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

I1 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

I2 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

I3 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

I4 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) **[**[F1] 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.

F1 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

I5 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

I6 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
I7 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
I8 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
I9 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
I10 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
I11 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
I12 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 **[**F2any 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 **[**F3enactment**]**.

F2 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)
F3 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
I13 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
I14 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
I15 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
I16 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
I17 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
I18 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
I19 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
I20 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
I21 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
I22 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
I23 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
I24 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
I25 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
I26 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
I27 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
I28 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
I29 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
I30 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
I31 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
I32 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
I33 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
I34 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
I35 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
I36 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
I37 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
I38 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
I39 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
I40 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
I41 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

I42 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

I43 Sch. 1 para. 43 in force at 8.12.2016, see **reg. 1(1)**

Commencement Information

I42 Sch. 1 para. 42 in force at 8.12.2016, see **reg. 1(1)**

I43 Sch. 1 para. 43 in force at 8.12.2016, see **reg. 1(1)**

[F4SCHEDULE 1A

Regulation 2

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

F4 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)

[F5Approved] body requirements

F5 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
I44 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
I45 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 [F6regulation 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.

F6 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
I46 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
I47 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
I48 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 **[**[F7]approved**]** (including consultancy services).

F7 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
I49 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
I50 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
I51 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, **[**[F8]approved**]**, whether those activities are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

F8 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
I52 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 **[**F9an 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.

F9 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

I53 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

I54 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 **[**F10approved**]**;

(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 **[**F11designated standards**]** and of these Regulations;

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

F10 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)

F11 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

I55 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
I56 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
I57 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
I58 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
I59 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
I60 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 **[**[F12]approved**]** body coordination group established **[**[F13]by 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.

F12 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)
F13 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
I61 Sch. 2 para. 18 in force at 8.12.2016, see **reg. 1(1)**

SCHEDULE 3

[F15Regulation 47]

Operational obligations of [F14approved] bodies

F14 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)

F15 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. [F16An approved] body must carry out conformity assessments in accordance with the relevant conformity assessment procedures.

F16 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

I62 Sch. 3 para. 1 in force at 8.12.2016, see **reg. 1(1)**

2. [F16An approved] body must carry out conformity assessments in a proportionate manner, avoiding unnecessary burdens on economic operators.

F16 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

I63 Sch. 3 para. 2 in force at 8.12.2016, see **reg. 1(1)**

3. [F16An 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.

F16 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

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

4. [F16An 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.

F16 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
I65 Sch. 3 para. 4 in force at 8.12.2016, see **reg. 1(1)**

5. Where **[**[F16]an 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.

F16 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
I66 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, **[**[F16]an 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).

F16 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
I67 Sch. 3 para. 6 in force at 8.12.2016, see **reg. 1(1)**

7. Where the **[**[F17]approved**]** 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 **[**[F17]approved**]** body must restrict, suspend or withdraw any certificate of conformity or approval.

F17 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
I68 Sch. 3 para. 7 in force at 8.12.2016, see **reg. 1(1)**

8. Paragraph 9 applies where **[**[F16]an 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.

F16 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
I69 Sch. 3 para. 8 in force at 8.12.2016, see **reg. 1(1)**

9. Where this paragraph applies, the **[**[F18]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.

F18 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

I70 Sch. 3 para. 9 in force at 8.12.2016, see **reg. 1(1)**

10. **[**[F16]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 **[**[F19]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 **[**[F20]approval under regulation 43**]** and any other activity performed, including cross-border activities and subcontracting.

F16 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)

F19 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)

F20 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

I71 Sch. 3 para. 10 in force at 8.12.2016, see **reg. 1(1)**

11. **[**[F16]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.

F16 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

I72 Sch. 3 para. 11 in force at 8.12.2016, see **reg. 1(1)**

12. **[**[F16]An approved**]** body must provide other **[**[F21]bodies 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.

F16 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)

F21 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

I73 Sch. 3 para. 12 in force at 8.12.2016, see **reg. 1(1)**

13. **[**[F16]An approved**]** body must participate in the work of any **[**[F22]approved body coordination group established by the Secretary of State**]**, directly or by means of its designated representatives.

F16 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)

F22 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

I74 Sch. 3 para. 13 in force at 8.12.2016, see **reg. 1(1)**

14. **[**[F16]An 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).

F16 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

I75 Sch. 3 para. 14 in force at 8.12.2016, see **reg. 1(1)**

[F23SCHEDULE 3A

Regulations 2, 6, 39 and 40

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

F23 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

I76 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

I77 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

I78 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

I79 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
I80 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
I81 Sch. 5 para. 4 in force at 8.12.2016, see **reg. 1(1)**

SCHEDULE 6

Regulation 40(b)

[F24]... Declaration of Conformity (No.XXXX)

F24 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
I82 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
I83 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
I84 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
I85 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 **[**F25statutory requirements**]**:

F25 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
I86 Sch. 6 para. 5 in force at 8.12.2016, see **reg. 1(1)**

6. References to the relevant **[**F26designated**]** standards used or references to the other technical specifications in relation to which conformity is declared:

F26 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
I87 Sch. 6 para. 6 in force at 8.12.2016, see **reg. 1(1)**

7. Where applicable, the **[**F27approved**]** body (name, number) performed (description of intervention) and issued the certificate:

F27 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
I88 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

I89 Sch. 6 para. 8 in force at 8.12.2016, see **reg. 1(1)**

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.