

STATUTORY INSTRUMENTS.

S.I. No. 135 of 2014

EUROPEAN UNION (PREVENTION OF SHARPS INJURIES IN THE HEALTHCARE SECTOR) REGULATIONS 2014

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I, RICHARD BRUTON, Minister for Jobs, Enterprise and Innovation, in the exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Council Directive 2010/32/EU of 10 May 2010¹ hereby make the following regulations:

PART 1

PRELIMINARY PROVISIONS

Citation

1. These Regulations may be cited as the European Union (Prevention of Sharps Injuries in the Healthcare Sector) Regulations 2014.

Interpretation

- 2. (1) In these Regulations—
- "Act of 2005" means the Safety, Health and Welfare at Work Act 2005 (No.10 of 2005);
- "Authority" means the Health and Safety Authority;
- "Biological Agents Regulations" means the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 (S.I. No. 572 of 2013);
- "Directive" means Council Directive 2010/32/EU of 10 May 2010¹ implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU;
- "compliance notice" shall be construed in accordance with Regulation 12(1);
- "employee" has the same meaning as it has in the Act of 2005;
- "employer" has the same meaning as it has in the Act of 2005;
- "health care services" means medical, surgical, diagnostic, nursing, paramedical, dental, chiropody, chiropractic, eye therapy, occupational therapy, physiotherapy or speech therapy services or treatment, or treatment or services provided in connection therewith, or similar services or treatment;
- "place of work" has the same meaning as it has in the Act of 2005; ¹OJ No. L. 134, 1.6.2010, p. 66.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 18th March, 2014.

"prohibition notice" shall be construed in accordance with Regulation 14(1);

"relevant worker" has the meaning assigned to it by paragraph (3);

"relevant employer" has the meaning assigned to it by paragraph (2);

"risk of exposure" means the risk of exposure to injury or infection from sharps;

"sharps risk assessment" has the meaning assigned to it by Regulation 4;

"sharps" means objects or instruments necessary for the exercise of specific healthcare activities, which are able to cut, prick or cause injury or infection.

- (2) In these Regulations, "relevant employer" means—
 - (a) an employer whose main activity is the management, organisation or provision of health care services ("healthcare employer"), and
 - (b) any other employer who provides services to a healthcare employer where those services are provided—
 - (i) under the authority of the healthcare employer, or
 - (ii) in a healthcare employer's place of work.
- (3) In these Regulations, "relevant worker"—
 - (a) in relation to a healthcare employer, means—
 - (i) an employee of that employer, and
 - (ii) any other individual who provides services to the healthcare employer where that individual works under the authority of that healthcare employer in that employer's place of work, and
 - (b) in relation to any other employer referred to in paragraph (2)(b), means an employee of that other employer where—
 - (i) the employee is providing services on behalf of that other employer to a healthcare employer, and
 - (ii) that other employer controls the activities of the employee in so far as those activities relate to providing those services.
- (4) A word or expression which is used in these Regulations and which is also used in the Directive has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directive.

Application

3. These Regulations apply to relevant employers in respect of their relevant workers in relation to places of work where health care services are provided.

PART 2

REOUIREMENTS RELATING TO THE USE OF SHARPS

Sharps risk assessment

- 4. (1) A relevant employer shall make a suitable and appropriate assessment of the risk of exposure to relevant workers (in these Regulations referred to as a "sharps risk assessment") in accordance with this Regulation.
- (2) A relevant employer shall carry out a sharps risk assessment in accordance with—
 - (a) subparagraphs (iii) and (iv) of paragraph (b) of Regulation 5, Regulation 7 and subparagraph (a) of paragraph (1) of Regulation 14 of, the Biological Agents Regulations, and
 - (b) sections 8, 10(1)(c), 11(4), 19, 20, 21 and 26(1)(b)(x) of, and Schedule 3 to, the Act of 2005.
- (3) In carrying out a sharps risk assessment, a relevant employer shall, for the purposes of identifying how a risk of exposure can be eliminated and identifying alternative systems that may eliminate or reduce the risk of exposure to a minimum, take account of—
 - (a) the available technology that eliminates or reduces the risk of exposure,
 - (b) how work is organised in the place of work,
 - (c) working conditions,
 - (d) the influence of factors related to the working environment, and
 - (e) the level of qualifications of relevant workers.
- (4) This Regulation is in addition to, and not in substitution for, Regulations 5 and 7 of the Biological Agents Regulations and sections 19 and 20 of the Act of 2005.

Elimination, prevention and protection

- 5. (1) Where the results of a sharps risk assessment reveal a risk of exposure to a relevant worker, a relevant employer shall eliminate that risk in so far as it is reasonably practicable by—
 - (a) specifying and implementing safe procedures for using and disposing of sharps and disposing of contaminated waste,
 - (b) eliminating the unnecessary use of sharps by implementing changes in practice on the basis of that assessment,

- (c) providing medical devices incorporating safety-engineered sharps protection mechanisms, where those mechanisms are available and appropriate, and
- (d) subject to paragraph (2), banning the practice of recapping of needles.
- (2) Recapping of needles is permitted where the needles have safety and protection mechanisms and do not pose a risk of injury.
- (3) A relevant employer shall, having regard to the activity and a sharps risk assessment, reduce the risk of exposure to as low a level as necessary to adequately protect the health and safety of a relevant worker, by—
 - (a) for the disposal of sharps, placing a notice of the procedures for disposal and clearly marked and technically safe containers for that disposal as close as possible to the area where the sharps are used or found,
 - (b) preventing the risk of infection by implementing safe systems of work by—
 - (i) developing a coherent overall prevention policy, which covers the matters referred to in subparagraphs (a) to (e) of Regulation 4(3),
 - (ii) providing training to relevant workers,
 - (iii) conducting health surveillance in compliance with section 22 of the Act of 2005 and Regulation 12 of the Biological Agents Regulations, and
 - (iv) providing suitable personal protective equipment for use by relevant workers.
- (4) Where a sharps risk assessment reveals a risk to the health and safety of relevant workers due to their exposure to a biological agent for which an effective vaccine exists, a relevant employer shall offer their relevant workers vaccination.
- (5) A relevant employer shall ensure, in relation to any vaccination offered under paragraph (4), that relevant workers are informed of the benefits and drawbacks of vaccination and failure to vaccinate.
- (6) A relevant employer shall ensure that any vaccination offered under paragraph (4) is made available free of charge to relevant workers.
- (7) A relevant employer, for the purpose of preventing a risk of exposure, shall—
 - (a) regularly reassess the safe procedures referred to in paragraph (1)(a), and

- (b) ensure that those safe procedures form an integral part of the information and training given to relevant workers in accordance with Regulations 6 and 7.
- (8) In this Regulation, "vaccination" where appropriate includes revaccination.

Information and awareness raising

- 6. (1) A relevant employer shall ensure, where there is a risk of exposure to relevant workers, that sufficient and appropriate information is given relating to—
 - (a) the risk of exposure to the health and safety of those employees,
 - (b) precautions to be taken to prevent the risk of exposure,
 - (c) the steps to be taken by those employees in the case of incidents and accidents involving sharps, and
 - (d) existing provisions in the Act of 2005, the General Application Regulations and the Biological Agents Regulations which apply for the protection of employees from risks to health and safety from sharps.
 - (2) A relevant employer shall advise relevant workers of—
 - (a) any support programme provided by that employer to relevant workers who have suffered a sharps injury, and
 - (b) good practices and safe systems of work regarding the prevention of incidents and accidents involving sharps.
 - (3) This Regulation is in addition to and not in substitution for—
 - (a) section 9, and paragraphs (a) and (b) of subsection (1) of section 10, of the Act of 2005, and
 - (b) Regulation 29 of the General Application Regulations.
- (4) In this Regulation, "General Application Regulations" means the Safety Health and Welfare at Work (General Application) Regulations 2007 (S.I. No. 299 of 2007).

Training and monitoring

- 7. (1) A relevant employer shall, where there is a risk of exposure to relevant workers, provide those relevant workers with suitable and sufficient training relating to that risk.
- (2) Without prejudice to the generality of paragraph (1), training provided under that paragraph shall include training in relation to—
 - (a) the correct use of medical devices incorporating safety-engineered sharps protection mechanisms,

- (b) the risks associated with exposure to blood and body fluid,
- (c) preventive measures including standard precautions, safe systems of work, procedures for the correct use and disposal of sharps and the importance of vaccination,
- (d) that employer's policies and procedures associated with sharps injuries and infections, including that employer's procedures for monitoring the safety of work practices relating to sharps,
- (e) the reporting and response procedures referred to in Regulations 8 and 9 and the importance of those procedures, and
- (f) measures to be taken where there is an injury or infection from sharps.
- (3) Where a new relevant worker commences work with a relevant employer and there is a risk of exposure to that employee, the relevant employer shall, prior to or upon commencement of that employment, provide training to that relevant worker in accordance with paragraph (1).
- (4) A relevant employer shall ensure that training provided in accordance with this Regulation takes account of-
 - (a) the results of monitoring by that employer of the safety of work practices relating to sharps,
 - (b) modernisation and improvements in the prevention and treatment of sharp injuries and infections, and
 - (c) any new or changed risks to the safety, health and welfare of relevant workers at work arising from the use of sharps.
 - (5) This Regulation is in addition to and not in substitution for—
 - (a) section 10 of the Act of 2005, and
 - (b) paragraphs (1) and (2) of Regulation 8 of the Biological Agents Regulations.

Reporting

- 8. (1) A relevant worker who becomes aware of any incident or accident involving injury or infection from sharps or the risk of injury or infection from sharps shall report the incident or accident to his or her relevant employer or immediate supervisor.
- (2) A relevant worker who becomes aware of any incident or accident involving sharps shall provide their relevant employer with all relevant information relating to the incident or accident as may reasonably be requested by that employer.

Response and follow-up

- 9. (1) A relevant employer shall put in place policies and procedures to be followed when a sharps injury occurs at a place of work.
- (2) A relevant employer shall implement the policies and procedures referred to in paragraph (1) when a sharps injury occurs.
- (3) A relevant employer shall ensure that relevant workers are informed of the policies and procedures referred to in paragraph (1).
- (4) Policies and procedures put in place under paragraph (1) shall ensure the confidentiality of—
 - (a) the nature of any sharps injury suffered by a relevant worker, and
 - (b) any diagnosis and treatment associated with that injury.
- (5) A relevant employer shall take immediate steps for the care of a relevant worker who suffers a sharps injury, including—
 - (a) the provision of post-exposure prophylaxis where this is considered necessary for medical reasons,
 - (b) ensuring that employee undergoes any medical tests where those tests are considered necessary for medical reasons, and
 - (c) conducting appropriate health surveillance in accordance with Regulation 5(3)(b)(iii).
- (6) Where a relevant employer considers it appropriate, that employer shall cause counselling to be made available to a relevant worker who suffers a sharps injury.
- (7) A relevant employer shall investigate and record the cause and circumstances of every incident or accident involving sharps—
 - (a) reported to him or her in accordance with Regulation 8(1), or
 - (b) of which he or she becomes aware.
- (8) Upon completing an investigation under paragraph (7), a relevant employer shall, where appropriate, take the necessary action to prevent a recurrence of the incident or accident.

PART 3

ENFORCEMENT

Chapter 1

Powers of inspectors

Inspectors

- 10. (1) A person who for the time being stands appointed as an inspector under section 62 of the Act of 2005 shall be an inspector for the purpose of these Regulations and the Directive.
- (2) An inspector shall, when exercising any power conferred on him or her by these Regulations, if requested to do so by any person affected, produce the certificate of authorisation or a copy of it furnished to him or her under section 62(2) of the Act of 2005.

Powers of inspectors

- 11. (1) An inspector may, for the purpose of these Regulations and the Directive—
 - (a) subject to paragraph (5), enter and inspect at all reasonable times any place where he or she has reasonable grounds for believing that—
 - (i) the place is used as a place of work,
 - (ii) health care services are being provided,
 - (iii) sharps are used or kept, or
 - (iv) books, records or documents relating to sharps and related articles, are kept,
 - (b) at such place referred to in paragraph (a), inspect and take copies of any books, records or other documents (including records or documents stored in non-legible form), or extracts therefrom, that he or she finds in the course of his or her inspection,
 - (c) remove any such books, records or other documents (including records or documents stored in non-legible form) from the place referred to in paragraph (a) and detain them for such period as he or she reasonably considers necessary for the purposes of his or her functions under these Regulations or the Directive,
 - (d) require—
 - (i) the employer,
 - (ii) any employee,

(iii) any person at the place referred to in paragraph (a), including the owner or person in charge of the place,

to produce to the inspector such books, records or other documents (and in the case of records or documents stored in non-legible form, produce to him or her a legible reproduction thereof) that are in that person's possession or procurement, or under that person's control, as he or she may reasonably require for the purposes of his or her functions under these Regulations or the Directive,

- (e) carry out or have carried out such examinations, tests, inspections, analyses or checks of—
 - (i) the place referred to in paragraph (a),
 - (ii) any sharps or related articles at that place,
 - (iii) any equipment, machinery or other articles at that place,

as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations or the Directive,

- (f) remove any sharps or related article from the place referred to in paragraph (a) and detain them for such period as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations or the Directive,
- (g) direct that such sharps or related articles found at the place referred to in paragraph (a) be destroyed where he or she, upon reasonable grounds, believes that use of those sharps or related articles would involve a risk of exposure,
- (h) require—
 - (i) the employer,
 - (ii) any employee,
 - (iii) any person at the place referred to in paragraph (a), including the owner or person in charge of that place,

to give to the inspector such information and assistance as the inspector may reasonably require for the purposes of his or her functions under these Regulations or the Directive,

- (i) examine, with regard to any matter under these Regulations or the Directive—
 - (i) any person whom the inspector has reasonable grounds for believing to be—
 - (I) the employer, or

- (II) an employee, or
- (ii) any person at the place referred to in paragraph (a) including the owner or person in charge of that place,

and require that person to answer such questions as the inspector may ask relative to those matters and to make a declaration of the truth of the answers to those questions, and

- (j) direct that a safety statement referred to in section 20 of the Act of 2005 be amended in accordance with subsection (5)(c) of that section.
- (2) Where any sharps or related article is used or kept at a place referred to in paragraph (1)(a), and a request is made in that behalf by an inspector in the exercise of his or her functions under these Regulations or the Directive, the relevant employer shall give to the inspector the name and address of the supplier from which the sharps or related article was purchased or otherwise obtained.
- (3) Before exercising the power conferred by subparagraphs (e) or (g) of paragraph (1), an inspector may consult such persons as appear to him or her to be appropriate for the purpose of ascertaining what dangers, if any, there may be in doing anything which he or she proposes to do in accordance with those paragraphs.
- (4) Where an inspector, in exercising any power under paragraph (1), takes possession of any sharps or related article found at any place concerned, he or she shall, if it is practicable for him or her to do so, take a sample thereof and give to the relevant employer or person in charge of that place a portion of the sample marked in a manner sufficient to identify it.
 - (5) An inspector shall not enter a dwelling other than—
 - (a) with the consent of the occupier, or
 - (b) in accordance with a warrant from a District Court issued under paragraph (7) authorising such entry.
- (6) Where an inspector in the exercise of his or her powers under this Regulation is prevented from entering any place an application may be made for a warrant under paragraph (7) authorising such entry.
- (7) Upon the information on oath of an inspector, a judge of the District Court may—
 - (a) for the purposes of enabling an inspector to carry out an inspection of any place where sharps or related articles are used or kept, or
 - (b) if satisfied that there are reasonable grounds for believing that information, books, documents or other records (including information,

books, documents or records stored in non-legible form) required by an inspector under these Regulations are held in any place,

issue a warrant authorising an inspector, accompanied by such other inspectors or members of An Garda Síochána as may be necessary, at any time or times, within one month from the date of issue of the warrant, on production of the warrant if requested, to enter that place, if need be by reasonable force, and exercise all or any of the powers conferred on an inspector by these Regulations.

- (8) A person commits an offence if he or she—
 - (a) obstructs or interferes with an inspector or a member of An Garda Síochána in the exercise of a power conferred on him or her by these Regulations or a warrant under paragraph (7) or impedes the exercise by the inspector or member, as the case may be, of such power,
 - (b) fails or refuses to comply with a request or requirement of, or to answer a question asked by, the inspector pursuant to this Regulation, or
 - (c) in purported compliance with a request or requirement referred to in paragraph (b) or in answer to a question referred to in that paragraph gives information that he or she knows to be false or misleading in any material respect.
- (9) A person who commits an offence under paragraph (8) is liable on summary conviction to a class A fine.
- (10) Where an inspector upon reasonable grounds believes that a person has committed an offence under these Regulations he or she may require that person to provide him or her with his or her name and the address at which he or she ordinarily resides.
- (11) A statement or admission made by a person pursuant to a requirement under subparagraphs (h) or (i) of paragraph (1) shall not be admissible as evidence in proceedings brought against the person for an offence (other than an offence under paragraph (8)).

Compliance notice

- 12. (1) Where an inspector is of the opinion that a person has contravened, or is contravening, any of these Regulations, the inspector may serve a notice in writing (in these Regulations referred to as a "compliance notice") on the person.
 - (2) A compliance notice shall—
 - (a) state that the inspector is of the opinion referred to in paragraph (1),
 - (b) specify the grounds for the inspector being of the opinion referred to in paragraph (1) and specify the Regulation or Regulations concerned,

- (c) require the person concerned to take such measures as are specified in the notice to cease the contravention,
- (d) specify the time period, commencing on the date of service of the notice, within which the measures referred to in subparagraph (b) shall be taken, which period shall not be earlier than the end of the period within which an appeal may be brought under Regulation 13,
- (e) inform the person concerned that he or she may appeal the compliance notice to the District Court in accordance with Regulation 13, and
- (f) state that if the person to whom the notice is addressed fails to take such measures as are specified in the notice within the time period specified in that notice, that person commits an offence.
- (3) An inspector may withdraw a compliance notice under this Regulation.
- (4) Where no appeal is made under Regulation 13 in respect of a compliance notice served under paragraph (1), an inspector may extend the time period specified under paragraph (2)(d).
- (5) A person to whom a compliance notice is addressed who fails to comply with the notice within the time period specified in that notice commits an offence.
 - (6) A person who commits an offence under this Regulation is liable—
 - (a) on summary conviction, to a class A fine or imprisonment for a term not exceeding 12 months or both, or
 - (b) on conviction on indictment, to a fine not exceeding €500,000 or to imprisonment for a term not exceeding 3 years or both.

Appeal against compliance notice

- 13. (1) A person on whom a compliance notice is served may, not later than 14 days from the date of service of the notice, appeal against the notice to a judge of the District Court sitting in the district in which that notice was served.
- (2) A person who appeals under paragraph (1) shall at the same time notify the Authority of the appeal and the grounds for the appeal.
- (3) Upon the hearing of an appeal under this Regulation, a judge of the District Court may confirm, revoke or vary the compliance notice.
- (4) A compliance notice in respect of which an appeal is brought under this Regulation shall take effect on the later of—
 - (a) the day next following the day on which the compliance notice is confirmed, varied or the appeal is withdrawn, or
 - (b) the day (if any) specified by the judge of the District Court in making an order under paragraph (3).

Prohibition notice

- 14. (1) Where an inspector is of the opinion that in any place of work where health care services are provided any situation or activity is occurring which—
 - (a) involves a contravention of any of these Regulations, and
 - (b) involves or is likely to involve a risk of serious personal injury to any person,

the inspector may serve a notice in writing on the relevant employer or the person in charge of that place of work (in these Regulations referred to as a "prohibition notice").

(2) A prohibition notice shall—

- (a) state that the inspector is of the opinion referred to in paragraph (1),
- (b) specify the situation or activity in respect of which the inspector is of the opinion referred to paragraph (1) and specify the Regulation or Regulations concerned,
- (c) prohibit, from such time as the inspector shall specify in the notice, the carrying on of the activity or continuation of the situation that gives rise to the risk until the matters that give rise to that risk are remedied,
- (d) inform the person concerned that he or she may appeal the prohibition notice to the District Court in accordance with Regulation 15, and
- (e) state that if the person to whom the prohibition notice is addressed fails to comply with the notice within the time period specified in the notice, that person commits an offence.
- (3) A prohibition notice may include directions—
 - (a) as to the measures to be taken in respect of the activity or situation to eliminate the risk referred to in paragraph (1),
 - (b) to bring the notice to the attention of any person affected by the notice, or to the attention of the public generally.
- (4) A prohibition notice shall take effect from such time as the inspector shall specify in the notice.
- (5) An inspector may withdraw a prohibition notice under this Regulation by notice in writing if—
 - (a) the inspector is satisfied that the situation or activity to which the notice relates no longer involves a risk of serious personal injury to any person,

- (b) the inspector is satisfied that the notice was issued in error or is incorrect in some material respect.
- (6) A person to whom a prohibition notice is addressed who fails to comply with the prohibition specified under subparagraph (c) of paragraph (2) from the time specified under that subparagraph commits an offence.
 - (7) A person who commits an offence under this Regulation is liable—
 - (a) on summary conviction, to a class A fine or imprisonment for a term not exceeding 12 months or both, or
 - (b) on conviction on indictment, to a fine not exceeding €500,000 or to imprisonment for a term not exceeding 3 years, or both.

Appeal against prohibition notice

- 15. (1) A person on whom a prohibition notice is served may, not later than 7 days after service of the notice, appeal against the notice to a judge of the District Court sitting in the district in which that notice was served.
- (2) The bringing of an appeal against a prohibition notice shall not have the effect of suspending the operation of the notice but the person bringing the appeal may apply to the court to have the operation of the notice suspended until the appeal is disposed of and, on such application, the court may, if it thinks proper to do so, direct that the operation of the notice be suspended until the appeal is disposed of.
- (3) A person who brings an appeal under paragraph (1), or makes an application for the suspension of the operation of a prohibition notice under paragraph (2), shall at the same time notify the Authority of—
 - (a) the appeal or the application, as the case may be, and
 - (b) the grounds for the appeal.
- (4) Upon the hearing of an appeal under this Regulation, a judge of the District Court may confirm, revoke or vary the prohibition notice.

Chapter 2

Prosecution of offences

- 16. (1) Summary proceedings in relation to an offence under these Regulations may be brought and prosecuted by the Authority.
- (2) Where a person is convicted of an offence under these Regulations in proceedings brought by the Authority, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the Authority the costs and expenses, measured by the court, incurred by the Authority in relation to the investigation, detection and prosecution of the offence including—

- (a) the costs and expenses incurred in taking samples,
- (b) the carrying out of examinations, tests, inspections, analyses or checks, and
- (c) the remuneration and expenses of consultants and advisors engaged by the Authority.

Service of notices

- 17. (1) A notice or other document that is required to be served on or given to a person under these Regulations shall be addressed to the person concerned by name, and may be so served on or given to the person in one of the following ways:
 - (a) by delivering it to the person;
 - (b) by leaving it at the address at which the person ordinarily resides or carries on business, or in a case in which an address for service has been furnished, to that address; or
 - (c) by sending it by post in a prepaid registered letter to the address at which the person ordinarily resident or, in a case in which an address for service has been furnished, to that address.
- (2) For the purpose of this Regulation, a company within the meaning of the Companies Acts shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body of persons shall be deemed to be ordinarily resident at its principal office or place of business.



Given under my Official Seal 14 March 2014.

RICHARD BRUTON,

Minister for Jobs, Enterprise and Innovation.

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

The purpose of these Regulations, is to transpose into Irish law 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. This Directive represents the first occupational safety and health Directive generated through social partners/dialogue mechanism.

The Regulations relate to the risks posed by sharps to those working in healthcare. They implement specific control measures to protect employees at risk, and require an appropriate response in the event of an incident occurring. The Regulations build on the more general duties under the Safety, Health and Welfare at Work Act, 2005 and the Safety, Health and Welfare at Work (Biological Agents) Regulations, 2013 (S.I. No. 572 of 2013) which apply across all industry sectors.

The Regulations define sharps as 'objects or instruments necessary for the exercise of specific healthcare activities, which are able to cut, prick or cause injury or infection'. This includes equipment such as needles, blades (such as scalpels) and other sharp medical instruments.

The Regulations apply to all employers and employees in the healthcare sector. This includes nurses, medical practitioners, nursing auxiliaries and assistants, cleaners, dental nurses, paramedics, home carers etc. The Regulations apply to students working in healthcare, self-employed persons in healthcare and any employees employed by organisations contracted to provide services for healthcare organisations such as cleaners and other ancillary staff.

An employer in healthcare is an employer whose main activity is the managing, organising and provision of healthcare ("healthcare employer"). These Regulations also apply to other employers who provide services to a healthcare employer, under the authority of a healthcare employer or in a healthcare employer's place of work. The duties on this employer only apply insofar as the employer has control over the relevant activities of their relevant employees.

Where an employee of a healthcare employer provides healthcare services in another employer's workplace or in the home of a patient, the employer will be required to comply with the proposed Regulations.

Employers whose main activity is not the provision of healthcare but whose employees may work with sharps will not fall within the scope of the Regulations (unless they are working on the premises of a healthcare employer who is subject to the proposed Regulations). Therefore organisations such as schools and prisons are not subject to the Regulations even though they might employ medical staff. Those employers remain subject to existing health and safety legislation.

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