A report on HSE’s consultation on proposals to implement European Directive 2010/32/EU on preventing sharps injuries in the hospital and healthcare sector.

Introduction

1. This report summarises the information that HSE received in response to its statutory consultation on proposals to implement the Council Directive 2010/32/EU on preventing sharps injuries in the hospital and healthcare sector. This report is intended to be read in conjunction with Consultation Document CD244, which can be found on the HSE website (http://www.hse.gov.uk/consult/condocs/cd244.htm).

2. HSE’s proposal is to introduce new Regulations, provisionally called the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013, to implement those parts of the Directive that are not already covered by existing health and safety law, to come into force on 11th May 2013.

3. The public consultation was carried out to obtain 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

Consultation

4. This consultation was open for a 3 month period between 8th August and 8th November 2012. HSE sent out 128 copies of the Consultative Document CD244 when the consultation opened. The Consultation was also widely promoted by HSE and through several partner stakeholder organisations. Respondents were asked to complete an
online questionnaire or to download and complete a response template and return this via email or by post.

5. HSE received a total of 158 responses to this consultation. A list of organisations that responded is listed at Annex 1\(^1\). The breakdown of those providing responses to this consultation is set out in Annex 2.

6. Many respondents chose to provide a narrative response rather than providing direct answers to the questions posed in the Consultative Document. As a result, a simple numerical analysis of the responses alone does not provide a complete picture of all the issues raised during consultation. This report presents

- A summary of the key issues that stakeholders raised in their narrative responses and the HSE response.
- A numerical analysis of the responses to specific questions (see Annex 3).

**Key issues from the consultation**

**Definition of ‘medical sharps’**

7. Most respondents agreed that the use of the term medical sharps is consistent with how it is commonly used by employers and workers in the healthcare sector.

8. However, a significant number answered this question to argue that the regulations should not apply to ‘clean’ sharps or sharps that have not been used on a patient, where there is no risk of an infection.

_HSE response_

9. The Directive applies to the risk of sharps injuries whether or not the needle is clean/sterilised, therefore we cannot exclude clean needles. Respondents primarily raised this issue in the context of the requirement to not recap such needles. See below for further comments on the recapping of needles.

**Application of the proposed Regulations**

10. HSE asked for examples of healthcare activities using medical sharps where the application of the proposed regulations could usefully be

\(^1\) Where a response appeared to be from an individual, the organisation for which they work has not been listed. Some respondents specifically requested that their replies were treated in confidence, these respondents are also not listed.
clarified. The Royal College of Nursing (RCN) and the Trade Union Congress (TUC) expressed concern that the proposed Regulations would not apply to some healthcare workers if their employer’s primary business was not the managing, organising and provision of healthcare. The examples they gave were service companies providing outsourced services to the healthcare sector, clinical trials in the pharmaceutical industry and retail pharmacies providing immunisations (e.g. flu jabs). The TUC stated that “If implemented in their present form, the regulations will give different levels of protection for healthcare workers to other workers who will face exactly the same risks”.

11. Some respondents argued that the regulations should be broadened to cover workers in other industry sectors who could also be exposed to the risk of a sharps injury, e.g. waste and recycling, railways, building maintenance, independent schools, prisons and police. For example, the All-Party Parliamentary Group on Occupational Health & Safety stated that, “The definition of medical sharps needs to be widened to include all sharps, regardless of whether used in a clinical setting. The current narrow application of the directive is a missed opportunity to genuinely deal with this problem across all sectors where sharps are a health issue. Workers outside the health care sector should be included”. Other respondents expressed similar concerns, including the Safer Needles Network (SNN), several Trade Unions and the Institute for Occupational Safety and Health.

12. The British Veterinary Association did not agree with extending the application of the Regulations, arguing that the risks of exposure to a blood borne virus from a used sharp in veterinary practice were far lower than in human healthcare. They stated that the proposed regulations should not apply to their sector. One Recycling and Waste Authority, whilst acknowledging that the regulations would not directly apply to their sector, stated they expected to see a reduction in the inappropriate disposal of sharps thus reducing the risk of a sharps injury to workers in their sector.

_HSE response_
13. The source Directive clearly applies only to the hospital and healthcare sector. Existing legislation already requires many of the measures in the Directive, so that workers outside of healthcare are not unprotected from risks of sharps injuries at work. It is not clear that the specific measures required by this set of regulations are relevant to other industry sectors. An extension to cover other sectors would represent an additional domestic measure and the government’s policy is not to over-implement European directives. Therefore we propose to retain the application of the Regulations as proposed in the Consultation.

14. The point made by the RCN and TUC concerning the application of the Regulations to healthcare workers working for employers whose main activity is not healthcare provides some examples where HSE can usefully clarify in our guidance who will and who will not be covered.

Clarity of what the Regulations require

15. The consultation asked whether it was clear what the proposed Regulations would require of employers and employees. Responses addressed the following issues:

a) Risk assessment

16. The Partnership for Occupational Safety and Health in Healthcare (POSHH) and the Royal College of Nursing (RCN) raised that the duty to risk assess before going to risk control measures is missing from the Regulations, which they were concerned will add to confusion and a possible disproportionate approach. They both suggested that this meant that at least the guidance should pull together the various strands of the existing and new regulations.

HSE response

17. Healthcare employers already have a legal duty under existing legislation\(^2\) to carry out a suitable and sufficient assessment of the risks posed by sharps. Repeating this requirement in the draft Regulations would qualify as “double banking” and would go against the Government’s policy on transposing European Directives. See below for further comments on HSE’s proposals for guidance.

\(^2\) Control of Substances Hazardous to Health Regulations 2002 (as amended) and The Management of Health and Safety at Work Regulations 1999 (as amended).
b) Selection of safer sharps - consultation with worker representatives

18. One of the principles on which the source Directive is based is that “Employers and workers’ representatives shall work together at the appropriate level to eliminate and prevent risks, protect workers’ health and safety, and create a safe working environment, including consultation on the choice and use of safe equipment, identifying how best to carry out training, information and awareness-raising processes” (Clause 4(7)). Several respondents commented on similar lines to the Unison response, which stated, “The role of worker representatives envisaged in the Directive goes far beyond that outlined in the draft regulations. The draft regulations should make reference to the requirement to involve workers’ representatives in the “consultation on the choice and use of safe equipment”.

HSE response

19. The existing legislation on worker consultation requires all employers to consult with their employee representatives when introducing safer sharps (including the planning thereof). HSE is averse to including this specific requirement in these new Regulations as it may imply that consultation is not required in the majority of other health and safety legislation where there is no specific requirement for consultation. Inserting a specific requirement in the Regulations would create a double requirement for the same thing and this would be potentially confusing for duty holders and against the Government’s policy for implementing European Directives.

20. We have included a requirement that the employer must “cooperate with worker representatives in that employer’s undertaking in developing and promoting the information specified in Schedule 1” (which is included explicitly in Clause 7 of the Directive, and transposed

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3 Safety Representatives and Safety Committees Regulations 1977, Regulation 4A (as amended) and Health and Safety (Consultation with Employees Regulations 1996, Regulation 3 (as amended).
into Regulation 5(1)). HSE’s view was that the existing regulations do not cover the activity as it is described in the Directive, and we may under-implement the Directive if we did not include this.

c) Recapping of needles

21. The recapping of needles by hand after use is a well-recognised cause of sharps injuries in the healthcare sector. The source Directive required that “the practice of recapping of needles shall be banned with immediate effect”. The Social Partners subsequently issued a clarification statement that indicated, “The practice of recapping refers to needles without safety and protection mechanisms”.

22. There were 55 responses to the consultation from organisations and individual practitioners in the specialist areas of Aseptic Pharmacy, Nuclear Medicine and Radiopharmacy. This represents 33.5% of all responses received to this consultation. The clear majority of these responses stated that their primary concern was that a complete ban on the recapping of needles in their area of practice would have serious unintended consequences for patient safety. The aseptic processes involve mixing (compounding) sterile products to make a sterile medicine ready for administration to a patient (many of whom will be immuno-suppressed and vulnerable to infection). These processes are conducted in specialist clean rooms and recapping (re-sheathing) needles is common practice to prevent microbiological contamination of the product (and therefore protect patients) and also to prevent chemical contamination of the work surface which may contaminate other products, eg with cytotoxic agents, or may harm the operator, eg radiation. Some of these responses reported that they had successfully introduced recapping devices to allow safe one-handed recapping (sometimes known as needle cap blocks). However, some said they had concerns about the effect of using such blocks on the efficiency of production of such medicines (and therefore the cost).

23. On the other hand, several respondents (including TUC, POSHH and Unison) stated, “The draft regulations [on recapping] appear to fall below the requirements of the Directive”. The RCN observed, “We understand the difficulties in some areas of clinical practice with an
absolute ban on all recapping and support a pragmatic solution to this problem. However we would not want the regulations to be read by some as a reason for recapping due to custom and practice or resistance to change or on cost grounds”

HSE response

24. In light of the comments made, HSE will consider if Regulation 4(1)(c) can be redrafted to clarify that recapping is only to be used where it is necessary to control a risk (which will include risk to patient safety); in addition to retaining the requirement in the draft for the risk to employees to be controlled by a suitable appliance, tool or equipment. This will allow pharmacists etc to carry out the necessary procedures to prepare medicines. However, they will need to review how they currently recap needles and ensure that suitable risk control measures are in place.

d) Reporting of sharps injuries

24. The draft Regulation 6 requires healthcare employees to report all sharps injuries to their employer and to provide their employer with information about the circumstances of their accident.

25. Several respondents, including the TUC, Unite, Unison, SNN, Society of Radiographers and RCN, expressed concerns about this duty. Most stated that they accepted that employees have a responsibility to report sharps injuries but argued that the overall management of health and safety is the responsibility of their employer. SNN stated that this duty on employees “may lead to confusion as to who is responsible for health and safety in the workplace” and referred to the principle referred to in Clause 4(11) to promote a “no blame culture”.

26. A few respondents commented that they saw the requirement to alert the employer to a sharps injury as being a positive measure, as it allows them to take action in response to prevent a recurrence and to provide the injured employee with post-exposure prophylaxis and counselling where appropriate.

HSE response

27. Clause 9(2) of the source Directive is clear in specifying that “Workers shall immediately report any incident or accident involving sharps to the
employer…” and the second bullet point in Clause 10 that “The worker must provide the relevant information at the appropriate time to complete the details of the accident or incident”. HSE’s view is that to remove the specific requirement for employees to report sharps injuries would result in under-implementation the Directive. Therefore, we propose to retain the requirement for employees to report sharps injuries as proposed in the Consultation, but will consider if it can be more clearly linked with the employer’s responsibilities to record, investigate, provide treatment and follow up the incident.

**e) Treatment of injured workers and follow up procedures**

28. The Health Protection Agency suggested amending the wording of Regulation 7(2)(a) to insert “and follow-up” after the word “treatment”. Their view was that this would emphasise the importance of follow-up for those patients receiving anti-viral treatment. Such follow-up includes monitoring for complications and adverse reactions, and checking for their viral status.

_HSE response_

29. HSE’s initial view is that the requirement in the regulations to ‘ensure treatment’ includes that appropriate follow up takes place. However, we will review this in light of this recommendation. In any case, we will include in our guidance reference to the appropriate Department of Health or other guidance for medical staff on post-exposure treatments and follow-up procedures.

**Guidance material**

30. A clear majority of respondents (88%) agreed with the proposal for HSE to build its guidance on the new regulations into its existing guidance material. A number of respondents argued that it was important that guidance on the existing requirements and the new regulations were pulled together in one document. In particular, that the findings of the relevant risk assessments must inform the appropriate control measures required. A number specified that the guidance should be in the form of an Approved Code of Practice.
31. We received some examples of specific uses of sharps where further clarification of what the new regulations will mean would be helpful. These included:

- How to deal with non-safety sharps provided by another employer or that have been prescribed for the patient, for example in care homes.
- Use of non-safety hypodermic (preformed) syringes provided for national vaccination programmes.
- Cannula for vascular access in children (Association of Paediatric Anaesthetists of Great Britain and Ireland).
- Safety of ‘parking’ a loaded syringe during dental treatment and dismantling traditional metal dental syringes.
- Dealing with recapping during the preparation and use of radiopharmaceuticals / nuclear medicine and aseptic pharmaceuticals.
- Dealing with used sharps in needle exchange services
- Risks of sharps injuries in community pharmacies, including unsafely disposed of needles in returned medicines [NB – the regulations will not apply to some community pharmacies].
- A University where student nurses are practising blood collection on mannequins [NB – the regulations would not apply here.].

32. HSE will ensure that our guidance deals with the generic issues of how the regulations apply and include some examples where there are specific issues. The relevant practitioners are best placed to provide detailed guidelines on appropriate safe systems of work for many of the above examples. The appropriate risk control measures need to be selected and applied in a way that is consistent with safe clinical practices. There is a balance to be achieved between providing guidance in one document (as requested) and ensuring that the right people with the appropriate technical understanding, who are in a position to keep their guidance up-to-date, provide it.

33. HSE’s view is that the regulations as proposed are relatively simple and are mainly prescriptive in nature. HSE guidance and guidance
from key stakeholders, will be provided to allow duty holders to understand the requirements of the law and to allow HSE to enforce it. We will consider the best format for HSE’s guidance, taking into account the above comments.

Miscellaneous comments

34. The consultation asked stakeholders whether there were any other issues, aside from the specific questions we asked, that they wanted to comment on.

a) HSE enforcement of the new Regulations

35. Unite the Union and RCN stated “a [HSE] targeted programme of inspection and enforcement” should accompany the introduction of the Regulations.

HSE response

36. HSE has a [Public Service Sector Strategy] 2012-15, which sets out our strategic regulatory approach in this sector and the priorities for action. HSE will follow this and apply HSE’s existing criteria for investigating complaints and reports of injuries to HSE made under the RIDDOR scheme. HSE Inspectors may take action if they identify sharps as a “matter of evident concern” during investigations or inspections.

b) Testing of the viral status of source patients

37. Royal College of Physicians and the Health Protection Agency felt that an opportunity had been missed for the Regulations to require the testing of the viral status (whether infected or not) of a patient who has been the source of blood contamination, especially where a blood sample is already available. The RCP explained that where a worker has been injured and the source patient is mentally incompetent to give permission for such a test, the information to facilitate prompt and appropriate management of the injured person is not available, and this gives rise to unnecessary anxieties for the injured person.

HSE response

The source Directive does not require such testing. This is primarily an issue about the capacity of the relevant patient and/or use of human
tissue. The appropriate legislation\textsuperscript{4}, common law and guidelines issued by the Human Tissue Authority and General Medical Council (http://www.gmc-uk.org/guidance/update_serious_communicable_diseases.asp) apply and it is not appropriate for health and safety legislation.

c) Immunisation passport for healthcare workers

38. The Association of Perioperative Practice (AfPP) suggested that the new Regulations should take the opportunity to require healthcare practitioners to provide a passport of immunisation to show up to date evidence of their own healthcare status, whilst noting that the responsibility for ensuring that staff are monitored or assessed remains with the (employer’s) occupational health department.

\textit{HSE response}

39. This issue is not addressed in this Directive and is primarily an issue for patient safety. Therefore, to include this measure in these Regulations would represent additional regulation for the UK, which is not justified in this case where we are primarily concerned with worker protection and transposition of this Directive.

\textsuperscript{4} Mental Capacity Act 2005 (England & Wales only), Adults with Incapacity (Scotland) Act 2000, Human Tissue Act 2004 and Human Tissue (Scotland) Act 2006.
Annex 1: List of organisations who responded to this consultation

Where it was not clear if a response was provided on behalf of a particular organisation or in a personal capacity we have not included the name of the organisation in this list.

Administration of Radioactive Substances Advisory Committee
All Party Parliamentary Group on Occupational Health and Safety
Association of National Health Occupational Physicians
Association of Paediatric Anaesthetists of Great Britain and Ireland
Association of Personal Injury Lawyers
British Dental Association
British Dental Trade Association
British Medical Association
British Nuclear Medicine Society
Care Quality Commission
Carillion plc
Chartered Institute of Wastes Management
Denplan Ltd
Expert Advisory Group on AIDS
GMB
Guild of Healthcare Pharmacists
Hambley Ltd
Health Protection Agency
Independent Healthcare Advisory Services
Institute of Occupational Safety and Health
Institute of Physics and Engineering in Medicine
London Consortium of Occupational Health Practitioners
Marie Curie Cancer Care
Merseyside Recycling and Waste Authority
NHS Confederation
NHS Pharmaceutical Aseptic Services Group
Nuffield Health
Partnership for Occupational Safety and Health in Healthcare
Paul Leadbetter Associates
PHSC plc
Pharmaceutical Services Negotiating Committee
Pharmacy Voice
Retractable Technologies, Inc
Royal College of Nursing
Royal College of Midwives
Royal College of Physicians
Royal Pharmaceutical Society
Safer Needles Network
Society of Radiographers
Sue Ryder
Thompsons Solicitors
Trade Union Congress
Unison
Unite the Union
**Annex 2: Breakdown of those providing responses to this consultation**

Responses received by role of respondent

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<th>Role</th>
<th>Number of responses</th>
<th>Percentage of all responses</th>
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<td>29.7</td>
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<td>An employer</td>
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<td>Health &amp; safety professional</td>
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<td>Trade Union official</td>
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<td>5.1</td>
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<tr>
<td>Training provider</td>
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<tr>
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<td>27.8</td>
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<td><strong>TOTAL</strong></td>
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<td>-</td>
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Breakdown of responses by type of organisation

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<th>Type of organisation</th>
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<tr>
<td>Consultancy</td>
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<td>Non-departmental public body</td>
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<td>26.6</td>
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Annex 3: Numerical summary of responses for each question

Question 1
1 Is the term “medical sharps” in the regulations consistent with how it is commonly used by employers and workers in the healthcare sector?
  • Number of responses agreeing = 71
  • Number of responses disagreeing = 57
  • Number of responses that did not specifically answer the question = 36

Question 2
2) In addition to the examples provided, are there other common circumstances under which people carry out healthcare activities using medical sharps where the application of the proposed regulations could be usefully clarified in guidance?
  • Number of responses agreeing = 42
  • Number of responses disagreeing = 82
  • Number of responses that did not specifically answer the question = 34

Question 3
3 Is it clear what actions employers and employees will need to take under the proposed regulations?
  • Number of responses agreeing = 58
  • Number of responses disagreeing = 68
  • Number of responses that did not specifically answer the question = 32

Question 4
4a) Do you agree that HSE’s guidance on the new regulations should be built into its existing relevant guidance?
  • Number of responses agreeing = 113
  • Number of responses disagreeing = 10
  • Number of responses that did not specifically answer the question = 35

4b) In addition to the organisations listed at paragraphs 31 and 32 are there other organisations that HSE should seek to work with to ensure that relevant non-HSE guidance aligns with the requirements of the new regulations
A large number of organisations were suggested by respondents to this question. The five most suggested organisations were the Royal College of
Nursing, the Department of Health, Trade Unions, the Institute for Occupational Safety and Health and the Care Quality Commission.

**Question 5**

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

- Number of responses agreeing = 23
- Number of responses disagreeing = 97
- Number of responses that did not specifically answer the question = 138

**Question 6**

This purpose of this question was to obtain information from stakeholders on the anticipated costs and benefits of complying with the proposed Regulations. The information gathered from the responses to this question was used to inform a post-Consultation Impact Assessment that was submitted to the Regulatory Policy Committee in December 2012. Once approved, this Impact Assessment will be archived on the Department for Business, Innovation and skill website (http://www.bis.gov.uk/).