EXPLANATORY MEMORANDUM TO

The Health and Safety (Sharp Instruments in Healthcare) Regulations (Northern Ireland) 2013

S.R. 2013 No. 108

1. Introduction

1.1. This Explanatory Memorandum has been prepared by the Department of Enterprise, Trade and Investment to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2. The Statutory Rule is made under powers conferred by Articles 17(1) and (2) and 55(2) of, and paragraphs 1(1), 7(1), 13, 14(1) and 15 and 19 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978 ("the 1978 Order") and is subject to the negative resolution procedure.

2. Purpose

2.1. These Regulations are required to implement Council Directive 2010/32/EU *implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU* ("the Directive") by 11th May 2013. The Directive aims to protect the health and safety of workers in the healthcare sector, the most significant risk is from an injury involving a contaminated needle and a consequent infection with a blood-borne virus (eg Hepatitis C).

3. Background

3.1. Directive 2010/32/EU was adopted by the European Council in May 2010 and has to be implemented by Member States by 11th May 2013.

3.2. The Directive was made under the social partner procedures set out in Article 155(2), under Title X (Social Policy) of the Treaty on the Functioning of the European Union. A social partner agreement was negotiated by the European Hospital and Healthcare Employers' Association (HOSPEEM) and the European Federation of Public Service Unions (EPSU), and the Directive requires that the measures in the agreement are implemented in national legislation.

3.3. The Directive contains a number of requirements, many of which are already in existing health and safety law. The social partners produced a joint clarification (February 2010) in response to questions raised by the Member States. This sets out the intentions behind their Agreement and has been taken into account in drawing up the proposed regulations. The Regulations transpose only those provisions in the Directive that are not specified in existing health and safety law. The wording of the Directive has been used except where changes are necessary to clarify what is required or to better align with existing requirements. A Transposition Note is attached to this memorandum as Annex A.

3.4. The Health and Safety at Work (Northern Ireland) Order 1978 ("the Order") aims to secure the health, safety and welfare of persons at work, and a body of existing Regulations made under the Order provide for the detailed requirements in relation to various aspects of risk assessment and the provision of control measures. In their Agreement, implemented by the Directive, HOSPEEM and EPSU set out a package of measures to protect workers in the healthcare sector from the risks of sharps injuries.

3.5. There is no reliable source of data on the number of sharps injuries to healthcare workers. Studies have estimated that there may be as many as 100,000 sharps injuries in the UK each year and a 2010 survey by the Care Quality Commission found that 2% of all NHS staff had suffered a needlestick injury in the previous 12 month period. A 2009 survey of Health and

Social Care staff in NI indicated the incidence of sharps injuries during the previous 12 months to be 1%. In addition to the health impact, the anxiety and side effects of post-exposure treatments have a significant personal impact on healthcare workers. Costs to health sector employers include lost time (for post incident investigation, treatment etc) and the costs of treatments to prevent or reduce the effects of an infection.

3.6. The Regulations are a limited, technical matter, of interest mainly to employers and workers in the healthcare sector. The existing health and safety legislation provides a good standard of protection for workers in all sectors from the risks of a sharps injury. The evidence is that the majority of injuries that occur in the healthcare sector could be prevented if existing safe systems of work were followed.

3.7. The Directive mostly covers the same ground as existing health and safety legislation but it does introduce some specific new duties on healthcare employers to:

- Introduce a small number of specific control measures;
- provide specific training and information to employees; and
- have specified arrangements in place following a sharps injury.

The Directive also introduces new duties on workers who suffer a sharps injury to:

- Notify their employer of the sharps injury; and
- provide their employer with information about the circumstances of the accident.

3.8. The Directive requires Member States to provide for effective, proportionate and dissuasive penalties in the event of any breach of the Directive. The UK has no legal mechanism under which social partners (employers and trade union representatives) can bring in sufficiently enforceable measures to meet the UK's obligation under the Directive. This option is therefore not available here, as it is in some European States. The European Court would not regard non-regulatory options as adequate means of implementing the Directive.

3.9. The Regulations have therefore been introduced to ensure those measures in the Directive not specifically addressed in existing health and safety legislation have been adequately transposed into domestic law.

4. Consultation

4.1. A consultation exercise ran from 3 December 2012 to 22 February 2013. There were approximately 600 consultees, including individuals and bodies representative of section 75 of the Northern Ireland Act 1998 and other organisations with an interest in equality and related issues (including each member of the Northern Ireland Assembly). In total there were 11 replies, 4 of which made no comment, 1 of which was fully supportive of the proposals and 6 of which made a number of comments in relation to the Regulations and supporting guidance. The main issues raised were:

- Concern that the Regulations do not address the risk of injury to workers outside the healthcare sector. However, the Directive only applies to the healthcare sector and the application of the Regulations reflects that. HSENI's view is that the existing legislation provides a good level of protection for employees across all sectors and there is no strong argument to extend the requirements beyond the healthcare sector; and

- concern that the Regulations, as drafted, under implemented the terms of the Directive which appeared to provide for a complete ban on recapping of needles. A statement made by HOSPEEM and EPSU provided clarification on the issue of recapping however, in light of concerns raised Regulation 5(c) has been redrafted. This is to clarify that recapping is only to be used where it is necessary to control a risk (which will include patient safety); in addition to retaining the requirement for the risk to employees to be controlled by a suitable appliance, tool or equipment.

4.2. A summary of the consultation responses and HSENIs response can be found on the HSENI website.

5. Equality Impact

5.1. The Rule has been screened for any possible impact on equality of opportunity affecting the groups listed in section 75 of the Northern Ireland Act 1998 and no adverse or differential aspects were identified.

6. Regulatory Impact

6.1. An Impact Assessment was conducted in respect of the corresponding Great Britain Statutory Instrument and is attached to this memorandum at Annex B. The Department of Enterprise, Trade and Investment is of the opinion that the analysis and considerations in respect of the costs arising from the proposals as set out in the Great Britain Impact Assessment can be applied proportionately to Northern Ireland.

6.2. Consequently:
- the total cost to the public, private and voluntary sectors of introducing the Regulations is estimated as £325,000 over a ten year period;
- the total cost to private business is estimated as £115,000 over a ten year period. However, in practice, the costs to private business are likely to be significantly less, possibly as little as £29, 250, based on the proportionately fewer number of independent hospitals relative to Trust hospitals in Northern Ireland than Great Britain.
- costs arising from implementation of the Regulations will include those associated with familiarisation, provision of information to employees, additional reporting of injuries and the review of risk assessments.

7. Financial Implications

7.1. As detailed above.

8. Section 24 of the Northern Ireland Act 1998

8.1. The Department has considered the matter of Convention rights and is satisfied that there are no matters of concern.

9. EU Implications

9.1. The Statutory Rule is essential to implement Directive 2010/32/EU.

10. Parity or Replicatory Measure

10.1. In Great Britain the corresponding Statutory Instrument is the Sharp Instruments in Healthcare Regulations 2013 (S.I. 2013/645), which was made on 18 March 2013 and will come into force on 11 May 2013.

11. Additional Information

11.1. Not applicable

Northern Ireland Transposition Table

Council Directive 2010/32/EU of 10 May 2010 Implementing the Framework Agreement on Prevention from Sharps Injuries in the Hospital and Healthcare Sector between HOSPEEM and EPSU

Article[1]	Copy out (yes/no)? If no – reason for elaboration	Northern Ireland Provision
Article 1 Requires the Member States to implement the Framework Agreement in the Annex.	**N/A**	**Does not require transposition.**
Article 2 Requires that penalties shall be effective, proportionate and dissuasive.	**N/A**	**Does not require transposition.**
Article 3 Requires the Member States to implement by 11 May 2013 and to make reference to the Directive.	**N/A**	**Does not require transposition.**
Annex **Preamble, General considerations and Clause 1: Purpose**	**N/A**	**Does not require transposition.** Considered preambular, obligations met by implementing substantive clauses in the Agreement.
Annex **Clause 2: Scope** "This agreement applies to all workers in the hospital and healthcare sector, and all who are under the managerial authority and supervision of the employers. Employers should deploy efforts to ensure that subcontractors follow the provisions laid down in this agreement."[2]	**No** Copy out would potentially extend duties on a healthcare employer as regards obligations towards employees of subcontractors. We considered this aspect to be met by existing requirements and to not require transposition. The same scope is achieved using a structure and wording that is sufficiently clear and precise for domestic legislation in the implementing Regulations (i.e. the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013).	Regulation 3 (Application) of the **Health and Safety (Sharp Instruments in Healthcare) Regulations (Northern Ireland) 2013** (the implementing Regulations) Article 5 of the **Health and Safety at Work (Northern Ireland) Order 1978** (N.I. 9)

[1]The Directive consists of 5 Articles which implement the Annex containing the eleven clause Framework Agreement between HOSPEEM and EPSU.

[2] See also, the HOSPEEM-EPSU joint clarification of the Framework agreement on prevention from sharp injuries in the hospital and healthcare sector ("the Social Partners' Clarification"). This states that, in relation to Clause 2:

- "Independent workers as well as workers in households (for example nurses visiting patients) are included if they carry out their function within the workplaces covered by the agreement and under the managerial authority of the healthcare employer".
- "[The agreement] covers all the individuals who have a working relationship with the healthcare employers and are exposed to the risk of medical sharps injuries. Besides nurses and doctors, there are also other workers, such as cleaners and porters who may be employed by a third party, who need to be covered because they can have direct contact with medical sharps while they are working".
- "The agreement applies to the self-employed if they are under the managerial authority and supervision of healthcare employer/organisation".
- "Nurses in private schools are covered if they are under the managerial authority and supervision of a healthcare employer. Nurses employed independently by private schools are not covered".

Article[1]	Copy out (yes/no)? If no – reason for elaboration	Northern Ireland Provision
Annex **Clause 3: Definitions**	**Yes – in part** Some terms duplicate existing requirements in primary legislation that by virtue of the Interpretation Act are not required for the purpose of implementing legislation, others are insufficiently precise or clear. Where possible, the wording of the implementing Regulations follows that of the Directive.	Regulations 2 (Interpretation), 3 (Application of duties) and 6 (Information and training) of the **Health and Safety (Sharp Instruments in Healthcare) Regulations (Northern Ireland) 2013**
Annex **Clause 4: Principles**	**N/A**	**Does not require transposition.** Considered preambular, obligations met by implementing substantive clauses in the Agreement.[3]
Annex **Clause 5: Risk Assessment** Provides that risk assessment shall be conducted in accordance with existing European requirements;[4] shall include an exposure determination, and shall take into account organisation and conditions of work, technology, level of qualifications and work-related psycho-social factors.	**N/A**	Regulation 3 (Risk assessment) of the **Management of Health and Safety at Work Regulations (Northern Ireland) 2000** (SR 2000/388) Regulation 6 (Assessment of the risk to health created by work involving substances hazardous to health) of the **Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003** (SR 2003/34)
Annex **Clause 6: Elimination, prevention and protection** Workers' exposure must be eliminated by specifying and implementing safe procedures for using and disposing of medical sharps and waste; banning the re-capping of needles;[5] developing an infection prevention policy; training; conducting health surveillance; using personal protective equipment and offering appropriate vaccines where necessary.[6]	**Yes – in part** Some requirements duplicate existing legislative provisions in relation to the safe disposal of medical sharps; safe systems of work; health and safety policy and arrangements; provision of health surveillance; use of personal protective equipment; vaccination of workers offered free of charge. New requirements, including the qualification of duties imposed on employers, are included in the implementing Regulations which follow the wording of the Directive where possible. However, the structure and wording are amended for reasons of legal certainty and to avoid imposing more onerous burdens on business than are practicable or appear in existing domestic legislation.	Regulations 5 (Use and disposal of medical sharps), 6 (Information and training) of and Schedules 1 and 2 to the **Health and Safety (Sharp Instruments in Healthcare) Regulations (Northern Ireland) 2013** Articles 4 and 10 of the **Health and Safety at Work (Northern Ireland) Order 1978** (N.I. 9) Regulations 5 (Health and safety arrangements) and 6 (Health surveillance) of the **Management of Health and Safety at Work Regulations (Northern Ireland) 2000** (SR 2000/388) Regulations 7 (Prevention or control of exposure to substances hazardous to health) and 11 (Health surveillance) of the **Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003** (SR 2003/34) Regulation 4 (Provision of personal protective equipment) of the **Personal Protective Equipment at Work Regulations (Northern Ireland) 1993** (SR 1993/20)

[3] See the Social Partners' Clarification, which states that "Clause 4 sets out the principles underpinning the agreement. These principles can be met by properly carrying out the requirements set out in clauses 5 to 10."

[4] Articles 3 and 6 of Directive 2000/54/EC and Articles 6 and 9 of Directive 89/391/EEC.

[5] See the Social Partners' Clarification, which states that "the practice of recapping refers to needles without safety and protection mechanisms. Modern devices with safety mechanisms are not banned unless they pose a risk of injury".

[6] See the Social Partners' Clarification, which states that "where the agreement refers to vaccinations, it is about vaccination for blood-borne infectious diseases for example HIV, hepatitis B and C. Influenza vaccination and other such vaccinations are not covered by the agreement."

Article[1]	Copy out (yes/no)? If no – reason for elaboration	Northern Ireland Provision
Annex **Clause 7: Information and awareness raising**[7] Employers shall highlight risks; provide guidance on legislation; promote good practice regarding the prevention and recording of incidents; raise awareness by developing activities and promotional materials in partnership with unions and provide information on support programmes.	**Yes – in part** Where possible, the wording of the implementing Regulations follows that of the Directive. However, alternative wording is used for legal certainty or drafting requirements. The new regulations clarify who must be provided with information and that worker representatives are only those appointed under existing legislation.	Regulation 6 (Information and Training) of and Schedule 1 to the **Health and Safety (Sharp Instruments in Healthcare) Regulations (Northern Ireland) 2013** Article 4(5) of the **Health and Safety at Work (Northern Ireland) Order 1978** (N.I. 9) Regulation 8 (Information and instructions) of the **Provision and Use of Work Equipment Regulations (Northern Ireland) 1999** (SR 1999/305)
Annex **Clause 8: Training** In addition to measures required by existing EU legislation,[8] appropriate training shall be made available on policies and procedures associated with the correct use of safer sharps; the risks of blood and body fluid exposures; preventive measures; the reporting, response and monitoring procedures; measures taken in case of injuries. Employers must release workers for training.	**Yes – in part** Some requirements duplicate existing legislative provisions in relation to training. The implementing Regulations limit the requirement for training only to employees at risk and to the extent that the training is relevant to the work that they do.	Regulation 6 (Information and training) of and Schedule 2 to the **Health and Safety (Sharp Instruments in Healthcare) Regulations (Northern Ireland) 2013** Regulation 13 (Capabilities and training) of the **Management of Health and Safety at Work Regulations (Northern Ireland) 2000** (SR 2000/388) Regulation 9 (Training) of the **Provision and Use of Work Equipment Regulations (Northern Ireland) 1999** (SR 1999/305) Regulation 12 (Information, instruction and training for persons who may be exposed to substances hazardous to health) of the **Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003** (SR 2003/34) Regulation 9 (Information, instruction and training) of the **Personal Protective Equipment at Work Regulations (Northern Ireland) 1993** (SR 1993/20)
Annex **Clause 9: Reporting**	**Yes – in part** The meaning and effect of Clause 9.1 is particularly unclear.[9] However, the Social Partners' Clarification states they did not intend to impose additional reporting requirements, so this element is not transposed.[10] The wording of Clause 9.2 has been clarified in the implementing Regulations to avoid unnecessary administrative burdens and allow any urgent medical treatment to take priority.	Regulation 8 (Notification of Injuries) of and Schedule 2 to the **Health and Safety (Sharp Instruments in Healthcare) Regulations (Northern Ireland) 2013** Regulation 3 (Notification and reporting of injuries and dangerous occurrences) of and Schedule 2 to the **Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1997** (SR 1997/455)

[7] "As sharps are considered as work equipment within the meaning of Directive 89/655/EEC, in addition to information and written instructions to be provided to workers specified in Article 6 of Directive 89/655/EC" (BUT: Directive 89/655/EC has been repealed and replaced with Directive 2009/104/EC – see now Article 8 of the latter Directive)

[8] Article 9 of Directive 2000/54/EC

[9] Clause 9.1: This includes the revision of the reporting procedures in place with health and safety representatives and/or appropriate employer/workers representatives. Reporting mechanisms should include local, national and European-wide systems. (*sic*)

[10] The Social Partners' Clarification states that "referring to reporting procedures, we are not asking the Member States to set up any new structures. We are referring to the procedures that already exist and are in place in every state. Our intention is to have the existing reporting systems properly used."

Article[1]	Copy out (yes/no)? If no – reason for elaboration	Northern Ireland Provision
Annex **Clause 10: Response and follow-up** Procedures must be in place for sharp injuries – in particular, the provision of prophylaxis and medical tests and health surveillance; investigation of circumstances and cause of the accident; consideration of counselling, and guaranteed medical treatment. Workers must be made aware of these procedures, and confidentiality must be respected.	**Yes - in part** Some requirements duplicate existing legislative provisions in relation to health surveillance, guaranteed medical treatment, rehabilitation, continued employment, access to compensation and protection of patient confidentiality. The wording of requirements to act in the event of an injury have been clarified by the implementing Regulations to ensure that the Directive is not extended unnecessarily. The implementing Regulations also define 'post-exposure prophylaxis' to provide clarity.	Regulations 7 (Arrangements in the event of injury) and 6 (Information and training) of and Schedule 1 to the **Health and Safety (Sharp Instruments in Healthcare) Regulations (Northern Ireland) 2013** Regulation 3 (Notification and reporting of injuries and dangerous occurrences) of and Schedule 2 to the **Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1997** (SR 1997/455) Regulation 11 of the **Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003** (SR 2003/34) Section 4 of and Schedule 1 to the **Data Protection Act 1998** (c.29)
Annex **Clause 11: Implementation**	**N/A** Specifies the manner of implementation at EU level.	**Does not require transposition.**

PART I

GREAT BRITAIN IMPACT ASSESSMENT

FOR

THE HEALTH AND SAFETY (SHARP INSTRUMENTS IN HEALTHCARE) REGULATIONS 2013 (S.I. 2013 NO. 645) ("THE GB REGULATIONS")

1. The following pages contain a copy of the Impact Assessment, prepared by the Great Britain Health and Safety Executive, in respect of the GB Regulations.

2. The Impact Assessment estimated the costs to dutyholders at £13 million over 10 years. The main costs that have been monetised in the impact assessment are around information and awareness raising, the reporting of injuries, familiarisation costs and risk assessments.

3. The total cost to business has been estimated as around £4.6 million over 10 years. The cost to business is an estimate, based on the percentage of total hospitals that are independent (36%) which is used as a proxy for the total independent healthcare sector, in the absence of more specific information.

4. The implementation of the Directive will deliver benefits in terms of its aim to reduce the risk of injuries from sharps and all the risks associated with this type of accident. It has not been possible to monetise the benefits of the Sharps Directive.

Title: Transposition of the Council Directive 2010/32/EU "Implementing the Framework Agreement on Prevention from Sharp Injuries in the Hospital and Healthcare Sector between HOSPEEM and EPSU" **IA No:** **Lead department or agency:** Health and Safety Executive **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 04/12/2012 **Stage:** Final **Source of intervention:** EU **Type of measure:** Secondary legislation **Contact for enquiries**: Martin Dilworth **HSE, Redgrave Court 5S.2, Merton Road, Bootle L20 7HS Tel: 0151 951 4335 martin.dilworth@hse.gsi.gov.uk**

Summary: Intervention and Options

RPC Opinion: GREEN

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£-13m	£-4.6m	£0.50m	No	NA

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 Sharps 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, independent 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 preferred option to implement this Directive is by introducing new Regulations that are provisionally titled the Health and Safety (Sharp instruments in Healthcare) Regulations 2013. These new regulations transpose the substantive clauses of the Directive not already specified in existing legislation and follow the wording of the Directive where possible. This option was selected as, in line with government policy on European legislation, it ensures effective transposition of the Directive while minimising the additional costs that will fall on UK businesses. The other options to implement the Directive originally considered are:

- Implement by amending existing health and safety Regulations to add in the substantive clauses of the Directive
- Implement using a new set of health and safety Regulations that entirely copies out the wording of the Directive.
- Do nothing

The reason for not pursuing these options further is provided in paragraphs 10 – 14 of the evidence base.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 04/2018					
Does implementation go beyond minimum EU requirements?			NO		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 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 SELECT SIGNATORY: _____ Date: _____

Summary: Analysis & Evidence Policy Option 1

Description: Implement using a new set of health and safety Regulations to transpose the substantive clauses of the Framework Agreement on prevention of sharps injuries in the hospital and healthcare sector.

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -9.2	**High:** -16	**Best Estimate:** -13

COSTS (£m)	Total Transition (Constant Price)	Yea	Average Annual (excl. Transition) (Constant	Total Cost (Present Value)
Low	8		0.13	**9**
High	14	1	0.19	**16**
Best Estimate	11		0.16	**13**

Description and scale of key monetised costs by 'main affected groups' Total costs include the one off costs of familiarisation, estimated between £1.5million and £4.6million, with between £0.5m and £1.7m estimated to fall to the private sector; a one off cost of providing information to employees, estimated to be between £1.5m and £2.9m, with an estimated £0.5m to £1.1m falling to the private sector; additional reporting of injuries estimated to cost between £1.1m and £1.6m over 10 years, with between £0.4m and £0.6m falling to the private sector. The total also includes the one-off 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, estimated to cost between £5.2 million and £6.8 million, with between £1.9m and £2.5m falling to the private sector.

Other key non-monetised costs by 'main affected groups' It has not been possible to quantify any additional costs arising from the expected increase in the use of safer sharps. This is because of the significant variability in the extent these sharps are currently used, what clinical procedures are performed and the type of safer sharps that could be introduced. It has also not been possible to quantify the potential additional cost of training to smaller service providers, or the cost of equipment required for procedures where re-capping of needles is required. All of these costs are thought to be limited compared to the quantified costs.

BENEFITS (£m)	Total Transition (Constant Price)	Yea	Average Annual (excl. Transition) (Constant	Total Benefit (Present Value)
Low	Nil		Nil	**Nil**
High	Nil		Nil	**Nil**
Best Estimate	NIl		NIl	**NIl**

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

Key assumptions/sensitivities/risks	3.5

There are some gaps in the data about the number of duty holders in the independent part of the healthcare sector, notably those GPs, dentists and care homes that only act independently. Despite significant attempts to find this information, no conclusive data could be obtained from official sources. We have obtained separate figures for the number of independent hospitals which account for 36% of all hospitals in GB. This percentage has been used to split the total costs between the public sector and business, on the assumption that the amount of healthcare performed privately in the hospital sector is a reasonable indicator of the proportion of all healthcare that is performed privately. There is no better evidence on which to apportion the total costs between the public sector and business.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of	Measure qualifies
Costs: 0.53	**Benefits** Not	**Net:** -£0.53	No	NA

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 direct 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 100,000 in the UK[1] (see paragraphs 93-95 for more details). 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. There is existing health and safety legislation in Great Britain that requires employers to protect employees against the risk of a sharps injury at work. Relevant legislation includes the Health and Safety at Work etc Act (1974), the Control of Substances Hazardous to Health Regulations 2002 (as amended) (commonly known as "COSHH") and the Management of Health and Safety at Work Regulations 1999. The regulations are supported by HSE guidance material. In addition, there is much well established guidance material on the safer use of sharps, for example that provided by NHS Employers and from several professional bodies such as the Royal College of Nursing.

4. Council Directive 2010/32/EU of 10 May 2010, implementing the Framework Agreement on Prevention from Sharps 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').

5. HSE proposes to introduce new health and safety Regulations to transpose those requirements of the Directive that are not already specified in UK law. These proposed regulations are

provisionally titled the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 and are required to come into force by 11th May 2013.

6. HSE carried out a public consultation on this proposal, including a draft version of the new Regulations, over a 3 month period between 8th August and 8th November 2012. HSE sought views on whether the application and action required by the proposed regulations was clear. HSE also sought to obtain further information on the anticipated costs and benefits of the proposed Regulations from relevant employers. While the data obtained from this consultation was not substantial it has been used to supplement the Consultation Stage Impact Assessment, and to confirm some of the assumptions and information included in it (Regulatory Policy Committee reference RPC12-HSE-1335).

7. The draft Regulations on which HSE consulted may be subject to some adjustments in response to comments received during the consultation and during the final stages of clearance. However, the preferred option for transposition has been confirmed. Therefore, the substantive costs and benefits in this Impact Assessment are unlikely to be altered by these changes.

Rationale for intervention

8. 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 needlesticks) and protecting workers at risk in the hospital and healthcare sector[3].

Policy objective

9. 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 in line with Government guidance on transposition, 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

10. 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 the preferred option are compared.

11. HSE considered whether it was possible to implement the Directive by using alternatives to regulation. However, the Directive requires that Member States provide "effective, proportionate and persuasive penalties in the event of a breach of the obligations of the Directive". In light of this, it is not possible to use approaches that seek to persuade businesses to take action by relying solely on information/education or that are based on economic instruments. HSE has thus concluded that it is not possible to implement this directive by non-legislative means alone.

12. The **Preferred Option** is to introduce a new set of regulations, The Health and Safety (Sharp Instruments In Healthcare) Regulations 2013 (hereafter 'the Regulations') to transpose the substantive clauses of the Agreement that go beyond existing UK legal requirements, following the wording of the Directive where possible.

13. Two further options were considered at consultation: firstly, to amend existing regulations to add in the substantive clauses of the Directive; and secondly to introduce a new set of regulations that entirely copied out the wording of the Directive. Both options were discounted at consultation on the grounds of being no more effective at reducing risk than the preferred option, whilst imposing a higher cost on industry. No further analysis of these two options has been performed in this final stage Impact Assessment.

14. The preferred option proposes to introduce the Regulations aimed at the healthcare sector alone. Compared to the options considered at consultation, it represents a proportionate approach and minimises unnecessary additional burdens by effectively removing non-healthcare businesses from further obligations. The Regulations transpose the substantive clauses of the Directive and follow the wording of the Directive where possible. Where further clarification around the requirements was needed, the Social Partners Clarification document was consulted, to ensure the Regulations appropriately capture the meaning of the Directive and to assist duty holders in understanding their requirements. .

Risks and assumptions

Evidence

15. 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 of the healthcare sector as a whole. This is because the sector is very diverse with duty holders ranging from very large hospital trusts to small dental practices. As well as variability in the type of healthcare provided, there is also variability in size and complexity of each healthcare unit. Consequently, any survey would require a very large sample size and high response rate in order to get robust 'average' estimates, and this would impose a significant cost on the industry. We know there are over 40 thousand employers in scope of the Regulations, (see Annex 2), and if a survey took each employer around one hour to complete, the cost of that time for just 25% of all employers in the healthcare sector would be almost £0.3million[11]. There could also be problems identifying all relevant duty holders, and so the survey results might be biased towards the larger institutions such as hospital trusts and ambulance trusts.

16. Given that the UK is obliged to implement the Council Directive 2010/32/EU (*implementing the Framework Agreement on prevention of sharp injuries in the hospital and healthcare sector between HOSPEEM and EPSU)* this cost to the healthcare sector cannot be justified. The impact assessment evidence will not help to inform any negotiation of compliance burdens and it will not help to refine policy making or to influence Europe.

Consultation evidence

[11] Based on the gross hourly wage rate for a manager in health and social services of £21.09 per the Annual Survey of Hours and Earnings 2011. This is then grossed up by 30% to £27.42 to include the full costs of employment, such as overheads and employer tax, NIC and pension contributions.

17. HSE has collected evidence via consultation to assist with the preparation of this Impact Assessment. HSE has received 158 responses. However, many did not address the questions on costs and benefits at all and amongst those who did there is some variability. This variation in responses confirms that no one in the sector is in a position to provide robust comprehensive information about the sector as a whole. This is a consequence of the Regulations covering a range of very different duty holders in the healthcare sector.

18. Using the Annual Population Survey (APS), it has been estimated that the new Regulations will cover 1.7 million healthcare workers, the vast majority of whom work in hospital trusts[12]. HSE has therefore interviewed in depth one particular trust based in Cheshire, to corroborate our understanding of the data collected via consultation. Whilst not representative of the industry as a whole, the trust have helped explain certain standard procedures across trusts and provide their perspective on the new Regulations. Where relevant, the assumptions in this Impact Assessment are informed by the findings from this detailed interview alongside the relevant data collected at consultation.

Other evidence collected

19. HSE has examined a wealth of literature on sharps injuries to inform this Impact Assessment, please see Annex 1. The evidence includes 9 responses to a questionnaire that was sent to 50 employers in the hospital and health care sector. While this does not provide representative data that can be extrapolated across the sample, it does provide some useful information. The evidence also includes the findings from an inspection initiative in September 2011, which examined how NHS Trusts/Boards manage the risks of exposure to employees from blood borne viruses (BBV) as a consequence of sharps injuries. 22 Trusts / Boards participated, or around 5%. Again, while this is not representative, it does provide some knowledge that has helped inform HSE's understanding of the baseline.

Key uncertainties

20. Whilst data has been collected on the number of relevant care providers in the NHS[13], it is unclear whether there are additional independent care providers that are not included in the counts. Many independent GPs and dental practitioners will also perform NHS work, and so will be included within the public numbers. HSE has contacted the Scottish and Welsh Governments, as well as the Health and Social Care Information Centre, but the data they have been able to provide is mostly related to NHS services. HSE does have a robust estimate of the number of independent hospitals, and so this forms the basis of the costs to business estimates in this impact assessment and is reported separately from the total cost.

21. While there is published data on the estimated number of sharps injuries in the UK of about 100,000 per annum, there is no indication which of these injuries relate to high risk exposures, and which are from low risk or clean sharps that have not been contaminated. However, alternative literature sources indicate that the number of sero conversions following sharps injuries in the past (i.e. the number of cases that go onto acquire Hepatitis C and HIV) have been in the low tens (see paragraph 95 for more details).

[12] Of the 1.7 million workers estimated from the Annual Population Survey (APS), approximately 1million will relate to workers in hospital trusts, or nearly 60%, see paragraph 37 for more information on the data used from the APS survey.

[13] Data has been taken from the following sources: Dr Foster (www.drfoster.co.uk) ; British medical Association (www.bma.org.uk) and Information Centre NHS (www.ic.nhs.uk) ; ISDScotland (www.isdscotland.org) ; the Statistics and Analysis Unit, Welsh Government; the Care Quality Commission (www.cqc.org.uk)

Assumptions

22. It has been assumed that the healthcare sector will remain constant in size over the next 10 years. In reality, it is possible that there could be some growth or contraction in the sector over that period, but this will depend on factors which are not possible to predict with any accuracy. Consequently, it is more robust to assume there will be no change in the sector.

23. It is assumed that compliance with additional requirements will be 100%. HSE does not have any better evidence available on which to base a more reliable estimate of compliance. Based on HSE experience, compliance by hospital trusts is expected to be high given that – for example – their health and safety performance is a key element of securing discounts on insurance cover through the NHS Litigation Authority (LA)[14]. HSE does not have any information on compliance by other sectors affected, such as care homes. To estimate a level of compliance below 100% that is not founded in evidence and which would reduce the estimated costs of these Regulations is not prudent. In the absence of evidence and to ensure this Impact Assessment is completed in a prudent and conservative manner, compliance with the new regulations has been assumed to be 100%.

24. The costs to business reported in this Impact Assessment are estimates based on the percentage of total hospitals that are independent. This is because while HSE has been able to collect data on the number of independent hospitals in GB, it has not been possible to collect definitive data on the number of GPs, dentists and care homes operating independently in Great Britain (see paragraph 20). The data shows that 36% of all hospitals are operating in the independent sector. If we assume that this is representative of the healthcare industry as a whole, then we can conclude that 36% of the total costs of the new Regulations will fall to business. This estimate has been used in the Impact Assessment to report the costs to business. It is thought that this is a more prudent approach than only including hospitals in the cost to business estimates, as this is clearly understating the costs to business. However, as this is a European Directive, the UK will not count the cost to business as an IN, under ONE IN ONE OUT rules.

25. The main costs that have been monetised in the impact assessment are around information and awareness raising, the reporting of injuries, familiarisation costs and risk assessments. The assumptions within each of these different cost areas are described in the relevant sections below.

26. 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.

27. It is assumed that costs start in 2013 when the Regulations come into force. This is classed as year zero in the appraisal period given that this IA is being written at the end of 2012.

[14] There are standards set by the NHS Litigation Authority (LA), see http://www.nhsla.com/Pages/Home.aspx The NHS LA regularly assess most NHS trusts against these standards. There is a set of risk management standards for each type of trust incorporating organisational, clinical, and health and safety risks. All NHSL LA standards are divided into three incremental levels, and trusts receive a corresponding discount from their contributors to the NHS LA risk pooling schemes for demonstrating compliance with the standards assessment.

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

28. The costs and benefits of the Regulations are considered below. The relevant costs and benefits are the *additional* requirements for the UK, compared to the baseline or notional 'do nothing' option (i.e. what is the current practice in the UK), arising from the provisions of the Regulations. Costs and benefits have only been analysed for the preferred option, which is to implement the requirements of the Directive through new Regulations.
29. HSE used the consultation to try to gather more information to inform the Impact Assessment. As explained in paragraph 17, although 158 responses were received, the information provided varied significantly and so it has not been possible to fill all of the gaps that existed pre consultation. However, a full analysis of impacts has been provided, using both qualitative and quantitative information where monetisation is not possible. A full bibliography of the evidence used can be found in Annex 1.
30. The Impact Assessment has been completed by analysing in turn each of the provisions in the Regulations which are expected to have some impact on the healthcare sector.

COSTS

31. Healthcare employers already have existing duties under current health and safety law to protect their employees against the risk of a sharps injury. The new Sharps Regulations will introduce some specific new duties for:
    a. Healthcare employers to implement a small number of specific control measures
    b. Healthcare employers to provide specified training to employees
    c. Healthcare employees to report all sharps injuries to their employer along with the circumstances of the accident

    These additional measures are already currently taken in the UK where good practice guidance is being followed. The costs associated with complying with the requirements of the new Regulations are considered on a Regulation by Regulation basis.

Regulation 3 - Application of duties

32. The proposed regulations will only apply to employers, contractors and workers in the healthcare sector. NHS Trusts / Boards, independent healthcare businesses, charitable organisations and other employers whose main activity is the managing, organising and provision of healthcare will be subject to the Regulations. 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 (to the extent of the contractors control of work involving medical sharps).
33. Both categories of employers described above will have to also take responsibility for those that work under their supervision and direction (e.g. students and interns). Employers whose main activity is not the provision of healthcare, but who may never the less work with medical sharps will not fall within the scope of the regulations

(unless working on the premises of a healthcare employer who is subject to the regulations).

Number of employers

34. We do not know exactly how many employers within the hospital and healthcare sector will be affected by the legislation. To construct an estimate occupations have been identified whose workforce we already know are exposed to sharps. This has been supplemented with sourced data from the Care Quality Commission (CQC), British Medical Association, NHS Information Centre, NHS National Services Scotland and from internet searches. 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. The total numbers estimated are included in Annex 2 and are just over 40 thousand based on the most up to date estimates.

35. 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".

Number of employees / workers affected.

36. 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.

37. 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.

Regulation 4 - Use and disposal of medical sharps

38. . This provision sets out a number of areas designed to reduce the risk of a sharps injury.

a) Use of medical sharps at work should be avoided so far as is reasonably practicable.

39. This provision allows duty holders to weigh up the balance of cost and risk associated with using alternatives to sharps. It is not possible to say how many clinical areas will discontinue using sharps and adopt a different approach instead as this will depend upon the procedures performed and the availability of alternatives that are reasonably practicable.

40. However, this clause will mean that duty holders should review their risk assessments and consider the use of sharps by their employees and whether there are any alternatives to using sharps. The cost to industry of reviewing and updating risk assessments has been considered in paragraphs 83-88.

b) When medical sharps are used at work, safer sharps are used so far as is reasonably practicable.

41. The rationale for introducing safer sharps where reasonably practicable is that, together with employee training, they reduce the risk of sharps injuries and so have the potential for long-term health benefits.

42. Data on the volume of safer sharps sold in the UK[6], 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.

43. The data is less clear for independent hospitals. Evidence from questionnaires[5] sent to the hospital and healthcare sector shows that some independent hospitals might have introduced safer sharps in some areas, but not in all, but there appears to be awareness that safer sharps are available.

44. An HSE inspection initiative[4] found 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.

45. 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 is supported by the findings from the interview held with the hospital trust in Cheshire. They confirmed that safety cannulae are in common use, and are in fact now cheaper than the standard version, due to the effect of the increased demand in the market. There are other areas, for instance safer needles, which are currently about 10 times more expensive than their standard counterparts. The trust confirmed that they have already been working to introduce safer sharps where this has been practicable, and will continue to do so following the coming into force of the Regulations. The safer devices are not always welcomed by the clinicians, as they can sometimes make procedures more difficult or time consuming. However, the trust confirmed that inconvenience would not be a reason not to consider the use of safer sharps in these clinical areas. They also suggested that although they would continue to consider where safer sharps can be used in the hospital trust in the absence of the Regulations, the Regulations themselves will probably speed up the introduction of safer sharps to more clinical areas.

46. It is not possible to quantify the aggregate total cost of duty holders moving to safer sharps over time. This is because we do not know the current baseline usage of safer sharps, and cannot predict in which clinical areas they can be easily introduced and how this will differ between duty holders. Currently the price of safer sharps can be considerable compared to standard varieties, but over time if demand increases, then the price could reduce. All these variables mean any aggregate cost estimate is not possible.

47. However, a case study is provided in the literature, of one hospital trust in Scotland[7]. It is estimated that for this 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[8.]

48. 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. The Directive also allows for risk to be taken into account, and so for some duty holders, on the balance of risk the decision may be to not purchase the safer sharps.

49. 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.

c) *Needles that are medical sharps are not capped after use unless the risk of injury to employees is effectively controlled by a suitable appliance.*

50. Although this is the first time this provision appears in UK regulation, 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. The interview with the hospital trust in Cheshire has confirmed that recapping does not take place as standard practice. Some procedures in specialist areas of medicine do require a cap to be replaced on the needle for reasons of patient safety or the process itself (e.g. in radio pharmacy, aseptic pharmacy and dentistry) and this will be allowed providing it can be justified by risk assessment and suitable equipment is used to control the risk of injury.

51. This provision in the Regulations will therefore only create a cost to duty holders who must re-cap needles as part of their procedures. These duty holders will have to purchase needle blocks to hold the needle in place while the cap is replaced. There might also be some productivity effects of having to use the needle block. There is also the cost of the additional time spent undertaking each procedure. If we assume each procedure takes approximately an extra 10 seconds, the cost of this time for a pharmacist is equivalent to about 7 pence, based on the true economic cost of time for a scientist which is estimated to be around £24[15] an hour. For a dentist, the cost of each procedure is estimated to be around 10 pence, based on the true economic cost of time for a dentist which is estimated to be around £37 an hour[16].

52. While this is illustrated as a few pence per procedure, the total costs to the duty holders will depend on how many procedures are undertaken per annum. Whilst some assumptions could be made to guesstimate the number of procedures per duty holder per annum, the total number of duty holders in these sectors is also relatively uncertain, as already explained and so total costs are not quantified. However, for illustration purposes, if there were 100 procedures that required re-capping performed per day in total across the pharmacy industry then the total cost per annum would be £1.5 thousand per annum (assuming 220 working days in a year). The total cost over 10 years would be about £13 thousand. Similarly, for dentists, if there are 1,000 procedures performed per day across the whole industry, the total cost per day to the industry would be £100. This equates to £22 thousand over the course of a year or about £180 thousand over 10 years. These costs are purely illustrative as it is not possible to estimate how many of these procedures might take place each year, but the illustrations help the reader to make comparison between this requirement and the rest of the requirements included in this Impact Assessment.

d) In relation to the safe disposal of medical sharps…… a) written instructions for employees and b) clearly marked and secure containers…..are located close to areas where medical sharps are used at work

[15] Based on the gross hourly wage rate of a 'Other professional, scientific and technical activities' per the Annual Survey of Hours and Earnings (ASHE) of £18.20, grossed up by 30% to reflect the true cost of employment, including employer NICs, tax and pension contributions, plus overheads.

[16] Based on the gross hourly wage rate of a 'Dental practitioner' per AHSE 2011, of £28.33, grossed up by 30% to reflect the true costs of employment, as per footnote 4.

53. This is already covered by industry best practice and is included in national healthcare guidance.

54. So, from experience of the industry, it is assumed that this is already happening in practice. A lot of sharps containers are automatically labelled with the correct disposal instructions. Although some containers may be moved to a position much closer to the working space, this would take a matter of seconds and in fact this may already be happening in some clinical areas. The majority of additional time imposed by this requirement (ie understanding that this is a legal requirement) is probably already captured in the cost of familiarisation. Additional costs are therefore expected to be minimal. This understanding has been confirmed with the hospital trust in Cheshire, via interview. They explained that they would not have to do anything differently to comply with this regulation, and agreed that they would assume this would be the same for most other duty holders.

e) An employer must review at suitable intervals the policies and procedures in place to make sure they remain up to date and effective.

55. It is assumed that this requirement is already generally covered by the requirement to review risk assessments. While there will be some additional costs associated with reviewing risk assessments when the new regulations come into force, these are considered in paragraph 82 – 88 of this IA It is not expected there will be any additional costs as a result of this requirement apart from the risk assessment costs already captured.

Regulation 5 – Information and training

Information and awareness raising

56. Regulation 5 (1) request that employers provide all employees who are exposed to a risk of injury at work from medical sharps with the information provided in Schedule 1 of the Regulations.

57. Regulation 5 also requires that to meet the above requirements, the employer must cooperate with worker representatives in that employer's undertaking in developing and promoting this information.

58. HSE understands that some degree of information and raising awareness is already taking place and that this is a continuous process. For instance, from interviewing the hospital trust in Cheshire, it was ascertained that they already have a policy in place that covers all of the areas specified in the Regulations. It was thought maybe an hour or two would be required to check the wording of this policy corresponds to the regulations, but that nothing would have to change in practice.

59. It is likely that hospital trusts and ambulance trusts will generally be similarly prepared on this Regulation, due to the health and safety standards they are required to meet by the NHS LA. It is therefore assumed that for all the hospital trusts and ambulance trusts in the UK, between 1 and 2 hours in total will be spent reviewing the policy they will already have covering this area. Some trusts may have more than one geographical location. However, there will just be one central policy for all sites and so this estimate of 1 – 2 hours is assumed to be reasonable for all sizes of trust.

60. As per Annex 2, it has been estimated that there are 337 hospital trusts, and 14 ambulance trusts. Combining the estimated 1 – 2 hours in total per trust to review the current procedures with the true economic cost of employing a hospital and health

service manager[17], the total cost to the public healthcare sector is estimated to be **between £12 thousand and £25 thousand** (with the range reflecting +/- 10% in the assumptions to reflect the uncertainty). It is assumed that this will be a one off cost. The total cost to the private hospitals is estimated to be between £7 thousand and £13 thousand on the same basis as hospital trusts. The total cost of information provision by hospitals and ambulance trusts is therefore estimated to be between **£20 thousand and £40 thousand** one off costs.

61. If any leaflets are required to inform staff of changes then there will also be printing costs, distribution costs, and then the cost of the time for the employees in hospitals and ambulance trusts to read the information. These costs are all dependent on how many employees there are in these trusts / private hospitals and how many might need to provide this information. There are too many uncertainties to estimate any such information about distribution costs, and as noted, the hospital trust in Cheshire did not see these costs would be required for other trusts like them.

62. Smaller duty holders, such as dental practices, pharmacies, GP practices and care homes might not already be compliant, and may instead need to hold a meeting to explain the information to their staff. The content of the meeting would not have to be very detailed and so it is assumed that between 1 and 2 hours in total of time would also cover the total time spent by staff in smaller health care providers on this requirement.

63. Based on the true economic cost of time for a health and social services manager (see footnote g) plus the true economic cost of time for a worker in the field of human health and social work activities[18], the total cost has been estimated. As set out in Annex 2, it is assumed that there are nearly 9,800 GP practices, 11,500 dental surgeries, nearly 6,400 care homes and hospices and around 13.200 community pharmacies. The total cost of time to these smaller duty holders associated with information and training is estimated to be between **£1.4 million and £2.9million,** with the estimated percentage of costs falling to private duty holders between **£0.53m and £1.1m** (based on the same proportion of total hospitals that are private, being 36%)..

64. The total quantified cost of training and information provision is somewhere **between £1.5million and £2.9million,** which is a one off cost. Of this total, the cost to business are estimated to be between **£0.53m and £1.1m**. This cost does not include all costs to employees in hospitals and ambulance trusts of engaging with the information, and nor does it include and printing and dissemination costs as these cannot be estimated with any accuracy.

65. The requirement to consult safety reps is not expected to have a significant cost as engagement with safety reps is already common place, and so the marginal cost of engagement over this new information is expected to be small. The hospital trust in Cheshire confirmed this is the case for their hospital. This issue will mostly be relevant in the public sector as representation in the independent sector is quite low.

Training

66. Part (4) of Regulation 5 requires that an employer provides 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[19], to the extent they are relevant to the type of work carried out.

[17] Gross hourly wage rates per ASHE 2011 of a Health and Social Services manager of £21.09, grossed up by 30% to £27.42 to reflect the true economic cost of employment.

[18] Gross hourly wage rate per ASHE 2011 of £14.52, grossed up by 30% to £18.88 reflect the true economic cost of employing that person.

[19] Schedule 2 specifies that the training to be provided to employees includes (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.

67. Training is already a requirement under domestic legislation. However HSE understand that the new Regulations would require that some small changes may be required to the content of the training to cover the requirements of the Regulations specifically. As already mentioned, Hospital trusts and ambulance services are covered by the NHS Litigation Authority standards, where assessors will look at training records for organisations. It is therefore assumed that for these sectors, the level of training provision around sharps risk is already fairly robust, and so additional costs will be minimal.

68. It is possible there will be additional costs for the smaller independent sectors, who may not have a comprehensive training plan already in place. However, due to the variability in these duty holders and the lack of data on the current baseline compliance, it is not possible to estimate these potential costs of training.

Regulation 6 – Reporting of Injuries

69. Regulation 6 requires that employees have to report as soon as is practicable to that employer, any incident at work in which he/she has suffered an injury from a medical sharp, and must provide, when requested, sufficient information as to the circumstances of the incident to enable the employer to make the necessary arrangements (see below).

70. HSE understands from the 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). The Regulations require that any accident or incident involving sharps is reported if it required more than 7 days off work.

71. From speaking to the hospital trust in Cheshire, it was found that they do have robust reporting processes that also include the reporting of sharps injuries that pose no risk and are caused by clean needles. However, they did mention that they would not expect all trusts to have such procedures already in place for sharps injuries that pose no risk of acquiring a blood borne virus.

72. This aligns with HSE's expectation, particularly for the smaller duty holders such as GPs, dentists, care homes and pharmacies.

73. There is no baseline data to help inform the estimate of how much longer might have to be required to ensure all sharps injuries are reported. However, the data shows that there are approximately 100,000 sharps injuries in the UK per annum, see paragraph 2. If, on average, each one of these injuries leads to an additional 5 minutes of time to report it than is currently the case, then the total additional time arising from compliance with this Regulation will be around 8,300 hours, The average of 5 minutes allows for the fact that some injuries will be high risk and will already be appropriately reported (and so no additional time will be required) and that some injuries will not be reported at all and so additional time will be required to report them. Based on the true economic cost of employing a worker in the hospital and healthcare sector (assuming the time is that of the employees), see footnote h, then the total cost of this additional time is estimated to be between £130 thousand and £190 thousand per annum, with a present value over 10 years of between **£1.1million and £1.6 million.** These costs have been apportioned to business on the same basis as the proportion of total hospitals that are independent, i.e. 36%. In other words, of this total, it is estimated that the additional reporting costs to business will be between **£0.4m and £0.6m**.

Regulation 7 – Arrangements in the event of an injury

74. Proposed regulation 7 requires that where an employer is notified of an incident, that they must record it, investigate the circumstances and take any necessary precautions to prevent a recurrence. Where the injury might have exposed the employee to a biological agent, then the employer must ensure that any treatment is available, including post exposure prophylaxis and that consideration is given to providing the employee with counselling.

75. HSE understands that the majority of Hospital Trusts and Ambulance Trusts will already meet these requirements, as part of the standards set out by the NHS LA. The findings from the interview with the hospital trust in Cheshire confirmed this, and highlighted that prophylaxis and counselling are offered where the risk associated with the injuries warrants it. It is not expected there will be any additional requirements for the hospital trusts and Ambulance trusts as a consequence, especially considering there are financial consequences if the trusts do not meet the NHS LA standards.

76. There could be additional costs for GPs, dentists, care homes and pharmacists from this regulation. However, it is thought that because the duty holders in these areas are healthcare professionals, they will be well aware of the risks associated with sharps injuries already, and so would be more inclined to make sure their workers receive the care required following an injury. For example, GPs could prescribe prophylaxis drugs directly. Also, as already explained, of the estimated 1.7 million workers covered by these Regulations, over 1 million are estimated to work in hospital trusts. Consequently, if the sharps injuries were evenly distributed amongst employers, then 60% would fall in hospital trusts, for whom no additional costs are expected. It is in fact likely that the injuries are not evenly distributed, and more occur in hospital trusts where sharps are used more frequently. So, while there could be additional costs to GPS, dentists, care homes and pharmacists of this regulation, it is not expected that they will be substantial, and cannot be quantified due to the lack of baseline data in this area and the variability between and within these different employers.

Familiarisation costs

77. Familiarisation costs will only fall to duty holders. Any dissemination of additional requirements in the Regulations will be made to employees via training (which is discussed in paragraphs 65 – 67) and possibly for clinical staff via regular monthly magazines and union communications. There will be no marginal cost of these employees reading about the sharps information compared to the other updates that they will be receiving at the same time. Thus, HSE has assumed that there will only be familiarisation costs for duty holders.

78. The familiarisation 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.

79. 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. Consultation responses were mixed about this assumption. 60% said they disagreed with the assumption of 5 – 10 staff undertaking familiarisation, but 17% also said that this was not something they could comment on. Those that disagreed provided no alternative estimate that would be more appropriate. In addition, the hospital trust in Cheshire, to whom the concept of familiarisation was explained fully, agreed that for most hospital trusts like them, 5 – 10 people would be assigned the task of understanding the regulations in depth and performing a gap analysis. They emphasised the

need for this to be just a small team of people so that some ownership of understanding the Regulations is achieved. In the absence of better data, the assumption of 5 – 10 people per hospital trust and ambulance trust has been used in this impact assessment.

80. For GPs, Dental surgeries, care homes and community pharmacies, it is assumed that there is just one person designated to health and safety, and so only one person would be responsible for the main familiarisation with the new regulations and guidance. The responses from consultation were that 19% agreed with this assumption, while 52% said it was not something they could comment on. 29% disagreed, but provided no better alternative estimates. So in the absence of anything more appropriate and because HSE understanding indicates this is reasonable, it is assumed that one person in each GP surgery, dental practice, care home and community pharmacy will undertake an in depth understanding of the regulations.

81. Using the estimated numbers of these different duty holders from Annex 2, it is calculated that in total there could be about 43 – 44 thousand 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.

82. 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. This estimate was supported at consultation and by the hospital trust in Cheshire. Applying the appropriate and adjusted hourly wage rates from ASHE 2011[20], the total cost of the time spent on familiarisation is estimated to be between **£1.5 million and £4.6 million.** This is the one off cost 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. For any that do, the marginal cost of understanding the sharps regulations compared to the cost of all the other regulations they will face will be minimal. The one off cost of familiarisation to business (estimated based on the same % of hospitals that are independent, i.e. 36%) is estimated to be between **£0.53m and £1.7m.**

Existing Duties that will require attention following the coming into force of the Regulations

Risk Assessment

83. It is already a requirement in UK law for employers to undertake a risk assessment under COSHH.[21] . An HSE inspection initiative designed to collect baseline data on current practice around sharps risk[5] 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.

84. The Directive requires that risk assessments should specifically take account of the risk from sharps injuries, and so it is likely that many healthcare employers will have to update their risk assessments.

85. All employers in the healthcare sectors will have to review their risk assessments in order to ascertain whether they are in compliance with the proposed regulations. Healthcare employers are already required by COSHH to regularly review risk assessments, so whilst there will be a

[20] 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)

cost associated with a specific review relating to sharps, the systems for carrying out such a review should already be established. As explained above, HSE has access to data for the estimated number of employers in the public healthcare sector (and independent 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. Some hospital trusts / ambulance trusts cover more than one geographical location. However, it is understood from discussions with the hospital trust in Cheshire that each trust will have central risk assessments, and the number of risk assessments is not a function of the number of sites.

86. Pre consultation, HSE's best estimate was 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. Evidence received at consultation has generally supported these assumptions. 94% of respondents agreed that all risk assessment would have to be reviewed; 58% agreed that for hospital trusts and ambulance trusts this could take between 2 and 3 hours. 62% agreed with the estimate of 0.5 hours to 1 hour for other sectors. Speaking with the hospital trust in Cheshire showed that for some trusts, the review process would be longer, which might depend on how many risk assessments they currently have. However, because this question was well responded to at consultation, (93 responses) and the majority agree with the assumptions made, then the estimates consulted on have been used in the cost calculations.

87. It is also likely that changes will have to be made to the risk assessments following the review. At consultation, 63% of respondees thought that it would take less than 10 hours to make these changes to all risk assessments, with 27% of those respondents assuming between 3 – 10 hours and 20% less than 1 hour. Based on this evidence, the weighted average response below 10 hours is around 4 hours. Allowing +/- 10% for uncertainty, the time taken to update risk assessments is estimated to take between 3 and 4 hours per employer. The total time associated with reviewing and updating risk assessments for hospital trusts and ambulance trusts will be between 5.and 7hours, and for other sectors between 4 and 5 hours. From speaking with the hospital trust in Cheshire, it is evident that the update of some of the risk assessments might just require changing the wording of the assessments, to be in line with the new Regulations. If this is the case, then the estimate of 3 – 4 hours may be an over estimate. However, as noted in paragraph 85, for some of the larger trusts, the estimate of 2 – 3 hours to review risk assessments might be a slight under estimate, based on the interview with the hospital in Cheshire. These effects are likely to cancel each other out, and so the estimated total time of 5 – 7 hours and 4 – 5 hours for Hospital Trusts / Ambulance Trusts and other healthcare providers respectively, is thought to be reasonable.

88. Using the cost of time assumptions outlined in footnote k, the total cost of reviewing the risk assessments is estimated to have a present value of between **£5.2 and £6.8 million** (assuming the review of risk assessment takes place in the first year of the appraisal period). The cost to business is estimated to be between around £1.9m and £2.5m, based on the assumption that private healthcare makes up about 36% of the total, based on the proportion of total hospitals that are operated independently.

Overall costs of Option 1

89. 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. The costs are targeted at the minimum numbers affected and the clarity of what is involved should ensure greater consistency across the sector.

90. 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 proposed Health and Safety (Sharp Instruments in Healthcare) Regulations 2013

Legislative requirement	Changes required	*Total cost*
Regulation 4 – safer sharps	When medical sharps are used at work, safer sharps are used so far as is reasonably practicable	*The increase in safer sharps use will depend on the current level of use, whether clinical procedures can be adapted to use the safer sharps, and the price of the safer sharps. There is too much uncertainty in these variables to predict the cost of this requirement.*
Regulation 4 – Re-capping of needles	Needles that are medical sharps are not capped after use unless the risk of injury to the employees is effectively controlled by a suitable appliance	*There could be some costs to specific duty holders, such as dentists and pharmacists (radio and aseptic). However, the cost will depend on how many times the procedures requiring recapping are performed per annum and this cannot be estimated with any accuracy.*
Regulation 5, Information provision	Providing information to employees on the risks from sharps	*About **£2.2million** in total one off costs (estimated about £0.8m falling to businesss).*
Regulation 5 - Training	An employer provides 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 the Regulations.	*Additional training costs cannot be quantified due to variability in the extent of additional action required to meet the new requirements*
Regulation 6 – reporting of injuries	All sharps injuries must be reported, not just those that are thought to be high risk	*About **£1.4million** in total over 10 years, equivalent annual cost of £0.16m. Estimated cost to business around £0.5m.*
Regulation 7 – **Arrangements in the event of injury**	Requiring employers to record injuries investigate and then to take necessary steps to prevent a recurrence.	*Small costs possible for smaller sectors but cannot be quantified*

Familiarisation	There will, be a cost of the time employers spend understanding their requirements in the new Regulations	*One off cost estimated to be about* ***£3m*** *(estimated costs of £1.1m falling to business).*
Existing Duties – risk assessment)	Under COSHH employers will be required to review their risk assessments as a result of the new Regulations, and update / produce new assessments	*One off cost estimated to be about* ***£6million****.(estimated costs of £2.2m falling to business.*
	.	
TOTAL ESTIMATED COSTS		***£13 MILLION TOTAL COSTS OVER A TEN YEAR PERIOD****, WITH ONE OFF COSTS OF AROUND £11MILLION.* *OF WHICH £4.6M OF TOTAL FALLS TO BUSINESS.*

BENEFITS

91. 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, information, awareness raising and monitoring

92. 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 health care 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

93. The best estimate of the number of sharps injuries sustained per annum is around 100,000 per annum.[1] This estimate would cover all injuries not just those which had a risk of seroconversion.

94. However, this is an estimate, and is not based on robust statistical analysis. This is partly due to the fact that some sharps injuries are not reported, particularly if the victim thinks it has come from a low risk source. There is an existing requirement under RIDDOR for employers to report all sharps injuries that result in an employee being off work for more than 7 consecutive days to HSE. However, most sharps injuries will not result in sickness absence and thus will not be reportable under RIDDOR rendering it incomplete as a reliable data source. 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.

95. For instance, between 1997 and 2007 there were 14 reported Hepatitis C seroconversions in healthcare workers in the UK [9]. 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[9].

Cost of injuries

96. 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.

97. 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.

98. 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.

99. HSE has estimated the cost of a reportable injury to be about £18,000 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 £12,000 of the cost).[22] 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.

100. 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 way of estimating ex ante how many injuries might be avoided as a result of the Directive.

Risk Reduction

[22] HSE cost estimates in 2010/11 prices, see http://www.hse.gov.uk/statistics/pdf/cost-to-britain.pdf

101. The proposed Regulations will introduce measures that should directly reduce risk: namely protection measures (such as safer sharps and ban on recapping) plus, information and awareness raising, training, reporting and response and follow-up.

102. 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 Regulations. However, there are areas where UK duty holders will have to take action, specifically reviewing 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.

103. For instance, research[10] 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.

104. The hospital trust in Cheshire agreed that the introduction of new legislation relating to sharps may not change much in practice at first, but it will focus minds on sharps, and will ensure that when resources are prioritised, that this area of health and safety is not overlooked. This will likely have some effect on risk of sharps injuries, but it is not possible to predict how quickly or by how much the risk of an injury might decrease over time.

105. As noted, these outcomes are expected as a result of the proposed Regulations, 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.

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. As explained in paragraph 14, a wide ranging survey could cost industry around £0.3million.

107. HSE asked a number of questions at consultation about the impact assessment and potential costs and benefits of the Regulations. However, although 158 responses were received these showed some variation which reflects the wide variety of different healthcare providers the regulations will cover. The evidence was corroborated with one hospital trust in Cheshire. This took up at least 10 hours of their time (4 members of staff) and so to repeat this process across more trusts would place a not inconsiderate burden on the sector and could not be representative without repeating a large number of times requiring hundreds of hours of time. There is a lot of evidence available to HSE that is specific to different parts of the sectors, or is illustrative, but due to the nature of the sectors, and the fact the baseline is not clear, it is not possible to extrapolate this information across the board in many cases.

108. All impacts have been described and monetised where possible. Given that the UK is obliged to implement the requirements of the Directive 2010/32/EU and the level of analysis has been sufficient to show that the option to introduce new Regulations ensures impacts are minimised, no further data collection is proposed.,

Direct costs and benefits to business calculations (following OIOO methodology)

109. 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.

110. The total cost to business has been estimated as around £4.6 million over 10 years, or Equivalent Annual Net Cost to Business of around £0.53m. .The cost to business is an estimate, based on the percentage of total hospitals that are independent (36%) which is used as a proxy for the total independent healthcare sector, in the absence of more specific information.

111. The total cost of the Regulations have been estimated to be around £13million over 10 years, with equivalent annual cost of around £1.5million.

Wider Impacts

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

Economic / Financial

Competition

113. Competition is not relevant to the UK public sector, which is one of the main sectors that the Regulations 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

114. HSE does not have a full profile of the private healthcare sector and so does not have robust information on what proportion of this sector is made up of small firms.

115. 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. HSE anticipates that there will be a high proportion of micro businesses in the private sector due to the nature of private dental practices, private GPs and private care homes. The total costs of the Regulations are estimated to be around £13million in this IA. According to Annex 2, there are just over 40 thousand services identified. Thus, the total costs per service are estimated to be about £307 over the 10 year appraisal period. Generally, the costs should be related to the size of the service too, so will be larger for the big hospital trusts than for GP practices. The average illustrates the maximum likely costs for the small businesses however.

Wider Environmental Issues

116. This is intended as 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.

117. 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.

118. 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.

119. It is not expected that there will be any other significant environmental impacts from the Directive.

Health and well being

120. 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.

121. 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

122. HSE's preferred option is to implement the Directive using the Regulations which follow the wording of the Directive where possible. Total costs are estimated to be around £13m over 10 years.

123. It is intended that HSE will produce guidance for the new Regulations and will embark on a small awareness raising campaign with industry. This has already involved participating in a number of events designed to publicise the new Regulations and to assist duty holders in understanding how to comply with the new requirements. There have also been a number of articles published in relevant trade journals. The HSE website has been updated to provide an introduction to and overview of the new Regulations. HSE has also been engaging with a number of key stakeholders to ensure interested parties are informed about the proposed regulations. HSE expects this promotional work to continue in the lead up to implementation in May 2013.

124. Enforcement of the new Regulations will form part of HSE's normal inspection work and reactive investigations. The extra costs of any additional time spent inspecting compliance with the requirements under these is expected to be quite small and, where material breaches in the law have been identified, these costs will be covered by HSE's cost recovery scheme.

Annexes

Annex 1: Bibliography

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

1. Saia M, Hofmann F, Sharman J, Abiteboul D, Campins M, Burkowitz J, Choe Y, Kavanagh S. Needlestick Injuries: Incidence and Cost in the United States, United Kingdom, Germany, France, Italy, and Spain. Biomedicine International (2010) 1: 41-49
2. HOSPEEM – EPSU joint clarification of the Framework agreement on prevention from sharp injuries in the hospital and healthcare sector. (http://register.consilium.europa.eu/pdf/en/10/st06/st06179.en10.pdf)
3. Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU. (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:134:0066:0072:EN:PDF)
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 on the grounds of proportionality
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.
6. Data on volume of safer sharps sold in the UK, provided by the NHS Suppliers on the purchase / supply of safety and non-safety devices between 2003 and 2011. www.nhsemployers.org
7. Paterson, C and Elder A.G. ; Safer Sharps Devices. An evaluation of Utility in NHS Scotland. A report for the Occupational Health and Safety Strategy Implementation Group, NHS Scotland. Sales Occupational Health Safety Service. NHS Lanarkshire.
8. Needlestick injury in 2008. Results from a survey of RCN members. Royal College of Nursing, 2008. http://www.rcn.org.uk/support/the_working_environment/health_and_safety/?a=203362
9. Eye of the Needle. United Kingdom Surveillance of Significant Occupational Exposure to Bloodborne Viruses in Healthcare Workers. November 2008
10. An evaluation by the Health and Safety Laboratory (HSL) into the efficacy of safer sharps. “Systematic Review – An evaluation of the efficacy of safer sharps devices,” 2011.

Annex 2: Estimated numbers of employers

The following are the estimated numbers of employers in the hospital and healthcare sector.

- HOSPITALS[(a)] : 337 hospital trusts in England, Scotland and Wales
- GP PRACTICES[(b)]: 9754 in England, Scotland and Wales
- DENTAL SURGERIES[(c)]: 11,531 in England and Scotland only – data for Wales is available for registered dentists only and so has had to be excluded from the analysis.
- AMBULANCE SERVICES[(d)]: 14 in England, Scotland and Wales
- CARE HOMES AND HOSPICES[(e)]: 6.355 in England and Scotland only
- COMMUNITY PHARMACIES[(f)] : 13.188 in England, Scotland and Wales
- INDEPENDENT HOSPITALS: 192

(a) – www.drfosterhealth.co.uk
(b) – www.bma.org.uk British Medical Association (2010) and Information Centre NHS (2009)
(c) - Dentists registered with the Care Quality Commission www.cqc.org.uk and NHS National Services Scotland www.isdscotland.org (2012)
(d) – 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)
(f) -NHS National Services Scotland ww.isdscotland.org (2012); Welsh Government statistical service; and Information Centre NHS (2012)

PART II

NORTHERN IRELAND COSTS AND BENEFITS

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

General

1. The Department of Enterprise, Trade and Investment is of the opinion that the analysis and considerations set out in the Great Britain Impact Assessment can be applied proportionately to Northern Ireland.

Costs

2. Based on the Great Britain impact assessment, the cost to Northern Ireland dutyholders is anticipated to be £325,000 over a 10 year period.

3. The total cost to private business in Northern Ireland is estimated as £115,000 over a ten year period. However, in practice, the costs to private business are likely to be significantly less, possibly as little as £29,250 based on the proportionately fewer number of independent hospitals relative to Trust hospitals in Northern Ireland than Great Britain.

4. The main costs to dutyholders are around information and awareness raising, the reporting of injuries, familiarisation costs and risk assessments.

Benefits

5. The implementation of the Directive will deliver benefits in terms of its aim to reduce the risk of injuries from sharps and all the risks associated with this type of accident. It has not been possible to monetise the benefits of the Sharps Directive.

6. The Regulations contribute to full implementation of EU Council Directive 2010/32/EU, thus avoiding the risk of infraction proceedings with the potential for significant financial penalties.

Conclusion

7. In the absence of any non legislative option the Regulations ensure the effective implementation of EU Directive 2010/32/EU implementing the Framework Agreement on prevention of sharp injuries in the hospital and healthcare sector between the European Hospital and Healthcare Employers' Association and the European Federation of Public Service Unions.