Department for
Business, Energy
& Industrial Strategy

Regulatory Delivery

PRESSURE EQUIPMENT (SAFETY) REGULATIONS 2016

Guidance

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Contents

1. Introduction

On 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. The government respected the result and triggered Article 50 of the Treaty on European Union on 29 March 2017 to begin the process of exit. Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period the Government will also continue to negotiate, implement and apply EU legislation.

The Directive on Pressure Equipment (PED - 2014/68/EU) was adopted on 15 May 2014 and all of provisions entered into force on 19 July 2016, replacing the previous Directive 97/23/EC.

The Directive was implemented into UK law by The Pressure Equipment (Safety) Regulations 2016 (SI 2016 No.1105).

The main changes relate to alignment of the New Legislative Framework (NLF) principles. The NLF is a set of legislative acts (including the Regulation (EC) No 765/2008 and the Decision No 768/2008/EC) that aim to create a more coherent and consistent legal framework for the marketing of products in the European Union across all sectors. The new content of the 2016 Regulations, amongst others, relate to definitions and detailed obligations of “economic operators” (which are manufacturers, importers or distributors); definitions of “placing on the market” and “making available on the market”; market surveillance procedures including the EU safeguard procedures and enforcement penalties applicable in the UK against offences committed.

2. Scope

The Regulations apply to pressure equipment and assemblies with a maximum allowable pressure PS greater than 0.5 bar, although there are a number of exclusions, which are set out in regulation 4 and Schedule 1 to the Regulations. “Pressure equipment” means vessels, piping, safety accessories and pressure accessories. “Assembly” means several pieces of pressure equipment assembled to form an integrated, functional whole.

These regulations do not apply to pressure equipment placed on the market before 8 December 2016.

For the avoidance of doubt, the manufacture of pressure equipment by private individuals for their own use is excluded from the scope of the Regulations.

3. Product classification

In order to know how the Regulations apply to specific items of pressure equipment, the manufacturer will need to know:

a) the type of equipment concerned, i.e. vessel, steam generator or piping;
b) the state of the intended fluid contents – gas or liquid; and
c) the fluid group of the intended contents – Group 1 or Group 2.

Group 1 comprises those substances and mixtures, as defined in points (7) and (8) of Article 2 of Regulation (EC) No 1272/2008 of the European Parliament and the Council on classification, labelling and packaging of substances and mixtures ("the CLP Regulation"), that are classified in accordance with the following physical or health hazard classes laid down in Parts 2 and 3 of Annex I to that Regulation:

(i) unstable explosives or explosives of Divisions 1.1, 1.2, 1.3, 1.4 and 1.5;

(ii) flammable gases, category 1 and 2;

(iii) oxidising gases, category 1;

(iv) flammable liquids, category 1 and 2;

(v) flammable liquids, category 3 where the maximum allowable temperature is above the flashpoint;

(vi) flammable solids, category 1 and 2;

(vii) self-reactive substances and mixtures, type A to F;

(viii) pyrophoric liquids, category 1;

(ix) pyrophoric solids, category 1;

(x) substances and mixtures which in contact with water emit flammable gases, category 1, 2 and 3;

(xi) oxidising liquids, category 1, 2 and 3;

(xii) oxidising solids, category 1, 2 and 3;

(xiii) organic peroxides types A to F;

(xiv) acute oral toxicity, category 1 and 2;

(xv) acute dermal toxicity, category 1 and 2;

(xvi) acute inhalation toxicity, category 1, 2 and 3; and

(xvii) specific target organ toxicity - single exposure, category 1.

Assistance with identifying the hazard classes of substances can be found on the European Chemicals Agency (ECHA) website.

Group 1 also comprises substances and mixtures contained in pressure equipment with a maximum allowable temperature TS which exceeds the flashpoint of the fluid.

Group 2 comprises substances and mixtures not referred to under group 1, within the definition of a fluid, including steam.

With this information the manufacturer can identify the relevant chart in Annex II of the Directive and determine the correct classification of the equipment by plotting the maximum allowable pressure and, in the case of vessels, the volume in litres or, for piping, the nominal size (DN).

The obligations of economic operators with regard to pressure equipment and assemblies depend on their classification. Equipment and assemblies within scope which are below or equal to the limits set out in the Regulations (see regulation 6(a)-(c) and 7) must be designed and manufactured in accordance with the sound engineering practice of a Member State in order to ensure safe use and must be accompanied by adequate instructions for use. Unless required by other applicable EU legislation, this second category of equipment and assembly must not bear the CE marking. This is set out in regulation 8 of the Regulations.

In the paragraphs below, unless indicated otherwise, the references to pressure equipment or assemblies does not include those under the limits referred to in regulation 8.

4. Obligations of manufacturers

The obligations of manufacturers of pressure equipment:

1. Before placing pressure equipment on the market or using it for their own purposes, a manufacturer must ensure that it has been designed and manufactured in accordance with the essential safety requirements.

2. The manufacturer then must classify the equipment or assembly into the appropriate category, determine the conformity procedure that applies and carry out the relevant conformity assessment procedure and draw up the relevant technical documentation. Once this has been done, a manufacturer must draw up a declaration of conformity, ensure that declaration accompanies the product and affix the CE marking to the product. Where applicable, they must also ensure that the identification number of the notified body is affixed to the equipment or assembly.

3. Manufacturers must keep the declaration of conformity up to date and keep it and the relevant technical documentation for 10 years.

4. Manufacturers must also label their products with their name, registered trade name or registered trade mark and address; the type batch or serial number (or other identification) in a language that is easily understood by the end user. Where the end user is in the UK, that language is English. This applies to all products (including those to which regulation 8 refers).

5. When placing pressure equipment or an assembly on the market, a manufacturer must ensure that it is accompanied by instructions and safety information in a language which can be easily understood by the end user. This applies to all products (including those to which regulation 8 applies).

6. When appropriate, with regard to the risks to the health and safety of consumers and other users, they must carry out sample testing and they must investigate any complaints that the pressure equipment is not in conformity and keep records of these complaints.

7. They must take action where they have reason to believe that any product is not in conformity with the Regulations.

5. Obligations of authorised representatives

Manufacturers may appoint authorised representatives to perform certain tasks on their behalves. The obligations of authorised representatives include:

1. An authorised representative must comply with all the duties imposed on the manufacturer under the Regulations that they are appointed by the manufacturer to perform including the manufacturer's obligation under Regulation 12 (duty to keep technical documentation and EU declaration of conformity) and Regulation 18 (provision of information and cooperation). A manufacturer who has appointed an authorised representative to perform tasks on their behalf remains responsible for the proper performance of those tasks.

2. As far as those duties are concerned as well as penalties for failure to comply with those duties any references in the Regulations to the manufacturer are to be taken as a reference to the authorised representative.

6. Obligations of importers

The obligations of importers include:

1. The importer must ensure that where relevant, the relevant conformity assessment has been carried out by the manufacturer; the manufacturer has drawn up technical documentation; the pressure equipment or assembly is CE marked and is accompanied by the required documents and that the manufacturer has complied with the labelling requirements imposed on the manufacturer.

2. The importer must keep a copy of the Declaration of Conformity and technical documentation for a period of 10 years after the pressure equipment or assembly has been placed on the market and must co-operate with and provide information to the enforcing authorities when requested.

3. When an importer has reason to believe that pressure equipment or an assembly is not in conformity with the essential safety requirements, the importer must not place the pressure equipment or assembly on the market.

4. The importer must provide their name trade, registered trade name and a postal address at which they can be contacted on the pressure equipment or assembly.

5. The importer must ensure that when placing pressure equipment or assembly on the market, they must ensure that it is accompanied by instructions which can be easily understood by end user in the Member State where it is to be made available. If that is the UK, the language is English.

6. The importer when appropriate, having regard to the risks to the health and safety of consumers and other users, must carry out sample testing of the pressure equipment or assembly and must investigate complaints about pressure equipment or assemblies that are not in conformity with the Regulations and keep a register of those complaints.

7. The importer must take action where they have reason to believe that the pressure equipment or assembly that they have placed on the market are not in conformity with the Regulations.

8. The importer must ensure that pressure equipment or assembly under their responsibility must be transported and stored in conditions that do not affect their conformity with the essential safety requirements.

7. Obligations of distributors

The obligations of distributors include:

1. Before making available on the market a distributor must take due care to ensure that it is in conformity with Part 2 of the Regulations, meaning that it conforms with the essential safety requirements and that each economic operator has complied or is complying with the obligations imposed on them under Part 2.

2. Before making pressure equipment or assembly available on the market, a distributor must verify that the pressure equipment or assembly bears the CE marking, is accompanied by the required documents, the instructions and safety information and that the manufacturer and importer have complied with their labelling and identification requirements.

3. They must ensure that pressure equipment or assembly under their responsibility must be transported and stored in conditions that do not affect their conformity with the essential safety requirements.

4. Where the distributor has reason to believe that the pressure equipment or assembly which the distributor has made available on the market is not in conformity with Part 2, they must not make it available on the market until it is brought into conformity.

5. The distributor must take action where they have reason to believe that the pressure equipment that they have made available on the market is not in conformity with the Regulations.

6. They must also cooperate with and provide information to enforcing authorities when requested.

8. Transitional arrangements

The EU Directive 2014/68/EU on pressure equipment from which these Regulations are transposed came fully into force on 19 July 2016 and as such from that date only products that are fully compliant with the EU Directive on pressure equipment 2014/68/EU may be placed on the EU market and enjoy free movement. The UK implemented the Directive on 8 December 2016 and products compliant with the 1999 Regulations implementing the Pressure Equipment Directive 97/23/EC could be placed on the UK market until 8 December 2016, the date these new Regulations came into force but they cannot be placed on the market in other member States. Products complying with the legislation of all member States implementing Pressure Equipment Directive 97/23/EC could be placed on the EU market until 18 July 2016.

9. Notified Bodies

Notified Bodies are independent organisations appointed by EU Member State governments and notified to the European Commission to carry out the procedures for conformity assessment and certification set out in the Regulations

A list of Notified Bodies, including UK Notified Bodies appointed under the Regulations, may be found on the NANDO website. Economic operators are free to select any suitable Notified Body from any Member State.

10. Enforcement

For products intended for workplace use, the Health and Safety Executive (HSE) is responsible for the enforcement of the Regulations in Great Britain. In Northern Ireland enforcement is the responsibility of the Health and Safety Executive for Northern Ireland (HSENI).

In Great Britain trading standards authorities, and in Northern Ireland district councils, are responsible for enforcing the Regulations in relation to consumer goods

The Regulations provides powers to market surveillance authorities to take action against economic operators for products that are not in conformity with the Regulations as set out in Regulation 71. Economic operators are also required to co-operate with the enforcement authority and on request, must provide information and take action as appropriate.

Safeguard procedure

The UK is required under the Regulations to take all appropriate measures to withdraw from the market or to prohibit, and restrict the supply of products bearing CE Marking which may endanger the health and safety of persons or property. Under the safeguard procedure (Regulation 72), the UK must inform the European Commission and other EU Member States immediately of any enforcement action taken indicating the reasons justifying the action. This will enable Member States to take action against similar products placed on the market on their territories. Similarly, if another Member State initiates the procedure with respect to action taken on their territories, certain actions are required of UK market surveillance authorities and the Secretary of State. The regulations allow the Secretary of State to raise an objection against the measures taken under the safeguard procedure initiated by another Member State. The European Commission will determine whether the action taken is justified; if so the UK enforcement authority must take necessary measures to ensure the product is withdrawn from the market. Where the European Commission find the action taken by the Member State initiating the safeguard procedure is not justified that Member State must withdraw the measure.

Regulator's Code

Market Surveillance Authorities must have regard to the Regulators' Code when developing the policies and operational procedures that guide their regulatory activities in this area. They should carry out their activities in a way that supports those they regulate to comply and grow, including choosing proportionate approaches that reflect risk.

In responding to non-compliance that they identify, regulators should clearly explain what the non-compliant item or activity is, the advice being given, actions required or decisions taken, and the reasons for these. Unless immediate action is needed to prevent a serious breach, regulators should provide an opportunity for dialogue in relation to the advice, requirements or decisions, with a view to ensuring that they are acting in a way that is proportionate and consistent. The Secretary of State takes account of the provisions of both the Regulators' Code and the Growth Duty in exercising his regulatory functions.

A link to the Regulator's Code can be found here:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300126/14-705-regulators-code.pdf

Penalties

Penalties can include:

- a fine or prison sentence of up to three months or to both on summary conviction or:
- a fine or prison sentence of up to two years or both on conviction on indictment

While it is matter for the enforcement authority to decide whether prosecution is appropriate in each case, should a prosecution take place, it is at discretion of the court to decide the penalties imposed on the offender.

11. European Commission Guidance

The European Commission has produced detailed guidance on the provisions of the Directive and its requirements which can be found here under the heading "PED guidance".

The Commission has produced guidance called the Blue Guide intended to contribute to a better understanding of EU product safety rules and to their more uniform and coherent application across different sectors and throughout the single market. A copy can be found at this link:

Blue Guide http://ec.europa.eu/DocsRoom/documents/18027

This publication is available at gov.uk/regulatorydelivery

Contact us if you have any enquiries about this publication, including requests for alternative formats, at: rd.enquiries@beis.gov.uk

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