Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (recast) (Text with EEA relevance)

CHAPTER 1

GENERAL PROVISIONS

Article 1

Scope

1 This Directive shall apply to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0,5 bar.

- 2 This Directive shall not apply to:
 - a pipelines comprising piping or a system of piping designed for the conveyance of any fluid or substance to or from an installation (onshore or offshore) starting from and including the last isolation device located within the confines of the installation, including all the annexed equipment designed specifically for pipelines; this exclusion shall not apply to standard pressure equipment such as may be found in pressure reduction stations or compression stations;
 - b networks for the supply, distribution and discharge of water and associated equipment and headraces such as penstocks, pressure tunnels, pressure shafts for hydroelectric installations and their related specific accessories;
 - c simple pressure vessels covered by Directive 2014/29/EU of the European Parliament and of the Council⁽¹⁾;
 - d aerosol dispensers covered by Council Directive 75/324/EEC⁽²⁾;
 - e equipment intended for the functioning of vehicles defined by the following legal acts:
 - (i) Directive 2007/46/EC of the European Parliament and of the Council⁽³⁾;
 - (ii) Regulation (EU) No 167/2013 of the European Parliament and of the Council⁽⁴⁾;
 - (iii) Regulation (EU) No 168/2013 of the European Parliament and of the Council⁽⁵⁾;
 - f equipment classified as no higher than category I under Article 13 of this Directive and covered by one of the following Directives:
 - (i) Directive 2006/42/EC of the European Parliament and of the Council⁽⁶⁾;
 - (ii) Directive 2014/33/EU of the European Parliament and of the Council⁽⁷⁾;
 - (iii) Directive 2014/35/EU of the European Parliament and of the Council⁽⁸⁾;
 - (iv) Council Directive 93/42/EEC⁽⁹⁾;
 - (v) Directive 2009/142/EC of the European Parliament and of the Council⁽¹⁰⁾;
 - (vi) Directive 2014/34/EU of the European Parliament and of the Council⁽¹¹⁾;
 - g equipment covered by point (b) of Article 346(1) TFEU;

- h items specifically designed for nuclear use, failure of which may cause an emission of radioactivity;
- i well-control equipment used in the petroleum, gas or geothermal exploration and extraction industry and in underground storage which is intended to contain and/or control well pressure; this shall comprise the wellhead (Christmas tree), the blow out preventers (BOP), the piping manifolds and all their equipment upstream;
- j equipment comprising casings or machinery where the dimensioning, choice of material and manufacturing rules are based primarily on requirements for sufficient strength, rigidity and stability to meet the static and dynamic operational effects or other operational characteristics and for which pressure is not a significant design factor; such equipment may include:
 - (i) engines including turbines and internal combustion engines;
 - (ii) steam engines, gas/steam turbines, turbo-generators, compressors, pumps and actuating devices;
- k blast furnaces including the furnace cooling system, hot-blast recuperators, dust extractors and blast-furnace exhaust-gas scrubbers and direct reducing cupolas, including the furnace cooling, gas converters and pans for melting, re-melting, degassing and casting of steel, iron and non-ferrous metals;
- 1 enclosures for high-voltage electrical equipment such as switchgear, control gear, transformers, and rotating machines;
- m pressurised pipes for the containment of transmission systems, e.g. for electrical power and telephone cables;
- n ships, rockets, aircraft and mobile off-shore units, as well as equipment specifically intended for installation on board or the propulsion thereof;
- o pressure equipment consisting of a flexible casing, e.g. tyres, air cushions, balls used for play, inflatable craft, and other similar pressure equipment;
- p exhaust and inlet silencers;
- q bottles or cans for carbonated drinks for final consumption;
- r vessels designed for the transport and distribution of drinks having a PS·V of not more than 500 bar·L and a maximum allowable pressure not exceeding 7 bar;
- s equipment covered by Directive 2008/68/EC and Directive 2010/35/EU and equipment covered by the International Maritime Dangerous Goods Code and the Convention on International Civil Aviation;
- t radiators and pipes in warm water heating systems;
- u vessels designed to contain liquids with a gas pressure above the liquid of not more than 0,5 bar.

Article 2

Definitions

For the purposes of this Directive, the following definitions shall apply:

(1) 'pressure equipment' means vessels, piping, safety accessories and pressure accessories, including, where applicable, elements attached to pressurised parts, such as flanges, nozzles, couplings, supports, lifting lugs;

- (2) 'vessel' means a housing designed and built to contain fluids under pressure including its direct attachments up to the coupling point connecting it to other equipment; a vessel may be composed of more than one chamber;
- (3) 'piping' means piping components intended for the transport of fluids, when connected together for integration into a pressure system; piping includes in particular a pipe or system of pipes, tubing, fittings, expansion joints, hoses, or other pressurebearing components as appropriate; heat exchangers consisting of pipes for the purpose of cooling or heating air shall be considered as piping;
- (4) 'safety accessories' means devices designed to protect pressure equipment against the allowable limits being exceeded, including devices for direct pressure limitation, such as safety valves, bursting disc safety devices, buckling rods, controlled safety pressure relief systems (CSPRS), and limiting devices, which either activate the means for correction or provide for shutdown or shutdown and lockout, such as pressure switches or temperature switches or fluid level switches and safety related measurement control and regulation (SRMCR) devices;
- (5) 'pressure accessories' means devices with an operational function and having pressure-bearing housings;
- (6) 'assemblies' means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole;
- (7) 'pressure' means pressure relative to atmospheric pressure, i.e. gauge pressure. As a consequence, vacuum is designated by a negative value;
- (8) 'maximum allowable pressure PS' means the maximum pressure for which the equipment is designed, as specified by the manufacturer, and defined at a location specified by him, being either the connection of protective and/or limiting devices, or the top of equipment or, if not appropriate, any point specified;
- (9) 'maximum/minimum allowable temperature TS' means the maximum/minimum temperatures for which the equipment is designed, as specified by the manufacturer;
- (10) 'volume (V)' means the internal volume of a chamber, including the volume of nozzles to the first connection or weld and excluding the volume of permanent internal parts;
- (11) 'nominal size (DN)' means a numerical designation of size which is common to all components in a piping system other than components indicated by outside diameters or by thread size; it is a convenient round number for reference purposes and is only loosely related to manufacturing dimensions; the nominal size is designated by DN followed by a number;
- (12) 'fluids' means gases, liquids and vapours in pure phase as well as mixtures thereof; fluids may contain a suspension of solids;
- (13) 'permanent joints' means joints which cannot be disconnected except by destructive methods;
- (14) 'European approval for materials' means a technical document defining the characteristics of materials intended for repeated use in the manufacture of pressure equipment which are not covered by any harmonised standard;
- (15) 'making available on the market' means any supply of pressure equipment or assemblies for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

- (16) 'placing on the market' means the first making available of pressure equipment or assemblies on the Union market;
- (17) 'putting into service' means the first use of pressure equipment or an assembly by its user;
- (18) 'manufacturer' means any natural or legal person who manufactures pressure equipment or an assembly or has such equipment or assembly designed or manufactured, and markets that pressure equipment or assembly under his name or trademark or uses it for his own purposes;
- (19) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- (20) 'importer' means any natural or legal person established within the Union who places pressure equipment or assemblies from a third country on the Union market;
- (21) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes pressure equipment or assemblies available on the market;
- (22) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (23) 'technical specification' means a document that prescribes technical requirements to be fulfilled by pressure equipment or assemblies;
- (24) 'harmonised standard' means harmonised standard as defined in point (c) of Article 2(1) of Regulation (EU) No 1025/2012;
- (25) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;
- (26) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;
- (27) 'conformity assessment' means the process demonstrating whether the essential safety requirements of this Directive relating to pressure equipment or assemblies have been fulfilled;
- (28) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (29) 'recall' means any measure aimed at achieving the return of pressure equipment or assemblies that have already been made available to consumers or other users;
- (30) 'withdrawal' means any measure aimed at preventing pressure equipment or assemblies in the supply chain from being made available on the market;
- (31) 'CE marking' means a marking by which the manufacturer indicates that the pressure equipment or assembly is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;
- (32) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products.

Article 3

Making available on the market and putting into service

1 Member States shall take all appropriate measures to ensure that pressure equipment and assemblies may be made available on the market and put into service only if they satisfy the requirements of this Directive when properly installed and maintained and used for the purposes for which they are intended.

2 This Directive shall not affect Member States' entitlement to lay down such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected during use of the pressure equipment or assembly in question provided that this does not mean modifications to such equipment or assembly in a way not specified in this Directive.

3 At trade fairs, exhibitions, demonstrations and other similar events, Member States shall not prevent the showing of pressure equipment or assemblies which do not comply with this Directive, provided that a visible sign clearly indicates that such pressure equipment or assemblies may not be made available on the market and/or put into service until they are brought into conformity. During demonstrations, appropriate safety measures shall be taken in accordance with any requirements laid down by the competent authority of the Member State concerned in order to ensure the safety of persons.

Article 4

Technical requirements

1 The following pressure equipment shall satisfy the essential safety requirements set out in Annex I:

- a vessels, except those referred to in point (b), for:
 - (i) gases, liquefied gases, gases dissolved under pressure, vapours and also those liquids whose vapour pressure at the maximum allowable temperature is greater than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:
 - for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 25 bar L, or with a pressure PS greater than 200 bar (Annex II, table 1),
 - for fluids in Group 2, with a volume greater than 1 L and a product of PS and V is greater than 50 bar·L, or with a pressure PS greater than 1 000 bar, and all portable extinguishers and bottles for breathing apparatus (Annex II, table 2);
 - (ii) liquids having a vapour pressure at the maximum allowable temperature of not more than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:
 - for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 200 bar L, or with a pressure PS greater than 500 bar (Annex II, table 3),
 - for fluids in Group 2 with a pressure PS greater than 10 bar and a product of PS and V greater than 10 000 bar L, or with a pressure PS greater than 1 000 bar (Annex II, table 4);

- b fired or otherwise heated pressure equipment with the risk of overheating intended for generation of steam or super-heated water at temperatures higher than 110 °C having a volume greater than 2 L, and all pressure cookers (Annex II, table 5);
- c piping intended for:
 - (i) gases, liquefied gases, gases dissolved under pressure, vapours and those liquids whose vapour pressure at the maximum allowable temperature is greater than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:
 - for fluids in Group 1 with a DN greater than 25 (Annex II, table 6),
 - for fluids in Group 2 with a DN greater than 32 and a product of PS and DN greater than 1 000 bar (Annex II, table 7);
 - (ii) liquids having a vapour pressure at the maximum allowable temperature of not more than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:
 - for fluids in Group 1 with a DN greater than 25 and a product of PS and DN greater than 2 000 bar (Annex II, table 8),
 - for fluids in Group 2 with a PS greater than 10 bar, a DN greater than 200 and a product of PS and DN greater than 5 000 bar (Annex II, table 9).
- d safety and pressure accessories intended for equipment covered by points (a), (b), and (c) including where such equipment is incorporated into an assembly.

2 The following assemblies which include at least one item of pressure equipment covered by paragraph 1 shall satisfy the essential safety requirements set out in Annex I:

- a assemblies intended for generating steam or superheated water at a temperature higher than 110 °C comprising at least one item of fired or otherwise heated pressure equipment presenting a risk of overheating;
- b assemblies other than those referred to in point (a), if the manufacturer intends them to be made available on the market and put into service as assemblies.

By way of derogation from the first subparagraph, assemblies intended for generating warm water at temperatures not greater than 110 °C which are manually fed with solid fuels and have a PS·V greater than 50 bar·L shall comply with the essential safety requirements referred to in points 2.10, 2.11, 3.4, 5 (a) and 5 (d) of Annex I.

3 Pressure equipment and assemblies below or equal to the limits set out in points (a), (b) and (c) of paragraph 1 and in paragraph 2 respectively shall be designed and manufactured in accordance with the sound engineering practice of a Member State in order to ensure safe use. Pressure equipment and assemblies shall be accompanied by adequate instructions for use.

Without prejudice to other applicable Union harmonisation legislation providing for its affixing, such equipment or assemblies shall not bear the CE marking referred to in Article 18.

Article 5

Free movement

1 Member States shall not, on grounds of the risks due to pressure, prohibit, restrict or impede the making available on the market or the putting into service under the conditions

specified by the manufacturer of pressure equipment or assemblies which comply with this Directive.

Member States shall not, on grounds of the risks due to pressure, prohibit, restrict or impede the making available on the market or the putting into service of pressure equipment or assemblies which comply with Article 4(3).

2 When a Member State has designated a user inspectorate in accordance with the requirements set out in Article 25, it may not, on grounds of the risks due to pressure, prohibit, restrict or impede the placing on the market or putting into service under the conditions provided for in Article 16, of pressure equipment or assemblies the conformity of which has been assessed by a user inspectorate designated by another Member State in accordance with the requirements set out in Article 25.

3 Member States may require, to the extent that it is needed for safe and correct use of pressure equipment and assemblies, the information referred to in points 3.3 and 3.4 of Annex I to be provided in the official language(s) of the Union which may be determined by the Member State in which the equipment or assembly is made available on the market.

- (1) Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.3.2014, p. 45).
- (2) Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (OJ L 147, 9.6.1975, p. 40).
- (3) Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) (OJ L 263, 9.10.2007, p. 1).
- (4) Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1).
- (5) Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52).
- (6) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).
- (7) Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251).
- (8) Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357).
- (9) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).
- (10) Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels (OJ L 330, 16.12.2009, p. 10).
- (11) Directive 2014/34/EU of the European Parliament and the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309).