

2016 No.

HEALTH AND SAFETY

**The Equipment and Protective Systems Intended for Use in
Potentially Explosive Atmospheres Regulations 2016**

Made - - - - - ***

Laid before Parliament ***

Coming into force - - - [date]

The Secretary of State is a Minister designated^(a) for the purposes of section 2(2) of the European Communities Act 1972^(b) in relation to measures relating to equipment and protective systems intended for use in potentially explosive atmospheres.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for certain references to provisions of EU instruments to be construed as references to those provisions as amended from time to time.

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A(c) of Schedule 2 to, the European Communities Act 1972:

PART 1

Preliminary

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 and come into force on 20th April 2016.

(2) These Regulations extend to England, Wales and Scotland.

Interpretation

2.—(1) In these Regulations—

the “1974 Act” means the Health and Safety at Work etc Act 1974^(a);

^(a) S.I. 1995/751.

^(b) 1972 c.68; section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), section 27(1) and the European Union (Amendment) Act 2008 (c.7), Schedule, Part 1.

^(c) Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 and amended by the European Union (Amendment) Act 2008, Schedule, Part 1.

the “1994 Directive” means Directive 94/9/EC of the European Parliament and the Council on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres;

“the 1996 Regulations” means the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996;

“accreditation” has the meaning set out in point 10 of Article 2 of RAMS;

“accreditation certificate” means a certificate, issued by the United Kingdom Accreditation Service or a national accreditation body in another member State, attesting that a conformity assessment body meets the notified body requirements;

“ATEX Directive” means Directive 2014/34/EU of the European Parliament and the Council on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (recast);

“attestation of conformity” means a declaration of conformity required to be drawn up in accordance with regulation 7(2) (Conformity assessment requirements);

“authorised representative” means a person appointed in accordance with regulation 17(1);

“CE marking” means a marking which takes the form set out in Annex II of RAMS (as amended from time to time);

“components” mean any items essential to the safe functioning of equipment and protective systems but with no autonomous function;

“conformity assessment” means the process demonstrating whether the essential safety requirements relating to a product have been fulfilled;

“conformity assessment body” means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;

“distributor” means any person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

“economic operator” means a manufacturer, authorised representative, importer or distributor;

“enforcing authority” means any person enforcing these Regulations under regulation 52 (enforcement)

“essential safety requirements” means the requirements set out in Schedule 1 (essential safety requirements);

“EU declaration of conformity” means a declaration of conformity required to be drawn up in accordance with regulation 7(1)(a) (EU declaration of conformity and CE marking);

“equipment” means 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 and the processing of material, as the case may be, and which are capable of causing an explosion through their own potential sources of ignition;

“equipment-category” means the classification of equipment, within each equipment group specified in Annex I of the ATEX Directive (as amended from time to time), determining the requisite level of protection to be ensured;

“equipment-group I” means equipment intended for use in underground parts of mines, and in those parts of surface installations of such mines, liable to be endangered by firedamp and/or combustible dust, comprising equipment categories M 1 and M2 as set out in Annex I of the ATEX Directive (as amended from time to time);

“equipment-group II” means equipment intended for use in other places liable to be endangered by explosive atmospheres, comprising categories 1, 2 and 3 as set out in Annex I of the ATEX Directive (as amended from time to time);

(a) 1974 c.37.

“explosive atmosphere” means a mixture with air, under which atmospheric conditions of flammable substances in the form of gases, vapours, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture;

“harmonised standard” has the meaning set out in point 1(c) of Article 2 of Regulation (EU) 1025/2012 of the European Parliament and of the Council on European standardisation^(a) (as amended from time to time);

“importer” means any person who—

- (a) is established within the EU; and
- (b) places a product from a third country on the EU market;

“intended use” means the use of a product prescribed by the manufacturer by assigning the equipment to a particular equipment-group and category or by providing all the information which is required for the safe functioning of a protective system, device or component;

“make available on the market” means any supply for distribution, consumption or use on the EU market in the course of a commercial activity, whether in return for payment or free of charge, and related expressions must be construed accordingly;

“manufacturer” means a person who—

- (a) manufactures a product; or
- (b) has such a product designed or manufactured and either
 - (i) markets the product under that person’s name or trade mark; or
 - (ii) uses such product for that person’s own purposes.

“national accreditation body” has the meaning set out in point 11 of Article 2 of RAMS.

“notified body requirements” means the requirements set out in Schedule 2 (notified body requirements);

“place on the market” means the first making available on the EU market, and related expressions must be construed accordingly;

“potentially explosive atmosphere” means an atmosphere which could become explosive due to local and operational conditions;

“protective systems” means devices other than components of equipment which are intended to halt incipient explosions immediately and/or to limit the effective range of an explosion and which are separately made available on the market for use as autonomous systems;

“RAMS” means Regulation (EC) 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93^(b);

“recall” means taking any measure aimed at achieving the return of a product that has already been made available to the end-user and related expressions must be construed accordingly;

“technical documentation” has the meaning given in regulation 6 (technical documentation and conformity assessment);

“technical specification” means a document that prescribes technical requirements to be fulfilled by a product;

“withdraw”, when used in relation to a product, means taking any measure aimed at preventing a product in the supply chain from being made available on the market and related expressions must be construed accordingly.

(2) In these Regulations, a reference to a product being “in conformity with Part 2” means that—

- (a) the product is in conformity with the essential safety requirements; and

^(a) OJ L 316, 14.11.2012, p. 12.

^(b) OJ L 218, 13.8.2008, p. 30.

- (b) each relevant economic operator has complied with the obligations imposed on them under Part 2 which must be satisfied at or before the time at which they make the product article available on the market.
- (3) In these Regulations (except in Part 4 (notification of conformity assessment bodies) and Schedules 2 (notified body requirements) and 3 (operational obligations of notified bodies)),
- (4) “notified body” means—
 - (a) a notified body within the meaning set out in regulation 42 (notified bodies); or
 - (b) a notified body under the laws of any other member State which implement the Directive.
- (5) In these Regulations (except in regulations 10 and 24 (monitoring) and Schedule 1 (essential safety requirements)), “risk” means a risk to—
 - (a) human health [and safety];
 - (b) domestic animals; or
 - (c) property.

Scope [Art 1]

- 3.—**(1) Subject to paragraph (3), these Regulations apply to products.
- (2) For the purposes of these Regulations a “product” shall mean—
 - (a) equipment and protective systems intended for use in potentially explosive atmospheres;
 - (b) safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion;
 - (c) components intended to be incorporated into equipment and protective systems referred to in paragraph (a).
- (3) These Regulations do not apply to—
 - (a) medical devices intended for use in a medical environment;
 - (b) equipment and protective systems where the explosion hazard results exclusively from the presence of explosive substances or unstable chemical substances;
 - (c) equipment intended for use in domestic and non-commercial environments where potentially explosive atmospheres may only rarely be created, solely as a result of the accidental leakage of gas;
 - (d) personal protective equipment covered by Council Directive 89/686/EEC of 21 December 1989^(a);
 - (e) seagoing vessels and mobile offshore units together with equipment on board such vessels or units;
 - (f) means of transport, i.e. vehicles and their trailers intended solely for transporting passengers by air or by road, rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, by public road or rail networks or by water. Vehicles intended for use in a potentially explosive atmosphere shall not be excluded from the scope of this Regulation;
 - (g) the equipment covered by Article 346(1)(b) of the Treaty on the Functioning of the European Union.

Exceptions for trade fairs, exhibitions and demonstrations [Art 3(3)]

4. Nothing in these Regulations prevents the showing of a product, which is not in conformity with Part 2, at a trade fair, exhibitions and demonstrations provided that a visible sign clearly indicates—

(a) OJ L 399, 30.12.1989, p. 18.

- (a) the products are not in conformity with Part 2; and
- (b) that the products are not available for sale until brought into conformity.

PART 2

Obligations of economic operators

Manufacturers

Design and manufacture in accordance with essential safety requirements [Art 6(1)]

5. Before placing a product on the market or using a product for their own purposes, a manufacturer must ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Schedule 1.

Technical documentation and conformity assessment [Art 6(2)]

- 6.** Before placing a product on the market or using it for their purposes, a manufacturer must—
- (a) have a relevant conformity assessment procedure carried out; and
 - (b) draw up the technical documentation referred to—
 - (i) for a product in respect of which the conformity assessment procedure in regulation 39(a) is being carried out, in point 3(c) of Module B of Annex III to the ATEX Directive (as amended from time to time);
 - (ii) for a product in respect of which the conformity assessment procedure in regulation 39(b) is being carried out, in point 3(c) of Module B of Annex III to the ATEX Directive (as amended from time to time);
 - (iii) for a product in respect of which the conformity assessment procedure in regulation 39(c) is being carried out, in point 2 of Module A of Annex VIII to the ATEX Directive (as amended from time to time);
 - (iv) for a product in respect of which the conformity assessment procedure in regulation 39(d) is being carried out, in Point 2 of Module G of Annex IX to the ATEX Directive (as amended from time to time).

EU declaration of conformity and CE marking [Art 6(2), para 1-3]

7.—(1) Where the conformity of a product, other than a component, has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the product on the market—

- (a) draw up an EU declaration of conformity in accordance with regulation 40 (EU declaration of conformity); and
- (b) affix the CE Marking in accordance with regulation 41 (CE Marking)

(2) Where the conformity of a component has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the component on the market, draw up a written attestation of conformity in accordance with regulation 39(3) (Conformity assessment procedures).

(3) Before placing a product on the market, the manufacturer must ensure that—

- (a) each product is accompanied by a copy of the EU declaration of conformity or attestation of conformity as appropriate; and
- (b) where a large batch of products and/or components is delivered to a single user, the batch or consignment may be accompanied by a single copy of the EU declaration or attestation of conformity as appropriate.

Retention of technical documentation and EU declaration of conformity [Art 6(3)]

8. A manufacturer must keep the technical documentation, the EU declaration of conformity or where applicable, the attestation of conformity drawn up in respect of the product for a period of 10 years beginning on the day on which the product was placed on the market.

Compliance procedures for series production [Art 6(4)]

9.—(1) A manufacturer must ensure that procedures are in place to ensure that a product manufactured in series remain in conformity with Part 2.

(2) In doing so, the manufacturer must take adequate account of—

- (a) any change in the design or characteristics of the product; and
- (b) any change in a harmonised standard or in another technical specification by reference to which the EU declaration of conformity or attestation of conformity was drawn up.

Monitoring [Art 6(4), para 1]

10. When appropriate, with regard to the risks to the health and safety of end-users presented by a product, a manufacturer must—

- (a) carry out sample testing of a product made available on the market;
- (b) investigate complaints that a product is not in conformity with Part 2;
- (c) keep a register of—
 - (i) complaints;
 - (ii) a product which is not in conformity with Part 2; and
 - (iii) a product recall; and
- (d) keep distributors informed of any such monitoring carried out under sub-paragraphs (a), (b) and (c).

Labelling and packaging of products [Art 6(5)]

11.—(1) Before placing a product on the market, a manufacturer must ensure that it bears a type, batch or serial number allowing its identification.

(2) Where the size or nature of the product does not allow it, the information in paragraph (1) must be provided on the packaging or in a document accompanying the product.

Labelling and packaging of products, other than components [Art 6(6)]

12.—(1) Before placing a product, other than a component, on the market a manufacturer must ensure that it—

- (a) bears the specific marking of explosion protection as referred to at paragraph 5(f) of Schedule 1; and
- (b) where applicable, the other markings and information referred to at paragraph 5 of Schedule 1.

(2) Where it is not possible to indicate the information specified in paragraph (1) on the product, the manufacturer must indicate that information—

- (a) on the packaging; or
- (b) in a document accompanying the product.

Information identifying manufacturer [Art 6(7)]

13.—(1) Before placing a product on the market, a manufacturer must indicate on the product—

- (a) the name, registered trade name or registered trade mark of the manufacturer; and

(b) a single postal address at which the manufacturer can be contacted.

(2) Where it is not possible to indicate the information specified in paragraph (1) on the product, the manufacturer must indicate that information—

(a) on the packaging; or

(b) in a document accompanying the product.

(3) The information specified in paragraph (1) must be in a language which can be easily understood by end-users and the competent national authority in the member State in which it is to be made available to such end-users.

Instructions and safety information [Art 6(8)]

14.—(1) When placing a product 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 end-users.

(2) The instructions and safety information referred to in paragraph (1) and any labelling must be clear and understandable.

Duty to take action in respect of a product placed on the market which is considered not to be in conformity [Art 6(9)]

15.—(1) A manufacturer who considers, or has reason to believe, that a product which that manufacturer has placed on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

(a) bring the product into conformity;

(b) withdraw the product; or

(c) recall the product.

(2) Where the product presents a risk, the manufacturer must immediately inform the market surveillance authority of the risk, and the competent national authorities of any member State in which the manufacturer made the product available on the market, of the risk, giving details of—

(a) the respect in which the product is considered not to be in conformity with Part 2; and

(b) any corrective measures taken.

Provision of information and cooperation [Art 6(10)]

16.—(1) Further to a reasoned request from the enforcing authority, a manufacturer, within such period as the authority may specify, must, provide the authority with all the information and documentation necessary to demonstrate that the product is in conformity with Part 2.

(2) The information referred to in paragraph (1)—

(a) may be provided electronically; and

(b) must be in a language which can be easily understood by the enforcing authority.

(3) A manufacturer must, at the request of the enforcing authority.

(4) A manufacturer must, at the request of the enforcing authority, cooperate with that authority on any action taken to—

(a) evaluate a product in accordance with regulation 55 (evaluation of products presenting a risk);

(b) eliminate the risks posed by a product which the manufacturer has placed on the market.

Authorised representatives [Art 7]

17.—(1) A manufacturer may, by written mandate, appoint a person established within the EU as their authorised representative to act on their behalf in relation to specified tasks. [Art 7(1)]

- (2) The mandate must allow the authorised representative to do at least the following—
- (a) in relation to a product covered by the mandate, perform the manufacturer’s obligations under—
 - (i) regulation 8 (retention of technical documentation and EU declaration of conformity); and
 - (ii) regulation 16 (provision of information and cooperation);
- (3) An authorised representative must be appointed to perform the manufacturer’s obligations under regulation 5 (design and manufacture in accordance with essential safety requirements), regulation 6 (technical documentation and conformity assessment) and regulation 7 (EU declaration of conformity and CE marking). [Art 7(1), para 2]
- (4) An authorised representative must comply with all duties imposed on the manufacturer in relation to each obligation under these Regulations that the authorised representative is appointed by the manufacturer to perform and, accordingly—
- (a) as far as those duties are concerned, references in these Regulations to the manufacturer (except in this regulation) are to be taken as including a reference to the authorised representative; and
 - (b) if the authorised representative contravenes or fails to comply with any of those duties, the authorised representative may be proceeded against as though the authorised representative were the manufacturer.
- (5) A manufacturer who has appointed an authorised representative to perform on their behalf an obligation under these Regulations remains responsible for the proper performance of that obligation.

Importers

Prohibition on placing on the market products which are not in conformity [Art 8(1)]

18. An importer must not place a product on the market unless it is in conformity with Part 2.

Requirements which must be satisfied before an importer places a product on the market [Art 8(2)]

- 19.—**(1) Before placing a product on the market, an importer must ensure that—
- (a) the relevant conformity assessment procedure has been carried out by the manufacturer;
 - (b) the manufacturer has drawn up the technical documentation;
 - (c) the product bears—
 - (i) the CE marking; and
 - (ii) where applicable, is accompanied by the EU declaration of conformity or the attestation of conformity and the required documents; and
 - (d) the manufacturer has complied with the requirements set out in regulation 11 (labelling and packaging of products), regulation 12 (Labelling and packaging of products, other than components) and regulation 13 (information identifying manufacturer).
- (2) In paragraph (1)(c)(ii), “required documents” means the documents that the manufacturer is required to provide with a product pursuant to—
- (a) regulation 7 (EU declaration of conformity and CE marking);
 - (b) regulation 11 (Labelling and packaging of products); and
 - (c) where applicable regulation 12 (Labelling and packaging of products, other than components).

Prohibition on placing on the market products considered not to be in conformity with the essential safety requirements [Art 8(2), para 1]

20.—(1) Where an importer considers, or has reason to believe, that a product is not in conformity with the essential safety requirements, the importer must not place the product on the market.

(2) Where the product presents a risk, the importer must inform the manufacturer and the market surveillance authority of that risk.

Information identifying importer [Art 8(3)]

21.—(1) Before placing a product on the market, an importer must indicate on the product—

- (a) the name, registered trade name or registered trade mark of the importer; and
- (b) a postal address at which the importer can be contacted.

(2) The information specified in paragraph (1) must be in a language which can be easily understood by end-users and the market surveillance authority in the member State in which it is to be made available to end-users.

(3) Where it is not possible to indicate the information specified in paragraph (1) on the product, the importer must indicate that information—

- (a) on the packaging; or
- (b) in a document accompanying the product.

Instructions and safety information [Art 8(4)]

22.—(1) When placing a product on the market, an importer must ensure that it is accompanied by instructions and safety information in a language which can be easily understood by end-users.

(2) The instructions and safety information referred to in paragraph (1) and any labelling must be clear and understandable.

Storage and transport [Art 8(5)]

23. An importer must ensure that, while a product is under the importer's responsibility, its storage or transport conditions do not jeopardise its conformity with the essential safety requirements.

Monitoring [Art 8(6)]

24. When appropriate, with regard to the risks to the health and safety of end-users presented by a product, an importer must—

- (a) carry out sample testing of a product made available on the market;
- (b) investigate complaints that a product is not in conformity with Part 2;
- (c) keep a register of—
 - (i) complaints;
 - (ii) products which are not in conformity with Part 2; and
 - (iii) product recalls; and
- (d) keep distributors informed of any such monitoring.

Duty to take action in respect of a product placed on the market which is considered not to be in conformity [Art 8(7)]

25. An importer who considers, or has reason to believe, that a product which the importer has placed on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

- (a) bring the product into conformity;
- (b) withdraw the product; or
- (c) recall the product.

26. Where the product presents a risk, the importer must immediately inform the market surveillance authority, and the competent national authorities of any member State in which the importer made the product available on the market, of the risk, giving details of—

- (a) the respect in which the product is considered not to be in conformity with Part 2; and
- (b) any corrective measures taken.

Provision of information and cooperation [Art 8(9)]

27.—(1) An importer must, further to a reasoned request from an enforcing authority and within such period as the enforcing authority may specify, provide the authority with all the information and documentation necessary to demonstrate that the product is in conformity with Part 2—

- (a) in paper or electronic form; and
- (b) in a language which can be easily understood by the enforcing authority.

(2) An importer must, at the request of the enforcing authority, cooperate with the authority on any action taken to—

- (a) evaluate a product in accordance with regulation 55 (evaluation of a product presenting a risk);
- (b) eliminate the risks posed by the product which the importer has placed on the market.

Retention of technical documentation and EU declaration of conformity [Art 8(8)]

28. Where an importer places a product on the market after [*day before the Regulations come into force*] the importer must for a period of ten years beginning on the day on which the product was placed on the market, keep and, upon request, make available to the enforcing authorities, in respect of that product—

- (a) a copy of the EU declaration of conformity or, where applicable, the attestation of conformity; and
- (b) the technical documentation.

Distributors

Duty to act with due care [Art 9(1)]

29. 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.

Requirements which must be satisfied before a distributor makes a product available on the market [Art 9(2)]

30.—(1) Before making a product available on the market, the distributor must verify that—

- (a) the product—
 - (i) bears the CE marking;
 - (ii) is accompanied by the EU declaration of conformity or the attestation of conformity;
 - (iii) is accompanied by the required documents;
 - (iv) is accompanied by instructions and safety information in a language which can be easily understood by end-users in the member State in which the product is to be made available on the market;

- (b) the manufacturer has complied with the requirements set out in regulation 11 (labelling and packaging of products), regulation 12 (labelling and packaging of products, other than components);
- (c) the importer has complied with the requirements set out in regulation 21 (information identifying importer)

(2) In paragraph (1)(a)(iii), “required documents” means the documents that the manufacturer or importer is required to provide with the product pursuant to—

- (a) regulation 11 (labelling and packaging of products) and regulation 12 (labelling and packaging of products, other than components);
- (b) regulation 13 (information identifying manufacturer)
- (c) regulation 21 (information identifying importer);
- (d) regulation 14 and regulation 22 (instructions and safety information).

Storage and transport [Art 9(3)]

31. The distributor must ensure that, while a product is under the distributor’s responsibility, its storage or transport conditions do not jeopardise its conformity with the essential safety requirements.

Prohibition on making available on the market products considered not to be in conformity with safety objectives [Art 9(2), para 2]

32.—(1) Where a distributor considers or has reason to believe that a product is not in conformity with the essential safety requirements, the distributor must not make the product available on the market until it has been brought into conformity.

(2) Where the product presents a risk, the distributor must inform the following persons of the risk—

- (a) the manufacturer or the importer; and
- (b) the market surveillance authority.

Duty to take action in respect of a product placed on the market which is considered not to be in conformity [Art 9(4)]

33.—(1) A distributor who considers, or has reason to believe, that a product which that distributor has placed on the market is not in conformity with Part 2 must ensure that the necessary corrective measures are taken to—

- (a) bring that product into conformity;
- (b) withdraw the product; or
- (c) recall the product.

(2) Where the product presents a risk, the distributor must immediately inform the market surveillance authority, and the competent national authorities of the other member States in which the distributor has made the product available on the market, of that risk, giving details of—

- (a) the respect in which the product is considered not to be in conformity with Part 2; and
- (b) any corrective measures taken.

Provision of information and cooperation [Art 9(5)]

34.—(1) A distributor must, further to a reasoned request from an enforcing authority and within such period as the authority may specify, provide the authority with all the information and documentation, in paper or electronic form, necessary to demonstrate that the product is in conformity with Part 2.

(2) A distributor must, at the request of the enforcing authority, cooperate with the authority on any action taken to—

- (a) evaluate the product in accordance with regulation 55 (evaluation of a product presenting a risk);
- (b) eliminate the risks posed by the product which the distributor has placed on the market.

Importers and distributors

Cases in which obligations of manufacturers apply to importers and distributors [Art 10]

35. An economic operator who would, but for this regulation, be considered an importer or distributor (“A”), is to be considered a manufacturer for the purposes of these Regulations and is subject to the obligations of the manufacturer under this Part, where A—

- (a) places a product on the market under A’s own name or trademark; or
- (b) modifies a product already placed on the market in such a way that it may affect whether the product is in conformity with Part 2.

All economic operators

Identification of economic operators [Art 11]

36.—(1) An economic operator (“E”) who receives a request from the market surveillance authority before the end of the relevant period, must, within such period as the authority may specify, identify to the authority—

- (a) any economic operator who has supplied E with a product; and
- (b) any economic operator to whom E has supplied a product.

(2) The relevant period is—

- (a) for information under paragraph (1)(a), a period of 10 years beginning on the day on which E was supplied with the product;
- (b) for information under paragraph (1)(b), a period of 10 years beginning on the day on which E supplied the product.

Prohibition on improper use of CE marking [Art 15]

37.—(1) An economic operator must not affix the CE marking to a product unless—

- (a) that economic operator is the manufacturer; and
- (b) the conformity of the product with the essential safety requirements has been demonstrated by a relevant conformity assessment procedure.

(2) An economic operator must not affix a marking to a product—

- (a) which is not the CE marking; but
- (b) which purports to attest that the product is in conformity with the essential safety requirements.

(3) An economic operator must not affix to a product a marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the CE marking.

(4) An economic operator must not affix to a product any other marking if the visibility, legibility and meaning of the CE marking would be impaired as a result.

PART 3

Conformity assessment

Presumption of conformity [Art 12] [Recital 20]

38.—(1) A product which is in conformity with a harmonised standard (or part of such a standard) the reference to which has been published in the Official Journal of the European Union is to be presumed to be in conformity with the essential safety requirements covered by that standard (or that part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

Conformity assessment procedures [Art 13]

39.—(1) For the assessment of conformity of equipment, and where necessary those devices referred to at regulation 3(2)(b), the manufacturer must follow one of the following procedures—

- (a) in the case of equipment-groups I and II, equipment-categories M 1 and 1, the manufacturer must follow the EU-type examination set out in Annex III to the ATEX Directive (as amended from time to time), in conjunction with—
 - (i) the procedure relating to production quality assurance referred to in Annex IV to the ATEX Directive (as amended from time to time); or
 - (ii) the procedure relating to product verification referred to in Annex V to the ATEX Directive (as amended from time to time).
- (b) in the case of equipment-groups I and II, equipment-categories M 2 and 2, the manufacturer must follow—
 - (i) for internal combustion engines and electrical equipment in these groups and categories, the EU-type examination referred to in Annex III to the ATEX Directive (as amended from time to time) in conjunction with—
 - (aa) the procedure relating to the conformity to type based on internal production control plus supervised product testing as referred to in Annex VI to the ATEX Directive (as amended from time to time); or
 - (bb) the procedure relating to product quality assurance referred to in Annex VIII to the ATEX Directive (as amended from time to time).
 - (ii) in the case of other equipment in these groups and categories—
 - (aa) the procedure relating to internal production control referred to in Annex VIII to the ATEX Directive (as amended from time to time); and
 - (bb) the manufacturer must communicate the technical documentation provided for in paragraph 2 of Annex VIII to the Directive (as amended from time to time) to a notified body who shall acknowledge receipt of it as soon as possible and retain it in accordance.
- (c) in the case of equipment-group II, equipment category 3, the procedure relating to internal production control referred to in Annex VIII to the ATEX Directive (as amended from time to time).
- (d) in the case of equipment-groups I and II, in addition to the procedures referred to in paragraphs (1)(a),(b) and (c) the manufacturer may also follow the procedure relating to unit verification referred to in Annex IX to the ATEX Directive (as amended from time to time).

(2) The procedure referred to in (1)(a) or (d) must be used for the conformity assessment of protective systems.

(3) For the assessment of conformity of components, the manufacturer or the authorised representative must—

- (a) follow the procedures referred to in paragraph (1), with the exception of the affixing of the CE marking and the drawing up of the EU declaration of conformity;
- (b) issue a written attestation of conformity, declaring the conformity of the components with Part 3 of these Regulations. Such attestation of conformity must—
 - (i) state the characteristics of the component; and
 - (ii) explain how the component must be incorporated into equipment or protective systems to assist compliance with the essential safety requirements referred to in Schedule 1 applicable to finished equipment or protective systems.

(4) With regard to the safety aspects referred to at paragraph 13 of Schedule 1, in addition to the conformity assessment procedures referred to in paragraphs (1) and (2), the manufacturer may also follow the procedure referred to in Annex VIII to the ATEX Directive (as amended from time to time).

(5) Where the procedures referred to in paragraphs (1), (2) and (4) have not been applied, the notified body, may authorise the placing on the market [and the putting into service], of a product, other than a component, in the member State concerned where—

- (a) the notified body is in receipt of a duly justified request from a manufacturer requesting the placing on the market [and the putting into service] of a product, other than a component where paragraphs (1), (2) and (4) have not been applied; and
- (b) the use of the product, other than a component is in the interests of protection.

EU declaration of conformity [Art 14(1)-(4)]

40.—(1) The EU declaration of conformity for a product must—

- (a) state that the fulfilment of the essential safety requirements have been demonstrated in respect of the product;
- (b) have the model structure set out in Annex X to the ATEX Directive (as amended from time to time);
- (c) contain the elements specified in the relevant conformity assessment procedures referred to in Annexes III to IX to the ATEX Directive (as amended from time to time);
- (d) be continuously updated;
- (e) be translated into the language or languages required by the member State in which the product is placed or made available on the market.

(2) Where a product is subject to more than one EU instrument requiring a declaration of conformity to be drawn up, the manufacturer must draw up a single EU declaration of conformity, which—

- (a) identifies the EU instruments concerned; and
- (b) includes references to the publication of those EU instruments in the Official Journal of the European Union.

CE Marking

41.—(1) Before the product is placed on the market, the CE marking must be affixed visibly, legibly and indelibly to the product. **[Art 16(1) and (2)]**

(2) Where it is not possible or warranted, on account of the nature of the product, to affix the CE marking in accordance with paragraph (1), the CE marking must be affixed to—

- (a) the packaging; and
- (b) the accompanying documents. **[Art 16(1)]**

(3) The CE marking must be followed by the identification number of the notified body which carried out the relevant conformity assessment procedure for the product, where that body is involved in the production control phase.

- (4) The identification number of the notified body must be affixed—
- (a) by the notified body itself; or
 - (b) under the instructions of the notified body, by the manufacturer. [Art 16(3)]
- (5) The CE marking and, where applicable, the identification number of the notified body must be followed by—
- (a) the specific marking of explosion protection as referred to in Schedule 1, paragraph 5(f);
 - (b) the symbols of the equipment-group and category; and
 - (c) where applicable, the other markings and information referred to in Schedule 1, paragraph 5. [Art 16(4)]
- (6) The CE marking and the markings, symbols and information referred to in paragraph (5), and, where applicable, the identification number of the notified body, may be followed by any other mark indicating a special risk or use. [Art 16(5)]
- (7) Products designed for a particular explosive atmosphere must be marked accordingly. [Art 16(5), para 2]

PART 4

Notification of conformity assessment bodies

Notified Bodies [Art 25(5)]

- 42.** For the purposes of this Part, a notified body is a conformity assessment body which—
- (a) has been notified to the European Commission and to the other member States under regulation 44 (notification); and
 - (b) in respect of which no objections are raised by the European Commission or the other member States—
 - (i) within two weeks of a notification, where an accreditation certificate is used; or
 - (ii) within two months of a notification, where accreditation is not used.

Presumption of conformity of notified bodies [Art 22]

43.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a harmonised standard (or part of such a standard), the reference of which has been published in the Official Journal of the European Union, the Secretary of State is to presume that the conformity assessment body meets the notified body requirements covered by that standard (or part of that standard).

- (2) The presumption in paragraph (1) is rebuttable.

Notification

44.—(1) The Secretary of State may notify to the European Commission and the other member States only those conformity assessment bodies that qualify for notification. [Art 25(1)]

(2) A conformity assessment body qualifies for notification if the first and second conditions below are met.

(3) The first condition is that the conformity assessment body makes an application to the Secretary of State for notification [Art 24(1)] and that the application is accompanied by—

- (a) [Art 24(2)] [Art 25(3)] a description of—
 - (i) the conformity assessment activities that the conformity body intends to carry out;
 - (ii) the conformity assessment modules for which the conformity assessment body claims to be competent; and

- (iii) the product for which the conformity assessment body claims to be competent; and either
 - (b) an accreditation certificate [**Art 24(2)**]; or
 - (c) [**Art 24(3)**] [**Art 25(4)**] the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the notified body requirements.
- (4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the notified body requirements.
- (5) For the purposes of paragraph (4), the Secretary of State may accept an accreditation certificate under paragraph (3)(b) as sufficient evidence that the conformity assessment body fulfils the notified body requirements.
- (6) When deciding whether to notify a conformity assessment body that qualifies for notification to the European Commission and the other Member States, the Secretary of State may—
- (a) have regard to any other matter which appears to the Secretary of State to be relevant; and
 - (b) set conditions that the conformity assessment body must meet.
- (7) The Secretary of State must inform the European Commission of the United Kingdom's procedures for the assessment and notification of conformity assessment bodies and any such changes to those procedures which the Secretary of State may, from time to time, consider appropriate. [**Art 25(6)**].

Contents of Notification

45.—(1) A notification under regulation 44 must include—

- (a) the details of—
 - (i) the conformity assessment activities in respect of which the conformity assessment body has made its application for notification;
 - (ii) the conformity assessment module or modules in respect of which the conformity assessment body has made its application for notification; and
 - (iii) the product in respect of which the conformity assessment body has made its application for notification; and either
- (b) an accreditation certificate; or
- (c) documentary evidence which attests to—
 - (i) the conformity assessment body's competence; and
 - (ii) the arrangements in place to ensure that the conformity assessment body will be monitored regularly and will continue to meet the notified body requirements.

Monitoring

46.—(1) The Secretary of State must monitor each notified body with a view to verifying that the notified body—

- (a) continues to meet the notified body requirements;
- (b) meets any conditions set in accordance with regulation [44(6)(b)]; and
- (c) carries out its functions in accordance with these Regulations.

(2) The Secretary of State must inform the European Commission of the United Kingdom's procedures for the monitoring of notified bodies, and any changes to those procedures. [**Art 20**].

Delegation to the United Kingdom Accreditation Service

47. The Secretary of State may authorise the United Kingdom Accreditation Service to carry out the following activities on behalf of the Secretary of State—

- (a) assessing whether a conformity assessment body meets the notified body requirements; and
- (b) monitoring notified bodies.

Changes to notifications [Art 27]

48.—(1) Where the Secretary of State determines that a notified body no longer meets a notified body requirement, or that it is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 44(6)(b), the Secretary of State must restrict, suspend or withdraw the body's status as a notified body under regulation 42.

(2) Where the Secretary of State determines that a notified body no longer meets a condition referred to in regulation 44(6)(b), the Secretary of State may restrict, suspend or withdraw the body's status as a notified body under regulation 42.

(3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the non-compliance.

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

- (a) give notice in writing to the notified body of the proposed action and the reasons for it;
- (b) give the notified body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and
- (c) consider any such representations made by the notified body

(5) Where the Secretary of State takes action under paragraph (1), the Secretary of State must immediately inform the Commission and the other member States.

(6) Where the Secretary of State has taken action in respect of a notified body under paragraph (1) or (2), or where the notified body has ceased its activity, the notified body must, at the request of the Secretary of State, transfer its files to another notified body or the Secretary of State.

Operational obligations of notified bodies [Art 29]

49. When a notified body carries out a relevant conformity assessment procedure, it must do so in accordance with Schedule 3 (operational obligations of notified bodies).

Subsidiaries and contractors [Art 23]

50.—(1) Where a notified body subcontracts specific tasks connected with conformity assessment, or has such activities carried out by a subsidiary, the activities are only to be treated as having been carried out by a notified body for the purposes of regulation 39 (conformity assessment procedures) where the conditions in paragraphs (2) and (3) are satisfied.

(2) The notified body must—

- (a) ensure that the subcontractor or subsidiary meets the notified body requirements; and
- (b) inform the Secretary of State accordingly.

(3) The notified body must have obtained the agreement of the client to the use of a subcontractor or subsidiary.

(4) Where a notified body subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the notified body must [for a period of 10 years beginning on the day on which the activities are carried out], keep at the disposal of the Secretary of State the documentation concerning—

- (a) the assessment of the qualifications of the subcontractor or the subsidiary; and
- (b) the conformity assessment activities carried out by the subcontractor or subsidiary under Annexes III to VII and Annex IX of the ATEX Directive (as amended from time to time).

[Art 23(4)]

(5) When monitoring a notified body in accordance with regulation 46, the Secretary of State must treat the notified body as responsible for the tasks performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established. [Art 23(3)]

PART 5

Market surveillance and enforcement

Designation of market surveillance authority

51.—(1) Subject to paragraph (2), in Great Britain, the market surveillance authority for a product is the Health and Safety Executive.

(2) In Great Britain, the market surveillance authority for a product is the Office for Nuclear Regulation, in so far as these Regulations apply to—

- (a) any person who places on the market or supplies a product intended exclusively or primarily for use on a GB nuclear site;
- (b) any person who puts into service a product on a relevant nuclear site.

(3) In paragraph (2), “relevant nuclear site” means a site which is—

- (a) a GB nuclear site;
- (b) an authorised defence site (within the meaning given in regulation 2(1) of the Health and Safety (Enforcing Authority) Regulations 1998);
- (c) a new nuclear build site (within the meaning given in regulation 2A of the Health and Safety (Enforcing Authority) Regulations 1998);

(4) In paragraph (4), “GB nuclear site” (within the meaning given in section 68 of the Energy Act 2013).

Enforcement

52.—(1) The market surveillance authority must enforce these Regulations and RAMS (in its application to a product or ensure that they are enforced.

(2) In Scotland, only the Lord Advocate may prosecute an offence under these Regulations.

Enforcement powers

53.—(1) Schedule 4 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act) is to have effect.

(2) In addition to the powers available to the market surveillance authority under paragraph (1) or (2), the authority may use the powers set out in Schedule 5 (compliance, withdrawal and recall notices).

Exercise of enforcement powers

54. When enforcing these Regulations, the market surveillance authority must exercise its powers in a manner which is consistent with—

- (a) regulation 55 (evaluation of a product presenting a risk);
- (b) regulation 56 (enforcement action in respect of products which are not in conformity and which present a risk);
- (c) regulation 57 (EU safeguard procedure);
- (d) regulation 58 (enforcement action in respect of products which are in conformity, but present a risk);
- (e) regulation 59 (enforcement action in respect of formal non-compliance);

- (f) regulation 60 (restrictive measures).

Evaluation of a product presenting a risk [Art 35(1)]

55. Where the market surveillance authority has sufficient reason to believe that a product presents a risk, the market surveillance authority must carry out an evaluation in relation to the product covering the relevant requirements of Part 2 applying in respect of that product.

Enforcement action in respect of products which are not in conformity and which present a risk [Art 35(1) para 2-Art 35(5)]

56.—(1) Where, in the course of the evaluation referred to in regulation 55, the market surveillance authority finds that the product is not in conformity with Part 2, it must, without delay, require a relevant economic operator to—

- (a) take appropriate corrective actions to bring the product into conformity with those requirements within a prescribed period;
- (b) withdraw the product within a prescribed period; or
- (c) recall the product within a prescribed period.

(2) The market surveillance authority must inform the notified body which carried out the conformity assessment procedure in respect of the product of—

- (a) the respect in which the product is not in conformity with Part 2; and
- (b) the actions which the market surveillance authority is requiring the relevant economic operator to take.

(3) Where the market surveillance authority considers that the lack of conformity referred to in paragraph (1) is not restricted to the United Kingdom, it must notify the Secretary of State of—

- (a) the results of the evaluation; and
- (b) the actions which it has required the economic operator to take.

(4) Where the Secretary of State receives a notice under paragraph (3), or otherwise considers that the lack of conformity referred to in paragraph (1) is not restricted to the United Kingdom, the Secretary of State must inform the European Commission and the other member States of—

- (a) the results of the evaluation; and
- (b) the actions which the market surveillance authority has required the economic operator to take.

(5) Where the relevant economic operator does not take adequate corrective action within the prescribed period, the market surveillance authority must take appropriate measures to—

- (a) prohibit or restrict the product being made available on the market in the United Kingdom;
- (b) withdraw the product from the United Kingdom market; or
- (c) recall the product.

(6) Where the market surveillance authority takes measures under paragraph (5), it must notify the Secretary of State of those measures without delay.

(7) Where the Secretary of State receives a notice under paragraph (6), or takes measures under paragraph (5), the Secretary of State must notify the European Commission and the other member States of those measures without delay.

(8) The notices in paragraphs (6) and (7) must include details about the product and, in particular—

- (a) the data necessary for the identification of the product which is not in conformity with Part 2;
- (b) the origin of the product;
- (c) the nature of the lack of conformity alleged and the risk involved;

- (d) the nature and duration of the measures taken;
 - (e) the arguments put forward by the relevant economic operator;
 - (f) whether the lack of conformity is due to either of the following—
 - (i) failure of the product to meet requirements relating to a risk;
 - (ii) shortcomings in the harmonised standards referred to in regulation 38 (presumption of conformity) conferring a presumption of conformity.
- (9) In this regulation, “prescribed period” means a period which is—
- (a) prescribed by the market surveillance authority; and
 - (b) reasonable and commensurate with the nature of the risk presented by the product.

EU safeguard procedure [Art 35(6)-(8)]

57.—(1) Where another member State has initiated the procedure under Article 35 of the ATEX Directive (as amended from time to time), the market surveillance authority must, without delay, inform the Secretary of State of—

- (a) any measures taken by the market surveillance authority in respect of the product; and
- (b) any additional information which the market surveillance authority has at its disposal relating to the lack of conformity of the product.

(2) Where another member State has initiated the procedure under Article 35 of the ATEX Directive (as amended from time to time), the Secretary of State must, without delay, inform the European Commission and the other member States of—

- (a) any measures taken by the market surveillance authority in respect of the product;
- (b) any additional information which the market surveillance authority has at its disposal relating to the lack of conformity of the product; and
- (c) any objections that the Secretary of State may have to the measure taken by the member State initiating the procedure.

(3) Where a measure taken by another member State in respect of a product is considered justified under Article 35(7) of the ATEX Directive (as amended from time to time), the market surveillance authority must ensure that appropriate measures, such as withdrawal, are taken in respect of the product without delay.

(4) Where a measure taken by another member State in respect of a product is considered justified by the European Commission under Article 36(1) of the ATEX Directive (as amended from time to time), the market surveillance authority must take the necessary measures to ensure that the product is withdrawn from the United Kingdom market. **[Art 36(2)]**

(5) Where the market surveillance authority has taken action under paragraph (3) or (4), it must inform the Secretary of State.

(6) Where the Secretary of State receives a notice under paragraph (5) or has taken action under paragraphs (3) or (4), the Secretary of State must inform the European Commission of the action taken. **[Art 36(2)]**

(7) If a measure taken by the market surveillance authority pursuant to regulation 56 is considered unjustified by the European Commission under Article 36(1) of the ATEX Directive (as amended from time to time), the market surveillance authority must withdraw that measure.

Enforcement action in respect of products which are in conformity, but present a risk [Art 37]

58.—(1) Where, having carried out an evaluation under regulation 55, the market surveillance authority finds that although a product is in conformity with Part 2, it presents a risk, the market surveillance authority must require a relevant economic operator to take appropriate measures to—

- (a) ensure that the product concerned, when placed on the market, no longer presents a risk;

- (b) withdraw the product within a prescribed period; or
- (c) recall the product within a prescribed period. **[Art 37(1)]**

(2) Where the market surveillance authority takes measures under paragraph (1), it must notify the Secretary of State immediately.

(3) Where the Secretary of State receives a notice under paragraph (2) or takes measures under paragraph (1), the Secretary of State must notify the European Commission and the other member States immediately.

(4) The notices referred to in paragraphs (2) and (3) must include details about the product and, in particular—

- (a) the data necessary for the identification of the product concerned;
- (b) the origin and the supply chain of the product;
- (c) the nature of the risk involved; and
- (d) the nature and duration of the measures taken by the enforcing authority.

[Art 37(3)]

(5) In this regulation, “prescribed period” means a period which is—

- (a) prescribed by the market surveillance authority; and
- (b) reasonable and commensurate with the nature of the risk presented by the product. **[Art 37(1)]**

Enforcement action in respect of formal non-compliance [Art 38]

59.—(1) Where the market surveillance authority makes one of the following findings relating to a product, it must require a relevant economic operator to put an end to the non-compliance concerned within a specified period—

- (a) the CE marking—
 - (i) has not been affixed; or
 - (ii) has been affixed otherwise than in accordance with regulations 37 (prohibition on improper use of CE marking) and 41 (CE marking);
- (b) where a notified body is involved in the production control phase for the product, the identification number of the notified body—
 - (i) has not been affixed; or
 - (ii) has been affixed otherwise than in accordance with regulation 41 (CE marking);
- (c) the EU declaration of conformity or the attestation of conformity as appropriate—
 - (i) does not accompany the product; or
 - (ii) has been drawn up otherwise than in accordance with regulations 7 (EU declaration of conformity and CE marking) and 40 (EU declaration of conformity);
- (d) the technical documentation is either not available or not complete;
- (e) the following product information has been affixed otherwise than in accordance with paragraph 5 of Schedule 1—
 - (i) specific marking of explosion protection in accordance with paragraph 5(f) of Schedule 1;
 - (ii) the symbols of the equipment-group and category; and
 - (iii) where applicable, the other markings and information required by paragraph 5 of Schedule 1.
- (f) the product information at (1)(e) has not been affixed;
- (g) the following product labelling information is absent, false or incomplete—
 - (i) the information specified in regulation 13 (information identifying manufacture)

- (ii) the information specified in regulation 21 (information identifying importer); or
- (h) any other administrative requirement imposed on the manufacturer or importer under Part 2 has not been fulfilled.

(2) Until the specified period has elapsed, the market surveillance authority must not commence proceedings under these Regulations, or take any other enforcement action under these Regulations, against the relevant economic operator in respect of the non-compliance concerned.

(3) Where the non-compliance referred to in paragraph (1) persists, the market surveillance authority must take appropriate measures to—

- (a) restrict or prohibit the product being made available on the market;
- (b) ensure that the product is withdrawn; or
- (c) ensure that the product is recalled.

(4) This regulation does not apply where a product presents a risk.

Restrictive measures

60. When enforcing these Regulations, the market surveillance authority must comply with the requirements of Article 21 of RAMS (as amended from time to time) in relation to any measure to—

- (a) prohibit or restrict a product being made available on the market;
- (b) withdraw a product; or
- (c) recall a product.

Offences

61.—(1) It is an offence for a manufacturer to contravene or fail to comply with any requirement of—

- (a) regulation 5 (design and manufacture in accordance with essential safety requirements);
- (b) regulation 6 (technical documentation and conformity assessment);
- (c) regulation 7 (EU declaration of conformity and CE marking);
- (d) regulation 8 (retention of technical documentation and EU declaration of conformity);
- (e) regulation 9 (compliance procedures for series production);
- (f) regulation 10 (monitoring);
- (g) regulation 11 (labelling and packaging of products);
- (h) regulation 12 (labelling and packaging of products other than components);
- (i) regulation 13 (information identifying manufacturer);
- (j) regulation 14 (instructions and safety information);
- (k) regulation 15 (duty to take action in respect of a product placed on the market which are considered not to be in conformity);
- (l) regulation 16 (provision of information and cooperation);

(2) It is an offence for an importer to contravene or fail to comply with any requirement of—

- (a) regulation 18 (prohibition on placing on the market products which are not in conformity);
- (b) regulation 19 (requirements which must be satisfied before an importer places a product on the market);
- (c) regulation 20 (prohibition on placing on the market products considered not to be in conformity with the essential safety requirements);
- (d) regulation 21 (information identifying importer);
- (e) regulation 22 (instructions and safety information);

- (f) regulation 23 (storage and transport);
 - (g) regulation 24 (monitoring);
 - (h) regulation 25 (duty to take action in respect of a product placed on the market which is considered not to be in conformity);
 - (i) regulation 26;
 - (j) regulation 27 (provision of information and cooperation);
 - (k) regulation 28 (retention of technical documentation and EU declaration of conformity).
- (3) It is an offence for a distributor to contravene or fail to comply with any requirement of—
- (a) regulation 29 (duty to act with due care);
 - (b) regulation 30 (requirements which must be satisfied before a distributor makes a product available on the market);
 - (c) regulation 31 (storage and transport);
 - (d) regulation 32 (prohibition on making available on the market products considered not to be in conformity with safety objectives);
 - (e) regulation 33 (duty to take action in respect of a product placed on the market which is considered not to be in conformity);
 - (f) regulation 34 (provision of information and cooperation).
- (4) It is an offence for a conformity assessment body to fail to comply with regulation 48 (changes to notifications).
- (5) It is an offence for any person to contravene or fail to comply with any requirement of a notice, other than a compliance notice, served on that person by an enforcing authority under these Regulations.
- (6) It is an offence for any person—
- (a) intentionally to obstruct—
 - (i) an officer of an enforcing authority (or officer of such authority) acting in pursuance of its powers and duties under these Regulations or Article 19 of RAMS;
 - (ii) a customs officer facilitating the action of an enforcing authority under these Regulations; or
 - (b) knowingly or recklessly to provide any statement, information, document or record which is false or misleading in a material respect in purported compliance with any requirement of these Regulations or Article 19 of RAMS.
- (7) It is an offence for a person who is not authorised to act on behalf of an enforcing authority to purport to exercise any of the powers of the enforcing authority under these Regulations or RAMS.

Penalties

62. A person guilty of an offence under regulation 61 is liable—

- (a) on summary conviction—
 - (i) in England and Wales, to a fine or imprisonment for a term not exceeding three months or to both;
 - (ii) in Scotland, to a fine not exceeding level 5 on the standard scale or imprisonment for a term not exceeding three months, or to both;
- (b) on conviction on indictment, to a fine or imprisonment for a term not exceeding two years or to both.

Defence of due diligence

63.—(1) Subject to paragraph (2), (4) and (6), in proceedings for an offence under regulation 61, it is a defence for a person (“P”) to show that P took all reasonable steps and exercised all due diligence to avoid committing the offence.

(2) P may not rely on a defence under paragraph (1) which involves a third party allegation unless P has—

- (a) served a notice in accordance with paragraph (3); or
- (b) obtained the leave of the court.

(3) The notice must—

- (a) give any information in P’s possession which identifies or assists in identifying the person who—
 - (i) committed the act or default; or
 - (ii) supplied the information on which P relied.
- (b) be served on the person bringing the proceedings not less than 7 clear days before—
 - (i) in England and Wales, the hearing of the proceedings;
 - (ii) in Scotland, the trial date.

(4) P may not rely on a defence under paragraph (1) which involves an allegation that the commission of the offence was due to reliance on information supplied by another person unless it was reasonable for P to have relied upon the information, having regard in particular—

- (a) to the steps that P took, and those which might reasonably have been taken, for the purpose of verifying the information; and
- (b) to whether P had any reason to disbelieve the information.

(5) In this regulation, “third party allegation” means an allegation that the commission of the offence was due—

- (a) to the act or default of another person; or
- (b) to reliance on information supplied by another person.

(6) This regulation does not apply in respect of proceedings for offences under regulation 62(6).

Liability of persons other than principal offender

64.—(1) Where the commission of an offence by one person (“A”) under regulation 61 is due to anything which another person (“B”) did or failed to do in the course of business, B is guilty of the offence and may be proceeded against and punished, whether or not proceedings are taken against A.

(2) Where a body corporate commits an offence, a relevant person is also guilty of the offence where the body corporate’s offence was committed—

- (a) with the consent or connivance of the relevant person; or
- (b) as a result of the negligence of the relevant person.

(3) In paragraph (2), “relevant person” means—

- (a) a director, manager, secretary or other similar officer of the body corporate;
- (b) in relation to a body corporate managed by its members, a member of that body corporate performing managerial functions;
- (c) in relation to a Scottish partnership, a partner; or
- (d) a person purporting to act as a person described in sub-paragraphs (a), (b) or (c).

Time limit for prosecution of offences

65.—(1) Subject to paragraph (3), in England and Wales, information relating to an offence under regulation 61 that is triable by a magistrates' court may be so tried if it is laid within 12 months after the date on which evidence sufficient in the opinion of the prosecutor to justify the proceedings comes to the knowledge of the prosecutor.

(2) Subject to paragraph (3), in Scotland—

- (a) summary proceedings for an offence under regulation 61 may be commenced before the end of 12 months after the date on which evidence sufficient in the Lord Advocate's opinion to justify the proceedings came to the Lord Advocate's knowledge; and
- (b) section 136(3) of the Criminal Procedure (Scotland) Act 1995 (time limit for certain offences) applies for the purpose of this paragraph as it applies for the purpose of that section.

(3) No proceedings may be brought more than 3 years after the commission of the offence.

(4) For the purposes of this regulation a certificate of the prosecutor (or in Scotland, the Lord Advocate) as to the date on which the evidence referred to paragraphs (1) and (2) came to light, is conclusive evidence.

(5) This regulation has effect subject to paragraphs 1(n) and 2(l) of Schedule 4 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act).

Service of documents

66.—(1) Any document required or authorised by these Regulations to be served on a person may be served by—

- (a) delivering it to that person in person;
- (b) leaving it at that person's proper address; or
- (c) sending it by post or electronic means to that person's proper address.

(2) In the case of a body corporate, a document may be served on a director of that body.

(3) In the case of a partnership, a document may be served on a partner or a person having control or management of the partnership business.

(4) For the purposes of this regulation, "proper address" means—

- (a) in the case of a body corporate or its director—
 - (i) the registered or principal office of that body; or
 - (ii) the email address of the secretary or clerk of that body;
- (b) in the case of a partnership, a partner or person having control or management of the partnership business—
 - (i) the principal office of the partnership; or
 - (ii) the email address of a partner or person having that control or management;
- (c) in any other case, a person's last known address, which includes an email address.

(5) If a person to be served with a document has specified an address in the United Kingdom (other than that person's proper address) at which that person or someone on that person's behalf will accept service, that address must also be treated as that person's proper address.

(6) In this regulation, "partnership" includes a Scottish partnership.

Recovery of expenses of enforcement

67.—(1) This regulation applies where a person commits an offence under regulation 61.

(2) The court may (in addition to any other order it may make as to costs or expenses) order the person to reimburse the enforcing authority for any expenditure which the enforcing authority has incurred in investigating the offence.

Action by enforcing authority

68.—(1) An enforcing authority may itself take action which an economic operator could have been required to take by a notice served under these Regulations where the conditions for serving such a notice are met and either—

- (a) the enforcing authority has been unable to identify any economic operator on whom to serve such a notice; or
- (b) the economic operator on whom such a notice has been served has failed to comply with it.

(2) If the enforcing authority has taken action under as a result of the condition in paragraph (1)(b) being met, the authority may recover from the economic operator, as a civil debt, any costs or expenses reasonably incurred by the enforcing authority in taking the action.

(3) A civil debt recoverable under paragraph (2) may be recovered summarily in England and Wales by way of a complaint pursuant to section 58 of the Magistrates' Courts Act 1980.

Appeals against notices

69.—(1) An application for an order to vary or set aside the terms of a notice served under these Regulations may be made—

- (a) by the economic operator on whom the notice has been served; and
- (b) in the case of a notice other than a recall notice, by a person having an interest in the product in respect of which the notice has been served.

(2) An application must be made before the end of the period of 21 days beginning with the day on which the notice was served.

(3) The appropriate court may only make an order setting aside a notice served under these Regulations if satisfied—

- (a) that the product to which the notice relates is in conformity with Part 2; or
- (b) that the enforcing authority failed to comply with regulation 54 (exercise of enforcement powers) when serving of the notice.

(4) On an application to vary the terms of a notice served under these Regulations, the appropriate court may vary the terms of the notice as it considers appropriate.

(5) In this regulation—

- (a) the “appropriate court” is to be determined in accordance with regulation 70 (appropriate court for appeals against notices); and
- (b) “notice” means any of the following—
 - (i) a notice to warn served in accordance with Schedule 4 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act);
 - (ii) a suspension notice served in accordance with Schedule 4 ;
 - (iii) a compliance notice served in accordance with Schedule 5 (compliance, withdrawal and recall notices);
 - (iv) a withdrawal notice served in accordance with Schedule 5;
 - (v) a recall notice served in accordance with Schedule 5.

Appropriate court for appeals against notices

70.—(1) In England and Wales, the appropriate court for the purposes of regulation 69 is—

- (a) the court in which proceedings have been brought in relation to the product for an offence under regulation 61 (offences);
 - (b) an employment tribunal seized of appeal proceedings against a notice which relates to the product and which has been served under or by virtue of paragraph 1 of Schedule 4 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act); or
 - (c) in any other case, a magistrates' court.
- (2) In Scotland, the appropriate court for the purposes of regulation 69 is—
- (a) the sheriff of a sheriffdom in which the person making the appeal resides or has a registered or principle office; or
 - (b) an employment tribunal seized of appeal proceedings against a notice which relates to the product and which has been served under or by virtue of paragraph 1 of Schedule 4 (Enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act).
- (3) A person aggrieved by an order made by a magistrates' court in England and Wales pursuant to an application under regulation 69, or by a decision of such a court not to make such an order, may appeal against that order or decision in England and Wales, to the Crown Court.

PART 6

Miscellaneous

Review

- 71.**—(1) The Secretary of State must from time to time—
- (a) carry out a review of these Regulations;
 - (b) set out the conclusions of the review in a report; and
 - (c) publish the report.
- (2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Directive is implemented in other member States.
- (3) The report must, in particular—
- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
 - (b) assess the extent to which those objectives are achieved; and
 - (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved by a system that imposes less regulation.
- (4) The first report under this regulation must be published before 5 years after [*coming into force date*].
- (5) Reports under this regulation are afterwards to be published at intervals not exceeding 5 years.

Transitional provisions [Art 41]

- 72.**—(1) Nothing in these Regulations prevents the making available on the market of a product which—
- (a) was placed on the market before 20 July 2016; and
 - (b) is in conformity with the 1996 Regulations, or the law of any other member State implementing the 1994 Directive.
- (2) For the purposes of these Regulations, a certificate issued, or approval granted, by a notified body under Schedule 6 of the 1996 Regulations, or any enactment of another member State which

implemented the 1994 Directive, is to be treated as a certificate issued or approval granted under Annex III to the ATEX Directive.

Consequential revocations, amendments and savings

73.—(1) The 1996 Regulations are revoked.

(2) The enactments referred to in paragraph (1) continue to apply, as if they had not been revoked, to a product placed on the market before [*date on which Regulations come into force*].

(3) The Electrical Equipment for Explosive Atmospheres (Certification) (Amendment) Regulations 1999 are revoked.

Date

Name
Title
Department for Business, Innovation and Skills

SCHEDULE 1

Regulation 2(1)

Essential Safety Requirements

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES (Annex II of the ATEX Directive)

Preliminary observations

1.—(1) Technological knowledge, which can change rapidly, must be taken into account as far as possible and be utilised immediately.

(2) For the devices referred to in 3(3), the essential health and safety requirements shall apply only in so far as they are necessary for the safe and reliable functioning and operation of those devices with respect to the risks of explosion.

Common requirements for Equipment and protective systems

General requirements

Principles of integrated explosion safety

2.—(1) Equipment and protective systems intended for use in potentially explosive atmospheres must be designed from the point of view of integrated explosion safety.

(2) In this connection, the manufacturer must take measures:

- (a) above all, if possible, to prevent the formation of explosive atmospheres which may be produced or released by equipment and by protective systems themselves; and
- (b) to prevent the ignition of explosive atmospheres, taking into account the nature of every electrical and non-electrical source of ignition.

(3) Should an explosion nevertheless occur which could directly or indirectly endanger persons and, as the case may be, domestic animals or property, to halt it immediately and/or to limit the range of explosion flames and explosion pressures to a sufficient level of safety.

(4) Equipment and protective systems must be designed and manufactured after due analysis of possible operating faults in order as far as possible to preclude dangerous situations.

(5) Any misuse which can reasonably be anticipated must be taken into account.

Special checking and maintenance conditions

3. Equipment and protective systems subject to special checking and maintenance conditions must be designed and constructed with such conditions in mind.

Surrounding area conditions

4. Equipment and protective systems must be so designed and constructed as to be capable of coping with actual or foreseeable surrounding area conditions.

Marking

5.—(1) All equipment and protective systems must be marked legibly and indelibly with the following minimum particulars—

- (a) name, registered trade name or registered trade mark, and address of the manufacturer;
- (b) CE marking (see Annex II to Regulation EC No 765/2008);

- (c) designation of series or type;
- (d) batch or serial number, if any;
- (e) year of construction;



- (f) the specific marking of explosion protection followed by the symbol of the equipment-group and category;
- (g) for equipment-group II, the letter 'G' (concerning explosive atmospheres caused by gases, vapours or mists); and/or
- (h) the letter 'D' (concerning explosive atmospheres caused by dust).

(2) Furthermore, where necessary, they must also be marked with all information essential to their safe use.

Instructions

6.—(1) All equipment and protective systems must be accompanied by instructions, including at least the following particulars—

- (a) a recapitulation of the information with which the equipment or protective system is marked, except for the batch or serial number (see paragraphs 5(1) and (2)), together with any appropriate additional information to facilitate maintenance (e.g. address of the importer, repairer, etc.);
- (b) instructions for safe—
 - (i) putting into service;
 - (ii) use;
 - (iii) assembling and dismantling;
 - (iv) maintenance (servicing and emergency repair);
 - (v) installation;
 - (vi) adjustment;
- (c) where necessary, an indication of the danger areas in front of pressure-relief devices;
- (d) where necessary, training instructions;
- (e) details which allow a decision to be taken beyond any doubt as to whether an item of equipment in a specific category or a protective system can be used safely in the intended area under the expected operating conditions;
- (f) electrical and pressure parameters, maximum surface temperatures and other limit values;
- (g) where necessary, special conditions of use, including particulars of possible misuse which experience has shown might occur;
- (h) where necessary, the essential characteristics of tools which may be fitted to the equipment or protective system.

(2) The instructions must contain the drawings and diagrams necessary for the putting into service, maintenance, inspection, checking of correct operation and, where appropriate, repair of the equipment or protective system, together with all useful instructions, in particular with regard to safety.

(3) Literature describing the equipment or protective system must not contradict the instructions with regard to safety aspects.

Selection of materials

7.—(1) The materials used for the construction of equipment and protective systems must not trigger off an explosion, taking into account foreseeable operational stresses.

(2) Within the limits of the operating conditions laid down by the manufacturer, it must not be possible for a reaction to take place between the materials used and the constituents of the potentially explosive atmosphere which could impair explosion protection.

(3) Materials must be so selected that predictable changes in their characteristics and their compatibility in combination with other materials will not lead to a reduction in the protection afforded; in particular, due account must be taken of the material's corrosion and wear resistance, electrical conductivity, mechanical strength, ageing resistance and the effects of temperature variations.

Design and construction

8.—(1) Equipment and protective systems must be designed and constructed with due regard to technological knowledge of explosion protection so that they can be safely operated throughout their foreseeable lifetime.

(2) Components to be incorporated into or used as replacements in equipment and protective systems must be so designed and constructed that they function safely for their intended purpose of explosion protection when they are installed in accordance with the manufacturer's instructions.

Enclosed structures and prevention of leaks

9.—(1) Equipment which may release flammable gases or dusts must wherever possible employ enclosed structures only.

(2) If equipment contains openings or non-tight joints, these must as far as possible be designed in such a way that releases of gases or dusts cannot give rise to explosive atmospheres outside the equipment.

(3) Points where materials are introduced or drawn off must, as far as possible, be designed and equipped so as to limit releases of flammable materials during filling or draining.

Dust deposits

10.—(1) Equipment and protective systems which are intended to be used in areas exposed to dust must be so designed that deposit dust on their surfaces is not ignited.

(2) In general, dust deposits must be limited where possible. Equipment and protective systems must be easily cleanable.

(3) The surface temperatures of equipment parts must be kept well below the glow temperature of the deposit dust.

(4) The thickness of deposit dust must be taken into consideration and, if appropriate, means must be taken to limit the temperature in order to prevent a heat build up.

Additional means of protection

11.—(1) Equipment and protective systems which may be exposed to certain types of external stresses must be equipped, where necessary, with additional means of protection.

(2) Equipment must withstand relevant stresses, without adverse effect on explosion protection.

Safe opening

12. If equipment and protective systems are in a housing or a locked container forming part of the explosion protection itself, it must be possible to open such housing or container only with a special tool or by means of appropriate protection measures.

Protection against other hazards

13.—(1) Equipment and protective systems must be so designed and manufactured as to—

- (a) avoid physical injury or other harm which might be caused by direct or indirect contact;
- (b) assure that surface temperatures of accessible parts or radiation which would cause a danger, are not produced;
- (c) eliminate non-electrical dangers which are revealed by experience;
- (d) assure that foreseeable conditions of overload do not give rise to dangerous situations.

(2) Where, for equipment and protective systems, the risks referred to in this paragraph are wholly or partly covered by other European Union legislation, this Regulation shall not apply or shall cease to apply in the case of such equipment and protective systems and of such risks upon application of that specific European Union legislation.

Overloading of equipment

14. Dangerous overloading of equipment must be prevented at the design stage by means of integrated measurement, regulation and control devices, such as over-current cut-off switches, temperature limiters, differential pressure switches, flowmeters, time-lag relays, overspeed monitors and/or similar types of monitoring devices.

Flameproof enclosure systems

15. If parts which can ignite an explosive atmosphere are placed in an enclosure, measures must be taken to ensure that the enclosure withstands the pressure developed during an internal explosion of an explosive mixture and prevents the transmission of the explosion to the explosive atmosphere surrounding the enclosure.

Potential ignition sources

Hazards arising from different ignition sources

16. Potential ignition sources such as sparks, flames, electric arcs, high surface temperatures, acoustic energy, optical radiation, electromagnetic waves and other ignition sources must not occur.

Hazards arising from static electricity

17. Electrostatic charges capable of resulting in dangerous discharges must be prevented by means of appropriate measures.

Hazards arising from stray electric and leakage currents

18. Stray electric and leakage currents in conductive equipment parts which could result in, for example, the occurrence of dangerous corrosion, overheating of surfaces or sparks capable of provoking an ignition must be prevented.

Hazards arising from overheating

19. Overheating caused by friction or impacts occurring, for example, between materials and parts in contact with each other while rotating or through the intrusion of foreign bodies must, as far as possible, be prevented at the design stage.

Hazards arising from pressure compensation operations

20. Equipment and protective systems must be so designed or fitted with integrated measuring, control and regulation devices that pressure compensations arising from them do not generate shock waves or compressions which may cause ignition.

Hazards arising from external effects

21.—(1) Equipment and protective systems must be so designed and constructed as to be capable of performing their intended function in full safety, even in changing environmental conditions and in the presence of extraneous voltages, humidity, vibrations, contamination and other external effects, taking into account the limits of the operating conditions established by the manufacturer.

(2) Equipment parts used must be appropriate to the intended mechanical and thermal stresses and capable of withstanding attack by existing or foreseeable aggressive substances.

Requirements in respect of safety-related devices

22.—(1) Safety devices must function independently of any measurement or control devices or both measurement and control devices required for operation.

(2) As far as possible, failure of a safety device must be detected sufficiently rapidly by appropriate technical means to ensure that there is only very little likelihood that dangerous situations will occur.

(3) The fail-safe principle is to be applied in general.

(4) Safety-related switching must in general directly actuate the relevant control devices without intermediate software command.

(5) In the event of a safety device failure, equipment and/or protective systems shall, wherever possible, be secured.

(6) Emergency stop controls of safety devices must, as far as possible, be fitted with restart lockouts. A new start command may take effect on normal operation only after the restart lockouts have been intentionally reset.

Control and display units

23. Where control and display units are used, they must be designed in accordance with ergonomic principles in order to achieve the highest possible level of operating safety with regard to the risk of explosion.

Requirements in respect devices with a measuring function for explosion protection

24.—(1) In so far as they relate to equipment used in explosive atmospheres, devices with a measuring function must be designed and constructed so that they can cope with foreseeable operating requirements and special conditions of use.

(2) Where necessary, it must be possible to check the reading accuracy and serviceability of devices with a measuring function.

(3) The design of devices with a measuring function must incorporate a safety factor which ensures that the alarm threshold lies far enough outside the explosion and/or ignition limits of the atmospheres to be registered, taking into account, in particular, the operating conditions of the installation and possible aberrations in the measuring system.

Risks arising from software

25. In the design of software-controlled equipment, protective systems and safety devices, special account must be taken of the risks arising from faults in the programme.

Integration of safety requirements relating to the system

26.—(1) Manual override must be possible in order to shut down the equipment and protective systems incorporated within automatic processes which deviate from the intended operating conditions, provided that this does not compromise safety.

(2) When the emergency shutdown system is actuated, accumulated energy must be dispersed as quickly and as safely as possible or isolated so that it no longer constitutes a hazard.

(3) This does not apply to electrochemically-stored energy.

Hazards arising from power failure

27. Where equipment and protective systems can give rise to a spread of additional risks in the event of a power failure, it must be possible to maintain them in a safe state of operation independently of the rest of the installation.

Hazards arising from connections

28.—(1) Equipment and protective systems must be fitted with suitable cable and conduit entries.

(2) When equipment and protective systems are intended for use in combination with other equipment and protective systems, the interface must be safe.

Placing of warning devices as parts of equipment

29. Where equipment or protective systems are fitted with detection or alarm devices for monitoring the occurrence of explosive atmospheres, the necessary instructions must be provided to enable them to be provided at the appropriate places.

Supplementary Requirements in respect of equipment

Requirements applicable to equipment in equipment-group I

Requirements applicable to equipment in category M 1 of equipment-group I

30.—(1) Equipment must be so designed and constructed that sources of ignition do not become active, even in the event of rare incidents relating to equipment.

(2) Equipment must be equipped with means of protection such that—

- (a) either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection; or
- (b) the requisite level of protection is ensured in the event of two faults occurring independently of each other.

(3) Where necessary, equipment must be equipped with additional special means of protection.

(4) It must remain functional with an explosive atmosphere present.

(5) Where necessary, equipment must be so constructed that no dust can penetrate it.

(6) The surface temperatures of equipment parts must be kept clearly below the ignition temperature of the foreseeable air/dust mixtures in order to prevent the ignition of suspended dust.

(7) Equipment must be so designed that the opening of equipment parts which may be sources of ignition is possible only under non-active or intrinsically safe conditions. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

(8) If necessary, equipment must be fitted with appropriate additional interlocking systems.

Requirements applicable to equipment in category M 2 of equipment-group I

31.—(1) Equipment must be equipped with means of protection ensuring that sources of ignition do not become active during normal operation, even under more severe operating conditions, in particular those arising from rough handling and changing environmental conditions.

(2) The equipment is intended to be de-energised in the event of an explosive atmosphere.

(3) Equipment must be so designed that the opening of equipment parts which may be sources of ignition is possible only under non-active conditions or via appropriate interlocking systems. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

(4) The requirements regarding explosion hazards arising from dust applicable to category M 1 must be applied.

Requirements applicable to equipment in category 1 of equipment-group II

Explosive atmospheres caused by gases, vapours or mists

32.—(1) Equipment must be so designed and constructed that sources of ignition do not become active, even in event of rare incidents relating to equipment.

(2) It must be equipped with means of protection such that—

- (a) either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection; or
- (b) the requisite level of protection is ensured in the event of two faults occurring independently of each other.

(3) For equipment with surfaces which may heat up, measures must be taken to ensure that the stated maximum surface temperatures are not exceeded even in the most unfavourable circumstances.

(4) Temperature rises caused by heat build-ups and chemical reactions must also be taken into account.

(5) Equipment must be so designed that the opening of equipment parts which might be sources of ignition is possible only under non-active or intrinsically safe conditions. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

(6) If necessary, equipment must be fitted with appropriate additional interlocking systems.

Explosive atmospheres caused by air/dust mixtures

33.—(1) Equipment must be so designed and constructed that ignition of air/dust mixtures does not occur even in the event of rare incidents relating to equipment.

(2) It must be equipped with means of protection such that—

- (a) either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection; or
- (b) the requisite level of protection is ensured in the event of two faults occurring independently of each other.

(3) Where necessary, equipment must be so designed that dust can enter or escape from the equipment only at specifically designated points.

(4) This requirement must also be met by cable entries and connecting pieces.

(5) The surface temperatures of equipment parts must be kept well below the ignition temperature of the foreseeable air/dust mixtures in order to prevent the ignition of suspended dust.

(6) With regard to the safe opening of equipment parts, paragraph 32(5) applies.

Requirements applicable to equipment category 2 of equipment-group II

Explosive atmospheres caused by gases, vapours or mists

34.—(1) Equipment must be so designed and constructed as to prevent ignition sources arising, even in the event of frequently occurring disturbances or equipment operating faults, which normally have to be taken into account.

(2) Equipment parts must be so designed and constructed that their stated surface temperatures are not exceeded, even in the case of risks arising from abnormal situations anticipated by the manufacturer.

(3) Equipment must be so designed that the opening of equipment parts which might be sources of ignition is possible only under non-active conditions or via appropriate interlocking systems. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

Explosive atmospheres caused by air/dust mixtures

35.—(1) Equipment must be designed and constructed so that ignition of air/dust mixtures is prevented, even in the event of frequently occurring disturbances or equipment operating faults which normally have to be taken into account.

(2) With regard to surface temperatures, paragraph 33(5) applies.

36. With regard to protection against dust, paragraph 33(3) applies.

37. With regard to the safe opening of equipment parts, paragraph 34(3) applies.

Requirements applicable to equipment in category 3 of equipment-group II

Explosive atmospheres caused by gases, vapours or mists

38.—(1) Equipment must be so designed and constructed as to prevent foreseeable ignition sources which can occur during normal operation.

(2) Surface temperatures must not exceed the stated maximum surface temperatures under intended operating conditions. Higher temperatures in exceptional circumstances may be allowed only if the manufacturer adopts special additional protective measures.

Explosive atmospheres caused by air/dust mixtures

39.—(1) Equipment must be so designed and constructed that air/dust mixtures cannot be ignited by foreseeable ignition sources likely to exist during normal operation.

(2) With regard to surface temperatures, paragraph 33(5) applies.

(3) Equipment, including cable entries and connecting pieces, must be so constructed that, taking into account the size of its particles, dust can neither develop explosive mixtures with air nor form dangerous accumulations inside the equipment.

Supplementary requirements in respect of protective systems

General requirements

40.—(1) Protective systems must be dimensioned in such a way as to reduce the effects of an explosion to a sufficient level of safety.

(2) Protective systems must be designed and capable of being positioned in such a way that explosions are prevented from spreading through dangerous chain reactions or flashover and incipient explosions do not become detonations.

(3) In the event of a power failure, protective systems must retain their capacity to function for a period sufficient to avoid a dangerous situation.

(4) Protective systems must not fail due to outside interference.

Planning and design

Characteristics of materials

41.—(1) With regard to the characteristics of materials, the maximum pressure and temperature to be taken into consideration at the planning stage are the expected pressure during an explosion occurring under extreme operating conditions and the anticipated heating effect of the flame.

(2) Protective systems designed to resist or contain explosions must be capable of withstanding the shock wave produced without losing system integrity.

(3) Accessories connected to protective systems must be capable of withstanding the expected maximum explosion pressure without losing their capacity to function.

(4) The reactions caused by pressure in peripheral equipment and connected pipe-work must be taken into consideration in the planning and design of protective systems.

Pressure-relief systems

42. If it is likely that stresses on protective systems will exceed their structural strength, provision must be made in the design for suitable pressure-relief devices which do not endanger persons in the vicinity.

Explosion suppression systems

43. Explosion suppression systems must be so planned and designed that they react to an incipient explosion at the earliest possible stage in the event of an incident and counteract it to best effect, with due regard to the maximum rate of pressure increase and the maximum explosion pressure.

Explosion decoupling systems

44. Decoupling systems intended to disconnect specific equipment as swiftly as possible in the event of incipient explosions by means of appropriate devices must be planned and designed so as to remain proof against the transmission of internal ignition and to retain their mechanical strength under operating conditions.

45. Protective systems must be capable of being integrated into a circuit with a suitable alarm threshold so that, if necessary, there is cessation of product feed and output and shutdown of equipment parts which can no longer function safely.

SCHEDULE 2

Regulation 2(1)

Notified body requirements [Art 21]

1. A conformity assessment body must be established in the United Kingdom and have legal personality.

2. A conformity assessment body must be a third party body independent of the organisation or the product it assesses.

3. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products it assesses is to be considered a conformity assessment body for the purposes of Regulation 44 (Notification) provided that such body can demonstrate—

- (a) its independence from such business association or professional federation; and
- (b) any conflict of interest.

4.—(1) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the representative of any of those parties.

(2) Sub-paragraph (1) does not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

5. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products, or represent the parties engaged in those activities.

6. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not engage in activity that may conflict with their independence of judgment or integrity in relation to conformity assessment activities for which they are notified (including consultancy services).

7. A conformity assessment body must ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

8. A conformity assessment body and its personnel must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in those activities.

9. A conformity assessment body must be capable of carrying out all of the conformity assessment activities in relation to for which it has been, or is to be, notified, whether those activities are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

10. A conformity assessment body must have at its disposal—

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures, and have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the process.

11. A conformity assessment body must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and must have access to the necessary equipment or facilities.

12. The personnel responsible for carrying out conformity assessment activities must have—

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments which the personnel carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential safety requirements, of the applicable harmonised standards and of the ATEX Directive and of these Regulations;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

13. A conformity assessment body must be able to guarantee the impartiality of its top level management and the personnel responsible for carrying out the conformity assessment activities.

14. The remuneration of the top level management and the personnel responsible for carrying out the conformity assessment activities must not depend on the number of assessments carried out or on the results of those assessments.

15. A conformity assessment body must have, and must satisfy the Secretary of State that it has, adequate civil liability insurance in respect of its activities.

16. A conformity assessment body must ensure that its personnel observe professional secrecy with regard to all information obtained in carrying out their tasks in accordance with these Regulations and that proprietary rights are protected.

17. Paragraph 16 does not prevent the personnel from providing information to the Secretary of State or an enforcing authority.

18. A conformity assessment body must participate in, or ensure that its personnel who are responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of any notified body coordination group established under the ATEX Directive and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

SCHEDULE 3

Regulation 49

Operational obligations of notified bodies [Art 29]

1. A notified body must carry out conformity assessments in accordance with the relevant conformity assessment procedures.

2. A notified body must carry out conformity assessments in a proportionate manner, avoiding unnecessary burdens on economic operators.

3. A notified body must perform its activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

4. A notified body must respect the degree of rigour and the level of protection required to ensure that the product is in conformity with the requirements of these Regulations.

5. Where a notified body finds that essential safety requirements or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it must require the manufacturer to take appropriate corrective measures and must not issue a certificate of conformity or grant an approval.

6. Where, in the course of the monitoring of conformity following the issue of a certificate or grant of an approval, a notified body finds that a product is no longer in conformity with the essential safety requirements, it must require the manufacturer to take appropriate corrective measures and must suspend or withdraw the certificate of conformity or approval (if necessary).

7. Where the notified body has required a manufacturer to take corrective measures and the manufacturer has failed to take such measures, or those measures have not had the required effect, the notified body must restrict, suspend or withdraw any certificate of conformity or approval.

8. Paragraph 9 applies where a notified body is minded to—

- (a) refuse to issue a certificate of conformity or grant an approval;
- (b) restrict, suspend or withdraw a certificate of conformity or approval.

9. Where this paragraph applies, the notified body must—

- (a) give the person applying for the certificate or approval, or the person to whom the certificate or approval was given, a notice in writing giving reasons and specifying the date on which the refusal, restriction, suspension or withdrawal is intended to take effect;
- (b) give the person applying for the certificate or approval, or the person to whom the certificate or approval was given, an opportunity to make representations within a reasonable period from the date of the notice; and
- (c) take account of any such representations before taking its decision.

[Art 31]

10. A notified body must inform the Secretary of State of—

- (a) any refusal, restriction, suspension or withdrawal of a certificate of conformity or approval;
- (b) any circumstances affecting the scope of, or conditions for, notification under regulation 44 (notification);
- (c) any request for information which it has received from an enforcing authority regarding conformity assessment activities; and
- (d) on request, conformity assessment activities performed within the scope of its notification under regulation 44 and any other activity performed, including cross-border activities and subcontracting.

[Art 30]

11. A notified body must make provision in its contracts with its clients enabling such clients to appeal against a decision—

- (a) to refuse to issue a certificate of conformity or grant an approval; or
- (b) to restrict, suspend or withdraw a certificate of conformity or approval.

12. A notified body must provide other bodies notified under the ATEX Directive carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

13. A notified body must participate in the work of any notified body coordination group established under the ATEX Directive, directly or by means of its designated representatives.

SCHEDULE 4

Regulation 52

Enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act

Enforcement powers under the 1974

1. For the purposes of enforcing these Regulations, the following sections of the 1974 Act apply subject to the modifications in paragraph 2—

- (a) section 19 (appointment of inspectors);
- (b) section 20 (powers of inspectors);
- (c) section 21 (improvement notices);
- (d) section 22 (prohibition notices);
- (e) section 23 (provisions supplementary to ss 21 and 22);
- (f) section 24 (appeal against improvement or prohibition notice);
- (g) section 25 (power to deal with cause of imminent danger);

- (h) section 25A (power of customs officer to detain articles and substances);
- (i) section 26 (power of enforcing authorities to indemnify inspectors);
- (j) section 27 (obtaining of information by the Executive, enforcing authorities etc);
- (k) section 27A (information communicated by Commissioners for Revenue and Customs);
- (l) section 28 (restrictions on disclosure of information);
- (m) section 33 (offences);
- (n) section 34 (extension of time for bringing summary proceedings);
- (o) section 35 (venue);
- (p) section 39 (prosecution by inspectors);
- (q) section 41 (evidence); and
- (r) section 42 (power of court to order cause of offence to be remedied or, in certain cases, forfeiture).

Modifications to the 1974 Act

2. The sections referred to in paragraph 1 are to apply as if—

- (a) references to “relevant statutory provisions” were references to—
 - (i) the provisions of the 1974 Act set out in paragraph 1, as modified by this paragraph; and
 - (ii) these Regulations;
- (b) in regulation 19—
 - (i) in subsection (1), for “Every enforcing authority” there were substituted “the Health and Safety Executive and the Office for Nuclear Regulation”;
 - (ii) in subsection (1), “within its field of responsibility” were omitted;
 - (iii) in subsection (2), paragraph (b) were omitted;
 - (iv) in subsection (3), for “enforcing authority which appointed him” there were substituted “Health and Safety Executive or the Office for Nuclear Regulation as the case may be”;
- (c) in section 20—
 - (i) in subsection (1), “within the field of responsibility of the enforcing authority which appointed him” were omitted;
 - (ii) in subsection (2)(c)(i), for “his (the inspector’s) enforcing authority” there were substituted “the Health and Safety Executive or the Office for Nuclear Regulation as the case may be”;
 - (iii) subsection (3) were omitted;
- (d) for section 22(2) there were substituted—

“(2) An inspector may serve a notice (in this Part referred to as “a prohibition notice”) on a person if, as regards any activities to which this section applies, the inspector is of the opinion that, as carried on or likely to be carried on by or under the control of the person in question, the activities involve or, as the case may be, will involve—

 - (a) a risk (within the meaning of regulation 2(4) of the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016); or
 - (b) a contravention of a relevant statutory provision.”;
- (e) in section 23, subsections (3), (4) and (6) were omitted;
- (f) in section 25A(1), for “an enforcing authority”, there were substituted “the Health and Safety Executive or the Office for Nuclear Regulation as the case may be”;
- (g) in section 26, for each of the following references there were substituted “the body”—

- (i) “the enforcing authority which appointed him”;
 - (ii) “that authority”; and
 - (iii) “the authority”;
- (h) in section 27—
 - (i) for “Executive”, on each occasion that it appears, there were substituted “Health and Safety Executive or the Office for Nuclear Regulation as the case may be”;
 - (ii) in subsection (1), paragraph (b) were omitted; and
 - (iii) in subsection (1), “or, as the case may be, to the enforcing authority in question” were omitted;
- (i) in section 27A(2)—
 - (i) for “an enforcing authority” there were substituted “the Health and Safety Executive”; and
 - (ii) the words from “, other than the Office for Nuclear Regulation” to the end were omitted;
- (j) in section 28—
 - (i) for “Executive”, on each occasion that it appears, there were substituted “Health and Safety Executive”;
 - (ii) in subsection (1)(a), “, other than the Officer for Nuclear Regulation (or an inspector appointed by it),” were omitted;
 - (iii) in subsection (1)(a), “, by virtue of section 43A(6) below” were omitted;
 - (iv) in subsection (3), “or any enforcing authority” were omitted;
 - (v) in subsection (4), “or an enforcing authority” were omitted; and
 - (vi) in subsection (5)(a), “or the purposes of the enforcing authority in question”;
- (k) in section 33—
 - (i) in subsection (1), the paragraphs (a) to (i) and (k) to (m) were omitted;
 - (ii) for subsection (2), there were substituted—
 - “(2) A person guilty of an offence under section 33 is liable—
 - (a) on summary conviction to imprisonment for a term not exceeding three months, a fine not exceeding level 5 on the standard scale or both;
 - (b) on conviction on indictment to imprisonment for a term not exceeding two years, a fine or both.”; and
 - (iii) section 33(3) were omitted;
- (l) in section 34—
 - (i) in subsection (1), paragraphs (a) and (b) were omitted; and
 - (ii) subsections (3) to (6) were omitted;
- (m) in section 35, for “any enforcing authority”, there were substituted “the Health and Safety Executive or the Office for Nuclear Regulation as the case may be”;
- (n) in section 39(1), for “enforcing authority” there were substituted “Health and Safety Executive or the Office for Nuclear Regulation”; and
- (o) in section 42, subsections (3A), (4) and (5) were omitted.

Compliance, withdrawal and recall notices

Compliance notice

1.—(1) An enforcing authority may serve a compliance notice on a relevant economic operator in respect of a product if the authority has reasonable grounds for believing that there is non-compliance.

(2) A compliance notice must—

(a) require the relevant economic operator on which it is served to—

(i) end the non-compliance within such period as may be specified in the notice; or

(ii) provide evidence, within such period as may be specified in the notice, demonstrating to the satisfaction of the enforcing authority that the non-compliance has not in fact occurred; and

(b) warn the economic operator that, if the non-compliance persists or if satisfactory evidence has not been produced under sub-paragraph (a) within the period specified in the notice, further action may be taken in respect of the product or any product of the same type made available on the market by that relevant economic operator.

(3) A compliance notice may include directions as to the measures to be taken by the economic operator to secure compliance, including different ways of securing compliance.

(4) Subject to paragraph (5), an enforcing authority may revoke or vary a compliance notice by serving a notification on the economic operator.

(5) An enforcing authority may not vary a compliance notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

Withdrawal notice

2.—(1) An enforcing authority may serve a withdrawal notice on a relevant economic operator in respect of a product if the authority has reasonable grounds for believing that—

(a) the product has been made available on the market; and

(b) there is non-compliance.

(2) A withdrawal notice must prohibit the relevant economic operator from making the product available on the market without the consent of the enforcing authority.

(3) A withdrawal notice may require the relevant economic operator to take action to alert end-users to any risk presented by the product.

(4) A withdrawal notice may require the relevant economic operator to keep the enforcing authority informed of the whereabouts of any product referred to in the notice.

(5) A consent given by the enforcing authority pursuant to a withdrawal notice, may impose such conditions on the making available on the market as the enforcing authority considers appropriate.

(6) Subject to paragraph (7), an enforcing authority may revoke or vary a withdrawal notice by serving a notification on the economic operator.

(7) An enforcing authority may not vary a withdrawal notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

Recall notice

3.—(1) The enforcing authority may serve a recall notice on a relevant economic operator in respect of a product if the authority has reasonable grounds for believing that—

(a) the product has been made available to end-users; and

(b) there is non-compliance.

(2) A recall notice must require the relevant economic operator to use reasonable endeavours to organise the return of the product from end-users to the relevant economic operator or another person specified in the notice.

(3) A recall notice may—

- (a) require the recall to be effected in accordance with a code of practice;
- (b) require the relevant economic operator to—
 - (i) contact end-users in order to inform them of the recall, to the extent that it is practicable to do so;
 - (ii) publish a notice in such form and such manner as is likely to bring to the attention of end-users any risk the product poses and the fact of the recall; or
 - (iii) make arrangements for the collection or return of the product from end-users or its disposal; or
- (c) impose such additional requirements on the relevant economic operator as are reasonable and practicable with a view to achieving the return of the product.

(4) In determining what requirements to include in a recall notice, the enforcing authority must take into consideration the need to encourage distributors and end-users to contribute to its implementation.

(5) A recall notice may only be issued by the enforcing authority where—

- (a) other action which it may require under these Regulations would not suffice to address the non-compliance;
- (b) the action being undertaken by the relevant economic operator is unsatisfactory or insufficient to address the non-compliance;
- (c) the enforcing authority has given not less than 10 days' notice to the relevant economic operator of its intention to serve such a notice; and
- (d) the enforcing authority has taken account of any advice obtained under subparagraph (6).

(6) A relevant economic operator which has received notice from the enforcing authority of an intention to serve a recall notice may at any time prior to the service of the recall notice require the authority to seek the advice of such person as the Institute determines on the questions of—

- (a) whether there is non-compliance; and
- (b) whether the issue of a recall notice would be proportionate.

(7) Subparagraphs (5)(b), (c) and (d) do not apply in the case of a product presenting a serious risk requiring, in the view of the enforcing authority, urgent action.

(8) Where a relevant economic operator requires the enforcing authority to seek advice under subparagraph (6), that relevant economic operator is to be responsible for the fees, costs and expenses of the Institute and of the person appointed by the Institute to advise the enforcing authority.

(9) In this regulation, “Institute” means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators.

(10) A recall notice served by the enforcing authority may require the relevant economic operator to keep the authority informed of the whereabouts of a product to which the recall notice relates, so far as the relevant economic operator is able to do so.

Interpretation

4. In this Schedule, “non-compliance” means that the product—

- (a) presents a risk; or
- (b) is not in conformity with Part 2 or RAMS (in its application to a product).

EXPLANATORY NOTE

(This note is not part of the Regulations)