td>
<td>The changes resulting in additional costs include the provision and use of safer sharp devices, a ban on replacing a needle cap</td>
<td>Very High (mainly from implementing safer sharps, but will depend on size of organisation)</td>
<td>High (ongoing cost of safer needles)</td>
<td></td>
</tr>
<tr>
<td>Legal requirement of the Directive where change is anticipated</td>
<td>Changes required</td>
<td>One-off cost</td>
<td>Recurring administrative cost</td>
<td>Recurring compliance cost</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>--------------</td>
<td>-------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>where there is a risk of injury, the placing of contaminated waste containers as close as possible to the work and providing information about vaccinations.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clause 7:</strong> Information and awareness-raising</td>
<td>Raising awareness of the risks associated with using sharps and the provision of promotional material on safer sharps and safe working practices.</td>
<td>Low</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td><strong>Clause 8:</strong> Training</td>
<td>Changes requiring a potential cost include training on the correct use of safer sharps, induction training for all new and temporary staff and training on reporting and follow-up procedures.</td>
<td>Medium</td>
<td></td>
<td>Medium (change to content only)</td>
</tr>
<tr>
<td><strong>Clause 9:</strong> Reporting</td>
<td>Workers to report any accident/incident involving a sharp</td>
<td>Medium</td>
<td></td>
<td>High</td>
</tr>
<tr>
<td><strong>Clause 10:</strong> Response and follow-up</td>
<td>Changes that may incur additional costs include the provision of post-exposure prophylaxis and the employer to</td>
<td>Medium</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Legal requirement of the Directive where change is anticipated</td>
<td>Changes required</td>
<td>One-off cost</td>
<td>Recurring administrative cost</td>
<td>Recurring compliance cost</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>------------------</td>
<td>-------------</td>
<td>-----------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Familiarisation</td>
<td>Extremely High</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Comparison with other options**

**Option 1**: Implement by amending existing health and safety regulations to add in the substantive clauses of the directive

77. It is estimated that the costs of Option 1 will be the same as in Option 2 (outlined above) except for the following areas:

78. It is estimated that familiarisation costs to duty holders will be higher under Option 1 than under Option 2. This is because all employers across all industry sectors, not just the healthcare sector, will have to refer to the existing legislation to determine what changes have been made. They will then need to determine whether the changes apply to them or not. This could be very time consuming, and some employers may decide to employ the services of a health and safety professional to assist them (an indirect cost associated with this option).

79. Because of not stipulating that the changes are aimed at the hospital and healthcare sector, non-healthcare employers may misunderstand the Directive and decide to implement the changes, resulting in over-compliance and additional costs. It is difficult to identify the number of duty holders that might over comply with the Directive precisely, but considering health sector employees make up 7% of the total UK workforce\(^1\), it would appear the Directive is only intended to apply to a relatively small majority of employers.

80. It is also possible that some non-healthcare employers, such as those in the waste and disposal industry, may choose to err on the side of caution and deliberately implement the changes regardless. They may decide to review and amend their risk assessments, policies, work systems, training instructions and reporting procedures, without seeing any direct benefit. They may even go as far as vaccinating their workforce, even though they are not at as high a risk of exposure to a BBV as those in the healthcare industry.

81. Both these scenarios incur additional, yet unnecessary, compliance costs to the employer compared to Option 2. However it is not possible to quantify by how much the compliance costs in Option 1 will differ from those in Option 2 as it is not possible to quantify how many additional non-healthcare duty holders may respond to the changes. More information on what effect Option 1 might have is being sought at consultation.

82. Overall, we estimate that the total familiarisation costs incurred across all industry sectors will be the most significant for this option.
**Option 3:** Implement using a new set of health and safety Regulations that entirely copies out the wording of the Directive.

83. It is estimated that the costs of Option 3 will be the same as those identified in Option 2, except for the following areas:

84. Familiarisation costs are expected to be greater than in Option 2, due to the potential ambiguity over some of the wording and the duplication with existing legislation. Also, employers may err on the side of caution and over-comply, attracting an extra cost.

85. The extra complexity and time it takes to understand the changes due to the copy out approach proposed in Option 3 mean that Option 2 is definitely more favourable.

**Summary of costs**

86. HSE feels that overall, most of the substantive requirements of the Directive are already covered, or partially covered, by existing legislation. Some measures, such as the introduction of safer sharp devices, do have a significant cost implication on the employer, but evidence shows the health care sector has been gradually converting to safer devices over several years of their own accord. One of the largest impacts of the Directive will be the familiarisation costs for duty holders, to understand their new requirements.

87. Table 2 attempts to summarise where we estimate the majority of the burden will fall for each option. The burden comprises of financial costs (e.g. purchasing safer sharps) and time spent familiarising and implementing each option.

**Table 2:** Table to show the relative burden of each option on the employer

<table>
<thead>
<tr>
<th>Option</th>
<th>Burden</th>
<th>Healthcare employer</th>
<th>Non-healthcare employer</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Amend existing regulations</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. New Regulations – additional requirements only</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. New Regulations – Entire copy out</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 3: Table to show estimated impact by Sector, as measured by degree of change required (not monetised costs)

<table>
<thead>
<tr>
<th>Sector</th>
<th>Current status</th>
<th>Workforce numbers effected</th>
<th>Level of familiarisation required</th>
<th>Actual change required</th>
<th>Average additional costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public</td>
<td>Good knowledge and already implementing requirements of the Directive</td>
<td>HIGH</td>
<td>LOW</td>
<td>LOW</td>
<td>LOW TO MEDIUM</td>
</tr>
<tr>
<td>Private</td>
<td>Some awareness of the Directive. Little proactive work to implement changes.</td>
<td>MEDIUM</td>
<td>MEDIUM</td>
<td>MEDIUM</td>
<td>MEDIUM</td>
</tr>
<tr>
<td>Charity</td>
<td>Little or no awareness of Directive</td>
<td>LOW</td>
<td>HIGH</td>
<td>HIGH</td>
<td>MEDIUM TO HIGH</td>
</tr>
</tbody>
</table>

Benefits

88. The Directive specifies that its aim is to reduce the risk of injuries from sharps and all the risks associated with this type of accident, specifically to achieve the safest possible working environment, to prevent workers’ injuries caused by all medical sharps, to protect workers at risk and to set up an integrated approach establishing policies in risk assessment, risk prevention, training, formation, awareness raising and monitoring.

89. Injuries to healthcare workers from sharps contaminated with a patient’s blood have the potential to transmit more than 20 infectious diseases; including blood borne viruses (BBV) that can have a serious impact on health. In addition to the health impact, the anxiety and side effects of post-exposure prophylaxis (PEP) have a significant personal impact on healthcare workers, with an infection having the potential to limit their career in healthcare and possibly their lives. Injuries involving chemical contamination of sharps are therefore a recognised hazard within the healthcare sector.

Data on injuries

90. There is no definitive information on the current level of all sharps injuries that are experienced each year in the NHS. This is partly due to the fact that some sharps injuries are not reported, if the victim thinks it is from a low risk source. Whilst under RIDDOR there is currently the requirement to report sharps injuries that result in over three days off work (N.B. this is soon to change to 7 days by law), it is likely that even some of the sharps injuries that are fairly high risk will not result in more than 3 days off work (and in the future 7 days). Thus, RIDDOR is an incomplete data source for the sharps injuries which this Directive intends to capture.

91. There are other sources of data that have been collected on the number of sharps injuries, but these tend to be at a certain point in time and are no longer...
up to date. Also, it is common that data is collected on how many sharps injuries lead to the contraction of an infectious disease, rather than on all sharps injuries.

92. For instance, between 1997 and 2007 there were 14 reported Hepatitis C seroconversions in healthcare workers in the UK. From the start of the virus up until 2007 there were 5 reported cases of HIV seroconversions in the UK (with none reported after 1999). During the same period there were 12 possible HIV seroconversions in healthcare workers.

93. The total number of sharps injuries has been estimated at around 100,000 per annum. This estimate would cover all injuries not just those which had a risk of seroconversion.

94. However, as previously mentioned there is no national reporting system for all sharps injuries, and although it is best practice guidance to record all injuries, it is not clear that this always happens.

Cost of Injuries

95. Sharps injuries create a cost not only on the victims, but also on their employers. There will also be costs to the victim of the pain, grief and suffering they will experience. These costs cannot be so easily expressed in monetary terms, but are real costs arising from the initial injury and then the period of uncertainty around whether the injury was high risk, and if so if it will lead to a seroconversion. The PEP drugs can produce uncomfortable side effects, which can lead to the victim being unable to work. There will therefore be a degree of pain, grief and suffering associated with the taking of these PEP drugs.

96. There are also costs to the employer in terms of the PEP treatment costs which the employer should provide, any vaccines required, lost time due to the incident, including the administration time to record the incident and administer the treatment, and any lost time due to the employee being absent from work. There might also be lab costs for the testing of specimens and possibly compensation claims by the victim if they seroconvert.

97. Attempts have been made in the literature to estimate the cost of a sharps injury. The cost estimates vary depending on what is included in the estimate, and on the whole the estimates do not include the private costs to the individual victims of the pain, grief and suffering that results from the injuries.

98. HSE has estimated the cost of a reportable injury to be about £17,000 and comprises financial costs (such as lost earnings and medical costs) and non-financial costs (being the value given to the pain, grief and suffering associated with the injury and about £11,000 of the cost). However, it is important to note that this is the cost of the average reportable injury, which may not cover the majority of sharps injuries. For some sharps injuries, the pain, grief and suffering would be much less, once the victim realised the risk associated with the injury was not high (HSE also estimates that the cost of a minor injury is around £300). In other cases where there was a real risk of biological transfer and the source was known to be infected, then there could be a prolonged period of anxiety for the victim. In reality the actual cost of sharps injuries might lie somewhere between HSE’s two cost estimates.

99. In order to ascribe a more realistic cost estimate to the average sharps injury, a detailed and costly study would be required to estimate what value people would put on avoiding the pain, grief and suffering associated with a sharps injury. This is not thought to be a proportionate approach for this impact assessment because there is no accurate data on the numbers of sharps injuries, and no real

---

10 HSE cost estimates in 2009/10 prices, see http://www.hse.gov.uk/statistics/pdf/cost-to-britain.pdf
way of estimating ex ante how many injuries might be a voided as a result of the Directive.

**Risk Reduction**

**Option 2**

100. There are a number of clauses in the Directive which could act to directly reduce risk: namely more targeted risk assessment, protection measures, information and awareness raising, training, reporting and response and follow-up. The proposal to inform employees of the benefits and drawbacks of vaccination and to consider offering counselling to victims would help to mitigate consequences and the proposal to introduce complete and timely reporting may help with learning lessons and so improving future risk reduction methods.

101. As already explained, HSE understand that UK healthcare employers are already complying with best practice guidance on sharps, which in the UK already includes many of the requirements in the Directive. However, there are areas where UK duty holders will have to take action, specifically making risk assessments specific to sharps injuries, purchasing safer sharps where the risk justifies it, undertaking awareness raising and setting up policies and procedures to deal with sharps injuries. While these areas could serve to reduce the risk and/or consequence of a sharps injury, it is not possible to quantify this risk reduction ex ante in a meaningful way.

102. For instance, research on safer sharps has shown that the use of these devices is considered to improve safety and reduce the incidence of healthcare worker sharps injuries. The effect of employers revisiting their risk assessments and work procedures may result in increased compliance rates compared to what is currently described as best practice or which exists in law. It is HSE’s experience that when awareness is raised in the workplace, compliance rates go up and the level of risk goes down.

103. As noted, these outcomes are expected as a result of the Directive, but it is not possible to quantify to what extent they might be achieved. Thus, it is not possible to quantify any health and safety benefits that might result from the Directive.

**Option 1**

104. It is possible that the risk reduction benefits of Option 1 may be slightly greater than those in Option 2 because of the effect whereby it is anticipated that a greater number of duty holders will comply with the Directive. However this effect is not possible to quantify: firstly the risk reduction under Option 2 cannot be quantified and secondly, the over compliance from duty holders above and beyond those in the healthcare sector cannot be quantified. However, it is expected that the extra benefits from Option 1 compared to Option 2 will be relatively insignificant. The comparison of options will be investigated further via consultation.

**Option 3**

105. If the confusion caused by copy out leads to requirements of the Directive not being implemented appropriately, or in fact to over compliance, then this may change the risk reduction achieved in Option 3 compared to Option 2 and Option 1. However, it is not possible to quantify this effect ex ante. However, it is clear that because the Directive will create confusion if not interpreted, this will create a cost on duty holders associated with the extra time required to understand the Directive. The comparison of options will be investigated further at consultation.
Rationale and evidence that justify the level of analysis used in the IA (proportionality approach)

106. The healthcare sector is extremely large, and it is thought that there could be a great deal of variation between the current practices in different NHS Trusts. One way in which robust evidence could be gathered would be to commission a wide ranging survey. However, this is not thought to be a proportionate response to this Directive because it has already been agreed by the Social Partners, and it is incumbent on the UK to implement the Directive into UK law. The UK has no power to negotiate areas of the Directive and so the marginal value of improving the analysis by such wide-ranging surveys is very limited. Also, because the healthcare industry is so varied, there could be a very wide range in responses to such a survey and so a lot of uncertainty in any estimates.

107. The UK intends to ask a number of questions at consultation to try to gain more of an understanding of what is currently happening in the sector and whether there will be additional impacts for duty holders. HSE will also undertake targeted evidence gathering from stakeholders, representing various sizes and locations of healthcare employers to gather some detailed information that can be used to support the impact assessment, with questions tailored to the duty holders in question and so more likely to produce answers that can be interpreted and analysed.

108. HSE believe that such an approach is proportionate to the policy change in question, and will work on the evidence collected at consultation to further the evidence base in this IA.

Risks and assumptions

109. As described in the analysis of the costs and benefits, HSE has collected a lot of evidence to try to inform the baseline in the UK for this Directive, but this is predominantly qualitative information and not representative.

110. Where HSE has identified there will be an impact as a result of the Directive, it has generally not been possible to quantify this due to lack of data in the following areas:

   a. The number of healthcare employers in the private sector and the charity sector and so the number of duty holders in these sectors
   b. The number of these employers who are currently undertaking best practice, and the number that will have to adopt different practices as a result of the Directive.
   c. The effect the Directive will have in terms of increasing the current level of compliance with best practice.
   d. The effect the Directive will have on reducing the risk of sharps injuries.

111. HSE intend to reduce the uncertainty in these areas and minimise gaps in our knowledge through consultation and targeted evidence gathering.

112. There is a risk that the healthcare sector will grow or contract over the next 10 years and these changes have not been predicted in the impact assessment due to uncertainty around this.

113. Costs and benefits are discounted over a period of 10 years. There is too much uncertainty beyond the period of ten years to justify any other time period for the analysis.

114. It is assumed that costs start in 2013, being one year on from the price base year which is 2012.
Direct costs and benefits to business calculations (following OIOO methodology)

115. As the changes to the regulations proposed are to implement an EU Directive, the impacts will not be classed as an IN for One In One Out purposes.

116. There will be impacts to the public sector, the private sector and the third sector as outlined in Table 3. It is not possible to quantify the costs to the private sector (business) at this stage of the process, but HSE is hoping to gather more information at consultation which will assist with the quantification of the impacts to business.

Wider Impacts

117. The following wider impacts have been considered as they are thought to bear relevance to the Sharps Directive or are areas which could be significant or sensitive and so require explanation as to why there will be no impact:

Economic / Financial

Competition

118. Competition is not relevant to the UK public sector, which is one of the main sectors that the Directive will cover. Also, the private health care sector is not significantly affected by international competition due to the nature of treatment by the private health care sector, being generally funded by UK health insurance policies. These will limit choice within the UK to the UK healthcare industry. The Directive is also levelling the playing field within Europe and within the UK.

Small firms

119. HSE do not have a full profile of the private healthcare sector and so do not know what proportion of this sector is made up of small firms. This is something HSE seeks to clarify at consultation.

120. However, given that the changes to the regulations proposed stem from a European Directive, there is no requirement for HSE to allow an exemption for micro businesses. The proportion of the industry that is comprised of micro businesses is also something that HSE is looking to find out more information about at consultation, but anticipate that it could make up a large proportion of the private sector due to the nature of private dental practices, private GPs and private care homes.

Wider Environmental Issues

121. This is an accident prevention initiative. As mentioned above, there could be safety benefits for workers, but if traditional sharps are being disposed of correctly then there could be fewer sharps being disposed of/entering waste/dumped and so environmental benefits.

122. It is not clear whether safer sharps will however provide more bulky waste or be more difficult to dispose of than standard sharps, and we are not clear on how the volume of safer sharps being used will increase over time.

123. It is not possible to say whether there will be impacts on greenhouse gas emissions, as this will depend in part on how the manufacturing of safer sharps compares to standard sharps. However, it is not thought this will be significant.

124. It is not expected that there will be any other significant environmental impacts from the Directive.
Health and well being

125. The Directive has four main objectives which are all around improving the health and well being of healthcare workers. These impacts have been described in the benefits section above.

126. There could also be a negative impact on health and well being if safer sharps are more painful for patients, or create a higher risk of infection. This is not certain and so it is not possible to quantify any such effect.

Summary and preferred option with description of implementation plan

127. HSE’s preferred option is Option 2, to implement the Directive using a new set of health and safety Regulations to transpose the substantive clauses of the Agreement, following the wording of the Directive where possible.

128. It is intended that HSE will produce guidance for the new regulations and will embark on a small awareness raising campaign with industry. This will involve advertising in trade journals, and on the HSE website an introduction to and overview of the new Regulations, as well as engaging with key stakeholders to assist in informing interested parties.

129. Enforcement of the new Regulations will form part of HSE’s normal inspection work and reactive investigations. The extra costs of the additional time spent inspecting the requirements under these Regulations have been met is expected to be quite small and, where breaches have been identified, these costs will be covered by HSE’s cost recovery scheme. The amount of time that HSE might spend on reactive investigations will depend on how often significant breaches occur which HSE believe need investigating. With the Directive stipulating that any accident or incident involving sharps shall be reported to the employer by workers, there is the potential for extra incidents to be reported to HSE that fall into the RIDDOR criteria. A proportion of those incidents reported are likely to fall, however, when the criterion under RIDDOR rises from 3 to 7 days off work.
Impact Assessment

Appendices

Appendix 1: Bibliography

The UK has gathered evidence that has informed the analysis. This information includes the following:


4. A report on an HSE inspection initiative, from September 2011, which examined how NHS Trusts/Boards managed the risks of exposure to employees from blood borne viruses (BBV) as a consequence of sharps injuries. 22 Trusts / Boards participated. Out of over 400 Trusts / Boards this equates to just 5%. The sample was not intended to be representative, but it is not appropriate to extrapolate results and conclusions across all Trusts / Boards.

5. Responses to questionnaires sent by HSE in 2011 to employers in the hospital and healthcare sector. Approximately 50 questionnaires were sent out, and only 9 responses were received. Consequently this evidence can only be seen as anecdotal.


Appendix 2: Estimated numbers of employers

The following table provides some data on the estimated numbers of employers in the hospital and healthcare sector.

<table>
<thead>
<tr>
<th>Service</th>
<th>Public</th>
<th>Private</th>
<th>Third</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospitals</strong>&lt;sup&gt;(a)&lt;/sup&gt;</td>
<td>337</td>
<td>192</td>
<td>Unknown</td>
</tr>
<tr>
<td>(England, Scotland and Wales)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GP Practices</strong>&lt;sup&gt;(b)&lt;/sup&gt;</td>
<td>9754</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>(England, Scotland and Wales)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dental Surgeries</strong>&lt;sup&gt;(c)&lt;/sup&gt;</td>
<td>11,531</td>
<td>(Some will be included in the 11,531)</td>
<td>Unknown</td>
</tr>
<tr>
<td>(England and Scotland only)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ambulance Services</strong>&lt;sup&gt;(d)&lt;/sup&gt;</td>
<td>13</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>(England and Scotland only)</td>
<td>(Ambulance Trusts)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Care Homes and Hospices</strong>&lt;sup&gt;(e)&lt;/sup&gt;</td>
<td>6355</td>
<td>(Some will be included in the 6355)</td>
<td>Unknown</td>
</tr>
<tr>
<td>(England and Scotland only)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(a) – [www.drfosterhealth.co.uk](http://www.drfosterhealth.co.uk)
(c) - Dentists registered with the Care Quality Commission [www.cqc.org.uk](http://www.cqc.org.uk) and NHS National Services Scotland [www.isdscotland.org](http://www.isdscotland.org) (2012)
(d) – [www.nhs.uk](http://www.nhs.uk) and NHS National Services Scotland (2012)
(e) – Care homes with nursing registered with the Care Quality Commission and NHS National Services Scotland (2012)
Annex C - List of the consultation questions

Comments should be sent no later than 8 November 2012:
By completing the online questionnaire or using contact details on page 2

Question 1 – see page 5

a) Is the use of the term ‘medical sharps’ in the regulations consistent with how it is commonly used by employers and workers in the healthcare sector?

b) If you think that this use is not consistent, please provide comments to support your answer.

Question 2 – see page 10

a) In addition to the examples provided above (paras 17-22), are there other common circumstances under which people carry out healthcare activities using medical sharps where the application of the proposed regulations could usefully be clarified in guidance?

b) If you think that there are, please provide details to support your answer.

Question 3 – see page 13

a) Is it clear what actions employers and employees will need to take under the proposed regulations (see paragraphs 27 - 29)?

b) Please provide comments to support your answer.

Question 4 – see page 15

a) Do you agree that HSE’s guidance on the new regulations should be built into its existing relevant guidance?

b) In addition to the organisations that produced the guidance listed at paragraph 31 and 32 are there other organisations that HSE should seek to work with to ensure that relevant non-HSE guidance aligns with the requirements of the new regulations.
Question 5 – see page 15
Does the proposed implementation date have any unintended consequences for the UK healthcare sector?

Question 6 – see page 17
To assist us with the impact assessment please answer the following:

a) Numbers of employers in the healthcare sector
IA 1. Please provide any information you have which will help us to fill in the gaps in Table 1; with appropriate references to the source of the information.

b) Review of Risk Assessments
IA 2. Do you agree or disagree with the following assumptions made by HSE in the impact assessment:
- All risk assessments relevant to sharps injuries will have to be reviewed
- It will take each hospital and ambulance trust between 2 and 3 hours to review the relevant risk assessments.
- It will take GPs, dental practices and care homes between 0.5 hours and 1 hour to review the relevant risk assessments.
IA 3. Please provide comments to support your answers to IA2.
IA 4. Can you estimate how many risk assessments your organisation may need to amend as a result of the proposed regulations?
IA 5. How long will it take your organisation to make amendments to a risk assessment?

c) Safer Sharps
IA 6. Does your organisation use any ‘safer sharps’ in its activities now?
IA 7. Will your organisation use an increased number of ‘safer sharps’ as a result of the proposed regulations?
IA 8. If you can, please provide an estimate of the % increase in the use of safer sharps by your organisation as a result of the proposed regulations, where 100% is that all possible traditional devices have been replaced by safer sharps?

Continues over page
Question 6 – continued – see page 17

d) Familiarisation

IA 9. Do you agree or disagree with the following assumptions made by HSE in the impact assessment about familiarisation costs, (in other words the time it will take to read and understand the new regulations).
   a) For each hospital and ambulance service between 5 and 10 people will have to spend time familiarising themselves with the proposed regulations.
   b) For each GP practice, Dental surgery and care home one person will spend time familiarising themselves with the proposed regulations.
   c) Each person will spend between 1 and 3 hours reading and understanding the proposed regulations.

e) Other impacts

IA 10. Please provide information about the cost impacts arising from other requirements in the regulations, specifically in relation to the following areas:
   a) Placing of secure containers and instructions for safe disposal of medical sharps close to the work area
   b) Not recapping needles where there is a risk of injury
   c) Procedures to be reviewed regularly
   d) Information and training
   e) Reporting of sharps injuries by workers and investigation of the circumstances and causes by employers
   f) Follow up of a sharps injury

If your information is:
- Published cost data, please provide the appropriate reference
- A summary of cost data already collated by your organisation – please provide a summary of what it covers and contact details for obtaining a copy

Benefits

IA 11. If you are able to identify any anticipated benefits to you (eg reduced costs of injuries) from implementation of the changes required by the proposed Regulations, please provide a description?

The full text of this and other Consultative Documents can be viewed and downloaded from the Health and Safety Executive web site on the internet: www.hse.gov.uk/consult/index.htm