REGULATORY IMPACT ANALYSIS (RIA)

SAFETY, HEALTH AND WELFARE AT WORK

(Prevention of Sharps Injuries in the Healthcare Sector) REGULATIONS 20…

(S.I. No. … of 20….)

30th October 2012

Contents

1. Foreword

The Health and Safety Authority, herein after referred to as 'the Authority', has prepared this Regulatory Impact Analysis (RIA) in line with the Revised RIA Guidelines, (Department of the Taoiseach, 2009).

This RIA considers the options and assesses the impacts of the requirement to transpose the Directive 2010/32/EU which implements the Framework Agreement on prevention of sharps injuries in the hospital and healthcare sector reached by the European Hospital and Healthcare Employers' Association (HOSPEEM) and the European Federation of Public Services Union (EPSU). The deadline for Member States to comply with the Directive is 11th May 2013.

The impact of transposing the Directive through the proposed new Regulations is expected to be minimal given that many of the obligations already exist in principles expounded in the Safety, Health and Welfare at Work Act 2005 and the Safety, Health and Welfare at Work (Biological Agents) Regulations 1994 and amended Regulations. The proposed new Regulations apply the same principles specifically to the issue of sharps injuries but are more explicit with regard to certain obligations such as the preparation of a risk assessment for sharps, switching to safety engineered devices, information and training on new devices, a ban on the practice of recapping needles and the care of the injured employee. The analysis concludes as many of the obligations are already in existence most healthcare employers will only need to extend existing practices to those areas where changes have not yet been implemented. Where costs are involved they are not considered to be disproportionate when balanced against the savings to be made by a reduction in the testing, treatment and follow up that is required when a sharps incident occurs.

2. Policy context

This RIA assesses the legislative proposal to transpose Council Directive 2010/32/EU of the 10th May 2010. The Directive implements the Framework Agreement on prevention of sharps injuries in the hospital and healthcare sector which was concluded by the European Hospital and Healthcare Employers' Association (HOSPEEM) and the European Federation of Public Services Union (EPSU).

Member states are required to bring into force the laws, regulations and administrative provisions necessary to comply with the Directive by 11th May 2013.

The Health and Safety Authority is the agency with responsibility for enforcing the new legislation in Ireland. In current Irish legislation the main provisions relating to the risk of exposure to injury from sharps at work are contained in the Safety, Health and Welfare at Work Act, 2005 and the Safety, Health and Welfare at Work (Biological Agents) Regulations, 1994 and amendment Regulations, 1998. The proposed new Regulations compile existing and new requirements specifically related to the prevention of sharps injuries in the healthcare context.

The issue of potentially harmful exposures to biological agents is addressed in the Safety, Health and Welfare at Work (Biological Agents) Regulations 1994 and 1998. In 2011, the Authority produced an information sheet on the prevention of sharps injuries in healthcare. Guidance related to the prevention of blood borne diseases in the healthcare setting and on handling healthcare waste is provided by the Department of Health.

Information from the European Biosafety Network (2011) indicates over one million needlestick injuries in Europe annually. It is not known how many needlestick injuries occur in Ireland in the healthcare setting each year as there is no national system for collating this information.

The Commission did not prepare an impact assessment for the Directive as it is not required to do so when it proposes to give legal effect to an agreement between social partners in accordance with Article 139(2) of the EC Treaty.

3. Objectives

The primary objective of the proposed legislation is to increase the level of protection for workers in the healthcare sector from injury or infection caused by use of sharps in the course of their work.

A secondary objective is to ensure that Ireland complies with Directive by the deadline of 11th May 2013 and thereby avoids any penalties imposed by the European Commission for non-compliance.

4. Options

The options for addressing the transposition of Directive 2010/32/EU are as follows:

Option 1 **Do nothing**

Option 2 **Introduce new Regulations**

Option 1, to do nothing, would leave Ireland in breach of the requirement for member states to transpose the Directive by 11th May 2013. The Commission could proceed to take legal action with potentially significant financial penalties arising for the state. It could further create a situation where workers in the Irish healthcare sector are afforded a lower level of protection from injuries from sharps than workers in other Member States. On this basis it is recommended to proceed with option 2, to transpose Directive 2010/32/EU into Irish law by way of the proposed Regulations. The impact of this option is assessed in detail in the following section.

5. Impact analysis

The impacts of the proposed Regulations are expected to be minimal on the basis that most provisions are already enforced in Irish legislation and that the cost of compliance will be offset by a reduction in the costs associated with the follow up procedures when a sharps incident occurs. New or further clarified requirements under the Directive are listed below:

(i) Based on risk assessment, the replacement of sharps with medical devices incorporating safety engineered protection mechanisms that can eliminate or reduce the levels of exposure to a minimum. Needle stick injury prevention devices include needles that retract into the syringe after use, those that have a protective shield over the needle and systems that do not use needles.

(ii) A risk assessment specifically for sharps injuries that requires certain specific elements to be considered, for example, the existence of replacement equipment, such as safety engineered devices, that can eliminate or reduce the levels of exposure to a minimum.

(iii) The provision of information and training specifically concerning the prevention of sharp injuries. For example where medical devices are provided which incorporate safety engineered protection mechanisms, workers must be trained in their correct use.

(iv) The practice of recapping needles that are sharps, that presents a risk of injury and/or infection, is prohibited.

(v) The provision of appropriate care, including medical care and counselling for the injured employee where appropriate.

5.1 Benefits of introducing proposed Regulations

Health and safety benefits: The introduction of the proposed Regulations should further reduce the risk of sharps injury for workers in the healthcare sector. Healthcare workers will benefit from the reassurance that there is a specific set of requirements to protect against this common occupational hazard.

Business benefits: A lower rate of sharps injuries will result in lower costs for employers. A sharps injury can result in significant costs associated with the injured party being required to leave their workplace and seek medical attention which can involve taking blood samples, treatment, follow up of the injured party and a significant amount of paperwork.

5.2 Costs of introducing proposed Regulations

Business costs: The expected impact of the proposed Regulations in terms of compliance costs is expected to be minimal given the significant work which has already been undertaken in the sector to address the risk of sharps exposure.

Many healthcare practices have already moved to safety engineered devices in line with the requirement to have a safe system of work under the Safety, Health and Welfare at Work Act 2005 particularly for those work practices involving most intensive use of sharps. The proposed Regulations will require employers to consider some areas of less intensive use and purchase new equipment as necessary. Where specific practices such as dental or anaesthetic work have retained the practice of recapping and where there is a risk of injury these employers will be required to adopt safer work practices and procedures so far as is reasonably practicable. The proposed changes will be advised to healthcare employers in advance of the introduction of the Regulations to facilitate preparation and planning.

The obligation to produce a risk assessment specifically for sharps injuries will have limited impact as many healthcare employers will already include sharps as a topic in their risk assessments given the importance of the hazard in the sector. Healthcare employers have an existing and on-going process of preparing risk assessments. This includes assessing the risk to employees of harmful exposures to biological agents which includes contaminated sharps. At most, the new obligation will involve the inclusion of this topic in the existing and on-going process of preparing the risk assessment.

In terms of information and training for new equipment it is usual for training and information to be provided to staff by suppliers as part of the package when purchasing new equipment; the employer will be required to supplement this training as required to ensure employee competency when using devices. This is unlikely to incur additional costs to the employer.

Providing care for an employee following a potentially harmful exposure to a blood borne virus is an established practice in healthcare. However there may be an additional burden here for smaller private healthcare providers who do not have easy access to the treatment and counselling that may be required for an employee following a potentially harmful exposure.

Enforcement costs: The expected impact of the proposed Regulations in terms of enforcement costs is expected to be minimal as inspectors already assess sharps hazards as part of inspections in the healthcare sector. Costs related to the preparation and publication of a guidance document to support the new Regulations will be accommodated in the Authority's annual budget allocation for guidance material.

6. Consultation

The proposed Regulations and a draft RIA was made available on the Authority's website for a period of 5 weeks from the 2nd April to the 7th May 2012. Key stakeholders were contacted directly, these were as follows;

- Department of Jobs, Enterprise and Innovation
- Department of Health
- Health Service Executive
- Health Information and Quality Authority
- Irish Congress of Trade Unions
- Dr Kevin Kelleher, Assistant National Director Integrated Services Directorate – Health Protection. Dr Kelleher is the Chair of the National Standing Committee on the Prevention of Transmission of Blood Borne Diseases in Healthcare Settings in Ireland.
- The Health and Social Care Regulatory Forum
- The members of the HSA Healthcare Steering Group
- The Health Service Executive Health and Safety Advisors' Forum

In total 19 submissions were received from the following individuals and Organisations:

- IOSH Healthcare Section
- Daughters of Charity
- HSA Healthcare Steering Group
- Infection Prevention Society
- Joyce Consulting Ltd
- Retired Infection Prevention &Control Nurse
- Bon Secours Hospital Cork
- Aut Even Hospital, Kilkenny
- Our Lady's Children's Hospital, Crumlin
- National Dental Infection Prevention & Control Committee, HSE Dental Services
- Irish Dental Association
- Nursing Homes Ireland
- Irish Nurses and Midwives Organisation
- Una Hogan Safety
- HSE Corporate Employee Relations Service

- M O'Dell, Retired
- Independent Hospitals Association of Ireland
- Health Protection Surveillance Centre
- An Bord Altranais

The submissions covered a wide range of issues. Some of the issues raised are outlined below:

- The prohibition on the recapping of needles that are sharps-
  the dental profession raised concerns regarding the prohibition of the practice of recapping needles that are sharps. The practice of recapping needles is common practice in dentistry nationally and internationally and is considered to be necessary to prevent other risks. There are recognised safe ways of recapping using a single handed technique.
  The HSA met with dentists from the Dublin Dental University Hospital, Trinity College Dublin and they were of the opinion that recommended best practice on recapping in the dental profession complies with this requirement as it is currently set out in the draft Regulations.

- The scope of the draft Regulations was queried with regard to the categories of employees covered (locums, students, others outside of healthcare such as prison officers) and the type of exposures to blood borne viruses (bites, infectious material).

- Role of employees - the point was made that the draft Regulations should do more to emphasise the responsibilities of the employees with regard to the prevention of sharps related incidents at work.

- Vaccination - the responsibility to provide vaccines to students was queried and confidentiality issues were raised.

- Health surveillance - difficulties that may arise for private practitioners in providing health surveillance and medical treatment for injured employees was raised.

- The financial impact of providing safety engineered protection devices was raised.

- The term 'well-resourced' and organised working environment' was thought to be vague and requiring clarification.

- The reference in the draft regulations to a 'no blame culture' was queried.

- The type of sharps incidents that need to be reported to the HSA was queried.

The issues raised during consultation were reviewed and considered and amendments were made to the Regulations as deemed necessary.

The Legislation and Guidance Sub-Committee of the Board at meeting no. 3 on the 8th June 2012, cleared the revised draft Regulations for submission to the Board at meeting no. 223 on the 29th June

2012. At that Board meeting queries were raised on the draft and Board requested that the draft Regulations return to the Legislation and Guidance Sub Committee of the Board for further consideration.

The queries raised were addressed by the Executive and the necessary amendments made. The draft Regulations were considered by the Legislation and Guidance Sub-Committee of the Board at meeting no. 4 on the 14th September 2012. Subject to a number of amendments being made the draft Regulations were cleared to go to Board meeting no.225 on the 5th October 2012. At this meeting the draft Regulations were cleared for submission to the Department of Jobs, Enterprise and Innovation for consideration with a view to formal legal settlement by the Office of Parliamentary Council to the Government.

7. Enforcement and Compliance

The Health and Safety Authority is the primary enforcer of occupational safety, health and welfare legislation through its inspection process. There will be approximately 350 inspections in the healthcare sector in total in 2013 and compliance with the Regulations relating to sharps will be monitored through the inspection programme in a number of these inspections.

8. Review

The Authority will review the impact of the proposed Regulations through monitoring of enforcement statistics, requests for information, reported incident data and reviewing progress with stakeholders in the sector.

References

HOSPEEM-EPSU joint clarification (8th February 2010) of the Framework agreement on prevention from sharps injuries in the hospital and healthcare sector.

European Biosafety Network (2011), *Toolkit for implementation of European Directive on Prevention from Sharps Injuries (Council Directive 2010/32/EU) in Member States*.

Department of Health (2005), *Prevention of transmission of blood-borne diseases in the health-care setting.*