For use only if the UK has left the EU without a deal

PRESSURE EQUIPMENT (SAFETY) REGULATIONS 2016 as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

Guidance

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1. Introduction

The Pressure Equipment (Safety) Regulations 2016 set out the essential safety requirements which must be met before products can be placed on the UK market. The purpose of the legislation is to protect consumers from unsafe products by requiring manufacturers to show how their products meet the ‘essential safety requirements’.

The Regulations regulate the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0.5 bar.

This guidance is designed to help you understand the Pressure Equipment (Safety) Regulations 2016, now the UK has left the EU, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (“2016 Regulations as amended”).

2. Legislative Background

The Pressure Equipment (Safety) Regulations 2016 implemented Directive 2014/68/EU on pressure equipment. The EU Withdrawal Act 2018 preserves the Regulations and enables them to be amended so as to continue to function effectively now the UK has left the EU. Accordingly, the 2019 Amendment Regulations fix any deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and make specific provision for the UK market.

3. Scope

The 2016 Regulations as amended 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.

4. Product classification

In order to know how the 2016 Regulations as amended 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 paragraph 7(a) of Part 2 of Schedule 3 to the 2016 Regulations as amended by regulation 46(c) of Schedule 24 to the 2019 Amendment Regulations:

(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 Health and Safety Executive (HSE) 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 conformity assessment table in Schedule 1B to the 2016 Regulations as introduced by regulation 44 of Schedule 24 to the 2019 Amendment Regulations 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).

Equipment and assemblies which are below or equal to the limits set out in regulations 6(a)-(c) or 7 of the 2016 Regulations as amended must be designed and manufactured in accordance with sound engineering practice in order to ensure safe use and must be accompanied by adequate instructions for use. Unless required by other applicable legislation, this second category of equipment and assembly must not bear the UK conformity mark. This is set out in regulation 8 of the 2016 Regulations as amended.

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.

5. Obligations of manufacturers

A manufacturer is a person who manufactures pressure equipment, or has pressure equipment designed or manufactured, and either markets that pressure equipment under their name or trademark or uses it for their own purposes.

The obligations of manufacturers of pressure equipment include:

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; or, in the case of equipment falling within regulation 8, that it meets the requirements of that regulation.
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 UKCA marking, or for a time limited period the CE marking to the product. Where applicable, they must also ensure that the identification number of the relevant conformity assessment 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 trademark and address; the type batch or serial number (or other identification). The name and address must be clear, legible and in easily understandable 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 clear, legible and in easily understandable English. 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, manufacturers must carry out sample testing and they must investigate any complaints that the pressure equipment or assemblies are not in conformity and keep records of these complaints.

7. Manufacturers must take action where they have reason to believe that any product is not in conformity with the 2016 Regulations as amended.

6. Obligations of authorised representatives

Manufacturers are able by written mandate to appoint authorised representatives to perform certain tasks on their behalf.

Mandated authorised representatives established in the EEA or Switzerland prior to the UK leaving the EU continue to be recognised as authorised representatives by the UK to act in the UK for the purposes of the legislation. However, any authorised representatives appointed and mandated after the UK left the EU to act in the UK must be established in the UK to be recognised under UK law.

Businesses with an existing authorised representative based in the EEA or Switzerland can therefore continue to use the same authorised representative.

No UK-based authorised representatives are recognised under EU law. This means they cannot carry out tasks on the manufacturer’s behalf for products being placed on the EU market. Therefore, a manufacturer exporting products to the EU, who wishes to appoint an authorised representative to carry out tasks for them in respect of those products, must appoint an authorised representative based in the EU.
The obligations of authorised representatives include:

1. An authorised representative must comply with all the duties imposed on the manufacturer under the 2016 Regulations as amended that they are appointed by the manufacturer to perform including the manufacturer’s obligation under regulation 12 (duty to keep technical documentation and UK 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 2016 Regulations as amended to the manufacturer are to be taken as a reference to the authorised representative.

7. Obligations of importers

An importer is a person or business based in the UK who places a product on the UK market from a country outside the UK. This means that UK businesses who used to act as a ‘distributor’ legally become an ‘importer’ if they place products from an EEA country or Switzerland on the UK market.

Importers have additional legal obligations which go beyond those of distributors, such as checking that manufacturers have carried out the right conformity assessment procedures and included their name, registered trade name or mark and a postal address on the equipment or, where this is not possible, on its packaging or in accompanying documentation.

To assist with the transition, the UK is applying a transitional period of 18 months to allow UK suppliers of goods from the EEA or Switzerland who become importers to provide their details on the accompanying documentation as an alternative to placing them on the product itself.

The EU does not have any such transitional provision. In the absence of this, some products being exported from the UK to the EU must be labelled with the EU-based importer’s address.

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 has the UKCA marking or for a time limited period the CE marking, 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, registered trade name and a postal address at which they can be contacted on the pressure equipment or assembly, or where this is not possible in its accompanying documentation (see above for exceptions on transition).

5. The importer must ensure that when placing pressure equipment or assembly on the market, it is accompanied by instructions in clear, legible and easily understandable English.

6. Having regard to the risks to the health and safety of consumers and other users, the importer, when appropriate, must carry out sample testing of the pressure equipment or assembly they have placed on the market and must investigate complaints about pressure equipment or assemblies that are not in conformity with the 2016 Regulations as amended 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 is not in conformity with the 2016 Regulations as amended.

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.

8. **Obligations of distributors**

   UK businesses which were distributors of pressure equipment within the EU single market should now consider whether they are importers from the EU single market and therefore what additional requirements they might face – see section 7 above. The same applies to distributors of goods from the EEA and Switzerland.

   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 2016 Regulations as amended, 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 UKCA marking, or for a time limited period the CE marking, and is accompanied by the required documents, instructions and safety information, and that the manufacturer and importer have complied with their labelling and identification requirements.

   3. The distributor must ensure that while pressure equipment or assembly are under their responsibility, their storage and transport conditions do not jeopardise their conformity with the essential health and safety requirements.

   4. Where the distributor has reason to believe that the pressure equipment or assembly 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 2016 Regulations as amended.
6. The distributor must also cooperate with and provide information to enforcing authorities following any requests.

9. Transitional arrangements

‘Deeming’ provision

Products which have undergone full conformity assessment under the equivalent EU requirements and bear the CE conformity mark are deemed compliant with the UK legislation and can be placed on the UK market as if they had been UKCA marked.

The UK continues to recognise the competency of EU recognised conformity assessment bodies (notified bodies) to assess products for the UK market. Products assessed by an EU recognised notified body prior to the UK leaving the EU do not need reassessment before being placed on the UK market. This means that for a time-limited period, products assessed by an EU recognised notified body can be placed on the UK market. (For the status of UK notified bodies, please see section 10 below).

This ‘deeming provision’ is available for a limited period. This will be the subject of amending legislation in the future at a time yet to be decided. The Government will consult with industry and provide notice before ending this time-limited period.

10. UK Conformity Mark

Assessment through third-party organisations:

The UKCA conformity mark will replace the CE marking for products placed on the UK market which have been assessed by a UK approved body. In all other cases, manufacturers will be able to continue using the CE marking for products being placed on the UK market instead of the new UKCA marking for a time-limited period. The Government will engage with industry before making any decision on when this period will end.

Rules around physically affixing the new UKCA conformity marking mirror those which currently apply for the application of the CE marking.

Self-assessment:

CE marking based on self-declaration of conformity by the manufacturer is still possible, including when exporting to the EU.

Manufacturers selling goods on the UK market can alternatively affix the new UKCA conformity marking before placing a product on the UK market. It will also be possible to affix both the UKCA marking and the CE marking to the same product on the basis of self-declaration. When exporting to the EU, the CE marking remains mandatory.

Placing CE marked goods on the UK market:

Goods that meet EU regulatory requirements, including those with a CE marking, which have been assessed by an EU recognised conformity assessment body or which have been self-declared can still be placed on the UK market for a time-limited period. ‘EU-recognised’ does not include UK approved bodies. Manufacturers which have had their products assessed by EU recognised bodies are obliged to use the CE marking and cannot use the UKCA marking.
Testing Certificates:

Where conformity assessment is a 2-stage process, it is possible for products to have an EU-type-examination certification (1st stage) followed by a UK declaration by the manufacturer or third party of the production process under the responsibility of a UK Approved Body (2nd stage). Such equipment and protective systems should have the UK conformity mark followed by the UK Approved Body Number.

Further guidance on UKCA marking can be found here: https://www.gov.uk/government/publications/prepare-to-use-the-ukca-mark-after-brexit/using-the-ukca-marking-if-the-uk-leaves-the-eu-without-a-deal

Pressure equipment exported to the EU Single Market must comply with EU Directive 2014/68/EU.

11. Approved Bodies

The UK has established a new framework for UK based bodies to assess products against UK rules. Existing UK notified bodies are granted new UK ‘approved body’ status and listed on a new UK database. This includes recognised third party organisations (RTPO) and user inspectorates (UI). There is no need for existing UK notified bodies, RTPO or UI to seek re-accreditation in order to benefit from UK approved body status. These approved bodies have been given a 4-digit identification number.

Approved bodies, RTPOs and UIs can assess products and processes for the UK market against UK essential safety requirements (which are substantially the same as EU essential requirements) with respect to the activities for which they have been approved.

Approved bodies, RTPOs and UIs are conformity assessment bodies which were UK based bodies that were notified by the Secretary of State before the UK left the EU, or that have been approved by the Secretary of State to carry out certain conformity assessment activities for the UK market as set out in the 2016 Regulations as amended.

UK approved bodies and RTPOs must be established in the UK and be independent of the manufacturer; UIs must act exclusively for the group of which it is part and must be based in the United Kingdom.

Approved bodies that are tasked with assessing the conformity of pressure equipment must, as well as test the equipment where necessary, also examine the technical documentation and supporting evidence in respect of pressure equipment to assess the adequacy of the technical design.

Where an approved body, RTPO or UI finds that essential safety requirements have not been met by a manufacturer, they must not issue a certificate of conformity or grant or approval and they must require the manufacturer to take corrective measures.

Pressure equipment material manufacturers who choose to have their material manufacturing quality-assurance systems assessed, as set out as an option in the 2016 Regulations as amended, must use an approved body competent to carry out this assessment.

A list of UK approved bodies can be found [link to be added].
12. Enforcement

For pressure equipment 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 relation to equipment or assemblies intended for use on relevant nuclear sites, it is the Office for Nuclear Regulation.

In Great Britain local Trading Standards authorities, and in Northern Ireland district councils, are responsible for enforcing the Regulations in relation to consumer goods i.e. those intended for private use or consumption.

The Regulations also provide powers to the Secretary of State or a person appointed to act on their behalf to enforce the Regulations.

The Regulations provide powers to the 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.

The UK market surveillance authorities (HSE, Local Authority Trading Standards, ONR) will take all appropriate measures to withdraw from the market, to prohibit or restrict the supply of pressure equipment which may endanger the health and safety of persons, domestic animals or property.

Regulators’ Code

Market surveillance authorities must continue to 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 Regulators’ Code can be found here:

Penalties

A person committing an offence under the Regulations may be liable to a penalty. Penalties can include:

- a fine or prison sentence of up to three months, or both, on summary conviction, or
- a fine or prison sentence of up to two years, or both, on conviction or indictment.
It is a matter for the enforcement authority to decide what action is appropriate in each case taking into account the circumstances of the case and the enforcement authorities’ own policies, operational procedures and practices in line with the Regulators’ Code. Should a prosecution take place, it is at the discretion of the court to decide the penalties imposed on the offender.

13. Where to find guidance about Directive 2014/68/EU


The European Commission’s ‘Blue Guide’ aims to give a better understanding of EU product safety rules and to their application across different sectors and throughout the EU single market. You can view that here: http://ec.europa.eu/DocsRoom/documents/18027/

14. Glossary

- **Approved Bodies** – A conformity assessment body which has been approved by the Secretary of State or was a UK ‘Notified Body’ prior to the UK leaving the EU.

- **Authorised Representative** – A person appointed in writing by a manufacturer to perform specific tasks for the manufacturer. Manufacturers remain ultimately responsible for ensuring these tasks are carried out properly. This includes persons who are based in the EU or Switzerland, if they were appointed before the UK left the EU.

- **Declaration of conformity** – A document prepared by the manufacturer which must detail, among other things, the following:
  - The specific equipment to which the declaration is referring;
  - The name and address of the manufacturer and, where applicable, their authorised representative.

  This must be kept by the manufacturer for a period of ten years from the date on which the equipment was placed on the market. This declaration must be made available to the enforcing authority upon request.

- **Distributor** – Any person in the UK supply chain, other than the manufacturer or the importer, who makes equipment available on the UK market.

- **Enforcing Authority** – In Great Britain, for equipment intended for use in the workplace, this is the Health and Safety Executive. For products for consumer use this is local Trading Standards authorities. In Northern Ireland, for equipment intended for use in the workplace, this is the Health and Safety Executive Northern Ireland. For products for consumer use this is district councils. For equipment intended for use on nuclear sites, it is the Office for Nuclear Regulation.

- **Importer** – A person established in the UK who places pressure equipment from a country outside of the UK on the market. A person who before the UK left the EU distributed pressure equipment within the EU (including the UK) or from Switzerland will now be an importer if they are bringing pressure equipment into the UK from another country (including EU Member States, the EEA or Switzerland).
• **Manufacturer** – A person who manufactures pressure equipment, or has pressure equipment designed or manufactured, and either markets that equipment under their name or trademark or uses it for their own purposes.

• **UK Conformity Marking** – The UKCA (UK Conformity Assessed) marking is the new UK conformity marking used for certain goods being placed on the UK market, in place of the CE marking which is the conformity marking used in the European Union.