STATUTORY INSTRUMENTS

2016 No. 1107

HEALTH AND SAFETY

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

Made - - - -	*15th November 2016*
Laid before Parliament	*16th November 2016*
Coming into force - -	*8th December 2016*

The Secretary of State is a Minister designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) 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(**3**) of Schedule 2 to, the European Communities Act 1972:

Modifications etc. (not altering text)

C1 Regulations modified (19.6.2021) by The Conformity Assessment (Mutual Recognition Agreements) and Weights and Measures (Intoxicating Liquor) (Amendment) Regulations 2021 (S.I. 2021/730), regs. 1, 4, **Sch. 1 para. 6**

(**1**) S.I. 1995/751.

(**2**) 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.

(**3**) 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.

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 8th December 2016 ("the commencement date").

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

Commencement Information

I1 Reg. 1 in force at 8.12.2016, see **reg. 1(1)**

Interpretation

2.—(1) In these Regulations—

the "1974 Act" means the Health and Safety at Work etc Act 1974(**4**);

the "1994 Directive" means Directive 94/9/EC of the European Parliament and of the Council on the approximation of the laws of the member States concerning equipment and protective systems intended for use in potentially explosive atmospheres(**5**)**[**F1(as it has effect immediately before IP completion day)**]**;

"the 1996 Regulations" means the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996(**6**);

[F2"approved body" has the meaning given to it in regulation 42;**]**

F3…

"ATEX Directive" means Directive 2014/34/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)(**7**);

"attestation of conformity" means a declaration of conformity required to be drawn up in accordance with regulation 7(3) (F4... declaration of conformity and **[**F5UK**]** Marking);

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

F6…

F7…

"component" means any item essential to the safe functioning of equipment and protective systems but with no autonomous function;

"conformity assessment" means the process demonstrating whether the essential health and safety requirements relating to a product have been fulfilled;

[F8"conformity assessment activities" means any activities connected with conformity assessment including calibration, testing, certification and inspection;**]**

(**4**) 1974 c.37.
(**5**) OJ L 100, 19.4.1994, p.1.
(**6**) S.I. 1996/192; amended by S.I. 1998/81, S.I. 2001/3766, S.I. 2005/830, S.I. 2011/1043, S.I. 2012/1809, S.I. 2014/469 and S.I. 2014/3248.
(**7**) OJ L 96, 29.3.2014, p. 309.

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

[F9"conformity assessment procedure" means a procedure referred to in regulation 39 (conformity assessment procedures);**]**

[F9"declaration of conformity" means a declaration of conformity required to be drawn up in accordance with regulation 7(1)(a) (declaration of conformity and UK marking);**]**

[F9"designated standard" has the meaning given to it in regulation 2A;**]**

"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;

"equipment" means machines, apparatus, fixed or mobile devices, control components and their instrumentation and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy or the processing of material or both and which are capable of causing an explosion through their own potential sources of ignition;

[F10"equipment category" means the classification of equipment, within each equipment group, specified in Schedule 1A to these Regulations;**]**

"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 or combustible dust or both, comprising equipment categories M 1 and M 2 **[**F11as set out in Schedule 1A to these Regulations**]**;

"equipment-group II" means equipment intended for use in other places liable to be endangered by explosive atmospheres, comprising equipment categories 1, 2 and 3 **[**F12as set out in Schedule 1A to these Regulations**]**;

"essential health and safety requirements" means the requirements set out in Schedule 1 (essential health and safety requirements);

F13…

F14…

"explosive atmosphere" means a mixture with air, under 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;

F15…

[F16"importer" means a person who—

(a) is established in the United Kingdom and places a product from a country outside of the United Kingdom on the market; or

(b) is established in Northern Ireland and places a product on the market that has been supplied to them for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge, from an EEA state;**]**

"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 of a product for distribution, consumption or use on the **[**F17market of Great Britain**]** in the course of a commercial activity, whether in return for payment or free of charge, and related expressions are to be construed accordingly;

"manufacturer" means a person who—

(a) manufactures a product, or has a product designed or manufactured, and

(b) markets that product—

(i) under that person's name or trade mark, or

(ii) uses such product for that person's own purposes;

"market surveillance authority" has the meaning set out in regulation 51 (designation of market surveillance authority);

F18 …

F19 …

F20 …

"place on the market" means make a product available on the **[**F21market of Great Britain**]** for the first time, and related expressions are to 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 or to limit the effective range of an explosion or both, and which are separately made available on the market for use as autonomous systems;

"putting into service" means the first use of a product by an end-user F22..., for the purposes for which it was intended, and related expressions are to be construed accordingly;

"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(**8**);

"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;

"relevant conformity assessment procedure" means a conformity assessment procedure referred to in regulation 39 (conformity assessment procedures);

"relevant economic operator" means, in relation to a product, an economic operator with obligations in respect of that product under Part 2;

"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;

[F23"UK marking" means the marking in the form set out in Annex 2 of RAMS;**]**

[F23"UK national accreditation body" means the body appointed by the Secretary of State in accordance with Article 4 of RAMS;**]**

"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.

[F24(1A) Schedule 1A reproduces the provisions of Annex I to the ATEX Directive with amendments to correct deficiencies in retained EU law.

(1B) A reference to a provision of Schedule 1A is a reference to the equivalent provisions of Annex I to the ATEX Directive as set out in Schedule 1A.

(**8**) OJ L 218, 13.8.2008, p. 30.

(1C) Schedule 3A reproduces the provisions of Annexes III to IX to the ATEX Directive with amendments to correct deficiencies in retained EU law.

(1D) A reference to any provision of Schedule 3A is a reference to the equivalent provisions of Annex III to IX of the ATEX Directive.**]**

(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 health and safety requirements; and

(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 available on the market.

F25(3) . . . . . .

(4) In regulations 10(1) and 24(1) (monitoring) and Schedule 1 (essential health and safety requirements), "risk" means a risk which could arise from lawful and readily predictable human behaviour.

(5) In the other provisions of these Regulations, "risk" means a risk—

(a) which could arise from lawful and readily predictable human behaviour, and

(b) which may result in harm to any of the following interests—

(i) health and safety of persons, in particular workers,

(ii) domestic animals, or

(iii) property.

F26(6) . . . . . .

F1 Words in reg. 2(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**, and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(n)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F2 Words in reg. 2(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F4 Word in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(d)(i)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F5 Word in reg. 2(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(d)(ii)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F6 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(f)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F7 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(g)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F8 Words in reg. 2(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(h)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F9 Words in reg. 2(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(i)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F10 Words in reg. 2(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(j)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F11 Words in reg. 2(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(k)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F12 Words in reg. 2(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(l)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F13 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(m)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F14 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(n)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F15 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(o)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F16 Words in reg. 2(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(p)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 17(2)); 2020 c. 1, Sch. 5 para. 1(1)

F17 Words in reg. 2(1) substituted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 2(2)(q) (as substituted by The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 (S.I. 2020/676), regs. 1(1), **4(13)(a)**)

F18 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(r)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F19 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(s)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F20 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(t)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F21 Words in reg. 2(1) substituted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 2(2)(u) (as substituted by The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 (S.I. 2020/676), regs. 1(1), **4(13)(b)**)

F22 Words in reg. 2(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(v)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F23 Words in reg. 2(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(2)(w)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F24 Reg. 2(1A)-(1D) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(3)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F25 Reg. 2(3) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(4)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F26 Reg. 2(6) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 2(5)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I2 Reg. 2 in force at 8.12.2016, see **reg. 1(1)**

[F27Designated standard

2A.—(1) Subject to paragraphs (6) and (7), in these Regulations a "designated standard" means a technical specification which is—

(a) adopted by a recognised standardisation body **[**F28or an international standardising body**]**, for repeated or continuous application, with which compliance is not compulsory; and

(b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

(2) For the purposes of paragraph (1), a "technical specification" means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—

(a) the characteristics required of a product, service or system, including—

(i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and

(ii) the requirements applicable to the product, service or system as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and

(b) production methods and processes relating to the product, where these have an effect on the characteristics of the product, service or system.

(3) For the purposes of this regulation a "recognised standardisation body" means any one of the following organisations—

(a) the European Committee for Standardisation (CEN);

(b) the European Committee for Electrotechnical Standardisation (Cenelec);

(c) the European Telecommunications Standards Institute (ETSI);

(d) the British Standards Institution (BSI).

[F29(3A) In this regulation "international standardising body" has the same meaning as it has for the purposes of the Agreement on Technical Barriers to Trade, part of Annex 1A to the agreement establishing the World Trade Organisation signed at Marrakesh on 15 April 1994 (as modified from time to time).**]**

(4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.

(5) Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with **[**F30such**]** technical specifications adopted by the other recognised standardisation bodies **[**F31or by international standardising bodies as the Secretary of State considers to be relevant.**]**

(6) The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph (1)(b).

(7) Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.

(8) The Secretary of State may by regulations amend paragraph (3) to reflect any changes in the name or structure of the recognised standardisation bodies.

(9) Regulations made under paragraph (8) are to be made by statutory instrument.

(10) A statutory instrument containing regulations made under paragraph (8) is subject to annulment in pursuance of a resolution of either House of Parliament.**]**

F27 Reg. 2A inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 3** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F28 Words in reg. 2A(1)(a) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 14(a)**; S.I. 2020/1662, reg. 2(ee)

F29 Reg. 2A(3A) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 14(b)**; S.I. 2020/1662, reg. 2(ee)

F30 Word in reg. 2A(5) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 14(c)(i)**; S.I. 2020/1662, reg. 2(ee)

F31 Words in reg. 2A(5) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 14(c)(ii)**; S.I. 2020/1662, reg. 2(ee)

Scope

3.—(1) These Regulations apply to products which—

(a) fall within the meaning of "product" in paragraph (2); and

(b) are not excluded by paragraph (3).

(2) A "product" means—

(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 sub-paragraph (a).

(3) The following products are excluded from the definition in paragraph (2)—

(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 fuel gas;

(d) personal protective equipment covered by Council Directive 89/686/EEC on the approximation of the laws of the member States relating to personal protective equipment(**9**);

(e) seagoing vessels and mobile offshore units together with equipment on board such vessels or units;

(**9**) OJ L 399, 30.12.1989, p. 18.

(f) means of transport (other than vehicles intended for use in a potentially explosive atmosphere), including vehicles and their trailers intended solely for transporting passengers by air or by road, rail or water networks and 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;

[[F32](g) products connected with the production of trade in arms, munitions and war material;**]**

(h) products which have been placed on the market before the commencement date.

F32 Reg. 3(3)(g) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 4** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I3 Reg. 3 in force at 8.12.2016, see **reg. 1(1)**

Exceptions for trade fairs, exhibitions and demonstrations

4. The provisions of Part 2 (and of Part 5, so far as applying in relation to obligations under Part 2) do not apply to the showing of a product which is not in conformity with Part 2, at a trade fair, exhibition or demonstration, provided that a visible sign clearly indicates that—

(a) the product is not in conformity with Part 2, and

(b) the product is not available for sale until brought into conformity with Part 2.

Commencement Information
I4 Reg. 4 in force at 8.12.2016, see **reg. 1(1)**

PART 2

Obligations of economic operators

Chapter 1

Manufacturers

Design and manufacture in accordance with essential health and safety requirements

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

Commencement Information
I5 Reg. 5 in force at 8.12.2016, see **reg. 1(1)**

Technical documentation and conformity assessment

6. Before placing a product on the market or using it for their own purposes, a manufacturer must—

(a) carry out the relevant conformity assessment procedure or have a relevant conformity assessment procedure carried out; and

[F33(b) draw up the technical documentation referred to—

(i) for a product in respect of which the conformity assessment procedure in regulation 39(1)(a) is being carried out, in paragraph 3(c) of Part 1 of Schedule 3A to these Regulations;

(ii) for a product in respect of which the conformity assessment procedure in regulation 39(1)(b) is being carried out, in paragraph 3(c) of Part 1 of Schedule 3A to these Regulations;

(iii) for a product in respect of which the conformity assessment procedure in regulation 39(1)(c) is being carried out, in paragraph 2 of Part 6 of Schedule 3A to these Regulations;

(iv) for a product in respect of which the conformity assessment procedure in regulation 39(1)(d) is being carried out, in paragraph 2 of Part 7 of Schedule 3A to these Regulations.]

F33 Reg. 6(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 5** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I6 Reg. 6 in force at 8.12.2016, see **reg. 1(1)**

[F34Declaration] of conformity and [F35UK] marking

7.—(1) Save for where a product is a component, where the conformity of a product with the essential health and safety requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the product on the market—

(a) draw up a declaration of conformity in accordance with regulation 40 (F36... declaration of conformity), and

(b) affix the [F37UK] Marking in accordance with regulation 41 ([F37UK] Marking).

(2) The manufacturer must keep the F38... declaration of conformity up-to-date.

(3) Where the conformity of a component with the essential health and safety requirements 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).

(4) Subject to paragraph (5), before placing a product on the market, the manufacturer must ensure that each product is accompanied by a copy of the F39... declaration of conformity or attestation of conformity as appropriate.

(5) Where a large number of products are delivered to a single user, the batch or consignment may be accompanied by a single copy of the F40... declaration or attestation of conformity as appropriate.

[F41(6) Where a product is subject to more than one enactment requiring the drawing up of a declaration of conformity, the manufacturer must draw up a single declaration of conformity which identifies each enactment by its title.]

F34 Word in reg. 7 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(a)(i)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F35 Word in reg. 7 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(a)(ii)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F36 Word in reg. 7(1)(a) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F37 Word in reg. 7(1)(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F38 Word in reg. 7(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F39 Word in reg. 7(4) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F40 Word in reg. 7(5) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F41 Reg. 7(6) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(e)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I7 Reg. 7 in force at 8.12.2016, see **reg. 1(1)**

Retention of technical documentation and [F42]... declaration of conformity

8. A manufacturer must keep the technical documentation and the [F43]... declaration of conformity (or where applicable, the attestation of conformity) drawn up in respect of a product for a period of 10 years beginning on the day on which the product is placed on the market.

F42 Word in reg. 8 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 7** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F43 Word in reg. 8 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 7** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I8 Reg. 8 in force at 8.12.2016, see **reg. 1(1)**

Compliance procedures for series production

9.—(1) A manufacturer of a product which is manufactured by series production must ensure that, before placing a product on the market, procedures are in place to ensure that any product so manufactured will be in conformity with Part 2.

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

(a) any change in the product design or characteristics, and

(b) any change in a **[**F44designated**]** standard or in another technical specification by reference to which the F45... declaration of conformity or attestation of conformity was drawn up.

F44 Word in reg. 9(2)(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 8(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F45 Word in reg. 9(2)(b) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 8(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I9 Reg. 9 in force at 8.12.2016, see **reg. 1(1)**

Monitoring

10.—(1) 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 manufactured by the manufacturer made available on the market,

(b) investigate complaints that a product manufactured by the manufacturer is not in conformity with Part 2, and

(c) keep distributors informed of any actions carried out under sub-paragraphs (a) and (b).

(2) A manufacturer must keep a register of—

(a) complaints that a product is not in conformity with Part 2,

(b) products which are found not to be in conformity with Part 2, and

(c) product recalls.

(3) A manufacturer must keep an entry made in the register for a period of at least 10 years beginning on the day on which the obligation to make the entry arose.

Commencement Information

I10 Reg. 10 in force at 8.12.2016, see **reg. 1(1)**

Labelling and packaging of products

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

(2) If the size or nature of the product does not provide sufficient space for the labelling requirements in paragraph (1), the manufacturer must ensure that the information is provided on the packaging or in a document accompanying the product.

Commencement Information

I11 Reg. 11 in force at 8.12.2016, see **reg. 1(1)**

Labelling and packaging of products, other than components

12. Save for where a product is a component, before placing a product on the market a manufacturer must ensure that it—

(a) bears the specific marking of explosion protection as referred to at paragraph 5(1)(f) of Schedule 1, and

(b) where applicable, bears the other markings and information referred to at paragraph 5 of Schedule 1.

Commencement Information

I12 Reg. 12 in force at 8.12.2016, see **reg. 1(1)**

Information identifying manufacturer

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 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 product packaging, or

(b) in a document accompanying the product.

[[F46](3) The information specified in paragraph (1) must be in a language which can be easily understood by end users and the market surveillance authority.**]**

F46 Reg. 13(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 9** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I13 Reg. 13 in force at 8.12.2016, see **reg. 1(1)**

[[F47]Provision of instructions and safety information

14. When placing a product on the market, a manufacturer must ensure that a product is accompanied by instructions and safety information that are clear, legible and in easily understandable English.**]**

F47 Reg. 14 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 10** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Duty to take action in respect of a product placed on the market which is considered not to be in conformity

15.—(1) A manufacturer who considers, or has reason to believe, that a product which the 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[F48]... 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.

F48 Words in reg. 15(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 11** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I14 Reg. 15 in force at 8.12.2016, see **reg. 1(1)**

Provision of information and cooperation

16.—(1) A manufacturer must, further to a reasoned request from the market surveillance authority, and within such period as the market surveillance authority may specify, provide the authority with 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 market surveillance authority.

(2) A manufacturer must, at the request of the market surveillance 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 a product which the manufacturer has placed on the market.

Commencement Information

I15 Reg. 16 in force at 8.12.2016, see **reg. 1(1)**

Authorised representatives

17.—(1) A manufacturer may, by written mandate, appoint a person established in the **[**[F49]United Kingdom**]** as their authorised representative to perform specified tasks on the manufacturer's behalf.

(2) A manufacturer who has appointed an authorised representative to perform, on the manufacturer's behalf, a task under these Regulations remains responsible for the proper performance of that task.

(3) The obligations laid down in regulation 5 (design and manufacture in accordance with essential health and safety requirements) and regulation 6(b) (technical documentation and conformity assessment) must not form part of an authorised representative's mandate.

(4) The mandate must allow the authorised representative to do at least the following in relation to a product covered by the mandate—

(a) perform the manufacturer's obligations under regulation 8 (retention of technical documentation and [F50]... declaration of conformity), and

(b) perform the manufacturer's obligations under regulation 16 (provision of information and cooperation).

(5) 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 mandate to perform and, accordingly as far as those duties are concerned, as well as the penalties for failure to comply with those duties, references in these Regulations (except in this regulation) to the manufacturer are to be taken as including a reference to the authorised representative.

F49 Words in reg. 17(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 12(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F50 Word in reg. 17(4)(a) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 12(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I16 Reg. 17 in force at 8.12.2016, see **reg. 1(1)**

Chapter 2

Importers

Prohibition on placing on the market products which are not in conformity

18. An importer must not place a product on the market unless it is in conformity with the essential health and safety requirements.

Commencement Information

I17 Reg. 18 in force at 8.12.2016, see **reg. 1(1)**

Requirements which must be satisfied before an importer places a product on the market

19.—(1) Before placing a product on the market, an importer must ensure that—

(a) a relevant conformity assessment procedure has been carried out by the manufacturer,

(b) the manufacturer has drawn up the technical documentation,

(c) the product—

(i) bears the **[**[F51]UK**]** marking where applicable,

(ii) is accompanied by the [F52]... declaration of conformity or the attestation of conformity as appropriate, and

(iii) is accompanied by 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)(iii), "required documents" means any documents that are required to be provided with a product pursuant to—

(a) regulation 11(2) (labelling and packaging of products);

(b) regulation 13(2)(b) (information identifying manufacturer);

(c) regulation **[**F53**]**14 (provision of instructions and safety information)**]**.

F51 Word in reg. 19(1)(c)(i) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 13(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F52 Word in reg. 19(1)(c)(ii) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 13(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F53 Words in reg. 19(2)(c) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 13(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I18 Reg. 19 in force at 8.12.2016, see **reg. 1(1)**

Prohibition on placing on the market products considered not to be in conformity with the essential health and safety requirements

20.—(1) Where an importer considers, or has reason to believe, that a product is not in conformity with the essential health and 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.

Commencement Information

I19 Reg. 20 in force at 8.12.2016, see **reg. 1(1)**

Information identifying importer

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 **[**F54**]**the market surveillance authority**]**.

[F55**]**(3) Paragraph (1) does not apply where—

(a) either—

(i) it is not possible to set out the information referred to in paragraph (1) on the product, or

(ii) the importer has imported the product from an EEA state or Switzerland and places it on the market within the period of **[**F56**]**seven years**]** beginning with IP completion day, and

(b) before placing the product on the market, the importer sets out the information referred to in paragraph (1)—

(i) on the packaging; or

(ii) in a document accompanying the product.**]**

F54 Words in reg. 21(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 14(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F55 Reg. 21(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 14(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2019/1246, regs. 1(3), **5** and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 2(1)(i)** and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(n)(iii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F56 Words in reg. 21(3)(a)(ii) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 4, **Sch. 3**

Modifications etc. (not altering text)

C2 Reg. 21 modified (temp.) (10.9.2019) by S.I. 2019/392, reg. 6 (as inserted by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(2)(4), **2(3)** (with reg. 18))

Commencement Information

I20 Reg. 21 in force at 8.12.2016, see **reg. 1(1)**

[[F57]**Provision of Instructions and safety information**

22. When placing a product on the market, an importer must ensure that the product is accompanied by instructions and safety information that are clear, legible and in easily understandable English.**]**

F57 Reg. 22 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 15** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Storage and transport

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

Commencement Information

I21 Reg. 23 in force at 8.12.2016, see **reg. 1(1)**

Monitoring

24.—(1) When deemed 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 by the importer on the market,

(b) investigate complaints that a product placed on the market by the importer is not in conformity with Part 2, and

(c) keep distributors informed of actions carried out under sub-paragraphs (a) and (b).

(2) An importer must keep a register of—

(a) complaints that a product is not in conformity with Part 2,

(b) products which are found not to be in conformity with Part 2, and

(c) product recalls.

(3) An importer must keep an entry made in the register for a period of at least 10 years beginning on the day on which the obligation to make the entry arose.

Commencement Information

I22 Reg. 24 in force at 8.12.2016, see **reg. 1(1)**

Duty to take action in respect of a product placed on the market which is considered not to be in conformity

25.—(1) 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.

(2) Where the product presents a risk, the importer must immediately inform the market surveillance authority[F58]... 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.

F58 Words in reg. 25(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 16** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I23 Reg. 25 in force at 8.12.2016, see **reg. 1(1)**

Provision of information and cooperation

26.—(1) An importer must, further to a reasoned request from the market surveillance authority and within such period as the market surveillance authority may specify, provide the authority with 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 market surveillance authority.

(2) An importer must, at the request of the market surveillance 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.

Commencement Information

I24 Reg. 26 in force at 8.12.2016, see **reg. 1(1)**

Retention of technical documentation and [F59]... declaration of conformity

27. An 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 market surveillance authority—

(a) a copy of the [F60]... declaration of conformity or, where applicable, the attestation of conformity, and

(b) the technical documentation.

F59 Word in reg. 27 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 17** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F60 Word in reg. 27 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 17** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I25 Reg. 27 in force at 8.12.2016, see **reg. 1(1)**

Chapter 3

Distributors

Duty to act with due care

28. 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.

Commencement Information

I26 Reg. 28 in force at 8.12.2016, see **reg. 1(1)**

Requirements which must be satisfied before a distributor makes a product available on the market

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

(a) the product—

(i) bears a **[**[F61]UK**]** marking where applicable;

(ii) is accompanied by the [F62]... declaration of conformity or the attestation of conformity;

(iii) is accompanied by the required documents;

[[F63](iv) is accompanied by instructions and safety information that are clear, legible and in easily understandable English;**]**

(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) and regulation 13 (information identifying manufacturer);

(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(2) (labelling and packaging of products);

(b) regulation 13(2)(b) (information identifying manufacturer);

(c) regulation 21(3)(b) (information identifying importer).

F61 Word in reg. 29(1)(a)(i) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 18(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F62 Word in reg. 29(1)(a)(ii) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 18(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F63 Reg. 29(1)(a)(iv) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 18(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I27 Reg. 29 in force at 8.12.2016, see **reg. 1(1)**

Storage and transport

30. Each distributor must ensure that, whilst a product is under that distributor's responsibility, its storage or transport conditions do not jeopardise its conformity with the essential health and safety requirements.

Commencement Information

I28 Reg. 30 in force at 8.12.2016, see **reg. 1(1)**

Prohibition on making available on the market where product not considered to be in conformity with safety objectives

31.—(1) Where a distributor considers, or has reason to believe, that a product is not in conformity with the essential health and safety requirements, the distributor must not make the product available on the market.

(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.

Commencement Information

I29 Reg. 31 in force at 8.12.2016, see **reg. 1(1)**

Duty to take action in respect of products made available on the market which are not in conformity

32.—(1) A distributor who considers, or has reason to believe, that a product which the distributor has made available on the market is not in conformity with Part 2 must make sure 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[F64]... 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.

F64 Words in reg. 32(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 19** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I30 Reg. 32 in force at 8.12.2016, see **reg. 1(1)**

Provision of information and cooperation

33.—(1) A distributor must, further to a reasoned request from the market surveillance authority and within such period as the authority may specify, provide the authority with 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 market surveillance 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 a product which the distributor has made available on the market.

Commencement Information

I31 Reg. 33 in force at 8.12.2016, see **reg. 1(1)**

Chapter 4

Importers and distributors

Cases in which obligations of manufacturers apply to importers and distributors

34. An economic operator ("A") who would, but for this regulation, be considered an importer or distributor, 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.

Commencement Information
I32 Reg. 34 in force at 8.12.2016, see **reg. 1(1)**

Chapter 5

All economic operators

Identification of economic operators

35.—(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.

Commencement Information
I33 Reg. 35 in force at 8.12.2016, see **reg. 1(1)**

Prohibition on improper use of [F65UK] marking

36.—(1) An economic operator must not affix the **[**F66UK**]** marking to a product unless—

(a) that economic operator is the manufacturer, and

(b) the conformity of the product with the essential health and safety requirements has been demonstrated by a relevant conformity assessment procedure.

(2) An economic operator must not affix to a product a marking (other than the **[**F66UK**]** marking) which purports to attest that the product is in conformity with the essential health and 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 **[**F66UK**]** marking.

(4) An economic operator must not affix to a product any other marking if the visibility, legibility and meaning of the **[**F66UK**]** marking would be impaired as a result.

F65 Word in reg. 36 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 20** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F66 Word in reg. 36 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 20** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I34 Reg. 36 in force at 8.12.2016, see **reg. 1(1)**

[F67Obligations which are met by complying with obligations in the ATEX Directive

36A.—(1) In this regulation—

(a) any reference to an Article or an Annex is a reference to an Article or an Annex of the ATEX Directive;

(b) "CE marking" has the meaning given to it in Article 2(26); and

(c) "harmonised standard" has the meaning given to in in Article 2(18).

(2) Subject to paragraphs (6) and (7) paragraph (3) applies where, before placing the product on the market, the manufacturer—

(a) ensures that the product has been designed and manufactured in accordance with the essential safety requirements set out in Annex II;

(b) ensures that the relevant conformity assessment procedures that apply to that product in accordance with Article 13(1) and (2) have been carried out;

(c) draws up the technical documentation referred to in Annexes III to IX;

(d) ensures that the records and correspondence relating to the conformity assessment procedures are prepared in or translated into English;

(e) affixes a CE marking and the inscriptions in accordance with Articles 15 and 16(1) to (4);

(f) draws up an EU declaration of conformity, in accordance with Article 14; and

(g) ensures that the declaration of conformity is prepared in or translated into English.

(3) Where this paragraph applies—

(a) the requirements of regulations 5, 6, 7(1), (3) and 7(6) are to be treated as being satisfied;

(b) regulations 2(a), 7(6), 8, 9(2), 17(4), 36 and 59 apply subject to the modifications in paragraph (10);

(c) Part 3 does not apply; and

(d) regulation 57 does not apply.

(4) Subject to paragraphs (6) and (7) paragraph (5) applies where, before placing a product on the market, the importer ensures that—

(a) the relevant conformity assessment procedure referred to in Article 13 has been carried out;

(b) the manufacturer has drawn up the technical documents relevant to the conformity assessment procedure followed; and

(c) the product bears the CE marking and inscriptions referred to in point 1.0.5 of Annex II.

(5) Where this paragraph applies—

(a) the requirements of regulation 19(1)(a) to (c) are to be treated as being satisfied; and

(b) regulations 2(a),18, 23 and 27 apply subject to the modifications in paragraph (10).

(6) This paragraph applies where there is no designated standard or part of a designated standard which corresponds exactly to a harmonised standard or part of a harmonised standard referred to in Article 12.

(7) Where paragraph (6) applies, paragraphs (2)(b) and (4)(a) are to be treated as requiring the manufacturer to carry out—

(a) the conformity assessment procedure set out in Article 13(1)(b); and

(b) the relevant conformity assessment procedure that applies to that product in accordance with Article 13(2).

(8) Paragraph (9) applies where, before making a product available on the market, a distributor ensures that the product bears the CE marking and inscriptions referred to in point 1.0.5 of Annex II.

(9) Where this paragraph applies—

(a) regulation 29(1)(a)(i) is to be treated as being satisfied; and

(b) regulations 2(a), 30 and 31(1) apply subject to the modifications in paragraph (10).

(10) The modifications referred to in subparagraphs (3)(b), (5)(b) and (9)(b) are that—

(a) any reference to "declaration of conformity" is to be read as a reference to the EU declaration of conformity;

(b) any reference to "UK marking" is to be read as reference to the CE marking;

(c) any reference to "essential safety requirements" is to be read as a reference to the essential safety requirements referred to in Annex II;

(d) any reference to "designated standard" is to be read as a reference to a harmonised standard;

(e) any reference to "relevant conformity assessment procedure" is to be read as a reference to the relevant conformity assessment procedures referred to in Article 13;

(f) any reference to "technical documentation" is a reference to the technical documentation referred to in Annexes III to IX.

F67 Regs. 36A-36D inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 21** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**) (as amended by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), Sch. 3 para. 17(3)); 2020 c. 1, **Sch. 5 para. 1(1)**

Conformity assessment procedure obligation which is met by complying with the ATEX Directive

36B.—(1) In this regulation any reference to an Article or Annex is a reference to an Article or an Annex of the ATEX Directive;

(2) Paragraph (3) applies where, prior to the manufacture of a product, the manufacturer ensures that the conformity assessment procedure that applies to that product in accordance with Annex III as referred to in Article 13(1)(a) and (b) has been carried out.

(3) Where this paragraph applies—

(a) any requirement to follow the Type-examination set out in Part 1 of Schedule 3A in regulation 39 is to be treated as being satisfied;

(b) any reference to "relevant conformity assessment procedure" in regulations 6(a), 7(1), 19(a), 36(1)(b), 40(c) and 41(3) is to be read as including the conformity assessment procedure set out in Annex III as referred to in Article 13(1)(a) and (b); and

(c) any reference to "technical documentation" in regulations 6(b), 8, 19(b) and 27(b) is to be read as including the technical documentation relating to the design of the product referred to in Annex III.

F67 Regs. 36A-36D inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 21** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**) (as amended by The Product Safety and Metrology

etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), Sch. 3 para. 17(3)); 2020 c. 1, **Sch. 5 para. 1(1)**

Expiry of regulations 36A and 36B

36C.—(1) Subject to paragraph (2), regulation 36A ceases to have effect at the end of the period of **[**F68four years**]** beginning with IP completion day.

(2) Notwithstanding the expiry of regulation 36A—

(a) any product which was placed on the market pursuant to regulation 36A may continue to be made available on the market on or after the expiry of regulation 36A;

(b) any obligation to which a person was subject under regulation 36A in respect of any product placed on the market pursuant to regulation 36A continues to have effect after the expiry of regulation 36A, in respect of that product.

(3) Subject to paragraph (4), regulation 36B ceases to have effect at the end of the period of **[**F69four years**]** beginning with IP completion day.

(4) Where a conformity assessment procedure has been completed pursuant to regulation 36B in relation to a product prior to the expiry of regulation 36B, regulation 36B continues to apply in respect of that pressure equipment or assembly where—

(a) the manufacturer arranges for the EU-Type examination certificate and any annexes to be transferred to an approved body;

(b) the approved body referred to in sub-paragraph (a) accepts responsibility for the EU-Type examination certificate; and

(c) the approved body issues a Type-examination certificate relying, or relying in part, on any examinations or tests undertaken prior to the issue of the EU-Type examination certificate.

(5) In paragraph (4) "EU-Type examination certificate" means a certificate issued after the conformity assessment referred to in regulation 36B(2) has been carried out.

F67 Regs. 36A-36D inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 21** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**) (as amended by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), Sch. 3 para. 17(3)); 2020 c. 1, **Sch. 5 para. 1(1)**

F68 Words in reg. 36C(1) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 2, **Sch. 1**

F69 Words in reg. 36C(3) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 2, **Sch. 1**

Qualifying Northern Ireland Goods

36D.—(1) In this regulation—

"the 2017 Regulations" means the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2017;

"CE marking" has the meaning given to it in regulation 2(1) of the 2017 Regulations;

"qualifying Northern Ireland goods" has the meaning given to it in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

"relevant conformity assessment procedure" has the meaning given to it in regulation 2(1) of the 2017 Regulations;

"technical documentation" has the meaning given to it in regulation 2(1) of the 2017 Regulations.

(2) Where paragraph (3) applies, a product is to be treated as being in conformity with Part 2.

(3) This paragraph applies where—

(a) a product—

(i) is in conformity with Part 2, within the meaning of regulation 2(2) of the 2017 Regulations; and

(ii) is qualifying Northern Ireland goods; and

(b) an importer has complied with the obligations set out in paragraph (4).

(4) The obligations referred to in paragraph (3)(b) are that, before placing the product on the market, the importer—

(a) complies with regulation 21;

(b) ensures that—

(i) the relevant conformity assessment procedure has been carried out in relation to the product;

(ii) the manufacturer has drawn up the technical documentation; and

(iii) the product bears the CE marking.**]**

F67 Regs. 36A-36D inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 21** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**) (as amended by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), Sch. 3 para. 17(3)); 2020 c. 1, **Sch. 5 para. 1(1)**

Translation of declaration of conformity

[F70]37. . . . . . .

F70 Reg. 37 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 22** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

PART 3

Conformity assessment

Presumption of conformity

38.—(1) A product which is in conformity with a **[**[F71]designated**]** standard (or part of such a standard) [F72]... is presumed to be in conformity with the essential health and safety requirements covered by that standard (or that part of that standard).

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

F71 Word in reg. 38(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 23(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F72 Words in reg. 38(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 23(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I35 Reg. 38 in force at 8.12.2016, see **reg. 1(1)**

Conformity assessment procedures

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—

[F73(a) for equipment-groups I and II, equipment-categories M1 and 1, the manufacturer must follow either—

(i) the Type-examination set out in Part 1 of Schedule 3A, in conjunction with either the procedure set out in—

(aa) Part 2 of Schedule 3A, or

(bb) Part 3 of Schedule 3A; or

(ii) the conformity based on unit verification referred to in Part 7 of Schedule 3A;**]**

[F74(b) for equipment-groups I and II, equipment-categories M2 and 2, the manufacturer must follow—

(i) for internal combustion engines and electrical equipment in these groups and categories the Type examination set out in Part 1 of Schedule 3A, in conjunction with either the procedure set out in either Part 4 or Part 5 of Schedule 3A;

(ii) for other equipment in these groups and categories the procedures set out in Part 6 of Schedule 3A;**]**

[F75(c) for equipment group II, equipment-category 3, the procedure relating to internal production control referred to in Part 6 of Schedule 3A;**]**

[F76(d) for equipment-groups I and II, instead of the procedures referred to in paragraphs (1)(a), (b) and (c), the manufacturer may follow conformity based on unit verification referred to in Part 7 of Schedule 3A.**]**

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

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

(a) follow the procedures referred to in paragraph (1), with the exception of—

(i) affixing the **[**F77UK**]** marking;

(ii) drawing up of the F78... declaration of conformity;

(b) issue a written attestation of conformity which must—

(i) confirm conformity of the component with Part 2 of these Regulations,

(ii) state the characteristics of the component, and

(iii) explain how the component must be incorporated into equipment or protective systems to comply with the essential health and safety requirements.

(4) In respect of the safety aspects referred to in paragraph 13 of Schedule 1, instead of the conformity assessment procedures referred to in paragraphs (1) and (2), the manufacturer may follow the procedure referred to in **[**F79Part 6 of Schedule 3A**]**.

(5) Where the procedures referred to in paragraphs (1), (2) and (4) have not been applied, the market surveillance authority, may authorise the placing on the market and the putting into service, of a product other than a component, F80... where—

(a) the market surveillance authority is in receipt of a duly justified request, requesting the placing on the market and the putting into service of a product, other than a component, and

(b) the use of that product is in the interests of protection.

(6) The manufacturer must ensure that the documents and correspondence relating to the conformity assessment procedures referred to in paragraphs (1) to (4) are in **[**F81English**]**.

F73 Reg. 39(1)(a) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F74 Reg. 39(1)(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F75 Reg. 39(1)(c) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F76 Reg. 39(1)(d) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F77 Word in reg. 39(3)(a)(i) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(e)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F78 Word in reg. 39(3)(a)(ii) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(f)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F79 Words in reg. 39(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(g)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F80 Words in reg. 39(5) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(h)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F81 Word in reg. 39(6) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 24(i)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I36 Reg. 39 in force at 8.12.2016, see **reg. 1(1)**

F82... Declaration of conformity

40. The F83... declaration of conformity for a product must—

(a) state that the fulfilment of the essential health and safety requirements have been demonstrated in respect of the product;

(b) have the model structure set out in Schedule 6;

(c) contain the elements specified in **[**F84Schedule 3A to these Regulations**]** for the relevant conformity assessment procedure followed in respect of the product.

F82 Word in reg. 40 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 25(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F83 Word in reg. 40 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 25(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F84 Words in reg. 40(c) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 25(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I37 Reg. 40 in force at 8.12.2016, see **reg. 1(1)**

[F85**UK] Marking**

41.—**[**F86(1) The UK marking must be affixed visibly, legibly and indelibly—

(a) to the product;

(b) to its data plate; or

(c) where paragraph (1A) applies, to—

(i) a label affixed to the product; or

(ii) a document accompanying the product.**]**

[F87(1A) For a period of **[**F88seven years**]** beginning with IP completion day, the UK marking may be affixed to—

(a) a label affixed to the product; or

(b) a document accompanying the product.**]**

(2) Where **[**F89paragraph (1A) does not apply and**]** it is not possible or warranted, on account of the nature of the product, to affix the **[**F90UK**]** marking in accordance with **[**F91paragraph (1)(a) or (b)**]**, the **[**F90UK**]** marking must be affixed to—

(a) the packaging, and

(b) the accompanying documents.

(3) The **[**F90UK**]** marking must be followed by the identification number of the **[**F92approved 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 **[**F92approved body**]** must be affixed—

(a) by the **[**F92approved body**]** itself, or

(b) under the instructions of the **[**F92approved body**]**, by the manufacturer or the authorised representative.

(5) The **[**F90UK**]** marking and, where applicable, the identification number of the **[**F92approved body**]** must be followed by—

(a) the specific marking of explosion protection as referred to in paragraph 5(1)(f) of Schedule 1,

(b) the symbols of the equipment-group and category, and

(c) where applicable, the other markings and information referred to in paragraph 5 of Schedule 1.

(6) Products designed for a particular explosive atmosphere must be marked accordingly.

F85 Word in reg. 41 heading substituted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 26(ac) (as inserted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 17(4)(b)**)

F86 Reg. 41(1) substituted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 26(a) (as substituted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 17(4)(a)**)

F87 Reg. 41(1A) inserted by S.I. 2019/696, Sch. 25 para. 26(aa) (as inserted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 17(4)(b)**)

F88 Words in reg. 41(1A) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 3, **Sch. 2**

F89 Words in reg. 41(2) inserted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 26(ab)(i) (as inserted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 17(4)(b)**)

F90 Word in reg. 41(2)-(5) substituted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 26(ac) (as inserted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 17(4)(b)**)

F91 Words in reg. 41(2) substituted (31.12.2020) by S.I. 2019/696, Sch. 25 para. 26(ab)(ii) (as inserted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 17(4)(b)**)

F92 Words in reg. 41 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 26(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I38 Reg. 41 in force at 8.12.2016, see **reg. 1(1)**

[F93PART 4

Approval of Conformity Assessment Bodies

F93 Pt. 4 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 27** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(n)(iv)(v)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Approved bodies

42.—(1) An approved body is a conformity assessment body which—

(a) has been approved by the Secretary of State pursuant to the procedure set out in regulation 43 (approval of conformity assessment bodies); or

(b) immediately before IP completion day was a notified body in respect of which the Secretary of State has taken no action under regulation 48(1) or (2) as it had effect

immediately before IP completion day to restrict, suspend or withdraw the body's status as a notified body.

(2) Paragraph (1) has effect subject to regulation 46 (restriction, suspension or withdrawal of approval).

(3) In this Part—

"notified body" means a body—

(a) which the Secretary of State had before IP completion day notified to the European Commission and the member States of the European Union, in accordance with Article 17 of the ATEX Directive; and

(b) in respect of which no objections had been raised as referred to in regulation 42(1)(b) as it had effect immediately before IP completion day.

"approved body requirements" means the requirements set out in Schedule 2.

Approval of conformity assessment bodies

43.—(1) The Secretary of State may approve only those conformity assessment bodies that qualify for approval.

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

(3) The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and that application is accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent;

(iii) the category of products in respect of which the conformity assessment body claims to be competent; and

(b) either—

(i) an accreditation certificate, or

(ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.

(4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

(5) For the purposes of paragraph (4), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (3)(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.

(6) When deciding whether to approve a conformity assessment body that applies for approval, 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) For the purposes of this regulation "accreditation certificate" means a certificate, issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.

Presumption of conformity of approved bodies

44.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a designated standard (or part of such standard), the Secretary of State is to presume that the conformity assessment body meets the approved body requirements covered by that standard (or part of that standard).

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

Monitoring

45. The Secretary of State must monitor each approved body with a view to verifying that the body—

(a) continues to meet the approved body requirements;

(b) meets any conditions set—

(i) in accordance with regulation 43(6)(b), or

(ii) in the case of an approved body which was a notified body immediately before IP completion day, in accordance with regulation 43(6)(b) as it applied immediately before IP completion day; and

(c) carries out its functions in accordance with these Regulations.

Restriction, suspension or withdrawal of approval

46.—(1) Where the Secretary of State determines that an approved body—

(a) no longer meets an approved body requirement, or

(b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 45(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 42 (approved bodies).

(2) Where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 45(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved 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 approved body of the proposed action and the reasons for it;

(b) give the approved 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 approved body.

(5) Where the Secretary of State has taken action in respect of an approved body under paragraph (1) or (2), or where an approved body has ceased its activity, the approved body must, at the request of the Secretary of State—

(a) transfer its files relating to the activities it has undertaken as an approved body to another approved body or to the Secretary of State, or

(b) keep its files relating to the activities it has undertaken as an approved body available for the Secretary of State and market surveillance authorities for a period of 10 years from the date they were created.

(6) The activities undertaken by an approved body referred to in paragraph (5) include any activities that the body has undertaken as a notified body.

Operational matters in relation to approved bodies

47.—(1) Subject to the terms of its appointment, an approved body must carry out the conformity assessment activities and procedures—

(a) in respect of which the body's approval was given under regulation 43, or

(b) in respect of which the body's notification as a notified body was made.

(2) Where an approved body carries out a conformity assessment procedure, it must do so in accordance with Schedule 3.

(3) An approved body must make provision for a manufacturer to be able to make an appeal against a refusal by the approved body—

(a) to issue a Type examination certificate referred to in Part 1 of Schedule 3B;

(b) to affix, or cause to be affixed, the body's identification number pursuant to regulation 41 (UK marking).

Subsidiaries and contractors

48.—(1) An approved body may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—

(a) the body is satisfied that the subcontractor or subsidiary meet the approved body requirements;

(b) the body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meet those requirements; and

(c) the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.

(2) The approved body which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).

(3) Where an approved body subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the approved body must, for a period of 10 years beginning on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all relevant documents concerning—

(a) the assessment of the qualifications of the subcontractor or the subsidiary; and

(b) the conformity assessment activity carried out by the subcontractor or subsidiary.

(4) In this regulation "subsidiary" has the meaning given to it in section 1159 of the Companies Act 2006;

Register of approved bodies

49.—(1) The Secretary of State must—

(a) assign an approved body identification number to each approved body; and

(b) compile and maintain a register of—

(i) approved bodies;

(ii) their approved body notification numbers;

(iii) the activities for which they have been approved; and

(iv) any restrictions on those activities.

(2) The register referred to in paragraph (1) must be made publicly available.

UK national accreditation body

50. The Secretary of State may authorise the UK national accreditation body to carry out the following activities on behalf of the Secretary of State—

(a) assessing whether a conformity assessment body meets the approved body requirements;

(b) monitoring approved bodies in accordance with regulation 45; and

(c) compiling and maintaining the register of approved bodies, in accordance with regulation 49.**]**

PART 5

Market surveillance and enforcement

Designation of market surveillance authority

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

(2) The market surveillance authority in Great Britain 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 paragraphs (2) and (3), "GB nuclear site" means a nuclear site in Great Britain (within the meaning given in section 68 of the Energy Act 2013(**10**)).

Commencement Information

I39 Reg. 51 in force at 8.12.2016, see **reg. 1(1)**

Enforcement

52.—(1) The market surveillance authority must enforce these Regulations and RAMS in its application to a product.

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

(**10**) 2013 c.32.

Commencement Information
I40 Reg. 52 in force at 8.12.2016, see **reg. 1(1)**

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), the authority may use the powers set out in Schedule 5 (compliance, withdrawal and recall notices).

Commencement Information
I41 Reg. 53 in force at 8.12.2016, see **reg. 1(1)**

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);

F94(c) . . . . . .

(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).

F94 Reg. 54(c) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 28** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I42 Reg. 54 in force at 8.12.2016, see **reg. 1(1)**

Evaluation of a product presenting a risk

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.

Commencement Information
I43 Reg. 55 in force at 8.12.2016, see **reg. 1(1)**

Enforcement action in respect of products which are not in conformity and which present a risk

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 action 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 **[**F95approved**]** 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 Great Britain, 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 Great Britain, the Secretary of State must inform the **[**F96Health and Safety Executive for Northern Ireland**]** 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 Great Britain,

(b) withdraw the product from the market in Great Britain, 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), the Secretary of State must notify the **[**F97Health and Safety Executive for Northern Ireland**]** 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 **[**[F98]designated**]** 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;

(b) reasonable and commensurate with the nature of the risk presented by the product.

F95 Word in reg. 56(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 29(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F96 Words in reg. 56(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 29(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F97 Words in reg. 56(7) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 29(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F98 Word in reg. 56(8)(f)(ii) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 29(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I44 Reg. 56 in force at 8.12.2016, see **reg. 1(1)**

EU safeguard procedure

[[F99]**57.** . . . . . .

F99 Reg. 57 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 30** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Enforcement action in respect of products which are in conformity, but present a risk

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.

(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), the Secretary of State must notify **[**[F100]the Health and Safety Executive for Northern Ireland**]** 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;

(d) the nature and duration of the measures taken by the market surveillance authority.

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

(a) prescribed by the market surveillance authority;

(b) reasonable and commensurate with the nature of the risk presented by the product.

F100 Words in reg. 58(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 31** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I45 Reg. 58 in force at 8.12.2016, see **reg. 1(1)**

Enforcement action in respect of formal non-compliance

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 remedy the non-compliance concerned within a specified period—

(a) the **[**F101UK**]** marking—

(i) where required, has not been affixed;

(ii) has been affixed otherwise than in accordance with regulations 36 (prohibition on improper use of **[**F101UK**]** marking) and 41 (**[**F101UK**]** marking);

(b) where **[**F102an approved**]** body is involved in the production control phase for the product, the identification number of the notified body—

(i) has not been affixed;

(ii) has been affixed otherwise than in accordance with regulation 41;

(c) the F103... declaration of conformity or the attestation of conformity as appropriate—

(i) does not accompany the product;

(ii) has been drawn up otherwise than in accordance with regulations 7 (F103... declaration of conformity and **[**F104UK**]** marking) and 40 (F103... declaration of conformity);

(d) the technical documentation is either not available or not complete;

(e) the following product information has not been affixed or has been affixed otherwise than in accordance with paragraph 5 of Schedule 1—

(i) specific marking of explosion protection in accordance with paragraph 5(1)(f) of Schedule 1;

(ii) the symbols of the equipment-group and category in accordance with paragraph 5(1)(g) of Schedule 1;

(iii) where applicable, the other markings and information required by paragraph 5(1) of Schedule 1;

(f) the following information that is required to be included in the labelling of the product is absent, false or incomplete—

(i) the information specified in regulation 13 (information identifying manufacturer)

(ii) the information specified in regulation 21 (information identifying importer);

(g) any other administrative requirement imposed on the manufacturer or importer under Part 2 has not been fulfilled.

(2) The market surveillance authority must not take any enforcement action against the relevant economic operator under these Regulations in respect of the non-compliance concerned until the period referred to in paragraph (1) has elapsed.

(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.

F101 Word in reg. 59(1)(a) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 32(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F102 Words in reg. 59(1)(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 32(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F103 Word in reg. 59(1)(c) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 32(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F104 Word in reg. 59(1)(c)(ii) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 32(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I46 Reg. 59 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information

I47 Reg. 60 in force at 8.12.2016, see **reg. 1(1)**

Offences

61.—(1) It is an offence for a person to contravene or fail to comply with any requirement of regulations 5 to 15, 16(2), 18 to 25, 26(2), 27 to 32, 33(2), 35 or 36.

(2) It is an offence for any person to contravene or fail to comply with any requirement of a withdrawal or recall notice served on that person by the market surveillance authority under these Regulations.

Commencement Information
I48 Reg. 61 in force at 8.12.2016, see **reg. 1(1)**

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 3 months or to both;

(ii) in Scotland, to a fine not exceeding the statutory maximum or imprisonment for a term not exceeding 3 months, or to both;

(b) on conviction on indictment, to a fine or imprisonment for a term not exceeding 2 years or to both.

Commencement Information
I49 Reg. 62 in force at 8.12.2016, see **reg. 1(1)**

Defence of due diligence

63.—(1) Subject to paragraphs (2) and (4), 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 diet.

(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 to—

(a) the steps that P took, and those which might reasonably have been taken, for the purpose of verifying the information, and

(b) 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.

Commencement Information
I50 Reg. 63 in force at 8.12.2016, see **reg. 1(1)**

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 any of the following—

(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;

(d) a person purporting to act as a person described in sub-paragraphs (a), (b) or (c).

Commencement Information
I51 Reg. 64 in force at 8.12.2016, see **reg. 1(1)**

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 which is 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 which is sufficient in the Lord Advocate's opinion to justify the proceedings came to the Lord Advocate's knowledge;

(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(o) of Schedule 4 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act).

Commencement Information
I52 Reg. 65 in force at 8.12.2016, see **reg. 1(1)**

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;

(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;

(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.

Commencement Information
I53 Reg. 66 in force at 8.12.2016, see **reg. 1(1)**

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 market surveillance authority for any expenditure which the market surveillance authority has incurred in investigating the offence.

Commencement Information
I54 Reg. 67 in force at 8.12.2016, see **reg. 1(1)**

Action by the market surveillance authority

68.—(1) The market surveillance 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 market surveillance 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 market surveillance authority has taken action 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 market surveillance 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(**11**).

Commencement Information

I55 Reg. 68 in force at 8.12.2016, see **reg. 1(1)**

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;

(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 and does not present a risk;, or

(b) that the market surveillance authority failed to comply with regulation 54 (exercise of enforcement powers) when serving 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);

(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);

(**11**) 1980 c.43; section 58 was amended by the Crime and Courts Act 2013 (c.22), Schedule 10 paragraph 40.

(iv) a withdrawal notice served in accordance with Schedule 5;

(v) a recall notice served in accordance with Schedule 5.

Commencement Information

I56 Reg. 69 in force at 8.12.2016, see **reg. 1(1)**

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 principal 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.

Commencement Information

I57 Reg. 70 in force at 8.12.2016, see **reg. 1(1)**

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 no later than 5 years after the commencement date.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding 5 years.

Commencement Information

I58 Reg. 71 in force at 8.12.2016, see **reg. 1(1)**

Transitional provisions

72.—(1) A certificate issued, or approval granted, by a notified body under Schedule 6 to 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 the ATEX Directive.

F105(2) . . . . . .

F105 Reg. 72(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 33** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I59 Reg. 72 in force at 8.12.2016, see **reg. 1(1)**

[F106Transitional provision in relation to EU Exit

72A.—(1) In this regulation—

"pre-exit period" means the period beginning with the commencement date and ending immediately before IP completion day;

(2) Subject to paragraph (3), where a product was made available on the market during the pre-exit period, despite the amendments made by Schedule 25 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, any obligation to which a person was subject under these Regulations as they had effect immediately before IP completion day, continues to have effect as it did immediately before IP completion day, in relation to that product.

(3) Paragraph (2) does not apply to—

(a) any obligation of any enforcing authority to inform the European Commission or the member States of any matter; or

(b) any obligation to take action outside of the market in respect of that product.

(4) Where during the pre-exit period—

(a) a product has not been placed on the market; and

(b) a manufacturer has taken any action under regulation 38 as it had effect immediately before IP completion day in relation to that product,

that action has effect as if it had been done under regulation 38 as it had effect on and after IP completion day.

[
F107(5) Subject to paragraph (6), where before 11pm on 31st December 2024—

(a) a product has not been placed on the market or put into service; and

(b) a manufacturer has taken any action under the conformity assessment procedure that applies to that product in accordance with Article 13 of the ATEX Directive

that action has effect as if it had been done under the applicable conformity assessment procedure referred to in regulation 39.

(6) Paragraph (5) does not apply—

(a) after the expiry of the validity of any certificate issued pursuant to the applicable conformity assessment procedure; and

(b) in any event, after 31st December 2027.**]]**

F106 Reg. 72A inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 34** (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(n)(vi)**)

F107 Reg. 72A(5)(6) inserted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), **16(2)**

Revocations and savings

73.—(1) Subject to paragraph (3) **[**F108and (3A)**]**, the 1996 Regulations, the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (Amendment) Regulations 2001(**12**) and the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (Amendment) Regulations 2005(**13**) are revoked.

(2) The Electrical Equipment for Explosive Atmospheres (Certification) (Amendment) Regulations 1999(**14**) are revoked.

[F109(3) Subject to the modifications made in paragraph (3A), the Regulations referred to in paragraph (1) continue to apply, as if they had not been revoked, to a product placed on the market before the commencement date.**]**

[F110(3A) The modifications in the 1996 Regulations referred to in paragraph (3) are as follows—

(i) any reference to "the Community" shall be read as including the United Kingdom;

(ii) any reference to "member State" shall be read as including the United Kingdom;

(iii) any reference to "notified body" shall be read as "approved body" as defined in the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016.**]**

F108 Words in reg. 73(1) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 35(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F109 Reg. 73(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 35(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

(**12**) S.I. 2001/3766.
(**13**) S.I. 2005/830.
(**14**) S.I. 1999/2550.

F110 Reg. 73(3A) inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 35(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I60 Reg. 73 in force at 8.12.2016, see **reg. 1(1)**

Consequential Amendments

74.—(1) In paragraph 1 of Schedule 3 to the Dangerous Substances and Explosive Atmospheres Regulations 2002(**15**) for "the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996" substitute "the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016".

(2) In relation to a product placed on the market before the commencement date, the amendments in paragraph (1) do not apply.

Commencement Information

I61 Reg. 74 in force at 8.12.2016, see **reg. 1(1)**

Margot James
Parliamentary Under Secretary of State Minister for Small Business, Consumers and Corporate Responsibility
Department for Business, Energy and Industrial Strategy

(**15**) S.I. 2002/2776.

SCHEDULE 1

Regulation 2(1)

Essential Health and 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 regulation 3(2)(b), the essential health and safety requirements must 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.

Commencement Information

I62 Sch. 1 para. 1 in force at 8.12.2016, see **reg. 1(1)**

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;

(b) to prevent the ignition of explosive atmospheres, taking into account the nature of every electrical and non-electrical source of ignition;

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

(3) 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.

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

Commencement Information

I63 Sch. 1 para. 2 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I64 Sch. 1 para. 3 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I65 Sch. 1 para. 4 in force at 8.12.2016, see **reg. 1(1)**

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) **[**[F111] UK marking**]**;

(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,

(i) the letter ‘G’ (concerning explosive atmospheres caused by gases, vapours or mists); or

(ii) the letter ‘D’ (concerning explosive atmospheres caused by dust); or

(iii) both the letter ‘G’ (concerning explosive atmospheres caused by gases, vapours or mists) and 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.

F111 Words in Sch. 1 para. 5(1)(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 36(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I66 Sch. 1 para. 5 in force at 8.12.2016, see **reg. 1(1)**

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 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.

Commencement Information

I67 Sch. 1 para. 6 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I68 Sch. 1 para. 7 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I69 Sch. 1 para. 8 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I70 Sch. 1 para. 9 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I71 Sch. 1 para. 10 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I72 Sch. 1 para. 11 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I73 Sch. 1 para. 12 in force at 8.12.2016, see **reg. 1(1)**

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 paragraph (1) are wholly or partly covered by **[**F112any other enactment**]**, these Regulations do not apply or cease to apply in the case of such equipment and protective systems and of such risks upon application of that specific **[**F113enactment**]**.

F112 Words in Sch. 1 para. 13(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 36(b)(i)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
F113 Word in Sch. 1 para. 13(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 36(b)(ii)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I74 Sch. 1 para. 13 in force at 8.12.2016, see **reg. 1(1)**

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

or similar types of monitoring devices, or both overspeed monitors and similar types of monitoring devices.

Commencement Information
I75 Sch. 1 para. 14 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I76 Sch. 1 para. 15 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I77 Sch. 1 para. 16 in force at 8.12.2016, see **reg. 1(1)**

Hazards arising from static electricity

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

Commencement Information
I78 Sch. 1 para. 17 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I79 Sch. 1 para. 18 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I80 Sch. 1 para. 19 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I81 Sch. 1 para. 20 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I82 Sch. 1 para. 21 in force at 8.12.2016, see **reg. 1(1)**

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 prevent dangerous situations from occurring.

(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 or protective systems or both must 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.

Commencement Information
I83 Sch. 1 para. 22 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I84 Sch. 1 para. 23 in force at 8.12.2016, see **reg. 1(1)**

Requirements in respect of 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 or ignition limits of the atmospheres to be registered, or both the explosion and ignition limits, taking into account, in particular, the operating conditions of the installation and possible aberrations in the measuring system.

Commencement Information
I85 Sch. 1 para. 24 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I86 Sch. 1 para. 25 in force at 8.12.2016, see **reg. 1(1)**

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) Sub-paragraph (2) does not apply to electrochemically-stored energy.

Commencement Information
I87 Sch. 1 para. 26 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I88 Sch. 1 para. 27 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I89 Sch. 1 para. 28 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I90 Sch. 1 para. 29 in force at 8.12.2016, see **reg. 1(1)**

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) Equipment 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.

Commencement Information
I91 Sch. 1 para. 30 in force at 8.12.2016, see **reg. 1(1)**

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 must 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 equipment category M 1 must be applied.

Commencement Information
I92 Sch. 1 para. 31 in force at 8.12.2016, see **reg. 1(1)**

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 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) 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.

Commencement Information
I93 Sch. 1 para. 32 in force at 8.12.2016, see **reg. 1(1)**

Explosive atmospheres caused by air and dust mixtures

33.—(1) Equipment must be so designed and constructed that ignition of air and 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) The requirement in sub-paragraph (3) 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 and dust mixtures in order to prevent the ignition of suspended dust.

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

Commencement Information
I94 Sch. 1 para. 33 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I95 Sch. 1 para. 34 in force at 8.12.2016, see **reg. 1(1)**

Explosive atmospheres caused by air and dust mixtures

35.—(1) Equipment must be designed and constructed so that ignition of air and 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, sub-paragraph 33(5) applies.

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

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

Commencement Information

I96 Sch. 1 para. 35 in force at 8.12.2016, see **reg. 1(1)**

Requirements applicable to equipment category 3 of equipment – group II

Explosive atmospheres caused by gases, vapours or mists

36.—(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.

Commencement Information

I97 Sch. 1 para. 36 in force at 8.12.2016, see **reg. 1(1)**

Explosive atmospheres caused by air and dust mixtures

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

(2) With regard to surface temperatures, sub-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.

Commencement Information

I98 Sch. 1 para. 37 in force at 8.12.2016, see **reg. 1(1)**

Supplementary requirements in respect of protective systems

General requirements

38.—(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.

Commencement Information
I99 Sch. 1 para. 38 in force at 8.12.2016, see **reg. 1(1)**

Planning and design

Characteristics of materials

39.—(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.

Commencement Information
I100 Sch. 1 para. 39 in force at 8.12.2016, see **reg. 1(1)**

Pressure-relief systems

40. 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.

Commencement Information
I101 Sch. 1 para. 40 in force at 8.12.2016, see **reg. 1(1)**

Explosion suppression systems

41. 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.

Commencement Information
I102 Sch. 1 para. 41 in force at 8.12.2016, see **reg. 1(1)**

Explosion decoupling systems

42. 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.

Commencement Information
I103 Sch. 1 para. 42 in force at 8.12.2016, see **reg. 1(1)**

43. 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.

Commencement Information
I104 Sch. 1 para. 43 in force at 8.12.2016, see **reg. 1(1)**

Commencement Information
I103 Sch. 1 para. 42 in force at 8.12.2016, see **reg. 1(1)**
I104 Sch. 1 para. 43 in force at 8.12.2016, see **reg. 1(1)**

[F114SCHEDULE 1A

Regulation 2

Criteria determining the classification of equipment-groups into categories (Annex I to the ATEX Directive)

F114 Sch. 1A inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 37** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

1. Equipment group I

(a) Equipment category M 1 comprises equipment designed and, where necessary, equipped with additional special means of protection to be capable of functioning in conformity with the operational parameters established by the manufacturer and ensuring a very high level of protection.

Equipment in this category is intended for use in underground parts of mines as well as those parts of surface installations of such mines endangered by firedamp and/or combustible dust.

Equipment in this category is required to remain functional, even in the event of rare incidents relating to equipment, with an explosive atmosphere present, and is characterised by means of protection such that:

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or the requisite level of protection is assured in the event of two faults occurring independently of each other.

Equipment in this category must comply with the supplementary requirements referred to in paragraph 30 of Schedule 1.

(b) Equipment category M 2 comprises equipment designed to be capable of functioning in conformity with the operational parameters established by the manufacturer and ensuring a high level of protection.

Equipment in this category is intended for use in underground parts of mines as well as those parts of surface installations of such mines likely to be endangered by firedamp and/or combustible dust.

This equipment is intended to be de-energised in the event of an explosive atmosphere.

The means of protection relating to equipment in this category assure the requisite level of protection during normal operation and also in the case of more severe operating conditions, in particular those arising from rough handling and changing environmental conditions.

Equipment in this category must comply with the supplementary requirements referred to in paragraph 31 of Schedule 1.

2. Equipment-group II

(a) Equipment category 1 comprises equipment designed to be capable of functioning in conformity with the operational parameters established by the manufacturer and ensuring a very high level of protection.

Equipment in this category is intended for use in areas in which explosive atmospheres caused by mixtures of air and gases, vapours or mists or by air/dust mixtures are present continuously, for long periods or frequently.

Equipment in this category must ensure the requisite level of protection, even in the event of rare incidents relating to equipment, and is characterised by means of protection such that:

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or the requisite level of protection is assured in the event of two faults occurring independently of each other.

Equipment in this category must comply with the supplementary requirements referred to in paragraphs 32 and 33 of Schedule 1.

(b) Equipment category 2 comprises equipment designed to be capable of functioning in conformity with the operational parameters established by the manufacturer and of ensuring a high level of protection.

Equipment in this category is intended for use in areas in which explosive atmospheres caused by gases, vapours, mists or air/dust mixtures are likely to occur occasionally.

The means of protection relating to equipment in this category ensure the requisite level of protection, even in the event of frequently occurring disturbances or equipment faults which normally have to be taken into account.

Equipment in this category must comply with the supplementary requirements referred to in paragraphs 34 and 35 of Schedule 1.

(c) Equipment category 3 comprises equipment designed to be capable of functioning in conformity with the operating parameters established by the manufacturer and ensuring a normal level of protection.

Equipment in this category is intended for use in areas in which explosive atmospheres caused by gases, vapours, mists, or air/dust mixtures are unlikely to occur or, if they do occur, are likely to do so only infrequently and for a short period only.

Equipment in this category ensures the requisite level of protection during normal operation.

Equipment in this category must comply with the supplementary requirements referred to in paragraphs 36 and 37 of Schedule 1.**]**

SCHEDULE 2

Regulation 2(1)

[F115Approved] body requirements

F115 Word in Sch. 2 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 38(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

1. A conformity assessment body must be established in Great Britain and have legal personality.

Commencement Information
I105 Sch. 2 para. 1 in force at 8.12.2016, see **reg. 1(1)**

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

Commencement Information
I106 Sch. 2 para. 2 in force at 8.12.2016, see **reg. 1(1)**

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 which it assesses is to be a conformity assessment body for the purposes of **[**F116regulation 43 (approval of conformity assessment bodies)**]** provided that such body can demonstrate—

(a) its independence from such business association or professional federation; and

(b) the absence of any conflict of interest.

F116 Words in Sch. 2 para. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 38(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I107 Sch. 2 para. 3 in force at 8.12.2016, see **reg. 1(1)**

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 products for personal purposes.

Commencement Information
I108 Sch. 2 para. 4 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I109 Sch. 2 para. 5 in force at 8.12.2016, see **reg. 1(1)**

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 **[**F117approved**]** (including consultancy services).

F117 Word in Sch. 2 para. 6 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 38(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I110 Sch. 2 para. 6 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I111 Sch. 2 para. 7 in force at 8.12.2016, see **reg. 1(1)**

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 who have an interest in the results of those activities.

Commencement Information
I112 Sch. 2 para. 8 in force at 8.12.2016, see **reg. 1(1)**

9. A conformity assessment body must be capable of carrying out all of the conformity assessment activities for which it has been, or is to be, **[**F118approved**]**, whether those activities are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

F118 Word in Sch. 2 para. 9 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 38(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I113 Sch. 2 para. 9 in force at 8.12.2016, see **reg. 1(1)**

10. A conformity assessment body must have —

(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 activities are to be carried out, ensuring the transparency of and the ability to reproduce those procedures, and have appropriate policies and procedures in place that distinguish between tasks it carries out as **[**F119an approved**]** body and other activities;

(c) procedures for the performance of conformity assessment 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.

F119 Words in Sch. 2 para. 10(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 38(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I114 Sch. 2 para. 10 in force at 8.12.2016, see **reg. 1(1)**

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 to enable it to perform those activities.

Commencement Information
I115 Sch. 2 para. 11 in force at 8.12.2016, see **reg. 1(1)**

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 **[**F120approved**]**;

(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 health and safety requirements, of the applicable **[**F121designated standards**]** and of these Regulations;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

F120 Word in Sch. 2 para. 12(a) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 38(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
F121 Words in Sch. 2 para. 12(c) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 38(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I116 Sch. 2 para. 12 in force at 8.12.2016, see **reg. 1(1)**

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

Commencement Information
I117 Sch. 2 para. 13 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I118 Sch. 2 para. 14 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I119 Sch. 2 para. 15 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I120 Sch. 2 para. 16 in force at 8.12.2016, see **reg. 1(1)**

17. Paragraph 16 does not prevent the personnel from providing information to the Secretary of State or the market surveillance authority pursuant to these Regulations or under any enactment.

Commencement Information
I121 Sch. 2 para. 17 in force at 8.12.2016, see **reg. 1(1)**

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 **[**F122approved**]** body coordination group established **[**F123by the Secretary of State**]** and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

F122 Word in Sch. 2 para. 18 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 38(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
F123 Words in Sch. 2 para. 18 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 38(e)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I122 Sch. 2 para. 18 in force at 8.12.2016, see **reg. 1(1)**

SCHEDULE 3

[F125Regulation 47]

Operational obligations of [F124approved] bodies

F124 Word in Sch. 3 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F125 Words in Sch. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**); 2020 c. 1, **Sch. 5 para. 1(1)**

1. [F126An approved] body must carry out conformity assessments in accordance with the relevant conformity assessment procedures.

F126 Words in Sch. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I123 Sch. 3 para. 1 in force at 8.12.2016, see **reg. 1(1)**

2. [F126An approved] body must carry out conformity assessments in a proportionate manner, avoiding unnecessary burdens on economic operators.

F126 Words in Sch. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I124 Sch. 3 para. 2 in force at 8.12.2016, see **reg. 1(1)**

3. [F126An approved] 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.

F126 Words in Sch. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I125 Sch. 3 para. 3 in force at 8.12.2016, see **reg. 1(1)**

4. [F126An approved] 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.

F126 Words in Sch. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I126 Sch. 3 para. 4 in force at 8.12.2016, see **reg. 1(1)**

5. Where **[**F126an approved**]** body finds that essential health and 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.

F126 Words in Sch. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I127 Sch. 3 para. 5 in force at 8.12.2016, see **reg. 1(1)**

6. Where, in the course of the monitoring of conformity following the issue of a certificate or grant of an approval, **[**F126an approved**]** body finds that a product is no longer in conformity with the essential health and 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).

F126 Words in Sch. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I128 Sch. 3 para. 6 in force at 8.12.2016, see **reg. 1(1)**

7. Where the **[**F127approved**]** 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 **[**F127approved**]** body must restrict, suspend or withdraw any certificate of conformity or approval.

F127 Word in Sch. 3 para. 7 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I129 Sch. 3 para. 7 in force at 8.12.2016, see **reg. 1(1)**

8. Paragraph 9 applies where **[**F126an approved**]** 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.

F126 Words in Sch. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I130 Sch. 3 para. 8 in force at 8.12.2016, see **reg. 1(1)**

9. Where this paragraph applies, the **[**[F128]approved**]** 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.

F128 Word in Sch. 3 para. 9 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I131 Sch. 3 para. 9 in force at 8.12.2016, see **reg. 1(1)**

10. **[**[F126]An approved**]** 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 **[**[F129]regulation 43 (approval of conformity assessment bodies)**]**;

(c) any request for information which it has received from the market surveillance authority regarding conformity assessment activities; and

(d) on request, any conformity assessment activities performed within the scope of its **[**[F130]approval under regulation 43**]** and any other activity performed, including cross-border activities and subcontracting.

F126 Words in Sch. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F129 Words in Sch. 3 para. 10(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F130 Words in Sch. 3 para. 10(d) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(e)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I132 Sch. 3 para. 10 in force at 8.12.2016, see **reg. 1(1)**

11. **[**[F126]An approved**]** 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.

F126 Words in Sch. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I133 Sch. 3 para. 11 in force at 8.12.2016, see **reg. 1(1)**

12. **[**F126An approved**]** body must provide other **[**F131bodies approved under these Regulations**]** 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.

F126 Words in Sch. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F131 Words in Sch. 3 para. 12 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(f)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I134 Sch. 3 para. 12 in force at 8.12.2016, see **reg. 1(1)**

13. **[**F126An approved**]** body must participate in the work of any **[**F132approved body coordination group established by the Secretary of State**]**, directly or by means of its designated representatives.

F126 Words in Sch. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F132 Words in Sch. 3 para. 13 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(g)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I135 Sch. 3 para. 13 in force at 8.12.2016, see **reg. 1(1)**

14. **[**F126An approved**]** body must—

(a) acknowledge receipt of the technical documentation provided by the manufacturer in accordance with regulation 39(1)(b)(ii)(bb) (conformity assessment procedures) as soon as possible; and

(b) retain the technical documentation referred to in sub-paragraph (a).

F126 Words in Sch. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 39(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I136 Sch. 3 para. 14 in force at 8.12.2016, see **reg. 1(1)**

[F133SCHEDULE 3A

Regulations 2, 6, 39 and 40

Conformity Assessment Procedures (Annexes III to IX of the ATEX Directive)

F133 Sch. 3A inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 40** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

PART 1

TYPE EXAMINATION

1. Type examination is the part of a conformity assessment procedure in which an approved body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of these Regulations that apply to it.

2. Type examination shall be carried out with the examination of a specimen, representative of the production envisaged, of the complete product (production type).

3. The manufacturer shall lodge an application for Type examination with a single approved body of his choice.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

(b) a written declaration that the same application has not been lodged with any other approved body,

(c) the technical documentation. The technical documentation shall make it possible to assess the product's conformity with the applicable requirements of these Regulations and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain at least the following elements:

(i) a general description of the product,

(ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

(iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

(iv) a list of the designated standards applied in full or in part and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied,

(v) results of design calculations made, examinations carried out, etc., and

(vi) test reports,

(d) the specimens representative of the production envisaged. The approved body may request further specimens if needed for carrying out the test programme.

4. The approved body shall:

4.1. examine the technical documentation, verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant designated standards, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.2. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant designated standards, these have been applied correctly;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant designated standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential health and safety requirements of these Regulations;

4.4. agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The approved body shall draw up an evaluation report that records the activities undertaken in accordance with paragraph 4 and their outcomes. Without prejudice to its obligations vis-à-vis the Secretary of State, the approved body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of these Regulations that apply to the product concerned, the approved body shall issue a Type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The Type examination certificate may have one or more annexes attached.

The Type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of these Regulations, the approved body shall refuse to issue a Type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The approved body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of these Regulations and shall determine whether such changes require further investigation. If so, the approved body shall inform the manufacturer accordingly.

The manufacturer shall inform the approved body that holds the technical documentation relating to the Type examination certificate of all modifications to the approved type that may affect the conformity of the product with the essential health and safety requirements of these Regulations or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original Type examination certificate.

8. Each approved body shall inform the Secretary of State concerning the Type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each approved body shall inform the other approved bodies concerning the Type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Health and Safety Executive for Northern Ireland may, on request, obtain a copy of the Type examination certificates and/or additions thereto. On request, The Health and Safety Executive for Northern Ireland may obtain a copy of the technical documentation and the results of the examinations carried out by the approved body. The approved body shall keep a copy of the Type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the Type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in paragraph 3 and fulfil the obligations set out in paragraphs 7 and 9, provided that they are specified in the mandate.

PART 2

CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2 and 5, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the Type examination certificate and satisfy the requirements of these Regulations that apply to them.

Manufacturing

2. The manufacturer shall operate an approved quality system for production, final product inspection and testing of the products concerned as specified in paragraph 3 and shall be subject to surveillance as specified in paragraph 4.

Quality system

3

3.1. The manufacturer shall lodge an application for assessment of his quality system with the approved body of his choice, for the products concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

(b) a written declaration that the same application has not been lodged with any other approved body,

(c) all relevant information for the product category envisaged,

(d) the documentation concerning the quality system,

(e) the technical documentation of the approved type and a copy of the Type examination certificate.

3.2. The quality system shall ensure that the products are in conformity with the type described in the Type examination certificate and comply with the requirements of these Regulations that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of these Regulations. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in paragraph 3.1(e) to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the approved body that has approved the quality system informed of any intended change to the quality system.

The approved body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

4

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the approved body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation,

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The approved body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the approved body may pay unexpected visits to the manufacturer. During such visits the approved body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The approved body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

UK marking, declaration of conformity and attestation of conformity

5

5.1. The manufacturer shall affix the UK marking and, under the responsibility of the approved body referred to in paragraph 3.1, the latter's identification number to each individual product other than a component that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model, other than a component and keep it at the disposal of the national authorities for 10 years after the product other than a component has been placed on the market. The declaration of conformity shall identify such product model for which it has been drawn up.

A copy of the declaration of conformity shall accompany every product, other than a component.

5.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

6. The manufacturer shall, for a period ending 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in paragraph 3.1,

(b) the information relating to the change referred to in paragraph 3.5, as approved,

(c) the decisions and reports of the approved body referred to in paragraphs 3.5, 4.3 and 4.4.

7. Each approved body shall inform the Secretary of State of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

Each approved body shall inform the other approved bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Authorised representative

8. The manufacturer's obligations set out in paragraphs 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

PART 3

CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2 and 5 and ensures and declares on his sole responsibility that the products concerned, which have been subject to the provisions of paragraph 3, are in conformity with the type described in the Type examination certificate and satisfy the requirements of these Regulations that apply to them.

Manufacturing

2. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the Type examination certificate and with the requirements of these Regulations that apply to them.

Verification

3. An approved body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the products with the approved type described in the Type examination certificate and with the appropriate requirements of these Regulations.

The examinations and tests to check the conformity of the products with the appropriate requirements shall be carried out by examination and testing of every product as specified in paragraph 4.

Verification of conformity by examination and testing of every product

4

4.1. All products shall be individually examined, and appropriate tests set out in the relevant designated standard(s) and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the Type examination certificate and with the appropriate requirements of these Regulations.

In the absence of such a designated standard, the approved body concerned shall decide on the appropriate tests to be carried out.

4.2. The approved body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the product has been placed on the market.

UK marking, declaration of conformity and attestation of conformity

5

5.1. The manufacturer shall affix the UK marking and, under the responsibility of the approved body referred to in paragraph 3, the latter's identification number to each individual product other than a component that is in conformity with the approved type described in the Type examination certificate and satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model other than a component and keep it at the disposal of the national authorities, for 10 years after the product, other than a component, has been placed on the market. The declaration of conformity shall identify such product model for which it has been drawn up.

A copy of the declaration of conformity shall accompany every product other than a component.

5.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

If the approved body referred to in paragraph 3 agrees and under its responsibility, the manufacturer may also affix the approved body's identification number to the products other than components.

6. If the approved body agrees and under its responsibility, the manufacturer may affix the approved body's identification number to the products during the manufacturing process.

Authorised representative

7. The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in paragraph 2.

PART 4

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING

1. Conformity to type based on internal production control plus supervised product testing is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the Type examination certificate and satisfy the requirements of these Regulations that apply to them.

Manufacturing

2. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the type described in the Type examination certificate and with the requirements of these Regulations that apply to them.

Product checks

3. For each individual product manufactured one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the type described in the Type examination certificate and with the corresponding requirements of these Regulations. The tests shall be carried out under the responsibility of an approved body, chosen by the manufacturer.

The manufacturer shall, under the responsibility of the approved body, affix the approved body's identification number during the manufacturing process.

UK marking, declaration of conformity and attestation of conformity

4

4.1. The manufacturer shall affix the UK marking to each individual product other than a component that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations.

4.2. The manufacturer shall draw up a written declaration of conformity for a product model other than a component and keep it at the disposal of the national authorities for 10 years after the product, other than a component has been placed on the market. The declaration of conformity shall identify such product model for which it has been drawn up.

A copy of the declaration of conformity shall accompany every product, other than a component.

4.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

Authorised representative

5. The manufacturer's obligations set out in paragraph 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

PART 5

CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE

1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2 and 5 and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the Type examination certificate and satisfy the requirements of these Regulations that apply to them.

Manufacturing

2. The manufacturer shall operate an approved quality system for final product inspection and testing of the products concerned as specified in paragraph 3 and shall be subject to surveillance as specified in paragraph 4.

Quality System

3

3.1. The manufacturer shall lodge an application for assessment of his quality system with the approved body of his choice, for the products concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well

(b) a written declaration that the same application has not been lodged with any other approved body,

(c) all relevant information for the product category envisaged,

(d) the documentation concerning the quality system, and

(e) the technical documentation of the approved type and a copy of the Type examination certificate.

3.2. The quality system shall ensure compliance of the products with the type described in the Type examination certificate and with the applicable requirements of these Regulations.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,

(b) the examinations and tests that will be carried out after manufacture,

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.,

(d) the means of monitoring the effective operation of the quality system.

3.3. The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of these Regulations. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in paragraph 3.1(e) in order to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the approved body that has approved the quality system informed of any intended change to the quality system.

The approved body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

4

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the approved body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation,

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The approved body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the approved body may pay unexpected visits to the manufacturer. During such visits the approved body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The approved body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

UK marking, declaration of conformity and attestation of conformity

5

5.1. The manufacturer shall affix the UK marking and, under the responsibility of the approved body referred to in paragraph 3.1, the latter's identification number to each individual product other than a component that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model, other than a component and keep it at the disposal of the national authorities for 10 years after the product other than a component has been placed on the market. The declaration of conformity shall identify such product model for which it has been drawn up.

A copy of the declaration of conformity shall accompany every product other than a component.

5.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

6. The manufacturer shall, for a period ending 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in paragraph 3.1,

(b) the information relating to the change referred to in paragraph 3.5, as approved,

(c) the decisions and reports of the approved body referred to in paragraphs 3.5, 4.3 and 4.4.

7. Each approved body shall inform the Secretary of State of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

Each approved body shall inform the other approved bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

Authorised representative

8. The manufacturer's obligations set out in paragraphs 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

PART 6

INTERNAL PRODUCTION CONTROL

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of these Regulations that apply to them.

Technical documentation

2. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain at least the following elements:

(a) a general description of the product,

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

(d) a list of the designated standards applied in full or in part and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied,

(e) results of design calculations made, examinations carried out, etc., and

(f) test reports.

Manufacturing

3. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in paragraph 2 and with the requirements of these Regulations that apply to them.

UK marking, declaration of conformity and attestation of conformity

4

4.1. The manufacturer shall affix the UK marking to each individual product other than a component that satisfies the applicable requirements of these Regulations.

4.2. The manufacturer shall draw up a written declaration of conformity for a product model other than a component and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product, other than a component, has been placed on the market. The declaration of conformity shall identify such product model for which it has been drawn up.

A copy of the declaration of conformity shall accompany every product other than a component.

4.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

Authorised representative

5. The manufacturer's obligations set out in paragraph 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

PART 7

CONFORMITY BASED ON UNIT VERIFICATION

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 3 and 5, and ensures and declares on his sole responsibility that the product concerned, which has been subject to the provisions of paragraph 4, is in conformity with the requirements of these Regulations that apply to it.

Technical documentation

2

2.1. The manufacturer shall establish the technical documentation and make it available to the approved body referred to in paragraph 4. The documentation shall make it possible to assess the product's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain at least the following elements:

(a) a general description of the product,

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

(d) a list of the designated standards applied in full or in part and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied,

(e) results of design calculations made, examinations carried out, etc., and

(f) test reports.

2.2. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product has been placed on the market.

Manufacturing

3. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with the applicable requirements of these Regulations.

Verification

4. An approved body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant designated standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the product with the applicable requirements of these Regulations, or have them carried out. In the absence of such a designated standard the approved body concerned shall decide on the appropriate tests to be carried out.

The approved body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved product, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.

UK marking, declaration of conformity and attestation of conformity

5

5.1. The manufacturer shall affix the UK marking and, under the responsibility of the approved body referred to in paragraph 4, the latter's identification number to each product other than a component that satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the national authorities for 10 years after the product, other than a component has been placed on the market. The declaration of conformity shall identify such product for which it has been drawn up.

A copy of the declaration of conformity shall accompany every product, other than a component.

5.3. The manufacturer shall draw up a written attestation of conformity and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

Authorised representative

6. The manufacturer's obligations set out in paragraphs 2.2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.**]**

SCHEDULE 4

Regulation 53(1)

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).

Commencement Information

I137 Sch. 4 para. 1 in force at 8.12.2016, see **reg. 1(1)**

Modifications to the 1974 Act

2. The sections of the 1974 Act 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) references to "risk" were references to risk within the meaning of regulation 2(5) of these Regulations;

(c) in section 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";

(d) 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) in subsection 2(h), for "him to have caused or to be likely to cause danger to health or safety", there were substituted "contravene the relevant statutory provisions or present a risk"; and

(iv) subsection (3) were omitted;

(e) in section 21—

(i) before paragraph (a), there were inserted—

"(za) is making available on the market a product which presents a risk;";

(ii) after "specifying the", there were inserted "risk, or"; and

(iii) after "requiring that person to", there were inserted "address the risk or";

(f) 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; or

(b) a contravention of a relevant statutory provision.";

(g) in section 23, subsections (3), (4) and (6) were omitted;

(h) in section 25A(1)—

(i) for "an enforcing authority or inspector", there were substituted "the Health and Safety Executive or the Office for Nuclear Regulation as the case may be";

(ii) for the "authority", there were substituted "the Health and Safety Executive or the Office for Nuclear Regulation as the case may be";

(i) for the title to section 26, there were substituted "Power to indemnify its inspectors";

(j) in section 26, for each of the following references there were substituted "the Health and Safety Executive or the Office for Nuclear Regulation as the case may be"—

(i) "the enforcing authority which appointed him";

(ii) "that authority"; and

(iii) "the authority";

(k) 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;

(l) for section 27A(2) there were substituted—

"(2) This subsection applies to the Health and Safety Executive, the Office for Nuclear Regulation and to an inspector";

(m) 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)(a), "or an enforcing authority" were omitted;

(v) in subsection (4), "or an enforcing authority" were omitted;

(vi) in subsection (4), "(including, in the case of an enforcing authority, any inspector appointed by it)" were omitted;

(vii) in subsection (5)(a), "or the purposes of the enforcing authority in question in connection with the relevant statutory provisions" were omitted;

(viii) in subsection (7), "14(4)(a) or" were omitted;

(ix) in subsection (7), for paragraph (b), there were substituted—

"(b) for the purposes of any legal proceedings or for the purposes of a report of any such proceedings;"; and

(x) subsection (9B) were omitted;

(n) 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 this section 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 the statutory maximum 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."; and

(iii) section 33(3) were omitted;

(o) in section 34—

(i) in subsection (1), paragraphs (a) and (b) were omitted;

(ii) in subsection (1), for the words from "and it appears" to the end, there were substituted "and it appears from the investigation or, in a case falling within paragraph (d), from the proceedings at the inquiry, that any of the relevant statutory provisions was contravened at a time which is material in relation to the subject-matter of the investigation or inquiry, summary proceedings against any person liable to be proceeded against in respect of the contravention may be commenced at any time within three months of the conclusion of the investigation or inquiry."; and

(iii) subsections (3) to (6) were omitted;

(p) 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";

(q) in section 39(1), for "enforcing authority which appointed him" there were substituted "the Health and Safety Executive or the Office for Nuclear Regulation as the case may be"; and

(r) in section 42, subsections (3A), (4) and (5) were omitted.

Commencement Information

I138 Sch. 4 para. 2 in force at 8.12.2016, see **reg. 1(1)**

SCHEDULE 5

Regulation 53(2)

Compliance, withdrawal and recall notices

Compliance notice

1.—(1) The market surveillance 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 market surveillance 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 the 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 sub-paragraph (5), the market surveillance authority may revoke or vary a compliance notice by serving a notification on the economic operator.

(5) The market surveillance 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.

Commencement Information

I139 Sch. 5 para. 1 in force at 8.12.2016, see **reg. 1(1)**

Withdrawal notice

2.—(1) The market surveillance 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 market surveillance 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 market surveillance authority informed of the whereabouts of any product referred to in the notice.

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

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

(7) The market surveillance 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.

(8) A withdrawal notice has effect throughout Great Britain.

Commencement Information

I140 Sch. 5 para. 2 in force at 8.12.2016, see **reg. 1(1)**

Recall notice

3.—(1) The market surveillance 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 market surveillance 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 market surveillance 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 market surveillance 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 market surveillance authority has taken account of any advice obtained under sub-paragraph (6).

(6) A relevant economic operator which has received notice from the market surveillance 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) Sub-paragraphs (5)(b), (c) and (d) do not apply in the case of a product presenting a serious risk requiring, in the view of the market surveillance authority, urgent action.

(8) Where a relevant economic operator requires the market surveillance authority to seek advice under sub-paragraph (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 market surveillance authority.

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

(10) A recall notice served by the market surveillance 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.

(11) Subject to sub-paragraph (12), the market surveillance authority may revoke or vary a recall notice by serving a notification on the economic operator.

(12) The market surveillance authority may not vary a recall notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

(13) A recall notice has effect throughout Great Britain.

Commencement Information
I141 Sch. 5 para. 3 in force at 8.12.2016, see **reg. 1(1)**

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.

Commencement Information
I142 Sch. 5 para. 4 in force at 8.12.2016, see **reg. 1(1)**

SCHEDULE 6

Regulation 40(b)

[F134]... Declaration of Conformity (No.XXXX)

F134 Word in Sch. 6 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 41(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

1. Product model/product (product, type, batch or serial number):

Commencement Information
I143 Sch. 6 para. 1 in force at 8.12.2016, see **reg. 1(1)**

2. Name and address of manufacturer and, where applicable, the authorised representative:

Commencement Information
I144 Sch. 6 para. 2 in force at 8.12.2016, see **reg. 1(1)**

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

Commencement Information
I145 Sch. 6 para. 3 in force at 8.12.2016, see **reg. 1(1)**

4. Object of the declaration (identification of product allowing traceability; it may, where necessary for the identification of the product, include an image):

Commencement Information
I146 Sch. 6 para. 4 in force at 8.12.2016, see **reg. 1(1)**

5. The object of the declaration described above is in conformity with the relevant **[**F135statutory requirements**]**:

F135 Words in Sch. 6 para. 5 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 41(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I147 Sch. 6 para. 5 in force at 8.12.2016, see **reg. 1(1)**

6. References to the relevant **[**F136designated**]** standards used or references to the other technical specifications in relation to which conformity is declared:

F136 Word in Sch. 6 para. 6 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 41(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I148 Sch. 6 para. 6 in force at 8.12.2016, see **reg. 1(1)**

7. Where applicable, the **[**F137approved**]** body (name, number) performed (description of intervention) and issued the certificate:

F137 Word in Sch. 6 para. 7 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 41(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I149 Sch. 6 para. 7 in force at 8.12.2016, see **reg. 1(1)**

8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

Commencement Information

I150 Sch. 6 para. 8 in force at 8.12.2016, see **reg. 1(1)**

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations transpose Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast) (OJ L 96, 29.3.2014, p.309) ("the Directive").

The Directive repeals and replaces Directive 94/9/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 100, 19.4.1994, p.1) which was implemented in Great Britain by the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996 (S.I. 1996/192) (as amended) ("the 1996 Regulations"). These Regulations revoke and replace S.I. 1996/192.

Regulation 3 defines a "product" for use within potentially explosive atmospheres or for incorporation into equipment and protective systems. Regulation 4 provides an exception, allowing the use of a product which is not in conformity with Part 2, for the purposes of trade fairs, exhibitions and demonstrations.

Part 2 sets out the obligations of economic operators. Regulations 5 to 17 set out the obligations specific to manufacturers. These obligations include ensuring that a product has been designed and manufactured in accordance with the essential health and safety requirements set out in Schedule 1, taking action where products are not in conformity, having a relevant conformity assessment procedure carried out, affixing the CE marking, obligations to retain technical documentation, appointment of authorised representatives and product requirements.

Regulations 18 to 27 set out the obligations that are specific to importers. These obligations include ensuring that importers are not placing on the market products which are not in conformity with the essential health and safety requirements and taking action where they are not, checking that the manufacturer has carried out a relevant conformity assessment procedure and labelled the products correctly, ensuring storage and transport conditions do not jeopardise conformity with essential health and safety requirements and product monitoring obligations.

Regulations 28 to 33 set out the obligations that are specific to distributors. These obligations include acting with due care to ensure that the product is in conformity with Part 2 and taking action where it is not, checking that the product bears the CE marking, ensuring storage and transport conditions do not jeopardise conformity with the essential health and safety requirements and checking that the products are labelled correctly.

Regulations 35 to 37 set out the obligations that manufacturers, importers and distributors have. These obligations include prohibitions on the improper use of CE marking and a requirement to translate the declaration of conformity into the language required by the Member State within which it is made available.

Part 3 sets out provisions concerning the conformity assessment procedure, declarations of conformity and CE marking.

Part 4 sets out provisions concerning the bodies which carry out conformity assessment procedures under the Regulations.

Part 5 sets out provisions for market surveillance and enforcement. Regulation 51 identifies the market surveillance authority which has an obligation to enforce the Regulations in respect of the products. Regulation 53 and Schedules 4 and 5 provide for the enforcement powers which the enforcing authorities are to have. Regulation 61 provides for the contravention of provisions of these Regulations to be an offence. Regulation 62 sets out the penalties that are to apply for offences under these Regulations.

Part 6 sets out transitional provisions and consequential amendments. The 1996 Regulations will continue to apply to any products which are in conformity and placed on the market prior to 8th December 2016.

A transposition note and full impact assessment of the impact that these Regulations will have on the costs of business, the voluntary sector and the public sector are available from the Product Safety Team, Department for Business, Energy and Industrial Strategy, 1 Victoria Street, London SW1H 0ET and are also published with the Explanatory Memorandum alongside these Regulations on www.legislation.gov.uk.

Changes to legislation:
There are currently no known outstanding effects for the The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016.