



Department for
Business, Energy
& Industrial Strategy

Regulatory Delivery

EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES REGULATIONS 2016

Guidance

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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 equipment and protective systems intended for use in potentially explosive atmospheres ([ATEX - 2014/34/EU](#)) was adopted on 26 February 2014.

The Directive was implemented into law in Great Britain by The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 (SI 2016 No. 1107). Equivalent regulations apply in Northern Ireland (The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2017).

This Guide relates, primarily, to the position in respect of the Great Britain Regulations. The European Commission has produced detailed guidance on the provisions of the Directive and its requirements, which should be referred to for further guidance. The European Commission's guidance can be found at:

<http://ec.europa.eu/DocsRoom/documents/16402/attachments/1/translations>

The main changes the Regulations introduced 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) 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 (defined as a manufacturer, authorised representative, importer or distributor); definitions of "placing on the market" and "making available on the market"; market surveillance procedures including the Union safeguard procedures and enforcement penalties applicable in the UK against offences committed.

2. Scope

The Regulations apply to equipment and protective systems intended for use in potentially explosive atmospheres as defined in regulation 3 (1) and (2).

Specifically, the Regulations relate to:

- equipment intended for use in potentially explosive atmospheres, defined as machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy or the processing of material and which are capable of causing an explosion through their own potential sources of ignition;

- protective systems intended for use in potentially explosive atmospheres, defined as devices which are intended to halt incipient explosions immediately and/or to limit the effective range of explosion flames and explosion pressures. Protective systems may be integrated into equipment or separately placed on the market for use as autonomous systems;
- safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but which are required for or contribute to the safe functioning of equipment and protective systems, with respect to the risks of explosion; and
- components defined as any item essential to the safe functioning of equipment and protective systems but with no autonomous function.

The same rules will apply everywhere in the European Union, so products complying with the requirements may be sold anywhere in the EU.

The Regulations do not apply to products listed in regulation 3(3).

The Regulations do not apply to products placed on the market before 8 December 2016.

3. Obligations of manufacturers

The obligations of manufacturers of products include:

1. Before placing a product on the market, a manufacturer must ensure that it has been designed, manufactured, installed and tested in accordance with the essential health and safety requirements and that they have had have a relevant conformity assessment procedure carried out and technical documentation drawn up.
2. Once this has been done, a manufacturer must draw up a declaration of conformity, or a written attestation of conformity (for components of products), ensure that declaration or attestation accompanies the product; affix the CE marking and the specific marking of explosion protection followed by the symbol of the equipment-group and category to the product.
3. Manufacturers must keep the declaration of conformity up to date and keep it and technical documentation for 10 years after the equipment has been placed on the market.
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) and ensure that they are accompanied by relevant instructions.
5. They must, when appropriate with regard to any risk posed to end-users, carry out sample testing of products and investigate any complaints that the products are not in conformity and keep records of these complaints.
6. They must take action where they have reason to believe that the products they have placed on the market are not in conformity with the Regulations.
7. They must also cooperate with and provide information to enforcing authorities following any requests.

4. Obligations of authorised representatives

Manufacturers are able to 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 mandate by the manufacturer to perform including manufacturer's obligation under regulation 8 (retention of technical documentation and EU declaration of conformity), and regulation 16 (provision of information and cooperation). A manufacturer remains responsible for the proper performance of any obligations the authorised representative performs on their behalf.
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.

5. Obligations of importers

The obligations of importers include:

1. Before placing a product on the market an importer must ensure that it is in conformity with the essential health and safety requirements.
2. The importer must ensure that the relevant conformity assessment has been carried out by the manufacturer; the manufacturer has drawn up technical documentation; the product is CE marked and is accompanied by the Declaration of Conformity or attestation of conformity (as applicable) as well as required labelling including the specific marking of explosion protection followed by the symbol of the equipment-group and category to the product and manufacturer's identification.
3. The importer must keep a copy of the Declaration of Conformity or attestation of conformity (as applicable) and technical documentation for a period of 10 years after the product has been placed on the market.
4. The importer must not place products on the market unless they conform with the essential health and safety requirements.
5. The importer must provide their name trade, registered trade name and a postal address at which they can be contacted on the product.
6. The importer must ensure that when placing a product on the market, 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 the end user is in the UK, that language must be English.
7. The importer must, when appropriate, with regard to any risk posed to end-users, carry out sample testing of products and investigate complaints about products that are not in conformity with the Regulations and keep a register of those complaints.
8. The importer must take action where they have reason to believe that the products that they have placed on the market are not in conformity with the Regulations.

9. The importer must ensure that whilst products are under their responsibility, their storage and transport conditions do not jeopardise their conformity with the essential health and safety requirements.
10. They must also cooperate with and provide information to enforcing authorities following any requests.

6. Obligations of distributors

The obligations of distributors include:

1. When making a product available on the market a distributor must act with due care to ensure that it is in conformity with Part 2 of the Regulations, which means the product must be in conformity with the essential health and safety requirements and that each economic operator has complied with the obligations imposed on them by Part 2 of the Regulations.
2. Where a distributor considers that a product is not in conformity with the health and safety requirements, the distributor must not make that product available on the market.
3. Before placing a product on the market, the distributor must verify that the product bears a CE marking (where applicable), is accompanied by the EU declaration of conformity or the attestation of conformity; that it is accompanied by instructions and safety information and that the importer and manufacturer have complied with their obligations as to required labelling including the specific marking of explosion protection followed by the symbol of the equipment-group and category to the product and their identification.
4. The distributor must take action where they have reason to believe that the products that they have made available on the market are not in conformity with the Regulations.
5. The distributor must ensure that whilst products are under their responsibility, their storage and transport conditions do not jeopardise their conformity with the essential health and safety requirements.
6. They must also cooperate with and provide information to enforcing authorities following any requests.

7. Transitional arrangements

The European Directive 2014/34/EU ATEX Directive from which these Regulations are transposed came fully into force on 20 April 2016 and as such from that date only products that are fully compliant with the European Directive 2014/34/EU (ATEX Directive) may be placed on the European market and enjoy free movement. The UK implemented the Directive on 8 December 2016 and so products compliant with the Equipment and Protective Systems Intended for Potentially Atmospheres Regulations 1996 implementing the Directive 94/9/EC (ATEX Directive) 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 Directive 94/9/EC could be placed on the EU market until 19 April 2016.

Certificates issued under the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996 or legislation implementing Directive 94/9/EC from other Member States shall remain valid.

8. 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.

9. Enforcement and penalties

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 \(HSENI\)](#).

The Office of Nuclear Regulation is responsible for enforcement in relation to products intended to be used on nuclear sites in Great Britain.

The Market Surveillance authority must enforce the Regulations and RAMS (Regulation (EC 765/2008 which sets out requirements for market surveillance of products).

Note: ATEX has separate Regulations for Northern Ireland not covered by this guidance

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 55 to 60. 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, property or the environment. Under the safeguard procedure, 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 (Regulation 57).

Regulation 57(2) allows the Secretary of State to raise an objection against the measures taken under the safeguard procedure initiated by another Member State. The Commission will determine whether the action taken is justified; if so, the UK enforcement authority must take necessary measures to ensure electrical equipment is withdrawn from the market. Where the European Commission finds the action taken by the Member State initiating the safeguard procedure is not justified, that Member State must withdraw that measure.

Regulators' 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 Regulators' Code can be found here:

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

Penalties

A person committing an offence under the Regulations will be liable to a penalty. 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.

10. 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 "Where can I find further guidance or support?"

The European 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/>



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