EXPLANATORY MEMORANDUM TO

THE HEALTH AND SAFETY (SHARP INSTRUMENTS IN HEALTHCARE) REGULATIONS

2013 No. 645

1. This explanatory memorandum has been prepared by the Health and Safety Executive (HSE) on behalf of the Department for Work and Pensions and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

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. Matters of special interest to the Joint Committee on Statutory Instruments

The Instrument is being laid with more than 21 days until it comes into force on the 11th May 2013, but within 21 days of the Easter recess. A query from the final cabinet committee clearances about costs falling on the NHS meant a slight delay and we were unable to lay sufficiently early in March to allow a clear 21 day run up to the Easter recess. The recent change to the House of Lords recess dates mean it is not now possible to lay after the recess, allow the 21 days, and still meet the the 11th May deadline imposed by the Directive.

4. Legislative Context

4.1 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.

4.2 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. This is not a commonly used procedure for adopting EU legislation. It is not subject to the usual parliamentary scrutiny. A scrutiny history is attached as Appendix 1.

4.3 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 Appendix 2.

5. Territorial Extent and Application

This instrument applies to Great Britain.

6. European Convention on Human Rights

As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- **What is being done and why**

7.1 The Health and Safety at Work etc Act 1974 (the Act) aims to secure the health, safety and welfare of persons at work, and a body of existing Regulations made under the Act 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 (European Hospital and Healthcare Employers' Association) and EPSU (European Federation of Public Service Unions) set out a package of measures to protect workers in the healthcare sector from the risks of sharps injuries.

7.2 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. 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.

7.3 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.

7.4 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.

7.6 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.

7.7 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. The Regulations have been prepared in accordance with the principles set out in Government's guidance for implementing European legislation.

- **Consolidation**

7.8 This Instrument does not amend another Instrument and consolidation is not required.

8. Consultation outcome

8.1 HSE consulted on the proposal for new Regulations over a 3 month period between 8th August and 8th November 2012. The consultation was targeted at healthcare employers, workers and other interested stakeholders. We particularly sought views from non-NHS healthcare employers and from across GB. The consultation sought views on:

- Whether the proposed regulations enable healthcare businesses and workers to identify what they need to do.
- How the regulations should be supported by guidance and who is best placed to provide that guidance.
- The initial assessment of the costs and benefits of the proposed changes.

8.2 HSE received 158 formal responses to the consultation. The majority indicated that it was clear what action was required by the Regulations, but see below for three issues that were raised. Many respondents chose to provide a narrative response to the consultation, rather than answering the questions posed in the consultative document, therefore it is not possible to provide a simple numerical analysis of the responses.

8.3 The main issues raised were:

a) Around half of the respondents commented that the Regulations do not address the risk of a sharps injury to workers outside the healthcare sector (eg housing and parks maintenance). However, the Directive only applies to the healthcare sector and the application of the Regulations reflects that. HSE'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.

b) There were three issues where respondents raised a concern on the basis that it was not clear what was required:

(i) The greatest number of responses (about one third) came from individual healthcare specialists in Radiopharmacy, Nuclear Medicine and Aseptic Pharmacy and their representative bodies. They were concerned that a ban on recapping of needles would cause unintended consequences to patient safety. While this objection was largely based on the requirement as it was worded in the Directive, HSE has responded by redrafting the Regulation to clarify that recapping is allowed where it is necessary to control a risk (including a risk to patient safety), but only where suitable safety equipment is used to control the risk of injury.

(ii) Some respondents wanted to see additional measures from the Directive included as duties in these Regulations (eg for employers to do a risk assessment, or to consult with their employees), arguing that it would be clearer if all relevant requirements were in one place. HSE's view is that existing health and safety legislation implements these requirements of the Directive. To include them in these Regulations would unnecessarily duplicate and potentially lead to greater confusion. The HSE guidance on the new Regulations will refer to the existing requirements, where appropriate.

(iii) A number of responses from trade unions did not want the duty on healthcare employees to notify sharps injuries to their employer (Regulation 8), arguing it would detract from the duty of the employer to have procedures for dealing with an injury (Regulation 7). On the other hand, some respondents welcomed this requirement as they are responsible for investigating such accidents and had experience of accidents not being promptly notified (if at all). As this requirement is specified in the Directive, we have to include it in the Regulations. HSE has responded by redrafting the relevant regulation to clarify the employer's arrangements for recording and investigating sharps injuries and its relationship with the employee's duty to notify such accidents.

8.4 A clear majority (88%) agreed with HSE's proposal to build guidance on these Regulations into its existing guidance material. We received some specific examples where clarification in guidance will be helpful (eg on who the Regulations will and will not apply to) and these will be addressed in HSE's generic guidance. We also received some queries about what would be required to adequately control the risk of a sharps injury for specific medical procedures. In these cases, we will work with the appropriate specialist body for those practitioners to ensure they produce guidance. See below for HSE's proposals for guidance.

8.5 The consultation also sought information to improve the data in the impact assessment. A few respondents were able to provide new data, which was used to inform the analysis of the impact on non-NHS healthcare businesses.

8.6 A summary report on the consultation is available on HSE's website.

9. Guidance

The legislation is relatively clear as to what is required. HSE will provide a free Information Sheet on how to comply with the Regulations on its HSE website, well in advance of the regulations coming into force on 11th May 2013. This will complement the existing HSE guidance on effective management of risks from sharps injuries and blood-borne viruses. HSE is working with organisations in the healthcare sector to provide information and awareness-raising events for employers and workers in the healthcare sector on the requirements of the new Regulations. We will also

work with specialist bodies where guidance on specific risk control measures for particular medical procedures is required.

10. Impact

10.1 HSE's final stage impact assessment concluded:
- the total cost to the public, private and voluntary sectors of introducing the Regulations is estimated as £13 million over a ten year period;
- the total cost to private business is estimated as £4.6 million over a ten year period:
- which is equivalent to an annual cost to private business of £0.5 million per year.
The main costs to employers in the healthcare sector were identified as reviewing existing risk assessments concerning sharps and the additional cost of purchasing sharps that incorporate safety devices.

10.2 The Regulatory Policy Committee approved the Final Stage Impact Assessment in January 2013. It will be published in the Department for Business, Innovation and Skills Impact Assessment Library and on www.legislation.gov.uk

11 Regulating small business

11.1 The legislation applies to small business. Small businesses cannot be exempted as they are not exempt from the directive.

11.2 HSE has a Public Service Sector Strategy 2012-15, which sets out our strategic regulatory approach in this sector and the priorities for action. This includes working with co-regulators and key stakeholders to provide leadership and guidance for smaller healthcare businesses, and using targeted HSE interventions where intelligence indicates evidence of poor performance.

11.3 HSE included representatives of small healthcare businesses (predominantly care homes and dentists) in those invited to respond to the consultation. Those that responded, did not indicate specific issues for small firms, other than that they are less likely to be aware of the requirements for change. HSE is contacting these bodies to see if we can better raise awareness of our guidance.

12 Monitoring & review

While the aim of the Regulations is to reduce the number of sharps injuries in the healthcare sector, it was not possible to differentiate the likely impact of these Regulations from generally improving risk control, new technologies and other changes that are ongoing. Therefore, while a reduction in injuries remains a significant success criterion, we will also wish to evaluate how useful businesses have found HSE's guidance on this issue. In line with the Government's Guiding Principles for EU legislation, the Regulations include a statutory requirement on the Secretary of State to review the Regulations every 5 years, in light of how they have been implemented in other member states and against the intended objective to reduce sharps injuries.

13. Contact

Anna Bliss at the Health and Safety Executive, Tel: 0151 951 3581 or email: anna.bliss@hse.gsi.gov.uk, is the initial point of contact for queries regarding the instrument.

14. List of Appendices

Appendix 1 – Scrutiny History
Appendix 2 – Transposition Note

Appendix 1

SCRUTINY HISTORY

1. Directive 2010/32/EU was the subject of a proposal for a Council Directive 15305/09 and was considered by EU Sub-Committee G (Social Policy and Consumer Affairs) by correspondence and cleared at its meeting of 25th February 2010.

2. House of Commons European Scrutiny Committee considered proposal 15305/09 at its meeting of 25th November 2009 and they asked for further information on the legal base of the proposal. The Committee received a reply from the Minster for Employment and cleared the proposal on 9th February 2010.

Appendix 2

TRANSPOSITION NOTE

Transposition Note

Transposition note for the partial implementation of 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 ("the Directive"). In transposing the Directive, the HOSPEEM-EPSU joint clarification of the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector ("the Social Partners' Clarification") has been taken into account and is referenced where relevant.

The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 do what is necessary to implement only the following parts of the Directive (other aspects of the Directive requiring transposition are implemented by existing legislation):

Article[1]	Purpose	Implementation	Responsibility
Annex Clause 2	Applies the agreement to all workers and persons under the supervision and direction of employers in the healthcare and hospital sector.[2]	Regulation 3 & 4	Secretary of State
Annex Clause 6	Requires specific risk control measures, including banning the re-capping of needles[3] and providing appropriate training.	Regulations 5 & 6 and Schedules 1 & 2	Secretary of State
Annex Clause 7	Requires the provision of information on sharps and specifies the content.	Regulation 6 and Schedule 1	Secretary of State
Annex Clause 8	Requires that employers provide training on sharps and specifies the content.	Regulation 6 and Schedule 2	Secretary of State
Annex Clause 9	Requires that workers report accidents involving sharps to the employer.	Regulation 8	Secretary of State
Annex Clause 10	Requires employers to have sharp injury response procedures in place and ensure workers are aware of them.	Regulations 6 & 7 and Schedule 1	Secretary of State

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

[2] See also Clause 3 of the Directive (Definitions) and the Social Partners' Clarification.

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