

dti

**PRODUCT STANDARDS**

Equipment and protective systems intended for use in potentially explosive atmospheres

GUIDANCE NOTES ON THE UK REGULATIONS

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This guide is intended to assist manufacturers of equipment and protective systems intended for use in potentially explosive atmospheres to understand the effect of the Regulations. It is not an authoritative interpretation of the Regulations, which is a matter for the Courts.

The guide seeks to explain the requirements of the Regulations in general terms and does not attempt to address detailed issues. You should refer to the Regulations themselves (SI 1996/192 and SI 2001/3766) for a full statement of the requirements.



# Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres - the Regulations in brief

The Directive on equipment and protective systems intended for use in potentially explosive atmospheres (94/9/EC) was adopted on 23 March 1994 and entered into force on 1 March 1996. The Directive is commonly referred to as the 'ATEX' Directive.

The Directive was implemented into GB law by The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996 (SI 1996/192), and in Northern Ireland by The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996 (SR 1996/247). GB law has been amended by The Equipment and Protective Systems (Amendment) Regulations 2001 (SI 2001/3766) Manufacturers have the option of complying with the Regulations or with health and safety provisions respectively in force in GB or NI on 23 March 1994 (the date of adoption of the Directive) during a transition period up to 1 July 2003.

At the end of the transition period, manufacturers in the UK **will have to comply** with the relevant GB or NI Regulations. All equipment and protective systems intended for use in potentially explosive atmospheres (as well as the specified devices) which are made or sold in the United Kingdom, including imports, will have to:

- satisfy wide ranging health and safety requirements;
- in some cases, be subject to type-examination by a notified body;
- in many cases be subject to conformity assessment procedures by a notified body;
- carry CE marking and information (generally about the manufacturer).

The same rules will apply everywhere in the Community, so equipment and protective systems (and such devices) complying with the Community requirements may be sold anywhere in the Community. There are also certain provisions relating to components (as defined).

This Guide relates, primarily, to the position in respect of the GB Regulations, but the position under the NI legislation is similar at the date of this publication.

(References in the Regulations, and this Guide, to the "Community" and "member States" include respectively references to the European Economic Area (EEA) and EEA States).

# Free movement of goods

Achieving the free movement of goods lies at the heart of an open market for business in Europe.

In May 1985, European Community Ministers agreed on a 'New Approach to Technical Harmonisation and Standards' in order to fulfil this objective.

'New Approach' Directives (that is Community laws) set out essential requirements (for safety, for example), written in general terms which must be met before products may be sold in the United Kingdom or anywhere else in the Community. European standards fill in the detail and are the main way for business to meet the essential requirements. The Directives also say how manufacturers are to show that products meet the essential requirements. Products meeting the requirements are to carry CE marking, which should mean that they can be sold anywhere in the Community/EEA<sup>(1)</sup>. Directive 94/9/EC on equipment and protective systems intended for use in potentially explosive atmospheres is one of these 'New Approach' Directives.

For wider background and to find out more about what this means for your business, get your copy of *Keeping your product on the market* by telephoning DTI's Publications Orderline on 0870 1502 500 (or Fax 0870 1502 333, Minicom 0870 1502 100, or e-mail [publications@dti.gsi.gov.uk](mailto:publications@dti.gsi.gov.uk)).

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<sup>(1)</sup> There are fifteen members of the Community - Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK. The EEA adds Iceland, Liechtenstein and Norway. Directive 94/9/EC has been adopted by the EEA Joint Committee and extends to the EEA.

# Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres

**Entry into force** of The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations S.I 1996 No.192: 1 March 1996 and of The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (Amendment) Regulations S.I.2001 No. 3766: 21 December 2001.

**Transitional arrangements:** the existing Directives on electrical equipment for use in potentially explosive atmospheres<sup>(1)</sup> will remain in force and EEC certificates of conformity issued under these Directives will remain valid until the expiry of the transition period allowed under the Regulations (i.e. 30 June 2003)<sup>(2)</sup>.

In addition, the Regulations do not apply to equipment and protective systems that comply with health and safety provisions in force on 23 March 1994 (the date of adoption of the Directive) until the expiry of that transition period.

**Coverage:** the Regulations apply to both electrical and mechanical equipment and protective systems for use on the surface, below ground and on fixed offshore installations. Specifically, the Regulations relate to :

- ❑ **all equipment** intended for use in potentially explosive atmospheres, defined as machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy or the processing of material and which are capable of causing an explosion through their own potential sources of ignition;
- ❑ **protective systems** intended for use in potentially explosive atmospheres, defined as design units which are intended to halt incipient explosions immediately and/or to limit the effective range of explosion flames and explosion pressures. Protective systems may be integrated into equipment or separately placed on the market for use as autonomous systems;
- ❑ **safety devices, controlling devices and regulating devices** intended for use outside potentially explosive atmospheres but which are required for or contribute to the safe functioning of equipment and protective systems, with respect to the risks of explosion;
- ❑ **components** defined as any item essential to the safe functioning of equipment and protective systems but with no autonomous function.

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<sup>(1)</sup> and <sup>(2)</sup> See pages 9 and 10

**Equipment Groups:** for the purposes of the Regulations equipment is divided into two groups:

- group I comprises equipment intended for use in underground parts of mines, and to those parts of surface installations of such mines, liable to be endangered by firedamp and/or combustible dust;
- group II comprises equipment intended for use in other places liable to be endangered by explosive atmospheres.

These groups are subdivided into categories as shown in Annex A.

**Products not covered by the Regulations:** the products listed in Annex B are not covered by the Regulations.

**Explosive and potentially explosive atmospheres:** for the purposes of the Regulations, an **explosive atmosphere** is a mixture with air, under atmospheric conditions, of flammable gases, vapours, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture. A **potentially explosive atmosphere** is an atmosphere which could become explosive due to local and operational conditions.

**Essential health and safety requirements:** equipment, protective systems and safety devices must satisfy the relevant essential health and safety requirements set out in Annex C.

The requirements take into account the intended use of the products and changes in technological knowledge as far as possible, with immediate utilisation. They include general measures requiring manufacturers to take steps to prevent the formation of explosive atmospheres by the equipment, protective system or safety device; to prevent the ignition of an explosive atmosphere by electrical and non-electrical sources; and to ensure that, should an explosion occur, it can be halted immediately or limited in range. Other aspects covered include:

- the materials used;
- design and construction;
- mechanical hazards and vibrations;
- safe opening;
- electrostatic hazards;
- hazards arising from external effects; and
- the integration of safety requirements.



**Methods of complying with the Essential Health and Safety Requirements:**  
manufacture in conformity with:

- ❑ specified European harmonised standards, whose reference numbers are published in the *Official Journal of the European Communities*, which will be published in the United Kingdom as identically worded British Standards; or
- ❑ harmonised standards specified in the Electrical Equipment for Explosive Atmospheres (Certification) Regulations 1990 in respect of electrical equipment for which a certificate of conformity to the harmonised standards was obtained in accordance with those Regulations which shall be valid until 30 June 2003 (unless it expires before that date) provided that the electrical equipment conforms to the type covered by that certificate; or
- ❑ in the absence of relevant specified European harmonised standards, existing national technical standards and specifications regarded as important or relevant to the proper implementation of the essential health and safety requirements may be used instead; or
- ❑ the essential health and safety requirements.

When using any standards, whether from the first, second or third point listed above, always check that:

- the standard(s) cover all of the essential health and safety requirements relevant to the product; and
- the standard(s) are to the latest version as representing the current state of technical knowledge.

In the absence of a relevant standard in respect of any such requirement, a manufacturer would have to demonstrate conformity of the product with the requirement itself.

**How to show the essential health and safety requirements are satisfied ('conformity assessment procedures'):** the Regulations define various procedures and specify the options available to manufacturers and to their authorised representatives established in the Community.

For equipment in group I, category (M)1 or in group II, category 1; for autonomous protective systems; for safety devices for such equipment or systems; and for components for such equipment, systems or devices, the options are either:

- (a) EC type-examination (see Annex D for details), followed by:
  - production quality assurance (see Annex E for details); or
  - product verification (see Annex F for details); or
- (b) Unit verification (see Annex J for details).

For equipment in group I, category (M) 2 or in group II, category 2; for safety devices for such equipment or systems; and for components of such equipment, systems or devices, the options are either:

For electrical equipment and internal combustion engines:

- (a) EC type-examination (see Annex D for details), followed either by:
  - conformity to type (see Annex G for details); or
  - product quality assurance (see Annex H for details); or
- (b) Unit verification (see Annex J for details); and

For other equipment in these groups:

- (a) internal control of production (see Annex I for details) and deposit the technical dossier specified in paragraph 3 of Annex I, with a notified body; or
- (b) Unit verification (see Annex J for details).

For equipment in group II, category 3; for safety devices for such equipment or systems; and for components for such equipment, systems and devices, the options are either:

- (a) internal control of production (see Annex I for details); or
- (b) Unit verification (see Annex J for details).

These options are set out in tabular form in Annex K.

Contents of the EC declaration of conformity required as part of the various conformity assessment procedures are listed in Annex L.

**CE marking:** In each case, adherence to the relevant conformity assessment procedure allows the manufacturer, or his authorised representative established in the Community, to affix CE marking and additional specific markings (see Annex M for details) to the appropriate equipment, protective system or safety device.

Components are not to carry CE marking. Instead, the manufacturer or his authorised representative established in the Community will have to issue an attestation of conformity declaring that the component meets the appropriate provisions of the ATEX Directive which apply to it; stating its characteristics; and explaining how it must be incorporated into the equipment, protective system or safety device to assist compliance with the essential requirements applicable to the finished equipment or protective system.

**Other Directives:** where equipment and protective systems covered by the Directive are subject to other Directives, CE marking indicates that the equipment and protective systems also fulfil the appropriate requirements of those Directives.

**Notified Bodies:** Member States shall appoint Notified Bodies that they consider satisfy the criteria laid down in Annex XI of the Directive for the purposes of undertaking the conformity assessment procedures of the Directive. A list of Notified Bodies appointed for the purposes of the GB Regulations is available from the DTI contact on page 12 of this Guide.

A Notified Body which is responsible, for any of the conformity assessment procedures referred to above, for the assessment of the conformity of electrical equipment placed on the market before 1 July 2003, shall take account of the results of tests and verifications already carried out in respect of the harmonised standards which are applicable under the Directives specified in "Repeal of Directives" on page 10 of this Guide.

**Safeguard procedure:** a member State is required to take all appropriate measures to withdraw from the market equipment, protective systems or safety devices bearing the CE marking and used in accordance with their intended purpose which are liable to endanger the safety of people and, where appropriate, domestic animals or property. The member State must immediately inform the European Commission of such action and give reasons. The Commission then notifies other member States of such an action.

Member States are required to take action against anyone who affixes the CE marking to equipment, protective systems or safety devices which do not conform to the Directive, and so inform the other member States.

**Free circulation:** Subject to that limitation on the grounds of safety or incorrect affixation of the CE marking, member States must not prohibit, restrict or impede the placing on the market and putting into service of equipment, protective systems or safety devices which comply with the provisions of the Directive, or components which are accompanied by a certificate of conformity and are intended for incorporation into equipment, protective systems or safety devices covered by the Directive.

Member States may not prevent equipment, protective systems or safety devices which do not comply with the Directive from being shown at trade fairs, exhibitions, demonstrations, etc. provided that a visible sign clearly indicates that the equipment, protective system or device does not conform and that it is not for sale until it has been brought into conformity.

**Implementation:** the Directive has been implemented in Great Britain by The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996 (SI 1996/192) and The Equipment and Potentially Explosive Atmospheres (Amendment) Regulations 2001 (SI 2001/3766) made under the European Communities Act 1972, and in Northern Ireland by The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996 (SR 1996/247).

**Enforcement:** the Health and Safety Executive (HSE) is responsible for the enforcement of the Regulations in Great Britain. In Northern Ireland enforcement is the responsibility of the Health and Safety Executive for Northern Ireland (HSENI).

The HSE has 7 regions with offices throughout Great Britain and, in Northern Ireland which is treated as one region, the HSENI office in Belfast. Each of these offices can advise suppliers of articles and substances for use at work regarding current standards and relevant legislation. HSE inspectors may also make preventive or reactive visits to suppliers.

Suppliers of equipment wishing to ensure that their products meet the requirements of the 1996 Regulations can make enquiries to one of the Notified Bodies, to HSE's Infoline Service (Tel: 08701 545500) or to their nearest HSE office or, in Northern Ireland, the Health and Safety Executive for Northern Ireland's Information and Advice Helpline (Tel: 0800 032 0121). Clearly it is in the supplier's own interest to discuss at an early stage any problems they may be having in applying the Regulations to their products.

**Repeal of Directives:** the following Directives will be repealed with effect from 1 July 2003:

- ❑ Council Directive 76/117/EEC of 18 December 1975 on the Approximation of the Laws of the Member States Concerning Electrical Equipment for Use in Potentially Explosive Atmospheres;
- ❑ Council Directive 79/196/EEC of 6 February 1979 on the Approximation of the Laws of the Member States Concerning Electrical Equipment for Use in Potentially Explosive Atmospheres Employing Certain Types of Protection (as last amended by Council Directive 90/487/EEC, Commission Directive 94/26/EC and Commission Directive 97/53/EC);
- ❑ Council Directive 82/130/EEC of 15 February 1982 on the Approximation of the Laws of the Member States Concerning Electrical Equipment for Use in Potentially Explosive Atmospheres in Mines Susceptible to Firedamp (as last amended by Commission Directives 91/269/EEC, 94/44/EC and 98/65/EC).

The respective 1996 Regulations revoke, with effect from 1 July 2003 the relevant Regulations (in Great Britain and Northern Ireland) which implemented those Directives.

The requirements of the 1996 Regulations (SI 1996/192 and SR 1996/247) become mandatory with effect from 1 July 2003. Certificates of conformity, issued under the "old ATEX Regulations" (i.e. which implemented those repealed Directives), will become invalid on 1 July 2003. Accordingly, manufacturers/importers will wish to ensure that stocks of products (electrical equipment), to which those certificates relate, are placed on the market and/or put into service in the EEA before that date so that they have the benefit of those certificates and do not have to be brought into compliance with the provisions of the 1996 Regulations.

**Availability of texts of harmonised standards:** these may be obtained from BSI Sales, 389 Chiswick High Road, London W4 4AL.

The European Commission has given a mandate to CEN and CENELEC (the European Standards bodies) to develop existing standards and produce new standards in support of the Directive.

**Availability of the text of the Directive:** the complete text of the Directive on equipment and protective systems intended for use in potentially explosive atmospheres has been published in the *Official Journal of the European Communities* (No L100 of 19.4.94, pages 1-29). Copies of this text are generally available from European Information Centres and European Documentation Centres located throughout the United Kingdom, who may provide them for a modest charge.

**Availability of the text of the Regulations:** The Regulations can be obtained on the HMSO web site: <http://www.legislation.hmsso.gov.uk/stat.htm>.

Alternatively printed versions are available from The Stationery Office.  
Tel: 0870 600 5522 Fax: 0870 600 5533

# Contact points

## **Directive and UK Regulations:**

Rosemary Wasserberg  
Department of Trade and Industry  
STRD4  
Bay 323  
151 Buckingham Palace Road  
London SW1W 9SS

Tel: 020 7215 1427  
Fax: 020 7215 1529  
Website: [www.dti.gov.uk/strd](http://www.dti.gov.uk/strd)

## **Standards:**

Karen Chambers  
British Standards Institution  
389 Chiswick High Road  
Chiswick  
London W4 4AL

Tel: 020 8996 7280  
Fax: 020 8996 7799  
Website: [www.bsi-global.com](http://www.bsi-global.com)

## **For information on the ATEX “Use” Directive 1999/92/EC and the DSEAR Regulations:**

John Brazendale  
Health and Safety Executive  
Room 102  
Daniel House  
Trinity Road  
Bootle  
Merseyside L20 3TW

Tel: 0151 951 3432  
Fax: 0151 951 3418  
Website: [www.hse.gov.uk](http://www.hse.gov.uk)

# Equipment groups and categories

## 1. Equipment-group I

**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 Annex C, 2.0.1.

**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 Annex C, 2.0.2.

## 2. Equipment-group II

**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 Annex C, 2.1.

**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.

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 Annex C, 2.2.

**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 Annex C, 2.3.



# Products not covered by the Regulations

- (a) Medical devices intended for use in medical environments.
- (b) Equipment and protective systems where the explosion hazard results solely from the presence of explosive or chemically unstable substances.
- (c) Equipment intended for use in domestic and non-commercial environments where potentially explosive atmospheres may only rarely be created, solely as a result of the accidental leakage of fuel gas.
- (d) Personal Protective Equipment covered by Directive 89/686/EEC as amended by Directives 93/95/EEC, 93/68/EEC and 96/58/EC.
- (e) Seagoing vessels and mobile offshore units together with equipment and protective systems on board such vessels or units.
- (f) Means of transport, that is vehicles and their trailers intended for transporting passengers and/or goods by air or on road, rail or water networks. Vehicles intended for use in a potentially explosive atmosphere are not excluded.
- (g) Equipment specifically designed for military purposes.

# Essential health and safety requirements relating to the design and construction of equipment and protective systems intended for use in potentially explosive atmospheres

## **PRELIMINARY OBSERVATIONS**

- A. Technological knowledge, which can change rapidly, must be taken into account as far as possible and be utilised immediately.
- B. For the devices referred to in Article 1 (2) in the ATEX Directive, the essential requirements shall apply only in so far as they are necessary for the safe and reliable functioning and operation of those devices with respect to the risks of explosion.

## **1 COMMON REQUIREMENTS FOR EQUIPMENT AND PROTECTIVE SYSTEMS**

### **1.0 General requirements**

#### *1.0.1 Principles of integrated explosion safety*

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

In this connection, the manufacturer must take measures:

- above all, if possible, to prevent the formation of explosive atmospheres which may be produced or released by equipment and by protective systems themselves;
- to prevent the ignition of explosive atmospheres, taking into account the nature of every electrical and non-electrical source of ignition;
- should an explosion nevertheless occur which could directly or indirectly endanger persons and, as the case may be, domestic animals or property, to halt it immediately and/or to limit the range of explosion flames and explosion pressures to a sufficient level of safety.

1.0.2 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.

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

1.0.3 *Special checking and maintenance conditions*


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

1.0.4 *Surrounding area conditions*

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

1.0.5 *Marking*

All equipment and protective systems must be marked legibly and indelibly with the following minimum particulars:

- name and address of the manufacturer;
- CE marking (see Annex L);
- designation of series or type;
- serial number, if any;
- year of construction;
- the specific marking of explosion protection  followed by the symbol of the equipment group and category;
- for equipment-group II, the letter 'G' (concerning explosive atmospheres caused by gases, vapours or mists); and/or the letter 'D' (concerning explosive atmospheres caused by dust).

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

## 1.0.6 *Instructions*

- (a) All equipment and protective systems must be accompanied by instructions, including at least the following particulars:
- a recapitulation of the information with which the equipment or protective system is marked, except for the serial number (see 1.0.5.), together with any appropriate additional information to facilitate maintenance (e.g. address of the importer, repairer, etc.);
  - instructions for safe:
    - putting into service;
    - use;
    - assembling and dismantling;
    - maintenance (servicing and emergency repair);
    - installation;
    - adjustment;
  - where necessary, an indication of the danger areas in front of pressure-relief devices;
  - where necessary, training instructions;
  - 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;
  - electrical and pressure parameters, maximum surface temperatures and other limit values;
  - where necessary, special conditions of use, including particulars of possible misuse which experience has shown might occur;
  - where necessary, the essential characteristics of tools which may be fitted to the equipment or protective system.
- (b) The instructions must be drawn up in one of the Community languages by the manufacturer or his authorised representative established in the Community.

On being put into service, all equipment and protective systems must be accompanied by a translation of the instructions in the language or languages of the country in which the equipment or protective system is to be used and by the instructions in the original language.

This translation must be made by either the manufacturer or his authorised representative established in the Community or the person introducing the equipment or protective system into the language area in question.

By way of derogation from this requirement, the maintenance instructions for use by the specialist personnel employed by the manufacturer or his authorised representative established in the Community may be drawn up in a single Community language understood by that personnel.

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

## 1.1 **Selection of materials**

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

1.1.2 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.

1.1.3 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, impact strength, ageing resistance and the effects of temperature variations.

## 1.2 **Design and Construction**

1.2.1 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.

1.2.2 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.

1.2.3 *Enclosed structures and prevention of leaks*

Equipment which may release flammable gases or dusts must wherever possible employ enclosed structures only.

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

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

1.2.4 *Dust deposits*

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.

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

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

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.

1.2.5 *Additional means of protection*

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

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

### 1.2.6 *Safe opening*

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.

### 1.2.7 *Protection against other hazards*

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 shall not give rise to dangerous situations.

Where, for equipment and protective systems, the risks referred to in this paragraph are wholly or partly covered by other Community Directives, this Directive shall not apply or shall cease to apply in the case of such equipment and protective systems and of such risks upon application of those specific Directives.

### 1.2.8 *Overloading of equipment*

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

### 1.2.9. *Flameproof enclosure systems*

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.

### 1.3 **Potential ignition sources**

#### 1.3.1 *Hazards arising from different ignition sources*

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.

#### 1.3.2 *Hazards arising from static electricity*

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

#### 1.3.3 *Hazards arising from stray electric and leakage currents*

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.

#### 1.3.4 *Hazards arising from overheating*

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.

#### 1.3.5 *Hazards arising from pressure compensation operations*

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.

### 1.4 **Hazards arising from external effects**

1.4.1 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.

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



## 1.5 Requirements in respect of safety-related devices

- 1.5.1 Safety devices must function independently of any measurement or control devices required for operation.

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

For electrical circuits the fail-safe principle is to be applied in general.

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

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

- 1.5.3 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.

- 1.5.4 *Control and display units*

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.

- 1.5.5 *Requirements in respect of devices with a measuring function for explosion protection*

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.

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

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

### 1.5.8 *Risks arising from software*

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.

## 1.6 **Integration of safety requirements relating to the system**

1.6.1 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.

1.6.2 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.

This does not apply to electrochemically-stored energy.

### 1.6.3 *Hazards arising from power failure*

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.

### 1.6.4 *Hazards arising from connections*

Equipment and protective systems must be fitted with suitable cable and conduit entries.

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

### 1.6.5 *Placing of warning devices as parts of equipment*

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.

## 2 **SUPPLEMENTARY REQUIREMENTS IN RESPECT OF EQUIPMENT**

### 2.0 **Requirements applicable to equipment in category M of equipment-group I**

#### 2.0.1 *Requirements applicable to equipment in category M I of equipment-group I*

- 2.0.1.1 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.

Equipment must be equipped with 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 ensured in the event of two faults occurring independently of each other.

Where necessary, this equipment must be equipped with additional special means of protection.

It must remain functional with an explosive atmosphere present.

- 2.0.1.2 Where necessary, equipment must be so constructed that no dust can penetrate it.

- 2.0.1.3 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.

- 2.0.1.4 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.

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

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

- 2.0.2.1 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.

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

- 2.0.2.2 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.

2.0.2.3 The requirements regarding explosion hazards arising from dust applicable to category M1 must be applied.

## 2.1 **Requirements applicable to equipment in category 1 of equipment-group II**

### 2.1.1 *Explosive atmospheres caused by gases, vapours or hazes*

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

It must be equipped with 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 ensured in the event of two faults occurring independently of each other.

2.1.1.2 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.

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

2.1.1.3 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.

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

### 2.1.2 *Explosive atmospheres caused by air/dust mixtures*

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

It must be equipped with 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 ensured in the event of two faults occurring independently of each other.

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

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

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

2.1.2.4 With regard to the safe opening of equipment parts, requirement 2.1.1.3 applies.

## 2.2 **Requirements for category 2 of equipment-group II**

### 2.2.1 *Explosive atmospheres caused by gases, vapours or mists*

2.2.1.1 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.

2.2.1.2 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.

2.2.1.3 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.

### 2.2.2 *Explosive atmospheres caused by air/dust mixtures*

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

2.2.2.2 With regard to surface temperatures, requirement 2.1.2.3 applies.

2.2.2.3 With regard to protection against dust, requirement 2.1.2.2 applies.

2.2.2.4 With regard to the safe opening of equipment parts, requirement 2.2.1.3 applies.

- 2.3 **Requirements applicable to equipment in category 3 of equipment-group II**
- 2.3.1 *Explosive atmospheres caused by gases, vapours or mists*
- 2.3.1.1 Equipment must be so designed and constructed as to prevent foreseeable ignition sources which can occur during normal operation.
- 2.3.1.2 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.
- 2.3.2 *Explosive atmospheres caused by air/dust mixtures*
- 2.3.2.1 Equipment must be so designed and constructed that air/dust mixtures cannot be ignited by foreseeable ignition sources likely to exist during normal operation.
- 2.3.2.2 With regard to surface temperatures, requirement 2.1.2.3 applies.
- 2.3.2.3 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.
- 3 **SUPPLEMENTARY REQUIREMENTS IN RESPECT OF PROTECTIVE SYSTEMS**
- 3.0 **General requirements**
- 3.0.1 Protective systems must be dimensioned in such a way as to reduce the effects of an explosion to a sufficient level of safety.
- 3.0.2 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.
- 3.0.3 In the event of a power failure, protective systems must retain their capacity to function for a period sufficient to avoid a dangerous situation.
- 3.0.4 Protective systems must not fail due to outside interference.

### 3.1 **Planning and design**

#### 3.1.1 *Characteristics of materials*

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.

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

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

3.1.4 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.

#### 3.1.5 *Pressure-relief systems*

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

#### 3.1.6 *Explosion suppression systems*

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.

#### 3.1.7 *Explosion decoupling systems*

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.

3.1.8 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.

# EC type-examination

1. This Annex describes that part of the procedure by which a notified body ascertains and attests that a specimen representative of the production envisaged meets the relevant applicable provisions of the ATEX Directive.
2. The application for the EC-type examination shall be lodged by the manufacturer or his authorised representative established within the Community with a notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition;
- a written declaration that the same application has not been lodged with any other notified body;
- the technical documentation, as described in point 3.

The applicant shall place at the disposal of the notified body a specimen representative of the production envisaged and hereinafter called 'type'. The notified body may request further specimens if needed for carrying out the test programme.

3. The technical documentation shall enable the conformity of the product with the requirements of the Directive to be assessed. It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product and shall to that extent contain:
  - a general type-description;
  - design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;
  - descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the product;
  - a list of the standards referred to in Article 5 of the Directive, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied;
  - results of design calculations made, examinations carried out, etc.;
  - test reports.



4. The notified body shall:
  - 4.1. examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as the components which have been designed without applying the relevant provisions of those standards;
  - 4.2. perform or have performed the appropriate examinations and necessary tests to check whether the solutions adopted by the manufacturer meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied;
  - 4.3. perform or have performed the appropriate examinations and necessary tests to check whether these have actually been applied, where the manufacturer has chosen to apply the relevant standards;
  - 4.4. agree with the applicant the location where the examinations and necessary tests shall be carried out.
5. Where the type meets the provisions of the Directive, the notified body shall issue an EC-type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination and the necessary data for identification of the approved type.

A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

If the manufacturer or his authorised representative established in the Community is denied a type certification, the notified body shall provide detailed reasons for such denial.

Provision shall be made for an appeals procedure.

6. The applicant shall inform the notified body which holds the technical documentation concerning the EC-type-examination certificate of all modifications to the approved equipment or protective system which must receive further approval where such changes may affect conformity with the essential requirements or with the prescribed conditions for use of the product. This further approval is given in the form of an addition to the original EC-type-examination certificate.
7. Each notified body shall communicate to the other notified bodies the relevant information concerning the EC-type-examination certificates and additions issued and withdrawn.
8. The other notified bodies may receive copies of the EC-type-examination certificates and/or their additions. The annexes to the certificates shall be kept at the disposal of the other notified bodies.

9. The manufacturer or his authorised representative established in the Community shall keep with the technical documentation copies of EC-type-examination certificates and their additions for a period ending at least 10 years after the last equipment or protective system was manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market.

# Production quality assurance

1. This Annex describes the procedure whereby the manufacturer who satisfies the obligations of point 2 below ensures and declares that the products concerned are in conformity with the type as described in the EC-type-examination certificate and satisfy the requirements of the ATEX Directive which apply to them. The manufacturer, or his authorised representative established in the Community, shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for EC monitoring, as specified in Section 4.
2. The manufacturer shall operate an approved quality system for production, final equipment inspection and testing as specified in Section 3 and shall be subject to monitoring as specified in Section 4.

### 3. Quality system

- 3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the equipment concerned.

The application shall include:

- all relevant information for the product category envisaged;
  - the documentation concerning the quality system;
  - technical documentation on the approved type and a copy of the EC-type-examination certificate.
- 3.2. The quality system shall ensure compliance of the equipment with the type as described in the EC-type-examination certificate and with the requirements of the Directive which 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 must permit a consistent interpretation of quality programmes, plans, manuals and records.

It shall contain, in particular, an adequate description of

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to equipment quality;
- the manufacturing, quality control and quality assurance techniques, processes and systematic actions which will be used;

- the examinations and tests which will be carried out before, during and after manufacture and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.;
- the means to monitor the achievement of the required equipment quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in Section 3.2. It shall presume conformity with these requirements in respect of quality systems which implement the relevant harmonised standard. The auditing team shall have at least one member with experience of evaluation in the equipment technology concerned. The evaluation procedure shall include an inspection visit to the manufacturer's premises. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination 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 uphold the system so that it remains adequate and efficient.

The manufacturer or his authorised representative shall inform the notified body which has approved the quality system of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in Section 3.2 or whether a re-assessment is required.

It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### **4. Surveillance under the responsibility of the notified body**

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 inspection purposes, allow the notified body access to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular

- the quality system documentation
- the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

- 4.3. The notified body shall periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.
- 4.4. Furthermore, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may carry out tests, or arrange for tests to be carried out, to check that the quality system is functioning correctly, if necessary. The notified body shall provide the manufacturer with a visit report and, if a test has taken place, with a test report.
5. The manufacturer shall, for a period ending at least 10 years after the last piece of equipment was manufactured, keep at the disposal of the national authorities:
  - the documentation referred to in the second indent of Section 3.1;
  - the updating referred to in the second paragraph of Section 3.4;
  - the decisions and reports from the notified body which are referred to in Section 3.4, last paragraph, Section 4.3 and Section 4.4.
6. Each notified body shall apprise the other notified bodies of the relevant information concerning the quality system approvals issued and withdrawn.

# Product verification

1. This Annex describes the procedure whereby a manufacturer or his authorised representative established within the Community checks and attests that the equipment subject to the provisions of point 3 below are in conformity with the type as described in the EC-type-examination certificate and satisfy the relevant requirements of the ATEX Directive.
2. The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees conformity of the equipment with the type as described in the EC-type-examination certificate and with the requirements of the Directive which apply to them. The manufacturer or his authorised representative established in the Community shall affix the CE marking to each piece of equipment and shall draw up a declaration of conformity.
3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the equipment, protective system or device referred to in Article 1(2) of the Directive, with the relevant requirements of the Directive, by examining and testing every product as specified in Section 4.

The manufacturer or his authorised representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last piece of equipment was manufactured.

## **4. Verification by examination and testing of each piece of equipment**

- 4.1. All equipment shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 of the Directive or equipment tests shall be carried out in order to verify their conformity with the type as described in the EC-type-examination certificate and the relevant requirements of the Directive.
- 4.2. The notified body shall affix or have affixed its identification number to each approved item of equipment and shall draw up a written certificate of conformity relating to the tests carried out.
- 4.3. The manufacturer or his authorised representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

# Conformity to type

1. This Annex describes that part of the procedure whereby the manufacturer or his authorised representative established within the Community ensures and declares that the equipment in question is in conformity with the type as described in the EC-type-examination certificate and satisfy the requirements of the ATEX Directive applicable to them. The manufacturer or his authorised representative established within the Community shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity.
2. The manufacturer shall take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured equipment or protective systems with the type as described in the EC-type-examination certificate and with the relevant requirements of the Directive.
3. The manufacturer or his authorised representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last piece of equipment was manufactured. Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the equipment or protective system on the Community market.

For each piece of equipment manufactured, tests relating to the anti-explosive protection aspects of the product shall be carried out by the manufacturer or on his behalf. The tests shall be carried out under the responsibility of a notified body, chosen by the manufacturer.

On the responsibility of the notified body, the manufacturer shall affix the former's identification number during the manufacturing process.

# Product quality assurance

1. This Annex describes the procedure whereby the manufacturer who satisfies the obligations of Section 2 ensures and declares that the equipment is in conformity with the type as described in the EC-type-examination certificate. The manufacturer or his authorised representative established within the Community shall affix the CE marking to each product and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for surveillance as specified in Section 4.
2. The manufacturer shall operate an approved quality system for the final inspection and testing of equipment as specified in Section 3 below and shall be subject to surveillance as specified in Section 4 below.

### 3. Quality system

- 3.1. The manufacturer shall lodge an application for assessment of his quality system for the equipment and protective systems, with a notified body of his choice.

The application shall include:

- all relevant information for the product category envisaged;
  - documentation on the quality system;
  - technical documentation on the approved type and a copy of the EC-type-examination certificate.
- 3.2. Under the quality system, each piece of equipment shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 of the ATEX Directive or equivalent tests shall be carried out in order to ensure its conformity with the relevant requirements of the Directive. 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 instruments. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain, in particular, an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- the examinations and tests which will be carried out after manufacture;
- the means to monitor the effective operation of the quality system;
- quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.



- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in Section 3.2. It shall presume conformity with these requirements in respect of quality systems which implement the relevant harmonised standard.

The auditing team shall have at least one member experienced as an assessor in the product technology concerned. The assessment procedure shall include an assessment visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner.

The manufacturer or his authorised representative shall inform the notified body which has approved the quality system of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in Section 3.2 or whether a re-assessment is required.

It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### **4. Surveillance under the responsibility of the notified body**

- 4.1. The purpose of surveillance is to ensure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer shall for inspection purposes allow the notified body access to the inspection, testing and storage premises and shall provide it with all necessary information, in particular:

- quality system documentation;
- technical documentation;
- quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

- 4.3. The notified body shall periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

- 4.4. Furthermore, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or arrange for tests to be carried out in order to check the proper functioning of the quality

system, where necessary; it shall provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer shall, for a period ending at least 10 years after the last piece of equipment was manufactured, keep at the disposal of the national authorities:
  - the documentation referred to in the third indent of Section 3.1;
  - the updating referred to in the second paragraph of Section 3.4;
  - the decisions and reports from the notified body which are referred to in Section 3.4, last paragraph, Section 4.3 and Section 4.4.
6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

# Internal control of production

1. This Annex describes the procedure whereby the manufacturer or his authorised representative established within the Community, who carries out the obligations laid down in Section 2, ensures and declares that the equipment satisfy the requirements of the ATEX Directive applicable to it. The manufacturer or his authorised representative established within the Community shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity.
2. The manufacturer shall establish the technical documentation described in Section 3 and he or his authorised representative established within the Community shall keep it at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last piece of equipment was manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the equipment on the Community market.

3. Technical documentation shall enable the conformity of the equipment with the relevant requirements of the Directive to be assessed. It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product. It shall contain:
  - a general description of the equipment,
  - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
  - descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the equipment,
  - a list of the standards applied in full or in part, and descriptions of the solutions adopted to meet the safety aspects of the Directive where the standards have not been applied,
  - results of design calculations made, examinations carried out, etc.,
  - test reports.
4. The manufacturer or his authorised representative shall keep a copy of the declaration of conformity with the technical documentation.
5. The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees compliance of the manufactured equipment with the technical documentation referred to in Section 2 and with the requirements of the Directive applicable to such equipment.

# Unit Verification

1. This Annex describes the procedure whereby the manufacturer ensures and declares that the equipment or protective system which has been issued with the certificate referred to in Section 2 conforms to the requirements of the ATEX Directive which are applicable to it. The manufacturer or his authorised representative in the Community shall affix the CE marking to the equipment or protective system and draw up a declaration of conformity.
2. The notified body shall examine the individual equipment or protective system and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article 5 of the Directive, or equivalent tests, to ensure its conformity with the relevant requirements of the Directive.

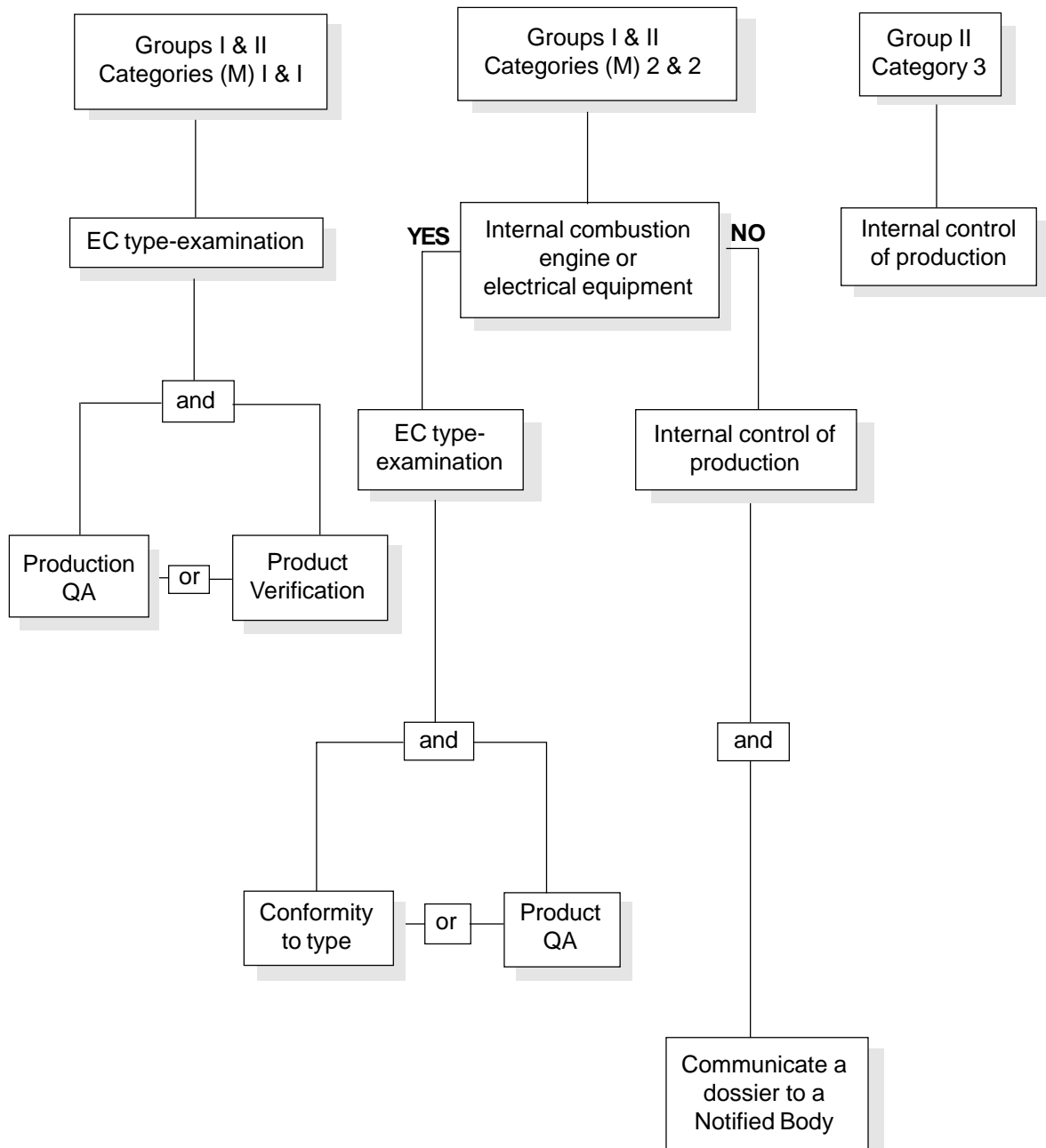
The notified body shall affix, or cause to be affixed, its identification number on the approved equipment or protective system and shall draw up a certificate of conformity concerning the tests carried out.

3. The aim of the technical documentation is to enable conformity with the requirements of the Directive to be assessed and the design, manufacture and operation of the equipment or protective system to be understood.

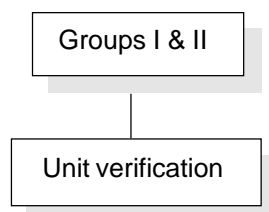
The documentation shall contain:

- a general description of the product;
- conceptual design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the equipment or protective system;
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied;
- results of design calculations made, examinations carried out, etc.;
- test reports.

# Conformity Assessment Procedures



OR



# Content of the EC declaration of conformity

The EC declaration of conformity must contain the following elements:

- the name or identification mark and the address of the manufacturer or his authorised representative established in the Community;
- a description of the equipment, protective system, or device referred to in Article 1(2) of the ATEX Directive;
- all relevant provisions fulfilled by the equipment, protective system, or device referred to in Article 1(2);
- where appropriate, the name, identification number and address of the Notified Body and the number of the EC-type-examination certificate;
- where appropriate, reference to the harmonised standards;
- where appropriate, the standards and technical specifications which have been used;
- where appropriate, references to other Community Directives which have been applied;
- identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer or his authorised representative established within the community.

# Conformity marking and additional specific markings

## CE CONFORMITY MARKING

The CE conformity marking must consist of the letters CE as illustrated in diagram 1 below followed by, where appropriate, the identification number of the notified body involved in the production control stage. It may not be smaller than 5mm in its vertical height, and the proportions in diagram 2, below, must be maintained whatever its size. The grid does not form part of the marking and is for information only. The minimum dimension may be waived for small-scale equipment, protective systems or devices referred to in Article 1(2) of the ATEX Directive.



Diagram 1

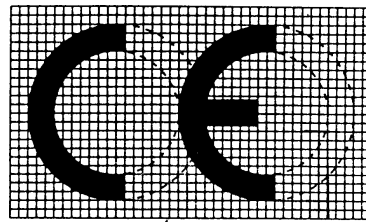


Diagram 2

The CE marking shall be affixed distinctly, visibly, legibly and indelibly to equipment and protective systems. The affixing of markings on the equipment or protective systems which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the equipment or protective systems, provided that the visibility and legibility of the CE marking is not thereby reduced.

Subject to the paragraph below, where equipment, a protective system or device is the subject of other Community Directives covering other aspects and which also provide for the affixing of the CE marking, such marking shall indicate that the equipment, protective system or device in question is also presumed to conform with the provisions of those other Directives.

Where one or more of the other Directives referred to in the paragraph above allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only with the Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the Official Journal of the European Communities, must be given in the documents, notices, or instructions required by the Directives and accompanying such equipment, protective system or device.

## ADDITIONAL SPECIFIC MARKINGS

Additional markings must enable full identification of equipment, protective systems and safety devices to be made. They must at least contain the following:

- ❑ the specific explosion protection mark, together with the mark indicating the equipment group and category; and, relating to equipment group II, the

letter 'G' (concerning explosive atmospheres caused by gases, vapours or mists) and/or 'D' (concerning explosive atmospheres caused by dust) as, for example, shown below;



- the name and address of the manufacturer;
- the designation of series or type and serial number;
- the year of production;
- restricted or other safety-related conditions of use.



# HSE Area Offices and HSE Northern Ireland

Inspectors are based in offices organised into divisions. The asterisk (\*) shows an office where you can also contact inspectors dealing with the manufacture, processing and storage of chemicals and onshore major hazards including gas transmission and distribution, pipelines and the road transport of dangerous substances.

## WALES & WEST DIVISION

*Covers Wales and the unitary authorities of Cornwall, Devon, Somerset, North West Somerset, Bath and North East Somerset, Bristol, South Gloucestershire, Gloucestershire, Hereford & Worcester, Shropshire and Staffordshire.*

(\*) Government Buildings,  
Phase 1,  
Ty Glas,  
Llanishen,  
CARDIFF CF14 5SH  
Tel: 029 2026 3000  
Fax: 029 2026 3120

The Marches House,  
Midway,  
NEWCASTLE-UNDER-LYME  
ST5 1DT  
Tel: 01782 602300  
Fax: 01782 602400

Inter City House,  
Mitchell Lane,  
Victoria Street,  
BRISTOL BS1 6AN  
Tel: 01179 886000  
Fax: 01179 262998

## HOME COUNTIES DIVISION

*Covers the counties of Bedfordshire, Berkshire, Buckinghamshire, Cambridgeshire, Dorset, Essex (except London Boroughs in Essex), Hampshire, Hertfordshire, Isle of Wight, Norfolk, Suffolk and Wiltshire.*

14 Cardiff Road,  
LUTON  
LU1 1PP  
Tel: 01582 444200  
Fax: 01582 444320

(\*) 39 Baddow Road,  
CHELMSFORD  
CM2 0HL  
Tel: 01245 706200  
Fax: 01245 706222

(\*) Priestley House,  
Priestley Road,  
BASINGSTOKE  
RG24 9NW  
Tel: 01256 404000  
Fax: 01256 404100

## **LONDON & SOUTH EAST DIVISION**

*Covers the counties of Kent, Surrey, East Sussex and West Sussex, and all London Boroughs*

St. Dunstons House,  
201-211 Borough High Street,  
LONDON SE1 1GZ  
Tel: 020 7556 2100  
Fax: 020 7556 2200

3 East Grinstead House,  
London Road,  
EAST GRINSTEAD  
RH19 1RR  
Tel: 01342 334200  
Fax: 01342 334222

International House,  
Dover Place,  
ASHFORD  
TN23 1HU  
Tel: 01233 624658  
Fax: 01233 634827

## **MIDLANDS DIVISION**

*Covers the counties of West Midlands, Leicestershire, Northamptonshire, Oxfordshire, Warwickshire, Derbyshire, Lincolnshire and Nottinghamshire.*

(\*) McLaren Building,  
35 Dale End,  
BIRMINGHAM B4 7NP  
Tel: 0121 607 6200  
Fax: 0121 607 6349

(\*) 1st Floor,  
The Pearson Building,  
55 Upper Parliament Street,  
NOTTINGHAM NG1 6AU  
Tel: 01159 712800  
Fax: 01159 712802

(\*)5th Floor Belgrave House,  
1 Greyfriars,  
NORTHAMPTON  
NN1 2BS  
Tel: 01604 738300  
Fax: 01604 738333

## **YORKSHIRE & NORTH EAST DIVISION**

*Covers the counties and unitary authorities of Hartlepool, Middlesbrough, Redcar and Cleveland, Stockton-on-Tees, Durham, Hull, North Lincolnshire, North East Lincolnshire, East Riding, York, North Yorkshire, Northumberland, West Yorkshire, Tyne & Wear, and the metropolitan Boroughs of Barnsley, Doncaster, Rotherham and Sheffield.*

(\*)Marshalls Mill  
Marshall Street  
LEEDS  
LS11 9YJ  
Tel: 0113 283 4200  
Fax: 0113 283 4296

(\*) Sovereign House,  
110 Queen Street,  
SHEFFIELD  
S1 2ES  
Tel: 0114 291 2300  
Fax: 0114 291 2379

(\*) Arden House,  
Regent Centre,  
Regent Farm Road,  
Gosforth,  
NEWCASTLE-UPON-TYNE  
NE3 3JN  
Tel: 0191 202 6200  
Fax: 0191 202 6300

## **NORTH WEST DIVISION**

*Covers the counties of Cheshire, Cumbria, Greater Manchester, Lancashire and Merseyside.*

Grove House,  
Skerton Road,  
MANCHESTER  
M16 0RB  
Tel: 0161 952 8200  
Fax: 0161 952 8222

(\*) Marshall House,  
Ringway,  
PRESTON  
PR1 2HS  
Tel: 01772 836200  
Fax: 01772 836222

## **SCOTLAND**

*Covers all the Scottish unitary authorities and island councils.*

(\*) Belford House,  
59 Belford Road,  
EDINBURGH  
EH4 3UE  
Tel: 0131 247 2000  
Fax: 0131 247 2121

Offshore Safety Division,  
Lord Cullen House,  
Fraser Place  
ABERDEEN AB25 3UB  
Tel: 01224 252500  
Fax: 01224 252662

375 West George Street,  
GLASGOW  
G2 4LW  
Tel: 0141 275 3000  
Fax: 0141 275 3100

## **NORTHERN IRELAND**

HSE Northern Ireland  
83 Ladas Drive  
BELFAST  
BT6 9FR  
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Fax: 02890 235383