

PRESSURE EQUIPMENT AND CE MARKING: IMPACT AND OPPORTUNITIES OF BREXIT

Institution of
**MECHANICAL
ENGINEERS**

Pressure equipment is essential to a large number of industries and sectors, ranging all the way from large-scale chemical and power facilities, to coffee machines in public cafés. The safe design and manufacture of pressure equipment is an essential activity, and must be adequately controlled and regulated. The UK has a proud history of pressure equipment manufacturing, and it is incumbent on Government to establish appropriate arrangements for pressure equipment legislation that affords the industry significant opportunities and leverage post-Brexit. Leaving the EU presents the UK with an opportunity to streamline existing legislation and to open up the UK market for future trade deals.

The Institution of Mechanical Engineers recommends that:

- 1. CE marking of pressure equipment should cease to be mandatory in the UK.** The CE mark should instead be recognised as a minimum benchmark for pressure equipment safety, and instead of being mandatorily applied, should be considered as one route to acceptance of pressure equipment in the UK. Other routes to acceptance of pressure equipment in the UK should be established where it can be demonstrated that at least an equivalent level of safety to the CE mark can be achieved. This approach should form part of Government negotiation with non-EU bodies and organisations.
- 2. The UK Pressure Systems Safety Regulations (PSSR) 2000 should be retained as UK legislation for pressure equipment.** The PSSR 2000 provide a means to ensure the safe design, manufacture and operation of pressure systems in the UK, and should be retained post-Brexit.
- 3. For export from the UK to the EU – the CE mark will still be formally required to be applied.** Therefore, Government should seek to maintain UK exporters' and other stakeholders' influence in developments in the European Pressure Equipment Directive in the EU.

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INTRODUCTION

Pressure equipment may be put on the free market in the European Union (EU) only once a Conformité Européenne (CE) mark has been applied. This is in accordance with the requirements of the European Pressure Equipment Directive (PED) 2014/68/EU.

Under the Directive, Notified Bodies (NoBos) and User Inspectorates (UIs) carry out 'conformity assessment' of pressure equipment, in order to assess compliance with a set of Essential Safety Requirements (ESRs).

For NoBos and UIs to function under the PED, they must either be based in the EU, or operate under a Mutual Recognition Arrangement (MRA).

In 2017 the Institution of Mechanical Engineers released a policy statement, Impact of Brexit: Medical Devices and CE Marking^[1]. This paper explores the relationship between CE marking and pressure equipment, and discusses options for the future.

Given the UK's decision to leave the EU, and the potential to leave the single market and customs union, there is a need to establish future arrangements for ensuring safety in design and manufacture of pressure equipment, and to determine the arrangements for conformity assessment and certification of pressure equipment in the UK. Such arrangements should consider the future access route for UK manufacturers into the EU market, while at the same time opening up the UK for international trade outside the EU.

In parallel, the UK NoBos' interests in being able to continue to operate in the EU beyond Brexit should be safeguarded. At the same time, the UK should aim to maintain influence over policy and strategy for pressure equipment legislation across the UK and Europe.

The UK pressure equipment design, manufacture and conformity assessment industry must be given clarity with regard to the regulatory requirements for pressure equipment that will be in place during the transition period for leaving the EU and beyond.

CURRENT LEGISLATION FOR PRESSURE EQUIPMENT

The Pressure Equipment (Safety) Regulations 2016 (PE(S)R 2016), are essentially trade regulations to enable the free movement of goods between the UK and the EU. The regulations contain ESRs that include risk-based assessment and proportional conformity assessment activity, both of which are considered compatible with traditional UK goal setting and 'ALARP' approaches.

Small modifications to these regulations to remove mandatory CE marking for the UK market (which is an approach recognised in other EU Regulations where barriers to trade are not factors), and to address recognition of conformity assessment bodies, would be necessary short term.

Longer term, the regulations should be rewritten to recognise trade relationships and mutual recognition of other UK trade partners, including the EU when appropriate agreements are in place.

Regarding the PSSR 2000 – whereas these regulations do not currently mandate the use of CE-marked equipment, they do contain provisions for non-CE-marked equipment to be introduced and accepted into the UK. The PSSR 2000 provide a recognised level of safety, including for putting into service, and hence bridge any perceived gap where CE marking is absent.

CE MARKING: FINDING THE RIGHT ROUTE TO MARKET

CE marking is a trade arrangement, and providing certainty is important to safeguard growth in the UK, while maintaining adequate levels of safety.

The recommendations in this paper do not seek to remove CE marking from the UK. Instead they seek to introduce a choice in that: where CE marking has been applied, the UK requirements will be met, and where CE marking has not been applied, an equivalent level of safety and suitability must be met in order to address the UK regulations.

This means that the UK regulations may, in time, come to recognise other national safety rules, such as the US National Board, ASME code certification marking, the Indian Boiler Regulations, the Japanese High Pressure Gas Control Law, where suitable trade relationships have been established, mutual recognition made and an equivalent level of safety has been demonstrated.

In practice, however, the Brexit transitional period should see no change in the current CE marking requirement. As the separation from EU Law continues, the PE(S)R 2016 should to be amended to reflect the acceptable safety and trade regimes.

To this end, the UK should introduce a control board to review and confirm suitability of new or changed requirements related to pressure equipment. The control board should also consult with the Health and Safety Executive (HSE), to ensure that a robust safety regime is retained.

This board would also act as the international collaboration vehicle for technical safety aspects of pressure equipment.

MAINTAINING UK INFLUENCE ON EU POLICY

The UK has a long history of collaboration with the EU throughout the pressure equipment industry. This must be enhanced post-Brexit, and is a definite positive benefit to the EU and our wider potential trade partners.

A critical aspect in maintaining UK influence on CE marking, is one of stability and certainty. Currently the majority of UK manufacturers utilise the services of UK-appointed conformity assessment bodies.

For the PED, there are four types of conformity assessment body recognised by the Directive:

1. Notified Body – notified to the Commission and Member States by a Member State
2. Recognised Third Party – recognised by a Member State as being competent to conduct certain activities
3. User Inspectorate – appointed by a Member State to act on behalf of a User in a Member State
4. A 'competent body established in the Community', acting in the frame of assessment of material suppliers' quality management systems.

The UK Brexit negotiations must quickly identify the mechanism for UK-appointed conformity assessment bodies to be recognised by the remaining EU Members.

Secondly the 'competent body' element, which in this specific case is recognition of UKAS-accredited certification bodies, must be addressed, by defining 'established in the Community' to UK- and UKAS-accredited bodies' benefit.

This does not have to be a concession by the remaining EU Members, if the positive benefits of UK technical contributions are recognised and promoted.

The conformity assessment bodies currently appointed by the UK are actively represented in EU co-ordination activities, thereby ensuring UK manufacturers' issues are represented and subsequently informed of discussions and outcomes.

The Institution of Mechanical Engineers supports the position of BSI to remain a part of the European Committee for Standardization (CEN), and the European Committee for Electrotechnical Standardization (CENELEC) post-Brexit. BSI states:

"All three organizations are entirely private bodies, and therefore not part of the EU's institutional framework, and BSI's continued membership should not accordingly be affected by Brexit."

BSI has secured membership of CEN and CENELEC after we leave the EU, by asserting its continued commitment to meeting the rules of participation in the system^[2].

CONSULTATION

IMechE has consulted the wider pressure equipment industry in the UK in making the three recommendations outlined in this paper.

There are a number of influential groups in the UK, whose voice has been sought in developing the recommendations in this paper:

- IMechE Pressure Systems Group
- UK Pressure Equipment Consultation Forum
- UK Pressure Vessel Manufacturers Forum
- Engineering Equipment and Materials Users Association
- Individual experts and consultants

On balance, it is considered that there are a significant number of opportunities afforded to the pressure equipment industry by Brexit, and hence the points outlined above in this paper are made to Government.

RECOMMENDATIONS

1. **CE marking of pressure equipment should cease to be mandatory in the UK. The CE mark should instead be recognised as a minimum benchmark for pressure equipment safety, and instead of being mandatorily applied, should be considered as one route to acceptance of pressure equipment in the UK. Other routes to acceptance of pressure equipment in the UK should be established where it can be demonstrated that at least an equivalent level of safety to the CE mark can be achieved. This approach should form part of Government negotiation with non-EU bodies and organisations.**

Under this arrangement, pressure equipment manufacturers worldwide may elect to comply with EU legislation as a means to fulfil UK expectations and requirements. Therefore, the current arrangements for EU-based manufacturers seeking to import into the UK would be maintained (and hence frictionless trade may continue), but at the same time pressure equipment manufacturers in non-EU countries will be able to export to the UK if it can be demonstrated that the imported pressure equipment has at least an equivalent level of safety to CE-marked pressure equipment.

Thus the UK will be better positioned to facilitate trade deals with non-EU countries, while at the same time being able to maintain confidence in the safety of imported equipment. The Pressure Equipment (Safety) Regulations 2016 should be accordingly amended to reflect this approach.

To encourage exports from the UK, the manufacturing base in the UK should be represented in a reciprocal fashion as part of bilateral trade deals. By recognising CE marking as a minimum level of safety for pressure equipment in the UK, this approach will therefore maintain equivalence to the current minimum EU trade requirements.

2. **The UK Pressure Systems Safety Regulations (PSSR) 2000 should be retained as UK legislation for pressure equipment.**

The PSSR 2000 provide a means to ensure the safe design, manufacture and operation of pressure systems in the UK, and should be retained post-Brexit.

It may however be necessary to review, consult on and modify some specific elements of the PSSR 2000, due to the removal of the CE mark as a mandatory requirement. For example, while regulations 4 and 5 of the PSSR require that an item of pressure equipment be designed and manufactured to be safe, under the PSSR 2000, the satisfaction of a 'competent person' is required only prior to putting the equipment into service. Therefore, the arrangements for the involvement of the competent person during design and manufacture (as would be the case for conformity assessment by a NoBo under the PED) may need to be reviewed.

Lastly, no 'stamp' or 'mark' is needed under the PSSR 2000, and it is considered that there is no need for the UK to now develop its own equivalent of the CE mark or kite mark.

3. **For export from the UK to the EU – the CE mark will still be formally required to be applied. Therefore, Government should seek to maintain UK exporters' and other stakeholders' influence in developments in the PED in the EU.**

This influence will include acceptance of UK Notified Bodies in the EU, and clarity as to the future operations of the United Kingdom Accreditation Service (UKAS).

The UK has an active collaboration with the EU concerning pressure equipment, and this should continue post-Brexit.

REFERENCES

- ¹ Impact of Brexit: Medical Devices and CE Marking. Institution of Mechanical Engineers 2017
- ² Standards policy on the UK leaving the EU. BSI 2018 <https://www.bsigroup.com/en-GB/about-bsi/uk-national-standards-body/standards-policy-on-the-uk-leaving-the-eu/>

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