# ATEX GUIDELINES (FIRST EDITION)

GUIDELINES ON THE APPLICATION OF COUNCIL DIRECTIVE 94/9/EC OF 23 MARCH 1994 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES CONCERNING EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES

**May 2000** 

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#### **NOTES**

1. These guidelines are intended to be a manual for all parties directly or indirectly affected by directive 94/9/EC commonly called the ATEX ("Atmosphères Explosibles") products directive. Readers' attention is drawn to the fact that this guide is intended only for facilitating the application of directive 94/9/EC and it is the text of the directive, which is legally binding. This document is not a legally binding interpretation of the directive. However, it represents a reference for ensuring consistent application of the directive by all those involved. The guidelines are intended to help ensure the free movement of products¹ in the European Union² by agreement of these explanations and clarifications, reached by consensus among Member States' government experts and other parties concerned. The existence of these harmonised interpretations is expected to minimise the number of safeguard clause applications, at least those originating from divergent interpretations.

- 2. These guidelines have been prepared by the competent services of the Directorate General Enterprise of the European Commission in collaboration with a group of government experts of Member States, representatives of European industry, European standardisation bodies and organisations entrusted with the technical tasks related to third party intervention in the conformity assessment procedures.
- 3. Guidelines are publicly available, but they are not binding in the sense of legal acts adopted by the Community. The legally binding provisions are those transposing directive 94/9/EC.
- 4. All references to the CE marking and EC Declaration of conformity in this Guide relate only to the directive 94/9/EC. To place products falling under directive 94/9/EC on the market in the EU territory all other relevant legislation must be applied.

For the purpose of this guide the term "product" covers equipment, protective systems,

devices, components and their combinations as they are defined in directive 94/9/EC.

According to the agreement related to the European Economic Area (EEA) (Council and Commission Decision 94/1/EC of 13 December 1993 (OJEC n° L 1 of 3 January 1994, p. 1) the territories of Liechtenstein, Iceland and Norway have to be considered, for the implementation of Directive 94/9/EC, in the same right as of the Community territory. When this term, Community territory, is used in this guide, the same applies to the EEA territory.

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Note: The information provided in Annexes 3 to 10 was correct as at May 2000

 $<sup>^3</sup>$  See Corrigenda to the English language version of directive 94/9/EC (OJ L 21.26.1.2000)

# 1. INTRODUCTION

#### 1.1 General comments

The objective of these guidelines is to clarify certain matters and procedures referred to in directive 94/9/EC<sup>4</sup> concerning equipment and protective systems intended for use in potentially explosive atmospheres. The guidelines should be used in conjunction with the directive and with the European Commission's "Guide to the implementation of directives based on New Approach and Global Approach (Blue Guide)".

These guidelines are aimed not only at the Member States' competent authorities, but also at the main economic operators concerned, such as manufacturers, their trade associations, the bodies in charge of the preparation of standards and those entrusted with the conformity assessment procedures.

First and foremost, this document must ensure that, when correctly applied, the directive leads to the removal of obstacles and difficulties related to the free circulation (free movement) of goods within the European Union (see footnote 2), which any of the groups concerned may encounter as regards the aspects relating to the presence of potentially explosive atmospheres. It should be noted that the statements in these guidelines refer only to the application of directive 94/9/EC unless indicated otherwise. All parties concerned should be aware of other requirements, which may also apply (see chapter 6).

The directive 94/9/EC is a "New Approach" directive laying down Essential Health and Safety Requirements and leaving it to standards, primarily European harmonised standards, to give technical expression of the relevant requirements contained in the directive.

Directive 94/9/EC is a total harmonisation directive, i.e. its provisions will replace existing divergent national and European legislation which cover the same subjects as now stipulated by directive 94/9/EC.

Directive 94/9/EC had to be transposed into national law by 1 September 1995. Its provisions have applied (on a voluntary basis only) since 1 March 1996.

However, the broad scope of directive 94/9/EC demonstrated the overriding need to provide for a transitional period, so as to ensure a smooth changeover to a New Approach Community-wide system.

# 1.2 Transitional period

The Council adopted directive 94/9/EC with a view to allowing a transitional period until 30 June 2003.

**During this transitional period** until 30 June 2003, a manufacturer **has the choice** of placing on the market and/or putting into service:

- i. products manufactured in accordance with the directive 94/9/EC, whereby the free movement of the products is guaranteed pursuant to the directive; or,
- products manufactured in accordance with national regulations in force in their territory at the date of adoption of this directive (i.e. 23 March 1994), whereby free movement of apparatus is guaranteed pursuant to Article 28 of the EC Treaty, albeit subject to the possible derogation provided for in Article 30;
   or,

- iii. electrical equipment for use in potentially explosive atmospheres employing certain types of protection manufactured in accordance with the "Old Approach" Council directive 79/196/EC<sup>5</sup> (as amended by Commission directives 84/47/EEC<sup>6</sup>, 88/571/EEC<sup>7</sup>, 94/26/EC<sup>8</sup> and 97/53/EC<sup>9</sup>); or,
- iv. electrical equipment for use in potentially explosive atmospheres in mines susceptible to firedamp manufactured in accordance with the "Old Approach" Council directive 82/130/EEC<sup>10</sup> (as amended by Commission directives 88/35/EEC<sup>11</sup>, 91/269/EC<sup>12</sup>, 94/44/EC<sup>13</sup> and 98/65/EC<sup>14</sup>).

During the transitional period the choice of the alternatives mentioned above is left to the manufacturer, but conformity to directive 94/9/EC will enable the free movement of products in the EU. Directive 94/9/EC applies to products whether they are manufactured inside or outside the EU.

The explosive atmosphere "framework" directive 76/117/EEC introduced procedures, which might be adopted by a manufacturer in relation to electrical equipment designed for use in potentially explosive atmospheres. The framework directive was complemented by "specific directives" making direct reference to European Harmonised Standards. The first of the "specific directives" was 79/196/EEC (see iii. above).

In 1982 a further directive (82/130/EEC) was adopted in respect of electrical equipment intended for use underground in mines susceptible to firedamp. This is generally known as the "Gassy Mines" directive. The directive also applies to such equipment for use in surface installations of such mines (see iv. above).

Both the first specific directive and Gassy Mines directive have been subject to a number of further directives by way of amendments and Adaptations to Technical Progress (ATPs) which enable manufacturers to use the latest editions of Harmonised Standards listed in those further directives.<sup>15</sup>. However, certificates of conformity already issued remain valid (unless their validity expires sooner) up to and including 30 June 2003, after which date the directive 94/9/EC becomes mandatory<sup>16</sup>.

Harmonised Standards, which are expected to enable presumption of conformity to directive 94/9/EC, should be available as soon as possible, at the latest by the time that this directive becomes mandatory. In the absence of Harmonised Standards manufacturers must apply adequate solutions in order to comply with the Essential Health and Safety Requirements (EHSRs).

<sup>&</sup>lt;sup>5</sup> OJ No L 43, 20.2.1979

<sup>&</sup>lt;sup>6</sup> OJ No L 31, 2.2.1984

<sup>&</sup>lt;sup>7</sup> OJ No L 311, 17.1.1988

<sup>&</sup>lt;sup>8</sup> OJ No L 157, 24.6.1994

<sup>9</sup> OJ No L 257, 20.9.1997

OJ No L 59, 2.3.1982

OJ No L 20, 26.1.1988

OJ No L 134, 29.5.1991

OJ No L 248, 23.9.1994 OJ NO L 257, 19.9.1998

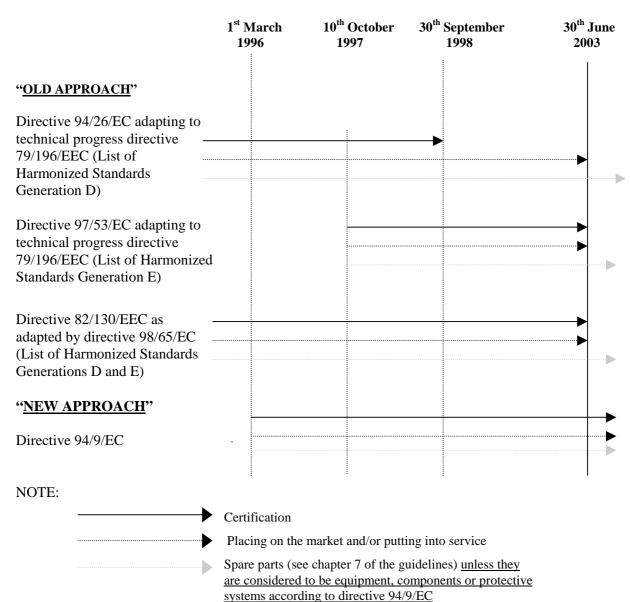
You will need to be aware that once a list is superseded the previous editions are not available (after a transitional period) as an option to enable conformity to be attested to the relevant old explosive atmospheres directive. An exception is the regulation in Annex B of directive 82/130/EEC, which form amendments to European standards.

For information, the most recent ATP to 79/196/EEC was detailed in directive 97/53/EC dated 11 September 1997. It lists the second editions of the EN 50014 series of standards and "E" generation of Certificates of Conformity are now available. Directive 82/130/EEC has been amended by directive 98/65/EC.

After 30 June 2003, all products placed on the market or put into service will have to conform to directive 94/9/EC as both the old explosive atmosphere directives and national regulations throughout the EU will have been repealed. The directive 94/9/EC will apply to all products within the scope of the old directives and will additionally cover non-electrical products and products for use in "dust" environments where the risk of an explosion may exist. Directive 94/9/EC applies to products placed on the market in the EU whether they are manufactured inside or outside of the Community.

For electrical equipment it is clear that the current Harmonised Standards, as listed in the old explosive atmosphere directives, will be useful as a step towards a demonstration of conformity to directive 94/9/EC before the full set of Harmonised Standards for the purposes of the directive 94/9/EC becomes available. As the standards listed in the old directives as amended, (see footnote 17), cover a number of the EHSRs (specified in the directive 94/9/EC) in their own right it may be easier for manufacturers to use these editions and then to apply additional measures covering those EHSRs not yet covered by Harmonised Standards. This is especially the case during the transitional period.

# OLD APPROACH AND NEW APPROACH PROVISIONS FOR THE TRANSITIONAL PERIOD



# 2. OBJECTIVE OF THE ATEX DIRECTIVE 94/9/EC

The objective of directive 94/9/EC is **to ensure free movement for the products to which it applies** in the EU territory. Therefore the directive, **based on Article 95 of the EC Treaty**, provides for harmonised requirements and procedures to establish compliance.

The directive notes that to remove barriers to trade via the New Approach, provided for in the Council Resolution of 7 May 1985<sup>17</sup>, essential requirements regarding safety and other relevant attributes need to be defined by which a high level of protection will be ensured. These **Essential Health and Safety Requirements (EHSRs)** are listed in directive 94/9/EC at Annex II.

After 30 June 2003 products may be placed on the market in the EU territory, freely moved and operated as designed and intended in the expected environment only if they comply with directive 94/9/EC (and other relevant legislation).

It should be noted that directive 94/9/EC provides for the first time Essential Health and Safety Requirements for non-electrical equipment intended for use in potentially explosive atmospheres and equipment intended for use in environments which are potentially explosive due to dust hazards and protective systems and for devices intended for use outside explosive atmospheres which are required for or contribute to the safe functioning of equipment or protective systems with respect to risks of explosion. This is an increase in scope compared to existing national regulations.

The requirements for compliance with the provisions of directive 94/9/EC will be further developed in the following chapters.

# 3. GENERAL CONCEPTS<sup>18</sup>

For the purpose of this guide the term "product" covers equipment, protective systems, devices, components and their combinations.

It has to be stressed that directive 94/9/EC carries obligations for the person who places products on the market and/or puts into service, be it the manufacturer, his authorized representative, the importer or any other responsible person. The directive does not regulate the use of equipment in a potentially explosive atmosphere. However, the use of equipment in potentially explosive atmospheres is regulated through directive 89/655/EEC. In brief, this directive states that products may only be used if conforming to the relevant directives (Article 95 directives) which are applied as appropriate to the product at the time of placing on the market or putting into service.

Furthermore it is intended to regulate the use of products in explosive atmospheres by a "Council directive on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres" which will be an individual directive within the meaning of Article 16 of directive 89/391/EEC and based on Article 138 of the EC Treaty. <sup>19</sup>

In general, the use of such products in potentially explosive areas has to be monitored as part of the surveillance activity undertaken by the competent authorities in the Member States.

OJ No C 136, 4.6.1985 p.1

For general definitions see also the "Guide to the implementation Directives based on New Approach and Global Approach" ("Blue Guide"). Further definitions specific to directive 94/9/EC are covered in chapter 4 of this guide.

See the amended proposal for a Council directive on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres.

OJ No C 184, 17.7.1997

# 3.1 Placing ATEX products on the market

This means the first making available, against payment or free of charge, of products, in the EU market, for the purpose of distribution and/or use in the EU.

#### Comments:

The concept of placing on the market determines the moment when products pass for the first time from the manufacturing stage to the market of the EU or the importing stage from a non-EU country to that of distribution and/or use in the EU. Since the concept of placing on the market refers only to the first time products are made available in the EU for the purpose of distribution and/or use in the EU, the ATEX directive 94/9/EC covers only *new* ATEX products manufactured within the EU and *new or used* ATEX products imported from a non-EU country

The directive's provisions and obligations concerning placing on the market apply after 30 June 2003 to each product individually and are irrespective of the date and place of manufacturing. It is the manufacturer's responsibility to ensure that each and all of his products comply where these fall under the scope of the directive.

"Making available" means the transfer of the product, that is, either the transfer of ownership, or the physical hand-over of the product by the manufacturer, his authorised representative in the EU or the importer to the person responsible for distributing these onto the EU market or the passing of the product to the final consumer, intermediate supplier or user in a commercial transaction, for payment or free of charge, regardless of the legal instrument upon which the transfer is based (sale, loan, hire, leasing, gift, or any other type of commercial legal instrument). The ATEX product must comply with the directive at the moment of transfer.

If a manufacturer, his authorised representative in the EU or the importer offers products covered by the directive in a catalogue, they are deemed not to have been placed on the market until they are actually made available for the first time. Therefore products offered in a catalogue do not have to be in full conformity with the provisions of the directive 94/9/EC, but this fact must be clearly advertised in the catalogue.

The placing of products on the market does not concern:

- the disposal of products from the manufacturer to his authorised representative established in the EU who is responsible on behalf of the manufacturer for ensuring compliance with the directive;
- imports into the EU for the purpose of re-export, i.e., under the processing arrangements;
- the manufacture of products in the EU for export to a non-EU country;
- the display of products at trade fairs and exhibitions<sup>20</sup>. These may not be in full conformity with the provisions of the directive 94/9/EC, but this fact must be clearly advertised next to the products being exhibited.

The person placing the product on the EU market, be it the manufacturer, his authorised representative or, if none of them is established in the EU, the importer or any other responsible person, must retain at the disposal of the competent authority the EC declaration of conformity. The technical documentation where applicable has to be made available on request of the enforcement authorities within a reasonable time (see Annexes III, VI, VIII). These documents shall be maintained by such a person at the disposal of the competent authorities for ten years after the last item has been manufactured. This applies to products manufactured in the EU as well as those imported from a non-EU country.

# 3.2 Putting ATEX products into service

This means the first use of products referred to in directive 94/9/EC in the EU territory, by its end user.

#### Comments:

Products covered by directive 94/9/EC are put into service when they are first used.

However, a product which is ready for use as soon as it is placed on the market and which does not have to be assembled or installed, and where the distribution conditions (storage, transport, etc.) makes no difference to the performance of the product, is considered to have been put into service as soon as it is placed on the market, if it is impossible to determine when it is first used.

#### 3.3 Manufacturer

This is the person responsible for the design and construction of products covered by directive 94/9/EC with a view to placing them on the EU market on his own behalf.

Whoever substantially modifies a product resulting in an "as-new" product<sup>21</sup>, with a view to placing it on the EU market, also becomes the manufacturer.

#### Comments:

The manufacturer bears responsibility for:

- undertaking an analysis to conclude if his product is subject to directive 94/9/EC and which requirements apply (as further explained in chapter 4);
- design and construction of the product in accordance with the Essential Health and Safety Requirements laid down in the directive;
- following the procedures for the assessment of the conformity of the product with the Essential Health and Safety Requirements laid down in the directive (see Article 8).

The manufacturer has sole and ultimate responsibility for the conformity of his product to the applicable directives. He must understand both the design and construction of the product to be able to declare such conformity in respect of all applicable provisions and requirements of the relevant directives.

The manufacturer may subcontract certain operations, e.g., product design or production, provided that he retains overall control and responsibility for the product as a whole. By the same token, he may use ready-made items or components, CE marked or not, to produce the product without losing his status as a manufacturer.

Articles 8 and 10 and their associated annexes of the directive 94/9/EC define the obligations incumbent on the manufacturer with regard to conformity assessment, CE marking, the EC declaration of conformity, written attestation of conformity (if relevant) and the arrangements for holding the EC declaration of conformity, together with the technical documentation, at the disposal of the competent authorities for a period of ten years after the last product has been manufactured.

# 3.4 Manufacturing of ATEX products for own use

Whoever puts into service products covered by the directive, which he has manufactured for his own use, is considered to be a manufacturer. He is obliged to conform to the directive in relation to putting into service.

<sup>21</sup> 

# 3.5 Authorised representative

This is the person or persons expressly appointed by the manufacturer by a written mandate to act on his behalf in respect of certain manufacturer's obligations within the EU. The extent to which the authorised representative may enter into commitments binding on the manufacturer is restricted by the relevant Articles of the directive and determined by the mandate conferred on him by the latter.

As an example, he could be appointed to undertake the testing in the EU territory, sign the EC declaration of conformity, affix the CE marking and hold the EC declaration of conformity and the technical documentation within the EU at the disposal of the competent authorities.

The quality assessment system of the authorised representative/responsible person will not be subject to assessment by a notified Body, but the quality assessment system of the real manufacturer. It would not be reasonable to assess a quality assessment system of a person who is not producing the product and might only be a trade agent.

#### Comments:

Articles 8 and 10 together with Annexes 3-9 of the directive 94/9/EC define the obligations incumbent on the authorised representative established within the EU with regard to conformity assessment, CE markings, EC declaration of conformity and the arrangements for holding this EC declaration of conformity, together with the technical documentation, at the disposal of the competent authorities for a period of ten years after the last product has been manufactured.

# 3.6 Other persons responsible for placing on the market

Where neither the manufacturer, nor the authorised representative is established within the EU, any other person resident in the EU who places the product on the EU market has obligations under the scope of the directive. The only obligation is to keep available the necessary documentation at the disposal of the competent authorities for ten years after the last product has been manufactured. In their capacity as "person responsible for placing on the market" they are not entitled to assume other responsibilities which are solely reserved to the manufacturer or his authorized representative (e.g. signing the EC declaration of conformity).

# 3.7 Equipment<sup>22</sup>

Equipment<sup>23</sup>, as defined in directive 94/9/EC, means machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy or the processing of material and which are capable of causing an explosion through their own potential sources of ignition.

Following discussions in the Standing Committee and the standardisation bodies it should be noted that intrinsically safe equipment is included in the scope of the directive.

It has become evident that a number of language versions of the ATEX Directives interpret some definitions in different ways. The information provided here is intended to inform interested parties throughout the EEA on the common approach agreed by the Member States. It does not, however, impact in any way on the different versions as implemented in relevant national legislation, nor the right of the manufacturer to choose this route should he

<sup>23</sup> Article 1.3(a) of the Directive

#### 3.7.1 Assemblies

From the term 'jointly' in the definition above it follows that an <u>assembly</u>, formed by combining two or more pieces of equipment, together with components if necessary, <u>has to be considered as a product falling under the scope of directive 94/9/EC (see footnote 1)</u>, provided that this assembly is placed on the market and/or put into service by a responsible person (who will then be the manufacturer of that assembly) as a single functional unit.

Such assemblies may not be ready for use but require proper installation. The instructions (Annex II, 1.0.6.) will have to take this into account in such a way, that compliance with directive 94/9/EC is ensured without any further conformity assessment, provided the installer has correctly followed the instructions.

In the case of an assembly consisting of different pieces of equipment as defined by directive 94/9/EC which were previously placed on the market by different manufacturers these items of equipment have to conform with the directive, including being subject to proper conformity assessment, CE-marking, etc. The manufacturer of the assembly may presume conformity of these pieces of equipment and may restrict his own risk assessment of the assembly to those additional ignition and other relevant hazards (as defined in Annex II), which become relevant because of the final combination. If additional hazards are identified a further conformity assessment of the assembly regarding these additional risks is necessary. Likewise, the assembler may presume the conformity of components which are accompanied by a certificate, issued by their manufacturer, declaring their conformity (Article 8.3, see also chapter 10).

However, if the manufacturer of the assembly integrates parts without a CE-marking into the assembly (because they are parts manufactured by himself or parts he has received from his supplier in view of further processing by himself) or components not accompanied by the above mentioned certificate, he shall not presume conformity of those parts and his conformity assessment of the assembly has to cover those parts as required.

Assemblies may be placed on the market in different ways:

#### 3.7.1.1 Assemblies, which are fully specified configurations of parts

Here the manufacturer has already defined one or more invariable combination(s) of parts and places them on the market as a single functional unit / single functional units.

An example could be instrumentation consisting of a sensor, a transmitter, a zener barrier and a power supply if provided by one manufacturer.

The above mentioned parts are <u>put together by the same person</u> (the manufacturer of the assembly), and placed on the market as a single functional unit. This person assumes responsibility for the compliance of the integral assembly with the directive.

The EC declaration of conformity, as well as the instructions for use must refer to the assembly as a whole. It must be clear (e.g. by enclosing a list of all parts and/or a list of the safety related data) which is/are the combination(s) that form(s) the assemblies. The manufacturer assumes responsibility for compliance with the directive, and must therefore, in accordance with Annex II 1.0.6, provide clear instructions for assembly/installation/operation/maintenance etc. in the instructions for use.

#### 3.7.1.2 Assemblies with various configurations

Here the manufacturer has defined a whole range of different parts, forming a "modular system". Either he or the user/installer selects and combines parts out of this range to form an assembly, which serves the specific task.

An example could be a modular system for flameproof switch- and control gear, consisting of a range of flameproof enclosures of different size, a range of switches, terminals, circuit breakers etc.

Although in this case the parts are <u>not</u> necessarily put together by the manufacturer of the assembly, and placed on the market as a single functional unit, <u>the manufacturer is responsible for the compliance of the assembly as long as the parts are chosen from the defined range and selected and combined according to his instructions.</u>

The EC Declaration of Conformity, as well as the instructions for use must refer to the "modular system" as a whole. It must be clear which are the parts that form the modular system and how they are to be selected to form a compliant assembly. Therefore the manufacturer must, in accordance with Annex II 1.0.6, provide clear instructions for selection of parts and their assembly /installation /operation /maintenance etc. in the instructions for use.

The conformity assessment of such modular systems may be done by assessing at least those of the possible and useful configurations, which are the most unfavourable regarding the relevant risks (worst cases). If those configurations are assessed to be conforming to the EHSRs of the directive 94/9/EC the manufacturer may conclude conformity of all other configurations as well. If later on other parts are to be added to the "modular system" it may of course become necessary to identify and assess the worst cases again.

The table on page 15 gives a condensed overview of the various situations regarding assemblies.

#### 3.7.2 Installations

A common situation is that pieces of already certified equipment are placed on the market independently by one or more manufacturer(s), and are not placed on the market by a single legal person as a single functional unit (as described in 3.7.1). Combining such equipment and installing at the user's premises is not considered as manufacturing and thus does not result in equipment; the result of such an operation is an installation and is outside the scope of directive 94/9/EC. The installer has to ensure that the initially conforming pieces of equipment are still conforming when they are taken into service. For that reason he has carefully to follow all installation instructions of the manufacturers. The directive does not regulate the process of installation. Installing such equipment will generally be subject to legal requirements of the Member States. An example could be instrumentation consisting of a sensor, a transmitter, a zener barrier and a power supply if provided by several different manufacturers installed under the responsibility of the user.

# 3.7.3 Electrical Equipment

Directive 94/9/EC does not define "Electrical Equipment". However, because such equipment is subject to its own conformity assessment procedure it may be useful to provide a definition, which has been generally accepted by the majority of Member States, as follows:

**Electrical Equipment**: Equipment as defined in chapter 3.7, containing electrical elements, is used for the generation, storage, measurement, distribution and conversion of electrical energy, for controlling the function of other equipment by electrical means or for processing materials by the direct application of electrical energy. It should be noted, that a final product assembled using both electrical and mechanical elements may not require assessment as electrical equipment provided the combination poses no additional risks (for further details see chapter 3.7.1).

Examples:

A <u>pump</u> (non-electrical) is assessed under the appropriate conformity assessment procedures and is then connected to an <u>electric motor</u> (electrical equipment) which has already been assessed. As long as the combined equipment poses no additional hazards, then no further assessment for the electrical part is necessary.

If the same pump and electric motor have not been through the appropriate conformity assessment procedures and are connected, then the resulting product is to be regarded as electrical equipment and the conformity assessment should treat it as such.

**Table 1:** Summary of Requirements for Assemblies

SITUATION: 1. parts: Assembly is composed of	Equipment, protective systems, devices (Art. 1.2) all CE-marked, and components accompanied by a written attestation (Art. 8.3). (parts with proven conformity)		Equipment, protective systems, devices (Art. 1.2), including non CE-marked, and components not accompanied by a written attestation (Art. 8.3). (parts without proven conformity)		
2. Configuration: Assembly is placed on the market as  Exactly defined configuration(s)  A "modular system" of parts, to be specifically selected and configurated to serve a specific purpose, maybe by the user/installer.		Exactly defined configuration(s)	A "modular system" of parts, to be specifically selected and configurated to serve a specific purpose, maybe by the user/installer.		
3. RESULT: Manufacturer may presume conformity for	All parts	All parts	Only parts with proven conformity	Only parts with proven conformity	
4. Conformity Assessment (CA)	CA has to cover the whole configuration regarding all risks, which might arise by the interaction of the combined parts, with respect to the intended use.	CA has to cover at least those of the possible and useful configurations, which are assessed to be the most unfavourable regarding all risks, which might arise, by the interaction of the combined parts, with respect to the intended use.	CA has to cover:  all parts without proven conformity regarding all risks, and  all configuration(s) regarding all risks which might arise by the interaction of the combined parts, both with respect to the intended use.	CA has to cover:  all parts without proven conformity which are part of the "modular system", regarding all risks, and  at least those of the possible and useful configurations, which are assessed to be the most unfavourable regarding all risks which might arise by the interaction of the combined parts, both with respect to the intended use.	
5. Information to be provided	a) Identification of all parts forming the assembly;	a) Identification of all parts forming the "modular system";	a) Identification of all parts forming the assembly;	a) Identification of all parts forming the "modular system";	
a) by EC-Declaration of conformity     b) by instructions for installation and use	sufficient to ensure that resulting assembly combined to fulfil the required purpose, and instructions for complies with all relevant EHSRs of directive 94/9/EC.		b) instructions for installation and use, sufficient to ensure that resulting assembly complies with all relevant EHSRs of directive 94/9/EC.	b) instructions for the selection of parts, to be combined to fulfill the required purpose, and instructions for installation and use, sufficient to ensure that resulting assembly complies with all relevant EHSRs of directive 94/9/EC.	

#### 3.8 Autonomous Function

A product is considered to have an autonomous function if it can be safely used to deliver, or contribute towards the delivery of, one or more of the intended functions of Article 1.2 or Article 1.3.a) or b), without the need to add any further parts. This does not preclude that specific instructions for installation and use are to be followed.

Some kind of products may, <u>depending on the extent of the conformity assessment already undertaken before being placed on the market and/or put into service</u>, be considered either as with or without autonomous function.

# 3.9 Protective Systems

Protective systems<sup>24</sup> means design units, other than components, which are intended to halt incipient explosions immediately and/or limit the effective range of explosion flames and explosion pressures.

Examples of autonomous protective systems are:

- flame arresters;
- water trough barriers;
- explosion relief systems (using e.g. bursting discs, vent panels, explosion doors, etc.);
- extinguishing barriers.

# 3.10 Components

A component<sup>25</sup> means any item essential to the safe functioning of equipment and protective systems but with no autonomous function.

Components intended for incorporation into equipment or protective systems which are accompanied by an attestation of conformity including a statement of their characteristics and how they must be incorporated into products (see Article 8(3)), are considered to conform to the applicable provisions of directive 94/9/EC. Ex – components as defined in the European standard EN 50014 are components in the sense of the ATEX directive 94/9/EC as well. **Components must not have the CE marking affixed** unless otherwise required by other directives (e.g. the EMC directive 89/336/EEC).

#### Examples:

- terminals;
- push button assemblies;
- relays;
- empty flameproof enclosures;
- ballasts for fluorescent lamps;
- meters (e.g. moving coil);
- encapsulated relays and contactors, with terminals and/or flying leads.

Article 1.3(b) of the Directive
Article 1.3(c) of the Directive

# 4. IN WHICH CASES DOES DIRECTIVE 94/9/EC APPLY?

The manufacturer, his authorised representative or the person who first places a product on the EU market or puts a product into service in the EU market has to decide whether it is covered by the directive 94/9/EC and, if so, apply its provisions. The manufacturer (in the broadest sense of the directive) must therefore make an ATEX analysis on the basis of directive 94/9/EC.

# 4.1 ATEX Analysis

#### 4.1.1 Is the specific explosive atmosphere covered by directive 94/9/EC?

Directive 94/9/EC is a directive following the "New Approach" and therefore is intended to enable the free movement of goods within the Community. This is achieved by harmonisation of legal safety requirements, following a risk-related approach. Its objective is also to eliminate or at least minimise the risks resulting from the use of certain products **in or in relation to** a potentially explosive atmosphere. This means that the probability of occurrence of an explosive atmosphere has to be looked at not only once and from a static point of view but all operational conditions, which may result from the processing course, have to be taken into account as well.

An explosive atmosphere for the purposes of directive 94/9/EC is defined as a mixture

- i) of flammable substances in the form of gases, vapours, mists or dusts;
- ii) with air;
- iii) under atmospheric conditions<sup>26</sup>;
- iv) in which, after ignition, the combustion spreads to the entire unburned mixture (It has to be noted that in the presence of dust not always the whole quantity of dust is consumed by the combustion).

An atmosphere, which could become explosive due to local and/or operational conditions, is called a **potentially explosive atmosphere**. It is only this kind of potentially explosive atmosphere which products falling under the directive 94/9/EC are designed for (see as well chapter 4.3 'Risk Assessment').

It is important to note, that products **are not covered by directive 94/9/EC**<sup>27</sup> where they are intended for use in or in relation to atmospheres which might potentially be explosive, but one or more of the **defining elements i) to iv) above are not present.** 

# 4.1.2 Which kinds of products are covered by directive 94/9/EC?

To be within the scope of the directive, a product has to be:

- a) **equipment**, as defined in Article 1.3.(a); or
- b) a protective system, as defined in Article 1.3.(b); or
- c) a component, as defined in Article 1.3.(c); or
- d) a safety, controlling or regulating device as defined in Article 1.2.

Examples for such atmospheres could be: Mixtures which are explosive without air (e.g. H<sub>2</sub> mixed with Cl<sub>2</sub>), mixtures of flammable substances with other oxidants than air, pressure and/or temperature conditions outside the atmospheric range, etc.

The directive 94/9/EC does not define atmospheric conditions. However, a surrounding temperature range of  $-20^{\circ}C$  to  $60^{\circ}C$  and a range of pressure between 0.8 bar and 1.1 bar may be appropriate as a basis for design and intended use of products. This does not preclude that products may be specifically designed and assessed for operation occasionally outside these conditions. It should be noted that electrical products are normally designed and tested fror use in the ambient temperature range  $-20^{\circ}C$  to  $40^{\circ}C$  in conformity with the standard EN 50014. Products designed for use outside of this range will require additional marking to be added and further testing as appropriate.

#### a) Equipment

Equipment is only considered to be within the scope of the directive it if is intended (either in whole or in part) to be used in a potentially explosive atmosphere; the fact that an intended potentially explosive atmosphere might be present inside the equipment is not relevant, but with the following possible exceptions:

If a product containing an intended potentially explosive atmosphere, for example a vessel, itself contains equipment with an autonomous function as defined in the directive, then the latter equipment is in effect in a potentially explosive atmosphere, albeit one which is contained by the vessel, and is therefore subject to the directive.

If equipment containing a potentially explosive atmosphere can, due to its construction, operation etc. create a potentially explosive atmosphere, which wholly or partially surrounds it, then such equipment is in effect in a potentially explosive atmosphere, and is therefore subject to the directive.

Another defining element of equipment in the sense of the directive is that it has to have its own potential source of ignition.

Potential sources of ignition could be: Electric sparks, arcs and flashes, electrostatic discharges, electromagnetic waves, ionising radiation, hot surfaces, flames and hot gases, mechanically generated sparks, optical radiation, chemical flame initiation<sup>28</sup>, compression.

In some cases a product may only contain a potentially explosive atmosphere which is deliberately ignited. It is clearly not the intention that these fall under the scope of directive 94/9/EC unless other relevant hazards are identified.

Equipment can be said to have its own potential source of ignition, if, when operated as intended (including malfunctions, etc. to an extent depending on its category - see Annex I of the directive) in an explosive atmosphere, it is capable of igniting the explosive atmosphere unless specific safety measures are taken. Therefore, equipment must ensure the required level of protection.

To ensure this required level of protection various techniques could be applied, e.g.: intrinsic safety, pressurisation, increased safety, etc.<sup>29</sup>

Account needs to be taken of the specific exclusion at Article 1 (4) of the directive 94/9/EC of equipment where explosion hazards result exclusively from the presence of explosive substances or unstable chemical substances.

For more examples see also the list of standards in Annex 6

These considerations lead to the following table:

Table 2: When is directive 94/9/EC applicable?

Situation		Result		
	Equipment with own potential source of ignition	Equipment to be used in or in relation to potentially explosive atmospheres	Equipment where an intended internal explosive atmosphere is present	Equipment within scope of directive 94/9/EC
A	YES	YES	YES	YES
В	NO	YES	YES	$\mathrm{NO}^{\mathrm{a}\mathrm{)b\mathrm{)}}}$
С	YES	NO	YES	$\mathrm{NO}^{\mathrm{a}\mathrm{)b\mathrm{)}}}$
D	YES	YES	NO	YES
Е	NO	NO	YES	$\mathrm{NO}^{\mathrm{a}\mathrm{)b\mathrm{)}}}$
F	YES	NO	NO	$NO^{b)}$
G	NO	YES	NO	$NO^{b)}$
Н	NO	NO	NO	$NO^{b)}$

but YES for products <u>inside</u> the internal potentially explosive atmosphere. Moreover it has to be considered that the equipment as a whole has to be capable of functioning in conformity with the operational parameters established by the manufacturer and ensuring the required level of protection according to Annex II, item 1.0.1 (Principles of integrated explosion safety). Also YES for non-electrical (mechanical) equipment where an intended explosive atmosphere is inside the equipment (e.g. fans, ventilators, blowers or compressors providing ignitable mixtures) and a potential source of ignition has to be assumed.

#### b) Protective system

From its intended function it is obvious that a protective system will always, at least partially, be installed and used **in** a potentially explosive atmosphere.

Because a protective system has the function to eliminate or reduce the dangerous effects of an explosion (a safety function) it is subject to the directive regardless as to whether it has its own potential source of ignition or not. In this first case it would have to comply with the specific EHSRs for equipment as well.

According to Article 1.3.(b) protective systems are placed on the market separately for use as autonomous systems<sup>30</sup>. Consequently their conformity with the relevant EHSRs of Annex II has to be assessed according to Article 8(2) and they have to be marked according to Article 10(2).

Of course 'protective systems' may also be placed on the market as an integral part of equipment. Technically speaking these remain 'protective systems' because of their function, but are not considered as protective systems in the sense of the directive regarding conformity assessment and marking. In such cases their conformity is assessed in the course of the conformity assessment of the equipment they are integrated into, using the procedures foreseen in Article 8 according to the Group and Category of that equipment. They are not separately marked.

It is, however, important to note that the specific EHSRs of Annex II.3 also apply for integrated 'protective systems'.

but YES for devices according to Article 1.2 of the directive, see below.

 $<sup>^{30}</sup>$ See Corrigenda to the English language version of directive 94/9/EC (OJ L 21, 26.1.2000).

#### c) Components

The two defining elements for components in Article 1.3.(c) are that they,

- are **essential to the safe functioning** of equipment and protective systems (otherwise they would not need to be subject to the directive); but,
- with **no autonomous function** (see 3.8) (otherwise they would have to be regarded either as equipment, protective system or as device according to Article 1.2).

This definition covers a vast range of parts commonly used in engineering including gauges, brakes, tanks, heating elements, hasps, carriages, counterweights, reels, cramps, connecting elements, levers, buckles, turning elements, etc.

According to Article 8.3 the conformity of components has to be assessed by means of the same procedures as the equipment, protective systems or devices according to Article 1(2) into which they are to be integrated.

For example, drive-belts, bearings, Zener diodes, etc. are not usually placed on the market with the explicit intention to be incorporated into equipment, protective systems or devices according to Article 1.2 but for general engineering purposes. Their conformity (i.e. their suitability for the intended purpose as regards safety of the product they are integrated into) has to be assessed in the course of the conformity assessment of the integral product.

If components are to be placed on the market with the explicit intention of incorporation into equipment, protective systems or devices according to Article 1.2, (as e.g. explosion proof terminal blocks, flameproof enclosures, etc.) they shall be assessed separately according to Article 8.3 and accompanied by a written attestation of conformity as referred to in Article 8.3. Otherwise Member states can prohibit, restrict or impede their placing on the market (Article 4.2) and cannot presume their conformity (Article 5.1).

#### d) Safety, controlling or regulating devices as defined in Article 1.2.

The two main issues of Article 1.2 are,

- i) that **safety devices**, **controlling devices** and **regulating devices**, if they contribute to or are required for the safe functioning of equipment or protective systems with respect to the risks of explosion are **subject to the directive**;
- ii) that devices are covered **even if** they are situated **outside the potentially explosive atmosphere**.

For such devices, the essential requirements shall only apply so far as they are necessary for the **safe** and reliable functioning and operation of those devices with respect to the risk of explosion (ANNEX II, Preliminary observation B)

The **definition** in i) leads to the following consequences:

- 1. Devices other than safety, controlling and regulating devices are not covered. (However, a device of any kind, contributing to or required for the safe functioning, could be considered a safety device);
- 2. **All devices**, including safety, controlling and regulating devices, **neither contributing** to **nor required** for the safe functioning with **respect to the explosion risk are not covered**;
- 3. Even **safety**, **controlling and regulating devices** contributing to or required for the safe functioning but **with respect to risks other than the explosion risk are not covered**;

#### Examples of devices falling under Article 1.2:

- A power supply feeding an intrinsically safe (Ex i) measurement system used for monitoring process parameters;
- A pump, pressure regulating device, backup storage device, etc. ensuring sufficient pressure and flow for feeding a hydraulically actuated safety system (with respect to the explosion risk);
- Overload protective devices for electric motors of type of protection EEx e 'Increased Safety';
- Controller units in a safe area, for an environmental monitoring system consisting of gas
  detectors distributed in a potentially explosive area, to provide executive actions if
  dangerous levels of gas are detected;
- Controller units for sensors temperature, pressure, flow, etc, located in a safe area, for
  providing information used in the control of electrical apparatus, used in production or
  servicing operations in a potentially explosive area.

#### Examples of devices not falling under Article 1.2:

• Switchgear, numeric controllers, etc. not related to any safety functions (with respect to the explosion risk); because of 2) above;

**Item ii)** states that devices, as defined above, are subject to the directive, even when outside the potentially explosive atmosphere.

For safety and economic reasons it will be preferable in most cases to install such devices in a non-hazardous area. However, sometimes it might be necessary to place such devices within a potentially explosive atmosphere. In such cases, although the directive does not explicitly say so, these devices can also be designated as equipment.

Two situations can be identified:

- If the device has its own potential source of ignition then, in addition to the requirements resulting from Article 1.2, the requirements for equipment will apply;
- If the device does not have its own potential source of ignition then the device will not be regarded as equipment but of course the requirements resulting from Article 1.2 will still apply.

# 4.2 Defining the Group and Category of Equipment

In order to determine the appropriate conformity assessment procedure, the manufacturer must first come to a decision based on the intended use, as to which Group and Category the product belongs. For the purposes of the directive equipment, including where necessary devices and components, is divided into two Groups. Devices have to be assessed according to the category of the equipment or protective system they are required for or contributing to.

**Group I** comprises equipment intended for use in the underground parts of mines, and to those parts of surface installations of such mines, likely to become endangered by firedamp and/or combustible dust;

**Group II** comprises equipment intended for use in other places likely to become endangered by explosive atmospheres.

These Groups are sub-divided into Categories, as shown below. The way in which this categorisation has been developed highlights one of the main distinctions of Group I and II. For Group I, the categorisation depends on (amongst other factors) whether the product is to be de-energised in the event of an explosive atmosphere occurring. For Group II, it depends where (see chapter 4.4) the product is intended to be used in and whether a potentially explosive atmosphere, is always present, or is likely to occur for a long or a short period of time.

Devices have to be assessed according to the category of the equipment or protective system they are required for or contributing to.

#### 4.2.1 Group I

#### Category M1

Products of this Category are required to remain functional for safety reasons when an explosive atmosphere is present and is characterised by integrated explosion protection measures functioning in such a way that:

- in the event of failure of one integrated measure, at least a second means of protection provides for a sufficient level of safety; or,
- in the event of two faults occurring independently of each other, a sufficient level of safety is ensured.<sup>31</sup>

#### Category M2

These products are intended to be de-energised in the event of an explosive atmosphere.

It is nonetheless foreseeable that explosive atmospheres could occur during the operation of Category M2 equipment, as the equipment might not be de-energised immediately. It is therefore necessary to incorporate protection measures, which provide a high level of safety. The protection measures relating to products of this Category provide a sufficient level of safety during normal operation even in the event of more severe operating conditions arising, from rough handling and changing environmental conditions.<sup>32</sup>

#### **4.2.2** Group II

**Category 1** comprises products designed to be capable of remaining within its operational parameters, stated by the manufacturer, and ensuring a <u>very high level of protection</u> for its intended use in areas in which explosive atmospheres caused by mixtures of air and gases, vapours, mists or air/dusts mixtures are **highly likely** to occur and are present continuously, for long periods of time or frequently (see chapter 4.4).

Equipment of this Category is characterised by integrated explosion protection measures functioning in such a way that:

- in the event of a failure of one integrated measure, at least a second independent means of protection provides for a sufficient level of safety; or,
- in the event of two faults occurring independently of each other a sufficient level of safety is ensured<sup>33</sup>.

Products relating to this Category must also comply with the supplementary requirements as detailed at Annex II, paragraph 2.0.1 of the directive 94/9/EC.

Products relating to this Category must also comply with the supplementary requirements as detailed at Annex II, paragraph 2.0.2 of the directive 94/9/EC.

Products relating to this Category must also comply with the supplementary requirements as detailed at Annex II, paragraph 2.1 of the directive 94/9/EC.

**Category 2** comprises products designed to be capable of remaining within their operational parameters, stated by the manufacturer, and based on a <u>high level of protection</u> for their intended use, in areas in which explosive atmospheres caused by mixtures of air and gases, vapours, mists or air/dust mixtures are **likely** to occur (see chapter 4.4).

The explosion protection relating to this Category must function in such a way as to provide a sufficient level of safety even in the event of equipment with operating faults or in dangerous operating conditions which normally have to be taken into account<sup>34</sup>.

Category 3 comprises products designed to be capable of keeping within its operational parameters, stated by the manufacturer, and based upon a <u>normal level of protection</u> for its intended use, considering areas in which explosive atmospheres caused by mixtures of air and gases, vapours, mists or air/dust mixtures are **less likely** to occur and if they do occur, do so infrequently and for a short period of time only.

The design of the products of this category must provide a sufficient level of safety during normal operation<sup>35</sup>.

Products relating to this Category must also comply with the supplementary requirements as detailed at Annex II, paragraph 2.2 of the directive 94/9/EC.

Products relating to this Category must also comply with the supplementary requirements as detailed at Annex II, paragraph 2.3 of the directive 94/9/EC.

#### 4.2.3 Levels of Protection for various Categories of Equipment

The various categories of equipment must be capable of functioning in conformity with the operational parameters established by the manufacturer to a certain level of protection.

Table 3: Levels of Protection

LEVEL OF	CATEGORY		PERFORMANCE OF	CONDITIONS OF OPERATION*	
PROTECTION			PROTECTION		
	GROUP I	GROUP II			
Very High	M 1		Two independent means of protection or safe even when two faults occur independently of each other.	Equipment remains energized and functioning when explosive atmosphere present	
Very High		1	Two independent means of protection or safe even when two faults occur independently of each other.	Equipment remains energized and functioning in Zones 0,1,2 (G) and/or 20, 21, 22 (D)	
High	M 2		Suitable for normal operation and severe operating conditions <sup>36</sup>	Equipment de-energised when explosive atmosphere present	
High		2	Suitable for normal operation and frequently occurring disturbances or equipment where faults are normally taken into account	Equipment remains energized and functioning in Zones 1, 2 (G) and/or 21, 22 (D)	
Normal		3	Suitable for normal operation	Equipment remains energized and functioning in Zone 2 (G) and/or 22 (D)	

\*Note: See as well directive 1999/92/EC on minimum requirements for improving the safety and health protection of workers operating in potentially explosive atmospheres<sup>3</sup> The equipment in the various categories must also comply with the relevant essential and supplementary requirements detailed in Annex II of the directive (Essential Health and Safety Requirements).

OJ L23, 28.1.2000

Although the wording of the requirements of equipment of category M2 and 2 is different in the relevant annexes of directive 94/9/EC, both these categories are dealt with in EN 50014 and specific standards in parallel. The technical protection concepts for category M2 and (gas) electrical apparatus according to EN 50014 series are identical. The requirements for category 2D (dust) might have to be considered separately.

#### 4.3 Risk Assessment for Products

In general it can be stated that compliance with the Essential Health and Safety Requirements of directive 94/9/EC is imperative in order to ensure the explosion proofing of equipment and protective systems. The requirements are intended to take account of existing or potential hazards deriving from the design and construction. However, following the philosophy of ATEX directive 94/9/EC the notion of intended use is of prime importance too. It is also essential that manufacturers supply full information.

To meet the requirements of directive 94/9/EC it is therefore absolutely necessary to conduct a risk assessment process. According to Annex II, 1.0.1 manufacturers are under an obligation to design equipment and protective systems from the point of view of integrated explosion safety. Integrated explosion safety is conceived to prevent the formation of explosive atmospheres as well as sources of ignition and, should an explosion nevertheless occur, to halt it immediately and / or to limit its effects. In this connection, the manufacturer must take measures with respect to the risks of explosion. In addition, as required in Annex II, 1.0.2 of the directive, equipment and protective systems must be designed and manufactured after <u>due analysis</u> of possible operating faults in order as far as possible to preclude dangerous situations.

Bearing in mind the commitments resulting from the relevant requirements of directive 94/9/EC requirements, a methodology on risk assessment should not only deal with designing and construction aspects but also provide a <u>common format or language</u> between designers and users.

#### Methods and/or techniques that could be applied

There are many possible methods and/or techniques for risk assessment, especially for hazard identification. A good identification technique has the following attributes:

- it is systematic, i.e. it guides the parties concerned so that all parts of the system, all phases of use and all reasonably anticipated hazards are considered;
- it employs brainstorming.

By using more than one technique the possibility of overlooking any relevant hazard is minimised. However, the additional time employed in using more than one technique needs to be balanced against the increased confidence in the results. The main output from the hazard identification stage is a numbered listing of hazardous events, which could result from the products involved as an input to the risk estimation stage.

Risk assessment methodology should comprise the risk profiles including the accidental parameters that can reasonably be anticipated. These aspects become subject to a risk assessment as a "series of logical steps to enable, in a systematic way, the examination of the hazards associated with products".

In principle the risk assessment comprises of four steps<sup>38</sup>:

- a) Hazard identifications: A systematic procedure for finding all of the hazards, which are associated with the products. Once a hazard has been recognized, the design can be changed to minimise it, whether or not the degree of risk has been estimated. Unless the hazard is recognized it cannot be addressed in the design.
- **Risk estimation:** Determination of the Probability of occurrence of the identified hazards and of the levels of severity of the possible harm of the considered hazards (see as well EN 1050).
- **Risk evaluation:** Comparison or the risk estimated with criteria in order to decide whether the risk is acceptable or whether the product design must be modified in order to reduce the risk.

For further information on risk assessment see EN 1127-1 –1997: Explosive atmospheres – Explosion prevention and protection – Part 1: Basic concepts and methodology

d) Risk reduction option analysis: The final step of risk assessment is the process of identifying, selecting and modifying design changes which might reduce the overall risk from products. Although risks can always be reduced further they can seldom be reduced to zero except by eliminating the activities.

Options, which address the hazardous events that make the greatest contributions to the total risk, have the greatest potential to reduce risk. Effectiveness in reducing risk always starts with changes to the design concept, i.e. inherently safe design.

#### 4.4 Classification

The classification of equipment Group I applies to equipment situated 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 classification applies to equipment intended for use in other places liable to be endangered by explosive atmospheres (industry). Manufacturers of products for use in potentially explosive atmospheres must give all details regarding groups and categories (see chapter 4.2) to decide in which zones their product could be used in, but they cannot anticipate what zones will exist. Classification of hazardous areas into zones is a task for the user whose premises/work activities contain or create such hazards.

Directive 1999/92/EC on minimum requirements for improving the safety and health protection of workers operating in potentially explosive atmospheres defines the various zones for gases, vapours and dusts.

# 5. EQUIPMENT SPECIFICALLY EXCLUDED FROM DIRECTIVE 94/9/EC

These exclusions are based on Article 1.4, laid down in directive 94/9/EC:

- medical devices intended for use in a medical environment;
- equipment and protective systems where the explosion hazard results exclusively from the presence of explosive substances or unstable chemical substances;
- 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;
- personal protective equipment covered by directive 89/686/EEC<sup>39</sup>. There are occasions where personal protective equipment with its own potential sources of ignition is intended for use in potentially explosive atmospheres. This type of personal protective equipment should follow the procedures laid down in directive 94/9/EC to provide the necessary level of explosion safety (see as well chapter 6);
- seagoing vessels and mobile offshore units together with equipment on board such vessels or units, because they are already covered by the IMO Convention. However, fixed offshore units together with equipment on board, and units and vessels, which are not considered to be seagoing (i.e. below 500 tonnes, not intended for high sea but intended for internal navigation on river, ship canal, lakes), are in the scope of directive 94/9/EC;

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OJ No L 399, 30.12. 1989, amended by Directive 93/95/EEC, OJ No L 276, 9.11.1993 and Directive 93/68/EEC OJ No L 220, 30.8.1993

- means of transport i.e. vehicles and their trailers intended solely for transporting passengers by
  air, road, rail or water networks, as well as means of transport in so far as such means are
  designed for transporting goods by air, by public road or rail networks or by water. Vehicles
  intended for use in a potentially explosive atmosphere shall not be excluded;
- equipment covered by Article 296 (1)(b) of the EC Treaty, i.e. designed and manufactured specifically for use by the armed forces or in the maintenance of law and order. Dual-purpose equipment is not excluded.

# 6. APPLICATION OF DIRECTIVE 94/9/EC ALONGSIDE OTHERS THAT MAY APPLY

In principle if a product is within the scope of other directives at the same time, all directives have to be applied in parallel to fulfil the special requirements of each directive.

In the case of directive 94/9/EC and the directive relating to **Electromagnetic Compatibility 89/336/EEC** (EMC), the directive 94/9/EC has to be applied to fulfil the requirements concerning "explosive atmospheres" safety requirements. The EMC directive must also be applied so as to ensure that the product does not cause electromagnetic disturbance and that its normal operation is not affected by such disturbances. There will be some applications, where the "normal" level for electromagnetic immunity provided by directive 89/336/EEC might not be sufficient for granting the necessary immunity level for safe performance under the scope of Directive 94/9/EC. In this case the manufacturer is required to specify the electromagnetic immunity achieved by his products according to Annex II 1.2.7 of directive 94/9/EC. For example, protective systems where the performance of data acquisition and data transmission may have direct influence on explosion safety.

Products for use <u>in</u> potentially explosive atmospheres are explicitly excluded from the scope of the **Low Voltage directive 73/23/EEC (LVD)**. All "Low Voltage essential objectives" have to be covered by the directive 94/9/EC (see Annex II 1.2.7). The standards published in the Official Journal of the European Communities with reference to directive 73/23/EEC may be listed in the declaration of conformity to fulfil the requirements 1.2.7 of Annex II of directive 94/9/EC. Not excluded from the scope of the LVD are the safety, controlling and regulating devices mentioned in article 1(2) of the directive 94/9/EC which are intended for use outside potentially explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems. In such cases both directives shall be applied.

The relation between directive 94/9/EC and the **Machinery directive 98/37/EC** is different. The directive 94/9/EC, which is a specific directive within the meaning of Article 1(4) of the Machinery directive, contains very specific and detailed requirements to avoid hazards due to potentially explosive atmospheres, while the Machinery directive itself contains only very general requirements against explosions (Annex I, 1.5.7 Machinery directive). With regard to explosion protection in a potentially explosive atmosphere directive 94/9/EC takes precedence and has to be applied. For other relevant risks concerning machines, the requirements of the Machinery directive also have to be applied.

In order to avoid possible overlapping with **Council directive 94/55/EC on transport of dangerous goods by road** most means of transport have been excluded from the scope of directive 94/9/EC (Art. 1 (4)). Generally, those vehicles still included in 94/9/EC do not leave the user's premises. Typical examples are means of transport on rails used in gassy mines, forklift trucks and other mobile machinery where the internal combustion engine, braking systems and electrical circuits may be potential sources of ignition.

It is possible for both directives to be applied in parallel. For example, where the manufacturer designs and constructs a means of transportation intended for transporting dangerous (in this case flammable) goods on public roads as well as for use in areas where explosive atmospheres may exist.

The equipment covered by the **Personal Protective Equipment (PPE) directive 89/686/EEC** is specifically excluded from directive 94/9/EC. However, the manufacture of PPE for use in explosive atmospheres is covered by Basic Health and Safety Requirement 2.6 in Annex II of the PPE directive. PPE intended for use in explosive atmospheres must be so designed and manufactured that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite. Following the EHSRs in directive 94/9/EC would be one way to demonstrate compliance.

Beside the above directives it is necessary to mention the relation of the ATEX directive 94/9/EC to the **Construction Products directive (CPD) 89/106/EEC**. During the standardisation work for both directives it was identified that (in a few areas) the scopes of both directives could overlap. The areas already identified where:

- explosion protection systems and fire suppression systems use the same media;
- both areas are using common hardware for distribution systems such as pipes, pipe hangers, nozzles, etc.

In general, it can be stated that in cases of doubt the Construction Products directive is applicable if the subject under discussion is fixed to a building and becomes then a part of the building or if it can be seen as a building itself (e.g. a silo). In such instances the CPD and the ATEX directive 94/9/EC apply in parallel. Compliance with the EHSRs of directive 94/9/EC will in general show compliance with the EHSRs of the CPD regarding explosion risks.

In this context it is important to note, that a Notified Body is only allowed to cover aspects related to two or more directives if the Body is notified under all these directives with an appropriate scope.

# 7. APPLICATION OF DIRECTIVE 94/9/EC TO USED, REPAIRED OR MODIFIED PRODUCTS AND TO SPARE PARTS 40

As a general rule, manufacturers need to consider whether the product is being placed onto the EU market or taken into service for the first time, or if the modifications are such that the intention or the result is to place a product onto the market, which has to be considered as a new product. If the answer to either of these questions is yes, then directive 94/9/EC fully applies. In all other cases the directive 94/9/EC does not apply and the responsible person will have to ensure that any other relevant national or EU legislation are considered as appropriate.

Within this context two points should be made:

- In the following paragraphs, these guidelines refer only to products for which directive 94/9/EC is potentially applicable. Products not subject to directive 94/9/EC are therefore excluded from these discussions.
- The application of directive 94/9/EC to an "as new" product is without any prejudice to intellectual property legislation. 41

The application of the ATEX Directive to a "as-new equipment" is without any prejudice to intellectual property legislation. See Directive 89/104/EEC relating to the marks and the decision of the European Court of 11th July 1996, C427/93, 429/93, 436/93 Bristol Meyer Squibb.

See directive 89/104EEC relating to the marks and the decision of the European Court of Justice of 11 July 1996 in Joined Gases C-427/93 and C-436/93 Bristol Meyer Squibb.

#### **Definitions**

**Used product and second hand product: a product** which has been placed on the EU market prior to the coming into force of directive 94/9/EC (see chapter 1.2) and put into service on the EU territory. This product was in compliance with the then applicable legislation: national or EU, depending on the date<sup>42</sup>. **The ATEX Directive 94/9/EC does not apply.** 

Used products that were on the market and used in the EU before the date of entry into force of directive 94/9/EC are not covered by it. These products have been marketed and used in accordance with the regulations in force at that time. They circulate in the EU based on Articles 28/30 of the EC Treaty unless they are modified so that they become "as-new products".

For used products imported from a non EU country and made available for the first time in the EU after 30 June 2003 for the purpose of distribution and/or use in the EU directive 94/9/EC shall apply.

**Reconditioned** (or **refurbished**<sup>43</sup>) **products**: these are used products which were on the market and used in the EU but whose performance has changed over time (due to ageing, obsolescence, etc.), and which have been modified so as to be **restored**. The case of products whose external appearance has been modified and improved by a cosmetic or aesthetic operation after they have been placed on the market and put into service is a particular form of refurbishment aimed at restoring the external appearance of the product<sup>44</sup>. If this occurs **with no substantial modification directive 94/9/EC does not apply.** 

**Reconfigured products:** reconfigured products are used products which were on the market and used in the EU but whose configuration has been modified, by the addition (upgrading) or the removal (downgrading) of one or more parts (components, sub-assemblies such as plug-in cards or modules, etc.). If this occurs with no substantial modification directive 94/9/EC does not apply.

**Substantial modification**: In the sense of directive 94/9/EC it is any modification affecting one or more of the EHSRs (e.g. temperature) or the integrity of a type protection (as defined in EN 50014). In this case **directive 94/9/EC has to be applied** (see situation regarding transitional period, chapter 1.2). **This does not preclude the application of other relevant directives.** 

The general principle is that directive 94/9/EC re-applies to a modified product where the modification is considered to be substantial and if it is intended to be placed again on the EU market for distribution and/or use.

**Repaired products**: These are products whose functionality has been restored following a defect without adding new features or any other modification. As this occurs after the product has been placed on the market and the product is not to be sold as a new product:

The ATEX Directive 94/9/EC does not apply.

This does not preclude that national regulations of the Member States on the working environment may require some kind of assessment of the repaired product as well.

**A spare part**: This is any item intended to replace a defective or worn out part of a product previously placed and put into service on the EU market. A typical repair operation would be replacement by a spare part.

Both terms, reconditioned / refurbished, as well as reconditioning / refurbishment are used interchangeably in this chapter.

See chapter 1 of this guide for transitional periods.

This can involve a modification of the electrostatic characteristics. The use of different materials or different external dimensions of the product might adversely change its ATEX performances. For example, a plastic enclosure may provide much lower electrostatic protection than a metallic enclosure.

If the manufacturer of the original spare part offers a new, different one in its place (due to technical progress, discontinued production of the old part, etc.), and it is used for the repair, the **repaired product** (as long as no substantial modification of the repaired product takes place) **does not need to be brought into conformity at this time with** directive 94/9/EC as the repaired product is not then placed on the market and put into service.

However, the manufacturer of the spare part is normally not required to comply with directive 94/9/EC unless the spare part represents an equipment or component as defined by the directive.

# 8. CONFORMITY ASSESSMENT PROCEDURES

#### 8.1 Products conforming to directive 94/9/EC

**Article 8** of the directive describes the procedures whereby the manufacturer or his authorised representative established within the EU ensures and declares that the product complies with directive 94/9/EC.

**Article 8.1(a)** describes the procedures in the case of equipment; autonomous protective systems; for safety devices for such equipment or systems; and for components for such equipment, systems or devices, under Groups I and II, Categories M1 and 1. The options are either:

- (i) EC-type examination<sup>45</sup> (Module B)<sup>46</sup> followed by:
  - production quality assurance<sup>47</sup> (Module D) or,
  - product verification<sup>48</sup> (Module F);
- (ii) Unit verification<sup>49</sup>(Module G).

**Article 8.1(b)** describes the procedure in the case of equipment, for safety devices as described in article 1(2) for such equipment and for components of such equipment or devices, under Groups I and II, Categories M2 and 2. The options are either:

#### For electrical equipment and internal combustion engines of Categories M2 and 2:

- (i) EC-type examination (Module B) followed by:
  - conformity to type50 (Module C) or,
  - product quality assurance51 (Module E)
- (ii) Unit verification (Module G).

See Annex III of the Directive.

See Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives (OJ No L 220 30.8.1993)

See Annex IV of the Directive.

See Annex V of the Directive.

See Annex IX of the Directive.

See Annex VI of the Directive.

See Annex VII of the Directive.

#### For other equipment of Categories M2 and 2:

- (i) Internal control of production (Module A) and deposit the technical documentation<sup>52</sup> with a Notified Body<sup>53</sup>, or,
- (ii) Unit verification (Module G).

**Article 8.1(c)** describes the procedure in the case of equipment; for safety devices for such equipment; and for components for such equipment and devices under Group II, Category 3. The options are either:

- (i) Internal control of production (Module A) or,
- (ii) Unit verification (Module G).

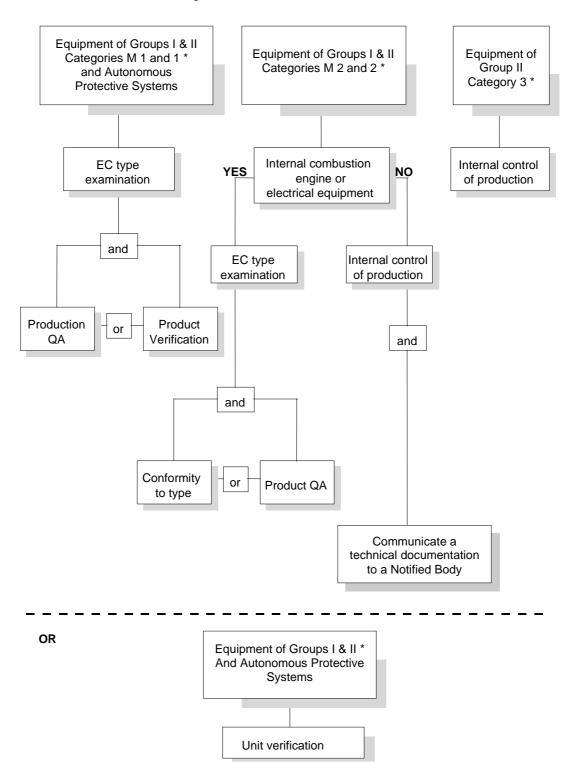
Further detail on each of these modules of conformity procedure can be found in the "Guide to the implementation of directives based on New Approach and Global Approach" (see footnote 19), and a chart showing the appropriate procedure is provided overleaf:

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See paragraph 3 of the Annex relating to the internal control of production.

Conditions of storage of documents shall be agreed between the Notified Body and its client.

# **Conformity Assessment Procedures**



# (\*) and their components if separately certified

Note: According to Article 8.4 for all equipment and protective systems of all groups and categories conformity to 1.2.7 of Annex II of the directive (protection against other hazards) can be fulfilled by following the procedure of internal control of production (Annex VIII).

# 8.2 Quality Assurance and verification at stage of manufacture

The conformity procedures outlined in chapter 8.1 involving EC-type examination also require that the manufacturer shall use a quality management system for production quality assurance or product quality assurance which has been assessed and approved by a Notified Body chosen by the manufacturer.

The requirements of the quality system are contained in item 3.2 of Annexes IV and VII of directive 94/9/EC. The Notified Body shall presume conformity with these requirements in respect of quality systems, which implement the relevant harmonised standards. <u>Prior evaluation</u> of a manufacturer's quality management system must be taken into due account in the assessment by the Notified Body which will assess how the quality system ensures compliance with the type as described in the EC-type-examination certificate and with the requirements of the Directive which apply.

<u>Alternatively, depending on the route of compliance chosen by the manufacturer</u>, the Notified Body shall undertake surveillance of manufacture in relation to the following production modules:

**Product verification** (Annex V): Undertake examination and tests of every product to check the conformity of the equipment, protective system or device with the requirements of directive 94/9/EC and draw up a certificate of conformity.

**Conformity to type (Annex VI)**: Be responsible for having tests carried out on each piece of equipment manufactured to check the explosion protection aspects of the design.

**Unit verification** (**Annex IX**): Examine individual equipment or protective system and carry out tests as defined in the harmonised standards, if they exist, or otherwise in European, international or national standards or conduct equivalent tests to ensure conformity with the relevant requirements of directive 94/9/EC and draw up a certificate of conformity.

# 8.3 Exceptional derogations of the Conformity Assessment Procedures<sup>54</sup>

All equipment and protective systems referred to in Article 1 (1) including components and the devices referred to in Article 1 (2) are covered by the provisions of Article 8 (5).

This article gives the competent authority of the relevant Member State the possibility, in exceptional circumstances, to authorise the placing on the market and putting into service products where the Conformity Assessment Procedures have not been applied. This exception is possible:

- following a duly justified and successful request to the competent authority of the relevant Member State: and.
- if the use of the product is in the interests of protection of health and safety, and where, for example, such interests would be hindered by the delay associated with Conformity Assessment Procedures; and,
- is restricted to the territory of the Member State concerned.

This provision could be applied in safety relevant cases, in which the products in question are needed urgently and there is insufficient time to undergo the complete Conformity Assessment Procedures (or to complete these procedures). The intention is to give Member States (in the interest of health and safety) the possibility to allow the placing on the market and putting into service innovative products without delay. Even in such cases the essential requirements of the directive must be fulfilled.

With regard to the restrictive application conditions it has to be emphasised that the use of this clause has to remain exceptional and must not become a normal procedure. In the interests of transparency

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and to assist administrative co-operation Member States are encouraged to provide the competent Commission services with details of any use of Article 8(5).

# 9 DESIGNATION OF NOTIFIED BODIES

Annex XI of directive 94/9/EC defines the criteria that these bodies must fulfil. Bodies which are able to provide proof of their conformity with Annex XI by presenting to their Competent Authorities a certificate of accreditation and evidence that all additional requirements have been met or other means of documentary proof as defined below, are considered notifiable and in this respect they conform to Annex XI of the directive. The appropriate (voluntary) harmonised standards of the EN 45000 series provide useful and appropriate mechanisms towards presumption of conformity to Annex XI. However, this does not rule out the possibility that bodies not conforming to the harmonised standards may be notified, on the grounds that compliance is obligatory only with respect to the criteria set out in Annex XI to the directive.

Notified Bodies provide the professional and independent judgements, which consequently enable manufacturers or their authorised representatives to fulfil the procedures in order to presume conformity to directive 94/9/EC. Their intervention is required

- for issuing of EC-type examination certificates, and for inspection, verification and testing of equipment, protective systems, devices and components before they can be placed on the market and/or put into service;
- for the assessment of manufacturer's quality assurance system in the production phase.

The bodies responsible for undertaking the work referred to in Article 8 of the directive must be notified by the Member State under whose jurisdiction they fall, on their own responsibility to the Commission and the other Member States of the EU. This notification also includes the relevant scope of competence for which that body has been assessed as technically competent to certify against the Essential Health and Safety Requirements as shown in the directive. For the Member States of the EU, this responsibility of notification involves the obligation to ensure that the Notified Bodies permanently maintain the technical competence required by directive 94/9/EC and that they keep their notifying authorities informed about the performance of their tasks.

Therefore, a Member State of the EU, which does not have a technically competent body under its jurisdiction to notify, is not required to make such a notification. This means that a Member State of the EU which does not have such a body is not required to create one if it does not feel the need to do so. A manufacturer always has the choice of contacting any body with the appropriate scope of technical competence, which has been notified by a Member State.

On their own responsibility Member States reserve the right not to notify a body and to remove an appointment. In the latter circumstance the relevant Member States shall inform the Commission and all other Member States.

For further information concerning Notified Bodies, e.g. testing, inspection facilities and sub-contracting, please see the "Guide to the implementation of directives based on New Approach and Global Approach".

#### 10. DOCUMENTS OF CONFORMITY

# 10.1 Documents issued by the manufacturer

# 10.1.1 EC Declaration of Conformity<sup>55</sup>

Once the <u>manufacturer</u> has undertaken the appropriate procedures to assure conformity with essential requirements of the directive it is the responsibility of the manufacturer or his authorised representative established in the EU to affix the CE marking and to draw up a written EC declaration of conformity.

The manufacturer or his authorised representative established within the EU keeps a copy of this EC declaration of conformity for a period of ten years after the last equipment has been manufactured.

Where neither the manufacturer nor his authorised representative is established within the EU, the obligation to keep the copy of the EC declaration of conformity available is the responsibility of the person who places the product on the EU market.

#### 10.1.2 Written Attestation of Conformity for Components

The EC declaration of conformity should not be confused with the <u>written attestation of conformity for components</u> mentioned in Article 8(3) of directive 94/9/EC. In addition to declaring the conformity of the components with the provisions of the directive, the written attestation of conformity has to state the characteristics of the components and how the components are to be incorporated into equipment or protective systems to ensure that the finished equipment or protective system meets the applicable Essential Health and Safety Requirements of directive 94/9/EC.

# 10.1.3 Documents accompanying the product

According to Articles 4(2) and 5(1) of directive 94/9/EC and for the purposes of market surveillance the EC declaration of conformity / the written attestation of conformity must accompany the information given with each single product or each batch of identical products.

# 10.2 Documents issued by the Notified Body

The EC type examination certificate is issued by the Notified Body as described in Annex III of the directive.

In addition the Notified Body may also issue the following documents according to the provisions of the relevant conformity assessment procedures:

- quality assurance notifications;
- conformity to type notification;
- product verification certificates;
- unit verification certificates;
- certificate of conformity.

These documents need not to accompany the product.

See Annex IV paragraph 1, Annex V. paragraph 2, Annex VI paragraph 1, Annex VII paragraph 1, Annex VIII paragraph 1, Annex IX paragraph 1 of the Directive.

# 11. MARKING OF EQUIPMENT

# 11.1 CE Marking

As a general rule New Approach directives including directive 94/9/EC provide for the affixing of the CE marking as part of the conformity assessment procedures in the perspective of total harmonisation. The conformity assessment procedures to be applied are described in the relevant New Approach directives, based on the conformity assessment procedures as defined by Council Decision 93/465/EEC. Where a product is subject to several directives, which all provide for the affixing of CE marking, the marking indicates that the product is presumed to conform to the provisions of all these directives. During the transitional period of a New Approach directive the manufacturer has the choice to either meet the requirements of this directive or the previous relevant regulations. The option chosen, and hence the extent of the conformity expression enshrined in the CE marking, must be indicated by the manufacturer in the accompanying documents.

As this guide has been especially drafted to facilitate the application of directive 94/9/EC, the following explanations refer only to this directive. If other directives are applicable in parallel, their provisions have to be taken into account in addition to those of directive 94/9/EC. 56

CE marking is used by the manufacturer as a declaration that he considers that the product in question has been manufactured in conformity with all applicable provisions and requirements of directive 94/9/EC and that the product has been the subject of the appropriate conformity assessment procedures.

The CE marking is mandatory and must be affixed before any equipment or protective system is placed on the market or put into service. As stated in Article 8 (3) components are excluded from this provision. Instead of being CE marked, components have to be delivered with a written attestation stating the conformity with the provisions of the directive, stating their characteristics and indicating how they must be incorporated into equipment or protective systems. This separate statement goes along with the definition of components, which have as structural parts no autonomous function.

In general the CE marking must be affixed during the production control phase by the manufacturer or his authorised representative established within the Community. In certain cases it is possible to affix the CE marking earlier, e.g. during the production phase of a complex product (e.g. a vehicle). It is then necessary that the manufacturer formally confirms the compliance of this product with the requirements of the directive in the production control phase. The CE marking must consist of the initials 'CE' taking the form described in Annex X of directive 94/9/EC. In general the CE marking must be affixed to the product or to its data plate. However, although it is not a requirement in directive 94/9/EC, it is considered reasonable to affix the CE marking to the packaging and to the accompanying documents if it is not possible to affix it to the product because of the product's size or nature.

It would be sensible, but it is not mandatory, to affix the CE marking to more than one place, for example, marking the outer packaging as well as the product inside, would mean that the marking can be ascertained without opening the package.

However, during the transitional period some products will be in compliance with the "Old Approach" directives concerning electrical equipment for use in potentially explosive atmospheres as well as in conformity with for example the EMC directive. These products bear the CE marking and can be used in potentially explosive atmospheres even though directive 94/9/EC has not been applied.

The CE marking shall be affixed distinctly, visibly, legibly and indelibly. It is prohibited to affix any marks or inscriptions that are likely to mislead third parties as to the meaning and form of the CE marking. The requirement for visibility means that the CE marking must be easily accessible for market surveillance authorities as well as visible for customers and users. For reasons of legibility a minimum height of 5 mm of the CE marking is required. This minimum dimension may be waived for small-scale products. The requirement for indelibility means that the marking must not be removed from the product without leaving traces noticeable under normal circumstances.

Depending on the conformity assessment procedure applied, a Notified Body may be involved in the design phase (Annex III), the production phase (Annexes IV, V, VI, VII, IX) or in both phases. The identification number of the Notified Body only has to accompany the CE marking if the Body is involved in the production control phase (see Article 10(1) of directive 94/9/EC). The CE marking and the identification number of the Notified Body do not necessarily have to be affixed within the territory of the Community. These can be affixed in a third country if the product, for example, is manufactured there and the Notified Body either performed tests on the product type or assessed the quality assurance system of the manufacturer in that country. The CE marking and the identification number can also be affixed separately, so long as the CE and body-number remain combined. In case of components only the identification number of the Notified Body has to be affixed.

Where equipment that has already been placed on the market is incorporated into a product, the integrated equipment must bear the CE marking and, if appropriate, the identification number of the Notified Body.

Whilst it is recognised that sub assemblies may have CE marking affixed in their own right these might not be visible following construction of the final product. This is acceptable as this information can be found elsewhere. However, the final product must have a single label clearly relating to its final assembly prior to it being placed on the market and/or taken into service. In affixing the CE marking to the final product the manufacturer or his authorised representative accepts full responsibility for the conformity of the final product to the applicable Essential Health and Safety Requirements of directive 94/9/EC and all other relevant directives.

#### 11.2 **Supplementary Marking**

#### 11.2.1 Specific Marking

Equipment, protective systems and components must bear the specific marking of explosion protection, the Ex in a hexagon, which is already well known from the old "explosive atmosphere" directives<sup>57</sup>. This marking has to be followed by the symbol of the Group and Category (on devices according to Article 1(2) of directive 94/9/EC the category should be indicated in brackets) and, relating to 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:

 $(E_X)_{IM2}$ Mining products, Group I, Category M2 ⟨€x⟩ <sub>II 1 G</sub>

Non-Mining products, Group II, Category 1 for use in gas/vapour/mist atmospheres

II 1 D Non-Mining products, Group II, Category 1 for use in dust – atmospheres Protective system, for use in gas/vapour/mist/dust - atmospheres

II (1) G D device according to Article 1(2) of directive 94/9/EC in the non-hazardous area with intrinsically safe circuits of category "Ex ia", which can be connected e.g. to

> category 1 equipment apparatus, which is installed in the boundary between different Zones, e.g.

**€**x II 1/2 G complying partly with category 1 and category 2

All products must be marked with name and address of the manufacturer, designation of series or type, serial number (if any) and the year of construction.

Council directives 76/117/EEC and 79/196/EEC, last modified by directive 97/53/EC, for surface equipment and Council directive 82/130/EEC, last modified by directive 98/65/EC, for mining equipment.

Where a product is covered by more than one New Approach directive, CE marking denotes compliance with the appropriate provisions of all relevant directives. However, where one or more of these directives are in their transitional period and, as a consequence, allow the manufacturer to choose which arrangements to apply, the CE marking indicates conformity only to those directives where application is mandatory and others which are so applied. In the case of these latter directives particulars must be given in the documents, notices or instructions accompanying the product or, where appropriate, on the data plate.

It is the intention of directive 94/9/EC that the design of the specific marking  $\stackrel{\text{Ex}}{}$  would follow the design, which was laid down in directive 84/47/EEC. Although there is no requirement in directive 94/9/EC it is recommended to continue to use the established design.

#### 11.2.2 Additional Marking

Because of the special importance for safety of products intended for use in potentially explosive atmospheres and in order to avoid any misunderstandings directive 94/9/EC provides for additional markings (see Annex II 1.0.5. Marking).

It is stated in Annex II 1.0.5 of the directive that equipment, protective systems and components must furthermore be marked with all necessary information essential to the safe use. According to this requirement the European standard series EN 50014 for electrical products for potentially explosive atmospheres foresees a supplementary marking. For detailed and complete information about marking according to the requirements of the European standards for electrical products it is necessary to use this standard series, which contain a number of useful examples. Most important are:

- the symbol EEx to indicate that the product is in compliance with one or more standards of this series
- the symbol for each type of protection used (o, p, q, d, e, ia, ib, m, etc.)
- explosion groups I, IIA, IIB, or IIC in case of type of protection d, i or q
- the symbol indicating the temperature class or the maximum surface temperature

For protection of electrical equipment used in potentially explosive gas atmospheres standard EN 50014 gives the general requirements. The standard for each different type of protection is symbolised by a letter as follows:

- « o » for oil immersion according EN 50015;
- « p » for pressurization according EN 50016;
- « q » for powder filling according EN 50017;
- « d » for flameproof enclosure according EN 50018;
- « e » for increased safety according EN 50019;
- « ia » or « ib » for intrinsic safety according EN 50020;
- « m » for encapsulation according EN 50028.

Electrical equipment shall conform to EN 50014 and one or more types of protection.

Further standards for electrical equipment categories 1 and 3 (EN 50021, EN 50284) are available.

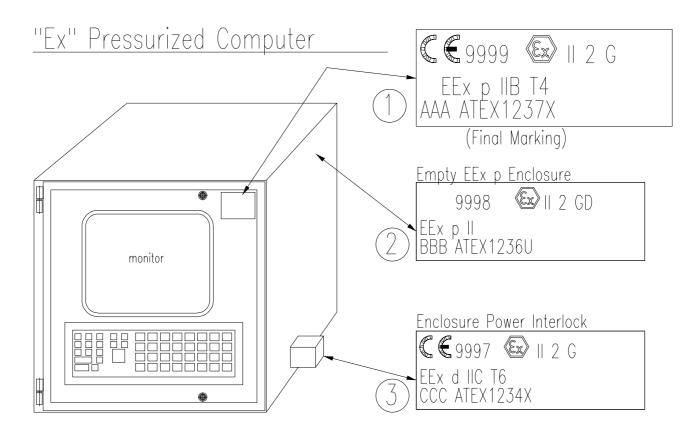
Comparable standards for mechanical products are still under development.

#### 11.2.3 Marking of small products

In accordance with the guidance given to the CE marking of products, it is also considered reasonable to affix all other marking to the packaging and the accompanying documents if it is not possible to affix it to the product because of the product's size or nature.

# 11.3 Examples for Marking<sup>58</sup>

Examples of marking on equipment and components are shown in the following illustration.



The system comprises a computer, which is adapted for safe use in a potentially explosive atmosphere by being contained within a pressurized atmosphere, within an enclosure, which also contains the pressurization control system and an interlock that will only allow power to be supplied when the enclosure has been purged. Power to the system is provide via a sealed cable gland. The system is designed in conformity with the pressurization protection standard "p" (EN 50016)

Other marking referred to in the directive, as for instance name and address of the manufacturer, date of manufacture, etc. are not shown in this example but nevertheless

required.

For each of the certified items of equipment the information in the boxes comprises:

1<sup>st</sup> line: marking according to 94/9/EC:

- CE marking on equipment, indicating compliance with directive 94/9/EC (not on components),
- identification number of the Notified Body involved in the production control stage,
- hexagon symbol, the specific marking of explosion protection,
- symbol of Group and Category and type of hazard, gas (G) or dust (D),
- serial number,
- year of construction unless it can be clearly identified from the serial number.

2<sup>nd</sup> line: additional marking according to standards to which the equipment conforms, as in EN 50014

- In cases where the manufacturer has not applied a standard it is recommended in the interest of safe use that the symbols of the Group and the temperature classification of electrical apparatus according to standard EN 50014, but without indication of EEx, should be marked (e.g. II C T4).

3<sup>rd</sup> line: marking according to certification:

- code of the Notified Body (e.g. AAA),
- year of issue (e.g. 98),
- issue of certificate (ATEX),
- number of certificate,
- X, if applicable, indicating that specific conditions apply as detailed in the certificate,
- U, if applicable, indicating that the item is a component.

# 12. SAFEGUARD CLAUSE<sup>59</sup> AND PROCEDURE

The safeguard clause referred to in Article 7 of the directive is the EU procedure whereby any measure taken by a Member State, on the grounds of non-compliance with the Essential Health and Safety Requirements and where it is deemed that equipment is liable to endanger persons, animals or property for the purpose of withdrawing from the market, prohibiting the placing on the market or restricting the free movement of equipment accompanied by one of the means of attestation provided for in the directive and therefore bearing the CE marking, must be immediately notified to the Commission by the Member State which has taken it.

In considering whether the safeguard clause should be triggered, Member States and the respective enforcement authorities will need to consider whether the non-compliance is substantial or can be considered a non-substantial non-compliance to be resolved without recourse to the procedures enabled via the safeguard mechanism.

For a detailed analysis of the "Safeguard clause", see the "Guide to implementation of the Community harmonisation Directives based on the New Approach and the Global Approach", sheet I/E, Chapters 2, 3, 4.

For example, a non-substantial non-compliance could consist of illegibility of the CE marking. In such cases, the Member State could issue a compliance notice to the manufacturer or authorised representative or take other actions allowed by national legislation to encourage the responsible person(s) to take appropriate corrective action.

Member States will need to consider in each case whether the non-compliance is liable to endanger persons, animals or property and if the safeguard clause is the most effective means of ensuring the safety of persons, animals or property, which remains paramount under this section of the directive.

Any notification, which fulfils the criteria of invoking the safeguard clause, is followed by a process of consultation between the Commission and the "parties concerned". The "parties concerned" primarily means all Member States of the EU, the manufacturer or his authorised representative established within the EU or, failing them, the person who placed the product on the EU market.

The consultation procedure enables the Commission, on the basis of the above reasons, to assess whether the restrictive measure is justified. This means that the measures notified to the Commission must be accompanied by detailed information specifying in particular the reasons why the Essential Health and Safety Requirements laid down in the directive have not been complied with by the product concerned.

Where the Commission finds, following such consultation, that the measures are justified, it immediately informs the Member State which took the initiative and the other Member States. In the Commission's view, the objective of informing the other Member States is to prompt these Member States to take appropriate measures in accordance with Article 3 of the directive.

Where the Commission finds that the measures, adopted by the Member State are not justified, it will ask that Member State to withdraw its measures and immediately to take the appropriate action to reestablish the free movement of the products in question on its territory. If a Member State refuses to follow the Commission's position the Commission reserves the right to proceed under Article 226 of the EC Treaty.<sup>60</sup>

In order to ensure transparency and the proper uniform application of the safeguard clause, Article 7.4 states that "the Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure".

In addition to this provision the directive foresees in Article 6 (1) a specific Standards Safeguard Clause. Where a Member State or the Commission considers that a harmonised standard does not fully meet the Essential Health and Safety Requirements of the directive they shall bring the matter before a special Committee set up under directive 98/34 EC<sup>61</sup>. The Committee shall examine the case and deliver an opinion to the Commission. In the light of this opinion the Commission shall inform Member States wether or not it is necessary to withdraw the references to those standards from the published information.

If the State concerned does not comply with the opinion within the period laid down by the Commission, the latter may bring the matter before the Court of Justice.

Article 226 of the EC Treaty: If the Commission considers that a Member State has failed to fulfil an obligation under this Treaty, it shall deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations.

Directive 98/34/EC of the European Parliament and the Council laying down a procedure for the provision of information in the field of technical standards and regulations; OJ No L 204, 21.7.1998, p. 37-48

# 13. HARMONISED EUROPEAN STANDARDS

Directive 94/9/EC provides manufacturers with the option of complying with its requirements by designing and manufacturing directly in accordance with the Essential Health and Safety Requirements, or to harmonised standards which are developed specifically to allow a presumption of conformity with those requirements. In other words, in the case of a challenge, the responsible national authorities will have to prove that the equipment is not in conformity with the Essential Health and Safety Requirements of the directive.

The presumption of conformity is conferred, in regulatory terms, only by the use of the national standards transposing a harmonised standard the reference of which is published in the OJEC. Where the relevant national standardisation body has not transposed the standard, use of the original harmonised standard or of a transposed standard in another Member of the EU confers the same presumption of conformity. However, such transposition must have taken place into the national standards collection of at least one of the Member States of the European Community.

Industry and many Notified Bodies are involved in the development of these standards and it is likely that these standards will be the preferred option for demonstrating compliance once they become available.

In the absence of harmonised standards, manufacturers may decide to use existing European, national and other technical standards and specifications regarded as important or relevant to cover the relevant essential requirements, together with additional controls addressing those other requirements not already covered. In view of the ongoing work still being carried out and the current availability of standards under directives 79/196/EEC and 82/130/EEC as amended it is recognised that this is also a useful route towards a presumption of conformity in the short-term.

The Notified Bodies have internally agreed to consider the following documents when assessing the conformity of a product to the Essential Health and Safety Requirements. The order of preference is from 1 down to 10 (the highest ranking is 1!):

- 1. Applicable harmonised standards
- 2. CENELEC/CEN published 2nd edition
- 3. Applicable EN standards 1st edition
- 4. Final EN projects ex : EN 50014 pr A1
- 5. EN projects
- 6. Applicable National standards (UK,D,Fr,It,..)
- 7. Interface documents CLC/CEN (if any)
- 8. Applicable ISO/IEC documents
- 9. Local testing procedure from a NB
- 10. Other available standards or part of standards (USA, Japan,...)

# 13.1 Standards published in the Official Journal

By way of information, Annex 5 contains a reference list of Harmonised European Standards that are to be published in the EC's Official Journal.

European standards are available from:

- CEN, rue de Stassart, 36, 1050 Bruxelles;
- CENELEC, rue de Stassart, 35, 1050 Brussels.

National transpositions of harmonised standards are available from the national standardisation bodies (see Annex 5).

The list of harmonised standards published in the Official Journal is also available at the following Internet address:

http://www2.echo.lu/nasd/

# 13.2 Standardisation Programme

Annexes 6 and 7 detail the two standardisation programmes addressed to the European standardisation bodies. Each one is the subject of a standardisation mandate drawn up by the European Commission.

The European Commission has granted a mandate to CEN/CENELEC to produce European standards. The mandate covers the standardisation work necessary for the optimum functioning of the directive in both the electrical and mechanical field.

The mandate requires intensive co-operation between CEN and CENELEC to carry out the following work:

- **1.** To review and, where appropriate, modify existing standards with a view to aligning them with the Essential Health and Safety Requirements of the directive;
- **2.** To establish the new standards required, giving priority to horizontal standards, which apply to broad ranges of products, rather than to specific products, with the need for them to be demonstrated on a case-by-case basis.

To carry out their mandate CEN established a new technical committee CEN/TC 305 "Potentially explosive atmospheres - explosion prevention and protection". Four Working Groups carry out the detailed work:

To carry out their mandate CENELEC allocated the work to TC 31 "Electrical Apparatus for Explosive Atmospheres", and its sub-committees. These Committees have been working in the potentially explosive atmosphere field for a considerable number of years and have produced a series of Standards under the Old Approach directive.

CENELEC and CEN are responsible for the preparation of standards of the electrical and non-electrical sectors of industry respectively. They have the responsibility to ensure that:

- there is uniform interpretation of the New Approach directive for potentially explosive atmospheres, and other relevant directives;
- safety requirements for the electrical and non-electrical sectors are compatible where they overlap, and the levels of safety sought are equivalent;
- The preparation of standards in the future by one of the organisations satisfactorily reflects the needs of the other, and vice versa.

Annex 1	Text of directive 94/9/EC	Pages 44 to 75
Annex 2	National measures transposing directive 94/9/EC	Pages 76 to 78
Annex 3.1	List of competent authorities known to the Commission regarding market surveillance of Directive 94/9/EC in Member States and EEA countries	Pages 79 to 84
Annex 3.2	Central contact points in charge of implementation of directive 94/9/EC in Member States and EEA countries	Pages 85 to 87
Annex 4	List of the Notified Bodies	Pages 88 to 97
Annex 5	List of Harmonised Standards	Pages 98 to 100
Annex 6	Standardisation programme issued by the Commission for preparation of harmonised standards under directive 94/9/EC relating to non-electrical equipment	Pages 101 to 102
Annex 7	Standardisation programme issued by the Commission for preparation of harmonised standards under directive 94/9/EC relating to electrical equipment	Pages 103 to 105
Annex 8	Questions and answers on the application of directive 94/9/EC including those concerning the Essential Health and Safety Requirements	Pages 106 to 113
Annex 9	Useful addresses	Pages 114 to 120

#### Annex 1

# DIRECTIVE 94/9/EC OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of 23 March 1994

on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres

# THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION.

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1).

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure referred to in Article 189b of the Treaty establishing the European Community,

Whereas it is the duty of Member States to protect, on their territory, the safety and health of persons and, where appropriate, domestic animals and property and, in particular, that of workers, especially against the hazards resulting from the use of equipment and systems providing protection against potentially explosive atmospheres;

Whereas mandatory provisions within the Member States determine the level of safety to be achieved by protective equipment and systems intended for use in potentially explosive atmospheres;

Whereas these are generally electrical and nonelectrical specifications having an effect on the design and structure of equipment which can be used in potentially explosive atmospheres;

Whereas the requirements to be met by such equipment differ from one Member State to another in respect of their extent and differing inspection procedures;

Whereas these differences are, therefore, likely to raise barriers to trade within the Community;

Whereas harmonization of national legislation is the only way in which to remove these barriers to free trade; whereas this objective cannot be satisfactorily achieved by the individual Member States; Whereas this Directive merely lays down the requirements vital to freedom of movement for the equipment to which it applies;

Whereas the regulations intended to remove technical barriers to trade are required to follow the new approach provided for in the Council resolution of 7 May 1985 (3), which requires a definition of the essential requirements regarding safety and other requirements of society without reducing existing, justified levels of protection within the Member States:

Whereas that resolution provides that a very large number of products be covered by a single Directive in order to avoid frequent amendments and the proliferation of Directives;

Whereas the existing Directives on the approximation of the laws of the Member States to electrical equipment for use in potentially explosive atmospheres have made positive steps towards protection against explosions via measures linked with the structure of the equipment at issue and which have helped to remove barriers to trade in this area;

Whereas, in parallel, a revision and expansion of the existing Directives is necessary since, more particularly, in an overall context, action must be taken to guard against the potential hazards arising from such equipment. This implies in particular that measures intended to guarantee effective protection of users and third parties must already be contemplated at the design and manufacturing states;

Whereas the form taken by the hazard, the protective measures and the test methods are often very similar, if not identical, for both mining and surface equipment; whereas it is, therefore, absolutely necessary to cover by a single Directive protective equipment and systems falling within both groups;

(3) OJ No. C 136, 04.06.1985, p. 1

<sup>(1)</sup> OJ No. C 46, 20.2.1992, p. 19

<sup>(2)</sup> OJ No. C 106, 27.4.1992, p. 9

Whereas the two groups of equipment referred to above are used in a large number of commercial and industrial sectors and possess considerable economic significance;

Whereas compliance with the basic safety and health requirements is essential in order to ensure the safety of protective equipment and systems; whereas those requirements have been subdivided into general and additional requirements which must be met by protective equipment and systems; whereas, in particular, the additional requirements are intended to take account of existing or potential hazards; whereas protective equipment and systems will, therefore, embody at least one of those requirements where this is necessary for their proper functioning or is to apply to their intended use; whereas the notion of intended use if of prime importance for the explosion-proofing of protective equipment and systems; whereas it is essential that manufacturers supply full information; whereas specific, clear marking of said equipment, stating its use in a potentially explosive atmosphere, is also necessary;

Whereas the intention is to prepare a Directive on operations in potentially explosive atmospheres which is based on Article 118a; whereas that additional Directive will, in particular, aim at explosion hazards which derive from a given use and/or types and methods of installation;

Whereas compliance with essential health and safety requirements is imperative if the safety of equipment is to be ensured; ,whereas judgement will have to be exercised in the implementation of those requirements in order to take account of both the technology obtaining at the time of manufacture and overriding technical and economic requirements;

Whereas, therefore, this Directive sets out essential requirements only; whereas, in order to facilitate the task of proving compliance with the essential requirements, harmonized European standards are necessary, more especially with regard to the nonelectrical aspects of protection against explosions standards relating to the design, manufacture and testing of equipment, compliance with which enables product to be presumed to meet such essential requirements; whereas harmonised European standards are drawn up by private bodies and must retain their non-mandatory status; whereas, for this purpose, the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are recognised as the bodies competent to adopt harmonized standards which follow the general

guidelines for cooperation between the Commission and those two bodies, signed on 13 November 1984; whereas, for the purposes of this Directive, a harmonised standard is a technical specification (European Standard or harmonization document) adopted by one or other of those bodies, or by both, at the prompting of the Commission pursuant to Council Directive 83/189/EEC of the 28 March 1983 providing for a procedure governing the provision of information on technical standards and regulations (1) and pursuant to the general guidelines referred to above:

Whereas the legislative framework should be improved in order to ensure that employers and workers make an effective and appropriate contribution towards the standardization process; whereas this should be completed by the time this Directive is implemented;

Whereas, in view of the nature of the risks involved in the use of equipment in potentially explosive atmospheres it is necessary to establish procedures applying to the assessment of compliance with the basic requirements of the Directives; whereas these procedures must be devised in the light of the level of risk which may be inherent in equipment and/or against which systems must protect the immediate environment; whereas, therefore, each category of equipment conformity must be supplemented by an adequate procedure or a choice between several equivalent procedures; whereas the procedures adopted comply fully with Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization Directives (2);

Whereas the Council has provided for the affixing of the CE marking by either the manufacturer or his authorized representative within the Community; whereas that marking means that the product complies with all the basic requirements and assessment procedures provided for by the Community law applying to that product;

<sup>(1)</sup> OJ No. L 109, 26.4.1983, p. 8. Directive as last amended by Directive 88/182/EEC (OJ N° L 81, 26.03.1988, p. 75)

<sup>(2)</sup> OJ No. L 220, 30.08.1993, p. 23

provided for by Article 100a of the Treaty, may take temporary measures to limit or prohibit the placing on the market and the use of equipment and protective systems in cases where they present a particular risk to the safety of persons and, where appropriate, domestic animals or property, provided that the measures are subject to a Community control procedure;

Whereas the recipients of any decision taken as part of this Directive must be aware of the reasons behind that decision and the means of appeal open to them;

Whereas, on 18 December 1985, the Council adopted a framework Directive on electrical equipment for use in potentially explosive atmospheres (76/117/EEC) (1) and, on 15 February 1982, a Directive concerning electrical equipment for use in potentially explosive atmospheres in mines susceptible to fire damp (82/130/EEC) (2); whereas, from the outset of harmonization work, the conversion into total harmonization of the optional and partial harmonization on which these Directives are based had been contemplated; whereas this Directive fully covers the scope of the above mentioned Directives and whereas, therefore, these Directives must be repealed;

Whereas the internal market incorporates an area without internal frontiers within which the free movement of goods, persons, services and capital is assured;

Whereas it is necessary to provide for a transitional arrangement enabling equipment manufactured in compliance with the national regulations in force at the date of adoption of this Directive to be marketed and placed in service,

#### HAVE ADOPTED THIS DIRECTIVE:

#### CHAPTER I

# Scope, placing on the market and freedom of movement

# Article 1

- 1. This Directive applies to equipment and protective guidelines for cooperation between systems intended for use in potentially explosive atmospheres.
- 2. Safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion are also covered by the scope of this Directive.
- 3. For the purposes of this Directive, the following definitions shall apply: Equipment and protective systems intended for use in potentially explosive atmospheres
- (a) 'Equipment' means machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy for the processing of material and which are capable of causing an explosion through their own potential sources of ignition.
- (b) 'Protective systems' means 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.
- (c) 'Components' means any item essential to the safe functioning of equipment and protective systems but with no autonomous function.

<sup>(1)</sup> OJ No. L 24, 31.1.1976, p. 45 as last amended by Directive 90/487/EEC (OJ N° L 270, 02.10.1990, p. 23)

<sup>(2)</sup> OJ No. L 59, 02.03.1982, p. 10

#### Explosive atmospheres

Mixture with air, under atmospheric conditions, of flammable substances in the form of gases, vapours, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture.

Potentially explosive atmosphere

An atmosphere which could become explosive due to local and operational conditions.

Equipment groups and categories

Equipment group I applies to 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.

Equipment group II applies to equipment intended for use in other places liable to be endangered by explosive atmospheres.

The categories of equipment defining the required levels of protection are described in Annex I.

Equipment and protective systems may be designed for a particular explosive atmosphere. In this case, they must be marked accordingly.

# Intended use

The use of equipment, protective systems, and devices referred to in Article 1 (2) in accordance with the equipment group and category and with all the information supplied by the manufacturer which is required for the safe functioning of equipment, protective systems and devices.

- 4. The following are excluded from the scope of this Directive: medical devices intended for use in a medical environment,
- equipment and protective systems where the explosion hazard results exclusively from the presence of explosive substances or unstable chemical substances,
- equipment intended for use in domestic and noncommercial environments where potentially explosive atmospheres may only rarely be created, solely as a result of the accidental leakage of fuel gas,
- personal protective equipment covered by Directive 89/686/EEC (1),

- seagoing vessels and mobile offshore units together with equipment on board such vessels or units,
- means of transport, i.e. vehicles and their trailers intended solely for transporting passengers by air or by road, rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, by public road or rail networks or by water. Vehicles intended for use in a potentially explosive atmosphere shall not be excluded.
- the equipment covered by Article 223 (1) (b) of the Treaty.

#### Article 2

- 1. Member States shall take all appropriate measures to ensure that the equipment, protective systems and devices referred to in Article 1 (2) to which this Directive applies may be placed on the market and put into service only if, when properly installed and maintained and used for their intended purpose, they do not endanger the health and safety of persons and, where appropriate, domestic animals or property.
- 2. The provisions of this Directive shall not affect Member States' entitlement to lay down, in due observance of the provisions of the Treaty, such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected when using the equipment, protective systems, and devices referred to in Article 1 (2) in question provided that this does not mean that such equipment, protective systems, or devices are modified in a way not specified in the Directive.
- 3. At trade fairs, exhibitions, demonstrations, etc., Member States shall not prevent the showing of equipment, protective systems, or the devices referred to in Article 1 (2) which do not conform to the provisions of this Directive, provided that a visible sign clearly indicates that such equipment, protective systems, and devices referred to in Article 1 (2) do not conform and that they are not for sale until they have been brought into conformity by the manufacturer or his authorized representative established in the Community. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons.

#### Article 3

Equipment, protective systems, and the devices referred to in Article 1 (2) to which this Directive applies must meet the essential health and safety requirements set out in Annex II which apply to them, account being taken of their intended use.

#### **Article 4**

- 1. Member States shall not prohibit, restrict or impede the placing on the market and putting into service in their territory of equipment, protective systems, or devices referred to in Article 1 (2) which comply with this Directive.
- 2. Member States shall not prohibit, restrict or impede the placing on the market of components which, accompanied by a certificate of conformity as referred to in Article 8 (3), are intended to be incorporated into equipment or protective systems within the meaning of this Directive.

# Article 5

- 1. Member States shall regard as conforming to all the provisions of this Directive, including the relevant conformity assessment procedures laid down in chapter II:
- equipment, protective systems, and devices referred to in Article 1 (2) accompanied by the EC declaration of conformity referred to in Annex X and bearing the CE marking provided for in Article 10,
- the components referred to in Article 4 (2), accompanied by the certificate of conformity referred to in Article 8 (3). In the absence of harmonized standards, Member States shall take any steps which they deem necessary to bring to the attention of the parties concerned the existing national technical standards and specifications regarded as important or relevant to the proper implementation of the essential health and safety requirements in Annex II.
- 2. Where a national standard transposing a harmonized standard, the reference for which has been published in the Official Journal of the European Communities, covers one or more of the essential health and safety requirements, the equipment, protective system, device referred to in Article 1 (2), or the component referred to in Article 4 (2), constructed in accordance with that standard shall be presumed to comply with the relevant essential health and safety requirements.

Member States shall publish the references of national standards transposing harmonized standards.

3. Member States shall ensure that appropriate measures are taken to enable the social partners to influence the process of preparing and monitoring the harmonized standards at national level.

#### **Article 6**

1. Where a Member State or the Commission considers that the harmonized standards referred to in Article 5 (2) do not entirely satisfy the relevant essential health and safety requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Committee set up under Directive 83/189/EEC, hereinafter referred to as 'the Committee', giving reasons therefor. The Committee shall deliver an opinion without delay.

Upon receipt of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the published information referred to in Article 5 (2).

- 2. The Commission may adopt any appropriate measure with a view to ensuring the practical application in a uniform manner of this Directive in accordance with the procedure laid down in paragraph 3.
- 3. The Commission shall be assisted by a Standing Committee, consisting of representatives appointed by the Member States and chaired by a representative of the Commission.

The Standing Committee shall draw up its own rules of procedure.

The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

4. The Standing Committee may furthermore examine any question relating to the application of this Directive and raised by its chairman either on the latter's initiative, or at the request of a Member State.

#### Article 7

- 1. Where a Member State ascertains that equipment, protective systems or devices referred to in Article 1 (2) bearing the CE conformity marking and used in accordance with their intended use are liable to endanger the safety of persons and, where appropriate, domestic animals or property, it shall take all appropriate meaures to withdraw such equipment or protective systems from the market, to prohibit the placing on the market, putting into service or use thereof, or to restrict free movement thereof. The Member State shall immediately inform the Commission of any such measure, indicating the reasons for its decision and, in particular, whether nonconformity is due to:
- (a) failure to satisfy the essential requirements referred to in Article 3;
- (b) incorrect application of the standards referred to in Article 5 (2); (c) shortcomings in the standards referred to in Article 5 (2).
- 2. The Commission shall enter into consultation with the parties concerned without delay. Where the Commission considers, after this consultation, that the measure is justified, it shall immediately so inform the Member State which took the initiative and the other Member States. Where the Commission considers. after this consultation, that the action is unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorized representative established within the Community. Where the decision referred to in paragraph 1 is based on a shortcoming in the standards and where the Member State at the origin of the decision maintains its position, the Commission shall immediately inform the Committee in order to initiate the procedures referred to in Article 6 (1).
- 3. Where equipment or a protective system which does not comply bears the CE conformity marking, the competent Member State shall take appropriate action against the person(s) having affixed the marking and shall so inform the Commission and the other Member States.
- 4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

#### CHAPTER II

#### Conformity assessment procedures

# Article 8

- 1. The procedures for assessing the conformity of equipment, including where necessary the devices referred to in Article 1 (2), shall be as follows:
- (a) equipment-group I and II, equipment-category M 1 and 1

The manufacturer or his authorized representative established in the Community must, in order to affix the CE marking, follow the CE type-examination procedure (referred to in Annex III), in conjunction with: - the procedure relating to production quality assurance (referred to in Annex IV),

- or the procedure relating to product verification (referred to in Annex V);
- (b) Equipment-group I and II, equipment-category M 2 and 2
- (i) In the case of internal combustion engines and electrical equipment in these groups and categories, the manufacturer or his authorized representative established in the Community shall, in order to affix the CE mark, follow the EC-type examination procedure (referred to in Annex III), in conjunction with: the procedure relating to conformity to type referred to in Annex VI, or
- the procedure relating to product quality assurance referred to in Annex VII;
- (ii) in the case of other equipment in these groups and categories, the manufacturer or his authorized representative established in the Community must, in order to affix the CE mark, follow the procedure relating to internal control of production (referred to in Annex VIII)

and

communicate the dossier provided for in Annex VIII, paragraph 3, to a notified body, which shall acknowledge receipt of it as soon as possible and shall retain it.

(c) equipment-group II, equipment-category 3

The manufacturer or his authorized representative established in the Community must, in order to affix the CE marking, follow the procedure relating to internal control of production referred to n Annex VIII;

#### (d) equipment-groups I and II

In addition to the procedures referred to in paragraph 1(a), (b) and (c), the manufacturer or his authorized representative established in the Community may also, in order to affix the CE marking, follow the procedure relating to CE unit verification (referred to in Annex IX).

- 2. The provisions of 1(a) or 1(d) above shall be used for conformity assessment of autonomous protective systems.
- 3. The procedures referred to in paragraph 1 shall be applied in respect of components as referred to in Article 4 (2), with the exception of the affixing of the CE marking. A certificate shall be issued by the manufacturer or his authorized representative established in the Community, declaring the conformity of the components with the provisions of this Directive which apply to them and stating their characteristics and how they must be incorporated into equipment or protective systems to assist compliance with the essential requirements applicable to finished equipment or protective systems.
- 4. In addition, the manufacturer or his authorized representative established in the Community may, in order to affix the CE marking, follow the procedure relating to internal control of production (referred to in Annex VIII) with regard to the safety aspects referred to in point 1.2.7 of Annex II.
- 5. Notwithstanding the previous paragraphs, the competent authorities may, on a duly justified request, authorize the placing on the market and putting into service on the territory of the Member State concerned of the equipment, protective systems and individual devices referred to in Article 1 (2) in respect of which the procedures referred to in the previous paragraphs have not been applied and the use of which is in the interests of protection.
- 6. Documents and correspondence relating to the procedures referred to in the above mentioned paragraphs shall be drawn up in one of the official languages of the Member States in which those procedures are being applied or in a language accepted by the notified body.

- 7. (a) Where the equipment and protective systems are subject to other Community Directives covering other aspects which also provide for the affixing of the CE marking referred to in Article 10, that marking shall indicate that the equipment and protective systems are also presumed to conform with the provisions of those other Directives.
- (b) However, where one or more of those Directives 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 said Directives, 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 the equipment and protective systems.

#### Article 9

- 1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the procedures referred to in Article 8, together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission. The Commission shall publish in the Official Journal of the European Communities a list of the notified bodies, with their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.
- 2. Member States shall apply the criteria laid down in Annex XI in assessing the bodies to be indicated in such notification. Bodies meeting the assessment criteria laid down in the relative harmonized standards shall be presumed to fulfil those criteria.
- 3. A Member State which has approved a body must withdraw its notification if it finds that the body no longer meets the criteria referred to in Annex XI. It shall immediately inform the Commission and the other Member States accordingly.

#### **CHAPTER III**

# CE conformity marking

# Article 10

- 1. The CE conformity marking shall consist of the initials 'CE'. The form of the marking to be used is shown in Annex X. The CE marking shall be followed by the identification number of the notified body where such body is involved in the production control stage.
- 2. The CE marking shall be affixed distinctly, visibly, legibly and indelibly to equipment and protective systems, supplementary to the provisions of point 1.0.5. of Annex II.
- 3. 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.

#### **Article 11**

Without prejudice to Article 7:

- (a) where a Member State establishes that the CE marking has been incorrectly affixed, the manufacturer or his authorized representative established within the Community shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Member State;
- (b) in the event of continuing non-conformity, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.

#### **CHAPTER IV**

#### Final provisions

# **Article 12**

Any decision taken pursuant to this Directive which restricts or prohibits the placing on the market and/or the putting into service or requires the withdrawal from the market of equipment, a protective system, or a device referred to in Article 1 (2) shall state the exact grounds on which it is based. Such a decision shall be notified forthwith to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.

#### **Article 13**

Member States shall ensure that all the parties involved in the application of the Directive are bound to observe confidentiality in respect of all information obtained in the performance of carrying out their tasks. This does not affect the obligations of the Member States and of the notified bodies regarding reciprocal information and the dissemination of warnings.

# Article 14

- 1. Directive 76/117/EEC, Directive 79/196/EEC (1) and Directive 82/130/EEC shall be repealed as from 1 July 2003.
- 2. EC certificates of conformity to the harmonized standards obtained in accordance with the procedures laid down in the Directives referred to in paragraph 1 shall continue to be valid until 30 June 2003 unless they expire before that date. Their validity shall continue to be limited to the harmonized standards indicated in the aforementioned Directives.

<sup>(1)</sup> OJ N $^{\circ}$  L 43, 20.2.1979, p. 20. Directive as last amended by Directive 90/487/EEC (OJ N $^{\circ}$  L 270, 02.10.1990, p. 23)

the assessment of the conformity of electrical equipment placed on the market before 1 July 2003 take account of the results of tests and verifications already carried out under the Directives referred to in paragraph 1.

# **Article 15**

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive before 1 September 1995. They shall forthwith inform the Commission thereof. The Member States shall apply these measures with effect from 1 March 1996. When Member States adopt the measures referred to in the first subparagraph, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such reference shall be laid down by Member States. 2. However, Member States shall allow the placing on the market and the putting into service of equipment and protective systems conforming with the national regulations in force in their territory at the date of adoption of this Directive for the period until 30 June 2003.

#### **Article 16**

This Directive is addressed to the Member States.

Done at Brussels, 23 March 1994.

For the European Parliament The President E. KLEPSCH

For the Council The President TH. PANGALOS

#### ANNEX I OF DIRECTIVE 94/9/EC

# CRITERIA DETERMINING THE CLASSIFICATION OF EQUIPMENT-GROUPS INTO CATEGORIES

#### 1. Equipment-group I

(a) 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 characterized 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 II, 2.0.1.

(b) 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-energized 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 II, 2.0.2.

# 2. Equipment-group II

- (a) 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 characterized 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 II, 2.1.

(b) 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 II, 2.2.

(c) 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 II, 2.3.

#### ANNEX II OF DIRECTIVE 94/9/EC

# 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 utilized immediately.
- B. For the devices referred to in Article 1 (2), 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 X, point A),
- designation of series or type,
- serial number, if any,
- year of construction,
- the specific marking of explosion protection (x) 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 authorized 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 authorized 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 authorized 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 1 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-energized 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 M 1 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 positional 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, which 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.

#### ANNEX III OF DIRECTIVE 94/9/EC

#### MODULE EC-TYPE EXAMINATION

- 1. This module 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 Directive.
- 2. The application for the EC-type examination shall be lodged by the manufacturer or his authorized 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 authorized 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, 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 authorized 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 effect 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 authorized 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 authorized 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.

# ANNEX IV OF DIRECTIVE 94/9/EC

# MODULE: PRODUCTION QUALITY ASSURANCE

- 1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 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 Directive which apply to them. The manufacturer, or his authorized 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 organizational 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 harmonized 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 authorized 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 text 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.

# ANNEX V OF DIRECTIVE 94/9/EC

#### MODULE: PRODUCT VERIFICATION

- 1. This module describes the procedure whereby a manufacturer or his authorized representative established within the Community checks and attests that the equipment subject to the provisions of point 3 are in conformity with the type as described in the EC-type-examination certificate and satisfy the relevant requirements of the 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 authorized 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), with the relevant requirements of the Directive, by examining and testing every product as specified in Section 4.

The manufacturer or his authorized 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 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 authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

#### ANNEX VI OF DIRECTIVE 94/9/EC

#### MODULE: CONFORMITY TO TYPE

- 1. This module describes that part of the procedure whereby the manufacturer or his authorized 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 Directive applicable to them. The manufacturer or his authorized 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 authorized 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 authorized 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.

# ANNEX V OF DIRECTIVE 94/9/EC

# MODULE: PRODUCT VERIFICATION

- 1. This module describes the procedure whereby a manufacturer or his authorized representative established within the Community checks and attests that the equipment subject to the provisions of point 3 are in conformity with the type as described in the EC-type-examination certificate and satisfy the relevant requirements of the 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 authorized 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), with the relevant requirements of the Directive, by examining and testing every product as specified in Section 4.

The manufacturer or his authorized 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 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 authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

#### ANNEX VI OF DIRECTIVE 94/9/EC

#### MODULE: CONFORMITY TO TYPE

- 1. This module describes that part of the procedure whereby the manufacturer or his authorized 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 Directive applicable to them. The manufacturer or his authorized 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 authorized 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 authorized 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.

#### ANNEX VII OF DIRECTIVE 94/9/EC

# MODULE: PRODUCT QUALITY ASSURANCE

- 1. This module 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 authorized 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 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 organizational 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 harmonized 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 authorized 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.

#### ANNEX VIII OF DIRECTIVE 94/9/EC

#### MODULE: INTERNAL CONTROL OF PRODUCTION

- 1. This module describes the procedure whereby the manufacturer or his authorized 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 Directive applicable to it. The manufacturer or his authorized 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 authorized 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 authorized 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 authorized 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.

#### ANNEX IX OF DIRECTIVE 94/9/EC

#### MODULE: UNIT VERIFICATION

- 1. This module 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 Directive which are applicable to it. The manufacturer or his authorized 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, 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.

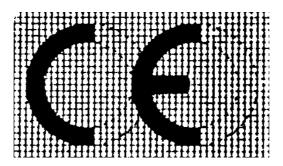
The documentation shall contain:

- 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.

#### ANNEX X OF DIRECTIVE 94/9/EC

#### A. CE Marking

The CE conformity marking shall consist of the initials 'CE' taking the following form:



If the marking is reduced or enlarged, the proportions given in the above graduated drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

This minimum dimension may be waived for small-scale equipment, protective systems or devices referred to in Article 1 (2).

#### B. 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 authorized representative established within the Community;
- a description of the equipment, protective system, or device referred to in Article 1 (2);
- 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 harmonized 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 authorized representative established within the Community.

#### ANNEX XI OF DIRECTIVE 94/9/EC

### MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES

- 1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of equipment, protective systems, or devices referred to in Article 1 (2) which they inspect, nor the authorized representative of any of these parties. They shall become involved neither directly nor as authorized representatives in the design, construction, marketing or maintenance of the equipment, protective systems or devices referred to in Article 1 (2) in question. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
- 2. The body and its inspection staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which may influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
- 3. The body shall have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it shall also have access to the equipment required for special verification.
- 4. The staff responsible for inspection shall have:
- sound technical and professional training;
- satisfactory knowledge of the requirements of the tests which they carry out and adequate experience of such tests;
- the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.
- 5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.
- 6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law or the Member State itself is directly responsible for the tests.
- 7. The staff of the body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.

#### National Provisions communicated by the Member States concerning:

Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres.

#### Austria

Verordnung des Bundesministers für wirtschaftliche Angelegenheiten über Geräte und Schutzsysteme zur bestimmungsgemäßen Verwendung in explosionsgefährdeten Bereichen (Explosionsschutzverordnung 1996 - ExSV 1996), Bundesgesetzblatt für die Republik Österreich, Nr 252/1996, ausgegeben am 11/6/1996.

#### **Belgium**

Arrêté royal du 22 juin 1999 déterminant les garanties de sécurité que doivent présenter les appareils et les systèmes de protection destinés à être utilisés en atmosphères explosibles (Moniteur belge du 25.09.1999). - Koninklijk besluit van 22 juni 1999 tot vaststelling van de veiligheidswaarborgen welke apparaten en beveiligingssystemen, bedoeld voor gebruik op plaatsen waar ontploffingsgevaar kan heersen, moeten bieden (Belgische Staatsblad van 25.09.1999).

#### **Denmark**

Bekendtgørelse nr. 696 af 18/08/1995 om indretning af tekniske hjælpemidler til anvendelse I eksplosionsfarlig atmosfære. Arbejdsmin., Arbejdstilsynet j.nr. 1995-852-219. Lovtidende A hæfte 132 udgivet den 29/08/1995 s.3640.ABEK.

Boligministeriets bekendtgørelse nr. 697 af 18/08/1995 om elektrisk materiel og elektriske sikringssystemer til anvendelse i eksplosionsfarlig atmosfære, Boligmin., Departementet 6.kt.,j.nr. D6-8256-1. Lovtidende A hæfte 132 udgivet den 29/08/1995 s.3665. BBEK.

Lov nr. 251 af 06/05/1993 om elektriske stærkstrømsanlæg og elektrisk materiel. Boligmin.j.nr. D2-6711-2. Lovtidende A hæfte 51 udgivet den 08/05/1993 s.1063. BLOV.

Arbejdsministeriets lovbekendtgørelse nr. 184 af 22/03/1995. Bekendtgørelse af lov om arbejdsmiljø, Arbejdsmin. 3.kt., j.nr. 1992-2100-20. Lovtidende A hæfte 41 udgivet den 31/03/1995 960. ALOV.

Bekendtgørelse nr. 177 af 20/03/1995 om administration m.v. af stærkstrømsloven. Boligmin., Departamentet, 6.kt., j.nr. D6-6713-2: Lovtidende A hæfte 39 udgivet den 28/03/1995 s.867. BBEK.

#### Germany

Zweite Verordnung zum Gerätsicherheitsgesetz und zur Änderung von Verordnungen zum Gerätesicherheitsgesetz vom 12/12/1996, Bundesgesetzblatt Teil I Nr. 65 vom 19/12/1996 Seite 1914.

#### Greece

N° B17081/2964 Protection Appliances and Systems for use in Explosive Atmospheres

#### Spain

Real Decreto número 400/96 de 01/03/1996, por el que se dicta las disposiciones de aplicación de la Directiva del Parlamento Europeo y del Consejo 94/9/CE, relativa a los aparatos y sistemas de protección para uso en atmósferas potencialmente explosivas, Boletín Oficial del Estado número 85 08/04/1996 Página 12903 (Marginal 7800)

#### **France**

Décret Numéro 96-1010 du 19/11/1996 relatif aux appareils et aux systèmes de protection destinés à être utilisés en atmosphère explosive, Journal Officiel du 24/11/1996 Page 17141

#### **Ireland**

European Communities (Equipment and Protective Systems Intended for Use in Explosive Atmospheres) Regulations, 1999, Statutory Instruments number 83 of 1999

#### **Italy**

Legge del 23/02/1995 n. 41, Gazzetta Ufficiale - Serie generale - del 23/02/1995 n. 45

Decreto del Presidente della Repubblica del 23/03/1998 n. 126. Regolamento recante norme per l'attuazione della direttiva 94/9/CE in materia di apparecchi e sistemi di protezione destinati ad utilizzati in atmosfera potenzialmente esplosiva. Gazzetta Ufficiale - Serie generale - del 04/05/1998 n. 101 pag. 5

#### Luxembourg

Règlement grand-ducal du 20/04/1995 concernant les appareils et les systèmes de protection destinés à être utilisés en atmosphères explosibles, Mémorial Grand-Ducal A Numéro 42 du 23/05/1995 Page 1185

Règlement grand-ducal du 20/04/1995 modifiant le règlement grand-ducal du 27/08/1976 portant application de la directive CEE du 19/02/1973 concernant le rapprochement des législations des Etats membres relatives au matériel électrique destiné à être employé dans certaines limites de tension, Mémorial Grand-Ducal A Numéro 42 du 23/05/1995 Page 1180

Règlement grand-ducal du 20/04/1995 modifiant le règlement grand-ducal du 21/04/1993 concernant la compatibilité électromagnétique, Mémorial Grand-Ducal A Numéro 42 du 23/05/1995 Page 1182

Règlement grand-ducal du 20/04/1995 portant adaptation au progrès technique du règlement grand-ducal du 13/08/1992 relatif au matériel électrique utilisable en atmosphère explosible des mines grisouteuses, Mémorial Grand-Ducal A Numéro 42 du 23/05/1995 Page 1183

#### **Netherlands**

Besluit van 18/09/1995, Staatscourant nummer 439 van 1995

Koninklijk besluit van 01/08/1995 tot vaststelling van een algemene maatregel van bestuur ter uitvoering van de Wet op de Gevaarlijke werktuigen (besluit explosievelig materieel), Staatsblad 1995, nr. 379

#### **Portugal**

Decreto-Lei n.º 112/96 de 05/08/1996. Estabelece as regras de segurança e de saúde relativas aos aparelhos e sistemas de protecção destinados a ser utilizados em atmosferas potencialmente explosivas, Diário da República I Série A n.º 180 de 05/08/1996 Página 2328

#### **Finland**

Asetus räjähdysvaarallisiin ilmaseoksiin tarkoitetuista laitteista ja suojausjärjestelmistä/Förordning om utrustning och säkerhetssystem som är avsedda för explosionsfarliga luftblandningar (917/96) 22/11/1996

Kauppa- ja teollisuusministeriön päätös räjähdysvaarallisiin ilmaseoksiin tarkoitetuista laitteista ja suojausjärjestelmistä/Handels- och industriminsiteriets beslut om utrustning och säkerhetssystem som är avsedda för explosionsfarliga luftblandningar (918/96) 27/11/1996

#### Sweden

Elsäkerhetsverkets föreskrifter om elektriska utrustningar för explosionsfarlig miljö, Elsäkerhetsverkets författningssamling (ELSÄK-FS) 1995:6

Arbetarskyddsstyrelsens kungörelse med föreskrifter om utrustningar för explosionsfarlig miljö, Arbetarskyddsstyrelsens författningssamling (AFS) 1995:5

#### **United Kingdom**

The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996, Statutory Instruments number 192 of 1996

Annex 3.1
LIST OF COMPETENT AUTHORITIES KNOWN TO THE COMMISSION REGARDING MARKET SURVEILLANCE OF
DIRECTIVE 94/9/EC IN MEMBER STATES AND EEA COUNTRIES

AUSTRIA	Competent authorities for electrical appliances of group I and II Bundesministerium für wirtschaftliche Angelegenheiten Sektion III Stubenring 1 A-1010 Wien	
	Bundesministerium für wirtschaftliche Angelegenheiten Abteilung IX/4 Landstrasser Hauptstrasse 55-57 A-1030 Wien	Tel:+43-171-100 ext. 8220 Fax:+43-1-7143582 friedrich.birkhan@bmwa.gv.at
	Competent authorities for other equipment of group I Bundesministerium für wirtschaftliche Angelegenheiten Gruppe III/B Landstrasser Hauptstrasse 55-57 A-1030 Wien	
BELGIUM	Ministère des Affaires Economiques ; Administration de l'Energie 16 Boulevard du Roi Albert II B - 1000 Bruxelles	Tel: +32-2-2064520 Fax: +32-2-2065731 jean-pierre.hirschbuhler@mineco.fgov.be
DENMARK	Electrical equipment: Electricitetsraadet Gothersgade 160 DK-1123 Compenhagen K Non-electrical equipment: National Working Environment Authority Landskronagade 33 DK-2100 Copenhagen Ø	Tel: +45-33-732000 Fax: +45-33-732099 er@elraadet.dk  Tel: +45-39-15-2000 Fax: +45-39-15-25-60 Bv1@arbejdstilsynet.dk

GERMANY Tel:+49-228-5272955 Bundesministerium für Arbeit und Sozialordnung, Rochusstraße 1, D - 53107 Bonn Fax:+49-228-5272958 ha.mattes@bma.bund.de Tel:+49-391-5674514 Ministerium für Arbeit, Frauen, Gesundheit und Soziales des Landes Sachsenanhalt Seepark 5-7 Fax:+49-391-5674522 D – 39116 Magdeburg ronald.mewes@ms.lsa-net.de Ministerium für Umwelt und Verkehr Baden-Württemberg Tel.:+49-711-1 26 26 43 Herrn Dipl.-Ing. Dirk von Locquenghien Fax:+49-711-1 26 28 31 Postfach 10 34 39 Dirk.vonlocquenghien@UVM.bwl.de D - 70029 Stuttgart Bayerisches Staatsministerium für Arbeit und Sozialordnung, Familie, Frauen und Gesundheit, Abteilung II, Tel.: +49-89-12 61 13 86 Winzererstr. 9 Fax: +49-89-12 61 20 83 D - 80 797 München Abt-2@stmas.bayern.de Landesamt für Arbeitsschutz, Gesundheitsschutz und technische Sicherheit Tel.: +49-30-90 21 50 00 Alt-Friedrichsfelde 60 Fax: +49-30-90 21 53 01 D - 10315 Berlin LAGetSI.Berlin@gmx.de Landesinstitut für Arbeitsschutz und Arbeitsmedizin Tel.:+49-03 31 86 83 0 Horstweg 57 Fax +49-03 31 86 43 35 D-14 478 Postdam Liaa.office@liaa.brandenburg.de Senator für Arbeit Tel.:+49-421-361 1 06 96/60 02 Frau Schleicher/Herr Jahn Fax:+49-421-361 1 66 38 Faulenstrasse 69 Office@arbeit-gwa.bremen.de D - 28 195 Bremen

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Hessisches Sozialministerium Herrn Dübbelde Dostojewskistr. 4 D - 65 187 Wiesbaden

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Fax:+49-0385-588 90 63

Sozialministeriium Mecklenburg-Vorpommern Wederstrasse 124 D-19055 Schwerin Herr Schössow

> Tel.:+49-0511 1 20 30 66/30 69 Fax:+49-0511-1 20 29 99

Niedersächsisches Ministerium für Frauen, Arbeit und Soziales Herrn Bonnet/Herr Heming Gustav-Bratlke-Allee 2 D-30169 Hannover

> Tel.:+49-211-86 18 35 79 Fax:+49-211-86 18 37 34

Ministerium für Arbeit, Soziales und Stadtentwicklung, Kultur und Sport Herr Küpper D-40190 Düsseldorf

Friedrich.Kuepper@massks.nrw.de

Landesamt für Arbeitsschutz und Arbeitsmedizin Postfach 2 24 D-98 502 Suhl	Tel.:+49-36 81-73 52 01 Fax:+49-36 81-73 52 09 <u>Lafas-lasf-thueringen@t-online.de</u>
Ministerium für Arbeit, Gesundheit und Soziales Herr Janke Adolf-Westphal-Strasse 4 D-24 143 Kiel	Tel.:+49-04 31 988 56 31 Fax :+49-04 31 988 54 16
Sächsisches Staatsministerium für Wirtschaft und Arbeit Herr Wiederhold/Frau Franke Wilhelm-Buck-Strasse 2 D-01097 Dresden	Tel.:+49-0351-5 64 85 50 Fax:+49-0351-5 64 85 09 FRANKBER@SMWA1.SMWA.SACHS EN.DE
Ministerium für Frauen, Arbeit, Gesundheit und Soziales Herr Rink Franz-Josef-Röderstrasse 23 D-66 119 Saarbrücken	Tel.:+49-0681-501 33 97 Fax:+49-0681-501 33 02 <u>Arbeitsschutz@mifags.saarland.de</u>
Landesamt für Umweltschutz und Gewerbeaufsicht Dienststelle Rheinallee 97-101 Abteilung 2 D-55 118 Mainz	Tel.:+49-61 31-9 670 Fax:+49-61 31 67 49 20 Lfug.ref25@t-online.de

SPAIN	Ministerio de Ciencia y Tecnologia Paseo de la Castellana, 160 Planta 12, Despacho 19, E – 28071 Madrid	Tel:+34-91-3494063 Fax :34-91-3494300 Joseportero@mcyt.es
FRANCE	Secrétariat d'Etat à l'Industrie; Direction de l'Action Régionale et de la Petite et Moyenne Industrie Sous- Direction de la Sécurité industrielle, Départment Atmosphères Explosives 22, rue Monge, F - 75005 Paris	Tel:+33-1-43195142 Fax:+33-1-43195021: robert.estival@industrie.gouv.fr
IRELAND	Health and Safety Authority 10 Hogan Place, IRL – Dublin 2	Tel:+353-1-6147077 Fax: +353-1-6147020 frankk@hsa.ie
LUXEMBOURG	Service de l'Energie de l'Etat 34, Avenue de la Porte-Neuve B.P. 10 L-2010 Luxembourg	Tel: +352-469746-1 Fax: +352-222524 see.direction@eg.etat.lu
NETHERLANDS	Ministerie van Sociale Zaken en Werkgelegenhedn P.O. Box 90801 NL – 2509 LV De, Haag	Tel:+31-70-3335034 Fax:+31-70-3336612
PORTUGAL	Ministério da Economia - Direcção-Geral da Energia Av. 5 de Outubro 87 1069-039 LISBOA, Portugal	Tel:+351-21-792200 Fax:+351-21-793540 Electricos@dge.pt
FINLAND	Safety Technology Authority; Electrical Safety (TUKES) P.O. Box 123; FIN - 001 81 Helsinki	Tel:+358-9-6167565 Fax:+358-9-6167466 marrku.suvanto@tukes.fi

SWEDEN	National Inspectorate of Explosives and Flammables	Tel: +46-87998330
	Box 1413	Fax: +46-8295225
	171 27 Solna, SWEDEN	gab@sprangamnes.se
	National Board of Occupational Safety and Health	Tel: +46-87309000
	Ekelundvägen 16	Fax: +46-87301967
	171 84 Solna, SWEDEN	pehrolof.sundh@arbsky.se
	National Electrical Safety Board	Tel:+46-851911200
	Box 1371	Fax:+46-851911202
	11193 Stockholm, SWEDEN	ingvar.enqvist@elsak.se
UNITED	Department of Trade and Industry; Standards & Technical Regulations Directorate	Tel:+44-171-2151595
KINGDOM	151 Buckingham Palace Road	Fax:+44-171-2151529
	GB – London SW1 W 9SS	peter.howick@tidv.dti.gov.uk
	Health and Safety Executive	Tel:+44-171-7176395
	Rose Court; 2 Southwark Bridge	Fax:+44-171-7176680
	UK – London SEI 9HS	kevin.walkin@hse.gov.uk
NORWAY	The Norwegian Directorate for Product and Electrical Safety	Tel: +47-22991100
	PO Box 8116 Dep;	Fax: +47-22991101
	N-0032 Oslo	Per.nass@prodel.dep.telemax.no
	The Directorate of Labour Inspection	Tel: +47-22957000; Fax: +47-22406214
	PO Box 8103 Dep; N-0032 Oslo	Per-arne.larsen@arbeidstilsynet.dep.no
	The Directorate for Fire and Explosion Prevention	Tel: + 47-33398800; Fax: + 47-33310660
	PO Box 335 Sentrum	Odd.hakenstad@dbe.dep.telemax.no
	N-3101 Tonsberg	
	The New York Date I are Directorate PO Dec 600 N 4001 Cr	T.1 . 47 5197(000 F 47 5197(220
	The Norwegian Petroleum Directorate; PO Box 600; N-4001 Stavanger	Tel: +47-51876000; Fax: +47-51876329
	I	Linda.halvorsen@npd.no

Annex 3.2
CENTRAL CONTACT POINTS IN CHARGE OF IMPLEMENTATION OF DIRECTIVE 94/9/EC IN MEMBER STATES AND EEA COUNTRIES

AUSTRIA	F. Birkhan Bundesministerium für Wirtschftliche Angelegenheiten; Abteilung IX/4 Landstraße Hauptstraße 55-57 A – 1030 Wien	Tel:+43-171-100 ext. 8220 Fax:+43-1-7143582 <u>friedrich.birkhan@bmwa.gv.at</u> <u>Atex@bmwa.gv.at</u>
BELGIUM	J.P. Hirschbühler Ministère des Affaires Economiques ; Administration de l'Energie Boulevard du Roi Albert II; B - 1000 Bruxelles	Tel: +32-2-2064520 Fax: +32-2-2065731 jean-pierre.hirschbuhler@mineco.fgov.be
DENMARK	A. Mortensen Arbejdstilsynet; Risksecretariat, Holbaeksvej 106 B DK – 4000 Roskilde	Tel: +45-46-350236 Fax:+45-46-322336 amo@arbejdstilsynet.dk
	Niels Rotne Electricitetsraadet Gothersgade 160 DK - 1123 Copenhagen DK	Tel.: +45 33 73 20 00 Fax: +45 33 73 20 99 Nr@elraadet.dk
FINLAND	T. Koivumäki Ministry of Trade and Industry P.O.Box 230 FIN – 00171 Helsinki  R. Mattinen Safety Technology Authority; Electrical Safety (TUKES) P.O. Box 123; FIN - 001 81 Helsinki	Tel:+358-9-1603722 Fax:+358-9-1602644 tapani.koivumaki@ktm.vn.fi  Tel:+358-9-6167576 Fax:+358-9-6167566 reijo.mattinen@tukes.fi

GERMANY	H. Mattes Bundesministerium für Arbeit und Sozialordnung, Rochusstraße 1, D - 53107 Bonn  R. Mewes Ministerium für Arbeit, Frauen, Gesundheit und Soziales des Landes Sachsenanhalt Seepark 5-7 D - 39116 Magdeburg	Tel:+49-228-5272955 Fax:+49-228-5272958 ha.mattes@bma.bund.de  Tel:+49-391-5674514 Fax:+49-391-5674522 ronald.mewes@ms.lsa-net.de
GREECE	C. Moussouros Ministry of Development; General Secretary of Industry Sisini 8, GR – 11528 Athens	Tel+30-1-720 45 36 Fax+30-1-7251300 Mousourosx@ypan.gr
SPAIN	J.J. Portero Sanchez Ministerio de Ciencia y Tecnologia Paseo de la Castellana, 160 Planta 12, Despacho 19, E – 28071 Madrid	Tel:+34-91-3494063 Fax:34-91-3494300 Joseportero@mcyt.es
FRANCE	R. Estival (or Nicole Renard) Secrétariat d'Etat à l'Industrie; Direction de l'Action Régionale et de la Petite et Moyenne Industrie Sous- Direction de la Sécurité industrielle, Départment Atmosphères Explosives et Canalisations 22, rue Monge, F - 75005 Paris	Tel:+33-1-43195142 Fax:+33-1-43195021: robert.estival@industrie.gouv.fr Nicole.renard@industrie.gouv.fr
IRELAND	F. Kellaghan Health and Safety Authority 10 Hogan Place, IRL – Dublin 2	Tel:+353-1-6147077 Fax: +353-1-6147020 frankk@hsa.ie

ITALY	E. Federici Ministero dell'Industria, del Commercio e dell'Artigianato DGSPC, Via Molise, 2, I – 00187 Roma	Tel:+39-06-47887951 Fax: +39-06-47887748 celeste@minindustria.it
LUXEMBOURG	<b>J-P. Hoffmann</b> Commissaire du Gouvernement à l'Industrie B.P. 10; L – 2010 Luxembourg	Tel:+352-46974620 Fax: +352-222524 jean-paul.hoffmann@eg.etat.lu
NETHERLANDS	R. Ferns Ministerie van Sociale Zaken en Werkgelegenhedn P.O. Box 90801 NL – 2509 LV De, Haag	Tel:+31-70-3335507 Fax:+31-70-3334026 rferns@minszw.nl
PORTUGAL	E.V. Lopes Direcção de Servuços de Energia Eléctrica Av. 5 de Outubro, 87 P – 1050 Lisboa	Tel:+351-1-7922700 Fax: +351-1-7939540 energia@mail.telepac.pt
SWEDEN	B. Andersson National Electrical Safety Board P.O. Box 178 S - 68124 Kristinehamn	Tel:+46-55015510 Fax:+46-55080478 bertil.andersson@elsak.se
UNITED KINGDOM	P. Howick Department of Trade and Industry; Standards & Technical Regulations Directorate 151 Buckingham Palace Road GB – London SW1 W 9SS	Tel:+44-171-2151595 Fax:+44-171-2151529 peter.howick@tidv.dti.gov.uk
	K. Walkin Health and Safety Executive Rose Court 2 Southwark Bridge UK – London SEI 9HS	Tel:+44-171-7176395 Fax:+44-171-7176680 kevin.walkin@hse.gov.uk

		TIFIED UNDER DIRECTI		
EQUIPMENT AND PROTECTIVE  Name and address of the notified bodies	SYSTEMS INTE Identification number	NDED FOR USE IN POTI Responsible for the following products	ENTIALLY EXPLOSIVE A  Responsible for the following procedures/modules	TMOSPHERES Annexes/Articles of the Directives
TÜV HANNOVER/SACHSEN-ANHALT e.V. TÜV CERT-ZERTIFIZIERUNGSSTELLE für Maschinen, Aufzugs- und Fördertechnik Am TÜV 1 D-30519 Hannover	0032	Equipment in equipment group II, category 1G as follows: Electrical equipment Components Safety devices, controlling devices and regulating devices	EC type-examination Production quality assurance Product verification Unit verification	Annex III Annex IV Annex V Annex IX
		Equipment in equipment group II, categories 2G and 3G as follows: Electrical equipment Internal combustion engines flight conveyor equipment Components Safety devices, controlling devices and regulating devices	EC type-examination Conformity to type Product quality assurance Internal control of production + receipt of technical file Unit verification	Annex III Annex VI Annex VII Article 8.1 (b) (ii) (Annex VIII) Annex IX
INSTITUT NATIONAL DE L'ENVIRONNEMENT INDUSTRIEL ET DES RISQUES (INERIS) Parc technique ALATA BP 2 F-60550 Verneuil en Halatte	0080	Equipment and protective systems intended for use in potentially explosive atmospheres	EC type-examination Production quality assurance Product verification Conformity to type Product quality assurance Internal control of production + receipt of technical file Unit verification	Annex III Annex IV Annex V Annex VI Annex VIII Article 8.1 (b) (ii) (Annex VIII) Annex IX
LABORATOIRE CENTRAL DES INDUSTRIES ÉLECTRIQUES (LCIE) Avenue du Général-Leclerc, 33, F-92266 Fontenay-aux-Roses	0081	Equipment and protective systems intended for use in potentially explosive atmospheres	EC type-examination Production quality assurance Product verification Conformity to type Product quality assurance Internal control of production + receipt of technical file Unit verification	Annex III Annex IV Annex V Annex VI Annex VIII Article 8.1 (b) (ii) (Annex VIII) Annex IX

PHYSIKALISCH-TECHNISCHE BUNDESANSTALT BRAUNSCHWEIG (PTB) Bundesallee 100 D-38116 Braunschweig	0102	Equipment in equipment group II, category 1G as follows: Electrical equipment Non electrical equipment Machines Electrostatic spray equipment Components Safety devices, controlling devices	EC type-examination Production quality assurance Product verification Unit verification	Annex III Annex IV Annex V Annex IX
		and regulating devices  Autonomous protective systems (with indication of explosion characteristics) in equipment group II, categories 1G, 2G and 3G as follows: Autonomous protective systems Components Safety devices, controlling devices and regulating devices and regulating devices Equipment in equipment group II, categories 2G and 3G as follows: Electrical equipment	EC type-examination Conformity to type Product quality assurance Internal control of	Annex III Annex VI Annex VII Article 8.1 (b) (ii) (Annex VIII)
TÜV PRODUCT SERVICE GmbH Ridlerstraße 31 D-80339 München	0123	Non electrical equipment Internal combustion engines Machines Electrostatic spray equipment Components Safety devices, controlling devices and regulating devices Autonomous protective systems (with indication of explosion characteristics) in equipment group II, categories 1G, 2G	EC type-examination Production quality assurance Product verification Conformity to type Product quality assurance	Annex III Annex IV Annex V Annex VI Annex VII Annex IX
		and 3G as follows:  Electrical equipment  Non electrical  equipment  Components  Safety devices,  controlling devices  and regulating devices  Machines	Unit verification	

DMT-ZERTIFIZIERUNGSSTELLE DER DMT-GESELLSCHAFT FÜR FORSCHUNG UND PRÜFUNG mbH Franz-Fischer-Weg 61 D-45307 Essen	0158	Equipment in equipment groups I and II, categories M1 and 1, as follows: Electrical equipment Non electrical equipment Machines Gas measurement installations Components Safety devices, controlling devices and regulating devices Autonomous protective systems (with indication of explosion characteristics) in equipment group II, categories 1G, 2G and 3G as follows: Autonomous protective systems Components Safety devices, controlling devices, controlling devices and regulating devices	EC type-examination Production quality assurance Product verification Unit verification	Annex III Annex IV Annex V Annex IX
		Equipment in equipment groups I and II, categories M2, 2 and 3, as follows: Electrical equipment Non electrical equipment Internal combustion engines Machines Gas measurement installations Components Safety devices, controlling devices and regulating devices	EC type-examination Conformity to type Product quality assurance Internal control of production + receipt of technical file Unit verification	Annex III Annex VI Annex VII Article 8.1 (b) (ii) (Annex VIII) Annex IX
LABORATORIO OFICIAL JOSÉ MARÍA DE MADARIAGA (LOM) c/Alenza 1-2 E-28003 Madrid	0163	Equipment in equipment groups I and II, categories M1 and 1, as follows:	EC type-examination Production quality assurance Product verification Conformity to type Product quality assurance Unit verification	Annex III Annex IV Annex V Annex VI Annex VII Annex IX
		Equipment in equipment groups I and II, categories M2, 2 and 3, as follows: Autonomous protective systems Components		

DEUTSCHE GESELLSCHAFT	0297	Equipment in	Production quality	Annex IV
ZUR ZERTIFIZIERUNG VON	0291	equipment groups I	assurance	Annex VII
MANAGEMENTSYSTEMEN		and II, categories M1		AIIIIEX VII
mbH		and 1, as follows:	Product quality	
— QUALITÄTS- UND			assurance	
		Electrical equipment		
UMWELTGUTACHTER (DQS)		Non electrical		
August-Schanz-Straße 21		equipment		
D-60433 Frankfurt/Main		Machines		
		Gas measurement		
		installations		
		Components		
		Safety devices,		
		controlling devices		
		and regulating devices		
		Equipment in		
		equipment groups I		
		and II, categories M2,		
		2 and 3, as follows:		
		Electrical equipment		
		Non electrical		
		equipment		
		Internal combustion		
		engines		
		Machines		
		Gas measurement		
		installations		
		Components		
		Safety devices,		
		controlling devices		
		and regulating devices		
		Autonomous		
		protective systems		
		Equipment in		
		equipment groups I		
		and II, categories M1,		
		M2, 1, 2 and 3 as		
		follows:		
		Autonomous		
		protective systems		
		Components		
		Safety devices,		
		controlling devices		
		and regulating devices		

KEMA REGISTERED QUALITY BV Utrechtseweg 310 Postbus 9035 NL-6800 ET Arnhem	0344	Equipment in equipment group II, in this case including equipment where the source of ignition is primarily electrical	Production quality assurance Product verification Conformity to type Product quality assurance Internal control of production + receipt of technical file Unit verification EC type-examination	Annex IV Annex VI Annex VII Article 8.1 (b) (ii) (Annex VIII) Annex IX Annex III
		Protective systems for equipment in group II where the source of ignition is primarily electrical	EC type-examination Production quality assurance Product verification Unit verification	Annex III Annex IV Annex V Annex IX
		Components which are parts of equipment in group II and of protective systems where the source of ignition is primarily electrical	EC type-examination Production quality assurance Product verification Conformity to type Product quality assurance Internal control of production + receipt of technical file Unit verification	Annex III Annex IV Annex V Annex VI Annex VII Article 8.1 (b) (ii) (Annex VIII) Annex IX
ITS Testing and Certification Ltd ITS House Cleeve Road Leatherhead UK- KT22 7SB Surrey	0359	Equipment groups I and II, categories M1 and 1 Equipment groups I and II, categories M2 and 2 Equipment group II, category 3 Protective systems Devices Components Equipment in	Internal control of production + receipt of technical file EC type-examination Production quality assurance Product verification Conformity to type Product quality assurance Unit verification	Article 8.1 (b) (ii) (Annex VIII) Annex III Annex IV Annex V Annex VI Annex VIII Annex VIII
		equipment groups I and II, categories M2, 2 and 3, as follows: Equipment group II, category 3 Protective systems Devices — Components		
SVERIGES PROVNINGS- OCH FORSKINGSINSTITUT (SP) Box 857 S-501 15 Borås	0402	All products excepted Internal combustion engines	EC type-examination Production quality assurance Product verification Conformity to type Product quality assurance Unit verification	Annex III Annex IV Annex V Annex VI Annex VII Annex IX

TÜV-ÖSTERREICH	0408	Equipment in	EC type-examination	Annex III
TÜV-A	0100	equipment group II, in	Conformity to type	Annex VI
Krugerstraße 16 A-1015 Wien		this case including equipment where the	Production quality assurance	Annex IV Annex VII
A-1013 WIEII		source of ignition is	Product quality	Annex V
		primarily electrical	assurance	Annex IX
		primarily dicollical	Product verification	AIIIOXIX
			Unit verification	
NEMKO AS	0470	— Electrical	EC type-examination	Annex III
Gaustadalleen 30		equipment	Production quality	Annex IV
PO Box 73 — Blindern			assurance	Annex V
N-01314 Oslo			Product verification	Annex VI
			Conformity to type	Annex VII
			Product quality	
INOTITUT COLENTIES UE DEC	0.400	0.6.4.1.1	assurance	A 111
INSTITUT SCIENTIFIQUE DES	0492	— Safety devices,	EC type-examination	Annex III
SERVICES PUBLICS		controlling devices	Production quality	Annex IV Annex V
— SIÈGE DE COLFONTAINE (ISSEP)		and regulating devices	assurance Product verification	Annex VI
Rue Grande 60			Conformity to type	Annex VII
B-7340 Colfontaine			Product quality	Annex IX
2 ro ro Conomano			assurance	7 1111074 17 4
			Unit verification	
SERVICE DE L'ÉNERGIE DE	0499	Equipment and	EC type-examination	Annex III
L'ÉTAT		protective systems	Production quality	Annex IV
BP 10		intended for use in	assurance	Annex V
L-2010 Luxembourg		potentially explosive	Product verification	Annex VI
		atmospheres	Conformity to type	Annex VII
			Product quality	Annex IX
			assurance Unit verification	
SIRA CERTIFICATION	0518	Equipment groups I	EC type-examination	Annex III
SERVICE		and II, categories M1	Production quality	Annex IV
Sira Test & Certification Limited		and 1	assurance	Annex V
South Hill		Equipment groups I	Product verification	Annex VI
UK-BR7 5EH Chislehurst Kent		and II, categories M2	Conformity to type	Annex VII
		and 2	Product quality	Article 8.1 (b) (ii)
		Equipment group II,	assurance	(Annex VIII)
		category 3	Internal control of	Annex IX
		Protective systems	production + receipt of	
		Devices	technical file Unit verification	
		Components Equipment group II,	Offic verification	
		category 3		
		Protective systems		
		Devices		
		<ul><li>Components</li></ul>		
		Equipment in		
		equipment groups I		
		and II, categories M2,		
VTT 41/T01***	0507	2 and 3, as follows:		
VTT AUTOMAATIO (VTT	0537	— Electrical	EC type-examination	Annex III
AUTOMATION)		equipment	Product verification	Annex V
VTT MDTPL 13071 FIN-02044 VTT Espoo			Conformity to type Unit verification	Annex VI Annex IX
1111-02044 VIIESPOU			OTHE VEHILLAUUH	VIIIIGY IV

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l)

BUNDESANSTALT FÜR MATERIALFORSCHUNG UND PRÜFUNG (BAM) Unter den Eichen 87 D-12205 Berlin	0589	Equipment in equipment groups I and II, categories M1 and 1, as follows:  Non electrical equipment Components Safety devices, controlling devices and regulating devices with risk of ignition from mechanically produced sparks Gas measurement installations Autonomous protective systems (with indication of explosion characteristics) in equipment group II, categories 1G, 2G and 3G as follows: Autonomous protective systems flameproof valves Components Equipment in equipment groups I and II, categories M2, 2 and 3, as follows: Non electrical equipment Components Safety devices, controlling devices and regulating devices with risk of ignition from mechanically produced sparks Gas measurement installations	EC type-examination Production quality assurance Product verification Unit verification Unit verification  EC type-examination Conformity to type Product quality assurance Internal control of production + receipt of technical file Unit verification	Annex III Annex IX  Annex III Annex III Annex VI Annex VIII Article 8.1 (b) (ii) (Annex VIII) Annex IX
ELECTRICAL EQUIPMENT CERTIFICATION SERVICE HEALTH AND SAFETY EXECUTIVE Harpur Hill UK-SK17 9JN Buxton Derbyshire	0600	Equipment groups I and II, categories M1 and 1 Equipment groups I and II, categories M2 and 2 Equipment group II, category 3 Protective systems Devices Components	EC type-examination Production quality assurance Product verification Conformity to type Product quality assurance Internal control of production + receipt of technical file Unit verification	Annex III Annex IV Annex V Annex VI Annex VII Article 8.1 (b) (ii) (Annex VIII) Annex IX

IBExU — INSTITUT FÜR	0637	Equipment in	Internal control of	Article 8.1 (b) (ii)
SICHERHEITSTECHNIK GmbH Institut an der Technischen Universität Bergakademie Freiberg Fuchsmühlenweg 7		equipment groups I and II, categories M2, 2 and 3, as follows:	production + receipt of technical file Unit verification EC type-examination Conformity to type	(Annex VIII) Annex IX Annex III Annex VI Annex VII
D-09599 Freiberg			Product quality assurance	
		Electrical equipment Non electrical equipment Internal combustion engines Machines Gas measurement installations Components Safety devices, controlling devices and regulating devices	EC type-examination Conformity to type Internal control of production + receipt of technical file Unit verification	Annex III Annex VI Article 8.1 (b) (ii) (Annex VIII) Annex IX
		Autonomous protective systems (with indication of explosion characteristics) in equipment group II, categories 1G, 2G and 3G as follows:	EC type-examination Product verification Unit verification Production quality assurance	Annex III Annex V Annex IX Annex IV
		Equipment in equipment groups I and II, categories M1, M2, 1, 2 and 3, as follows:	EC type-examination Production quality assurance Product verification Unit verification	Annex IV Annex V Annex IX
		Autonomous protective systems Components Safety devices, controlling devices and regulating devices Equipment in equipment groups I and II, categories M1 and 1, as follows: Electrical equipment Non electrical equipment Machines Gas measurement installations Components Safety devices, controlling devices and regulating devices	EC type-examination Product verification Unit verification	Annex III Annex V Annex IX

CESI — CENTRO ELETTROTECNICO SPERIMENTALE ITALIANO GIACINTO. MOTTA SpA Via Rubattino, 54 I-20134 Milano	0722	Equipment and protective systems intended for use in potentially explosive atmospheres	EC type-examination Production quality assurance Product verification Conformity to type Product quality assurance Internal control of production + receipt of technical file Unit verification	Annex III Annex IV Annex V Annex VI Annex VII Article 8.1 (b) (ii) (Annex VIII) Annex IX
ZELM EX PRÜF- UND ZERTIFIZIERUNGSSTELLE Siekgraben 56 D-38124 Braunschweig	0820	Equipment in equipment group II, category 1G as follows:	EC type-examination Product verification Conformity to type Unit verification	Annex III Annex V Annex VI Annex IX

#### LIST OF HARMONISED STANDARDS

Commission communication in the framework of the implementation of Directive 94/9/EC of the European Parliament and Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres

#### March 2000

(Text with EEA relevance)

#### Publication of titles and references of harmonized standards under the directive

#### EN

European Standards Body (*)	Reference and title of the standard	Reference document	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard Note 1
CEN	EN 1127-1: 1997 : Explosive atmospheres – Explosion prevention and protection – Part 1 : Basic concepts and methodology.		NONE	
CENELEC	EN 50014:1997 Electrical apparatus for potentially explosive atmospheres - General requirements		NONE	-
	Amendment A2:1999 to EN 50014:1997		Note 3	-
	Amendment A1:1999 to EN 50014:1997		Note 3	-
CENELEC	EN 50015:1998 Electrical apparatus for potentially explosive atmospheres - Oil immersion "o"		NONE	-
CENELEC	EN 50017:1998 Electrical apparatus for potentially explosive atmospheres - Powder filling "q"		NONE	-
CENELEC	EN 50021:1999 Electrical apparatus for potentially explosive atmospheres - Type of protection "n"		NONE	-
CENELEC	EN 50054:1998 Electrical apparatus for the detection and measurement of combustible gases - General requirements and test methods		NONE	-
CENELEC	EN 50055:1998 Electrical apparatus for the detection and measurement of combustible gases - Performance requirements for Group I apparatus indicating up to 5 % (v/v) methane in air		NONE	-
CENELEC	EN 50056:1998 Electrical apparatus for the detection and measurement of combustible gases - Performance requirements for Group I apparatus indicating up to 100 % (v/v) methane in air		NONE	-

European Standards Body (*)	Reference and title of the standard	Reference document	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard Note 1
CENELEC	EN 50057:1998 Electrical apparatus for the detection and measurement of combustible gases - Performance requirements for Group II apparatus indicating up to 100 % lower explosive limit		NONE	-
CENELEC	EN 50058:1998 Electrical apparatus for the detection and measurement of combustible gases - Performance requirements for Group II apparatus indicating up to 100 % (v/v) gas		NONE	-
CENELEC	EN 50104:1998 Electrical apparatus for the detection and measurement of oxygen - Performance requirements and test methods		NONE	-
CENELEC	EN 50241-1:1999 Specification for open path apparatus for the detection of combustible or toxic gases and vapours Part 1: General requirements and test methods		NONE	-
CENELEC	EN 50241-2:1999 Specification for open path apparatus for the detection of combustible or toxic gases and vapours Part 2: Performance requirements for apparatus for the detection of combustible gases		NONE	-
CENELEC	EN 50281-1-1:1998 Electrical apparatus for use in the presence of combustible dust Part 1-1: Electrical apparatus protected by enclosures - Construction and testing		NONE	-
CENELEC	EN 50281-1-2:1998 Electrical apparatus for use in the presence of combustible dust Part 1-2: Electrical apparatus protected by enclosures - Selection, installation and maintenance  And corrigendum December 1999 to EN 50281-		NONE	-
CENELEC	1-2:1998 EN 50281-2-1:1998 Electrical apparatus for use in the presence of combustible dust Part 2-1: Test methods - Methods for determining the minimum ignition temperatures of dust		NONE	-
CENELEC	EN 50284:1999 Special requirements for construction, test and marking of electrical apparatus of equipment group II, Category 1 G		NONE	-

Note 1: Generally the date of cessation of presumption of conformity will be the date of withdrawal ("dow"), set by the European standards body, but attention of users of these standards is drawn to the fact that in certain exceptional cases this can be otherwise.

Note 3: In case of amendments, the referenced standard is EN CCCCC:YY, its previous amendments, if any, and the new, quoted amendment. The superseded standard (column 4) therefore consists of EN CCCCC:YY and its previous amendments, if any, but without the new quoted amendment. On the date stated, the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

Example: For EN 50014:1997, the following applies:

CENELEC	EN 50014:1997	
	Electrical apparatus for potentially explosive	NONE -
	atmospheres – General requirements	[There is no
	[The referenced standard is EN 50014:1997]	superseded standard]
	Amendment A1:1999 to EN 50014:1997	Note 3
	[The referenced standard is EN 50014:1997	[The superseded -
	+A1:1999 to EN 50014:1997]	standard is
		EN 50014:1997]
	Amendment A2:1999 to EN 50014:1997	Note 3
	[The referenced standard is EN 50014:1997	[The superseded -
	+A1:1999 to EN 50014:1997	standard is
	+A2:1999 to EN 50014:1997]	EN 50014:1997
		+A1:1999 to
		EN 50014:1997]

#### Note:

- Any information concerning the availability of the standards can be obtained either from the European standardization organizations or from the national standardization bodies of which the list is annexed to the Council Directive 98/34/EEC $^{62}$  amended by the Council Directive 98/48/EC $^{63}$ .
- Publication of the references in the OJEC does not imply that the standards are available in all the Community languages
- The Commission ensures the updating of this list.
- This list replaces all the previous lists published in the Official Journal of the European Communities.

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OJ no. L 204, 21.07.1998

<sup>63</sup> OJ no. L 217, 05.08.1998

## Standardisation programme issued by the Commission for preparation of harmonised standards under directive 94/9/EC relating to non-electrical equipment (correct as at 1.5.00)

The TC 305 working groups are actively developing the following standards:

1	Determination of explosion characteristics of dust clouds - Part 1: Determination of the maximum explosion pressure of dust clouds
2	Determination of explosion characteristics of dust clouds - Part 2: Determination of the maximum rate of pressure rise of an explosion of dust clouds
3	Determination of explosion characteristics of dust clouds - Part 3: Determination of the minimum explosive concentration of dust clouds
4	Determination of the limiting oxygen concentration for dust clouds
5	Determination of the minimum ignition energy of dust clouds
6	prEN 1839: Determination of the lower and upper explosion limit of gases and vapours
7	Determination of the spontaneous ignition behaviour of dust accumulations
8	Determination of the minimum ignition temperature of gases and vapours
9	Determination of the limiting oxygen concentration for gases and vapours
10	Determination of the maximum explosion pressure and the maximum rate of pressure rise of gases and vapour - Part-1 Determination of the maximum explosion pressure
11	Determination of the maximum explosion pressure and the maximum rate of pressure rise of gases and vapour - Part-2 Determination of the maximum rate of pressure rise
12	prEN 134631: Non electrical equipment for potentially explosive atmosphere – Part 1 : Basic methodology and requirements
13	Non-electrical equipment for potentially explosive atmospheres - Part 2: Protection by flow restricting enclosure
14	Non-electrical equipment for potentially explosive atmospheres - Part 3: Protection by flameproof enclosure
15	Non-electrical equipment for potentially explosive atmospheres - Part 4: Protection by inherent safety
16	Non-electrical equipment for potentially explosive atmospheres - Part 5: Protection by constructional safety
17	Non-electrical equipment for potentially explosive atmospheres - Part 6: Protection by control of ignition sources
18	Non-electrical equipment for potentially explosive atmospheres - Part 7: Protection by pressurisation
19	Selection of non-electrical equipment for use in potentially atmosphere
20	Safety requirements for ignition protected fans

21	Explosion suppression system
22	Explosion proof equipment
23	prEN 12874: Flame arresters - Specifications, operational requirements and test procedures
24	Explosion venting devices
25	Gas explosion venting systems
26	Active explosion extinguishing barriers
27	Explosion barriers
28	prEN 13237-1: Terms and definitions for equipment and protective systems intended for use in potentially explosive atmosphere
29	Methodology for risk assessment of equipment and protective systems for intended use in potentially explosive atmospheres
30	prEN 13462 : Explosive atmosphere - Explosion prevention and protection in mines - Basic concepts & methodology
31	Explosion barriers for mines
32	Potentially explosive atmospheres - Application of quality systems

Application of directive 94/9/EC in relation to Machinery Directive 98/37/EC:

CEN has identified 50 standards listed under the machinery safety programme, which contain explosion hazards and may be used in potentially explosive atmospheres. These standards, being developed by a number of different technical committees, will be assessed for suitability within the context of the Directive 94/9/EC.

## I. Standardisation programme issued by the Commission for preparation of harmonised standards under directive 94/9/EC relating to electrical equipment (correct as at 1.5.00)

The TC 31 committee and sub-committees are actively developing the following standards:

- 1 EN 50014:1997 Electrical apparatus for potentially explosive atmospheres General requirements
- 2 EN 50015:1998 Electrical apparatus for potentially explosive atmosphere Oil immersion ''o''
- 3 EN 50017 :1998 Electrical apparatus for potentially explosive atmospheres Powder filling 'q'
- 4 EN 50021: 1998 Electrical apparatus for potentially explosive atmospheres Type of Protection 'n'
- 5 EN 50054:1998 Electrical apparatus for the detection and measurement of combustible gases General requirements and test methods
- 6 EN 50055:1998 Electrical apparatus for the detection and measurement of combustible gases Performance requirements for Group I apparatus indicating up to 5% (V/V) methane in air
- 7 EN 50056:1998 Electrical apparatus for the detection and measurement of combustible gases Performance requirements for Group I apparatus indicating up to 100% (V/V) methane
- 8 EN 50057:1998 Electrical apparatus for the detection and measurement of combustible gases Performance requirements for Group II apparatus indicating up to 100% lower explosive limit
- 9 EN 50058:1998 Electrical apparatus for the detection and measurement of combustible gases Performance requirements for Group II apparatus indicating up to 100%(V/V) gas
- 10 EN 50104 : 1998 Electrical apparatus for the detection and measurement of oxygen Performance requirements and test methods
- EN 50241-1: 1999 Specification for open path apparatus for the detection of combustible or toxic gases and vapour Part-1: General requirements and test methods
- EN 50241-2: 1999 Specification for open path apparatus for the detection of combustible or toxic gases and vapours Part-2: Performance requirements for apparatus for the detection of combustible gases
- EN 50281-1-1: 1998- Electrical apparatus for use in the presence of combustible dusts Part I-1: Electrical apparatus protected by enclosures Construction and testing
- EN 50281-1-2: 1998- Electrical apparatus for use in the presence of combustible dusts Part 1-2: Electrical apparatus protected by enclosures Selection, installation and maintenance

15	EN 50281-2-1: 1998- Electrical apparatus for use in the presence of combustible dusts Part 2-1: Methods for determining the minimum ignition temperatures for dust
16	EN 50284 : 1999 - Special requirements for construction, testing and marking of electrical apparatus of equipment group II, category 1G
17	prEN 50303 : Electrical Apparatus for potentially explosive atmospheres- equipment Group I Category M1
18	prEN 50281-1-3 : Equipment for use in the presence of combustible dust – Part 1-3 : Classification of areas where combustible dust are or may be present
19	prEN 60079-10: Electrical apparatus for potentially explosive atmospheres – Part-10-Classification of hazardous areas for gases
20	prEN 60079-14: Electrical apparatus for potentially explosive atmospheres. – Part-14-Selection, installation, maintenance and repair of electrical apparatus for use in hazardous areas
21	prEN 50018 : Electrical apparatus for potentially explosive atmospheres - Flameproof enclosure 'd'
22	prEN $50020$ : Electrical apparatus for potentially explosive atmospheres - Intrinsic safety 'i'
23	prEn 50039 : Electrical apparatus for potentially explosive atmospheres - Intrinsically safe electrical
24	prEN 50019 : Electrical apparatus for potentially explosive atmospheres - Increased safety 'e' $$
25	prEN 50033 : Cap lamps for mines susceptible to firedamp
26	prEN 50028 : Electrical apparatus for potentially explosive atmospheres - Encapsulation type 'm'
27	prEN 50016 : Electrical apparatus for potentially explosive atmospheres - Pressurisation apparatus ' p'
28	pr EN 500 : Transportable Pressurised rooms without and with an internal source of release
29	prEN 50050 : Electrical apparatus for potentially explosive atmospheres - Electrostatic hand-held spraying equipment
30	prEN 50053-1: Requirements for the selection, installation and use of electrostatic spraying equipment for flammable materials - Part 1: Hand-held electrostatic paint spray guns with an energy limit of 0.24mJ and their associated apparatus
31	prEN 50053-2: Requirements for the selection, installation and use of electrostatic spraying equipment for flammable materials - Part 2: Hand-held electrostatic powder spray guns with an energy limit of 5mJ and their associated apparatus
32	prEN 50053-3: Requirements for the selection, installation and use of electrostatic spraying equipment for flammable materials - Part 3: Hand-held electrostatic flock spray guns with an energy limit of 0.24 mJ or 5 mJ and their associated apparatus
33	prEN 50176: Electrical apparatus for potentially explosive atmospheres - Part 1: Automatic electrostatic spraying installations for flammable liquid

- prEN 50177: Electrical apparatus for potentially explosive atmospheres Part 2: Automatic electrostatic spraying installations for flammable coating powder
- prEN 50223: Electrical apparatus for potentially explosive atmospheres Automatic electrostatic installations for flammable flock material
- prEN 50....: Electrical Apparatus for potentially explosive atmospheres electrostatic spray guns "Waterborne paint"

#### II. EN 50014 First Edition

The EN 50014 series were first published in the three official languages, French, German and English in 1977. Since the inception of the series a number of the standards have been amended and have been brought into operation by updating the directives 79/196/EEC and 82/130/EEC by the European Commission. These updating directives, which subsequently were included in the laws of the Member States, allowed certificates of conformity referring to the amendments, to be issued.

Following the issue of amendments to directives 79/196/EEC and 82/130/EEC it became necessary for the European Community test houses to indicate on Certificates of Conformity, the amendment status of the directive. A generation indicator letter has been included on certificate number e.g. Ex 94 C 9067.

#### III. EN 50014 Second Edition

The 1979 series of standards were revised and published on an on-going basis since 1993 as the 2<sup>nd</sup> Edition En 50014 series of standard. The 2<sup>nd</sup> Edition series takes into account all the amendments of the original 1<sup>st</sup> edition interpretation sheets, and changes implemented at international level by IEC in the 79 Series of standards. To complete the cycle of publication under the directives 79/196/EEC and 82/130/EEC it was necessary for the Commission to develop and amend the Old Approach directives with respect to the second edition series. This was introduced and accepted by the Committees on adaptation to technical progress of directives 79/196/EEC and 82/130/EEC. Following this acceptance it was possible to issue Group I and II conformity certificates based on the second edition. Previously only national certificates of assurance to the second editions could be issued where a particular standard had been published.

#### IV. EN 50014 Third Edition

The new second edition standards formed the basis of the work program for the third edition, developed by CENELEC TC 31, for the new ATEX directive 94/9/EC. TC 31 had decided that the Second Edition series embodied the present state of the art and that no major technical changes were needed for compliance with the Essential Health and Safety Requirements (EHSRs) of the Directive. Some non-technical changes were necessary and were introduced in the third edition. The directive contains technical requirements that are not covered presently by the standards and will require research before incorporation into the third edition standards.

# Questions and answers on the application of directive 94/9/EC including those concerning the Essential Health and Safety Requirements

#### **Question 1:**

A closed vessel (process vessel, storage tank etc.) contains volatile flammable liquid. The inside of the vessel should be classified as zone 0 generally, and the equipment inside the vessel - stirrer etc. - falls within the scope of 94/9/EC. The zone could be 1 or 2 as well. Now, assume that the surrounding of the vessel is unclassified area as a result of the construction of the vessel in steel, which functions as a barrier. Also, disregard apparatus such as a safety relief valve, which could lead to (partial) classification of the outside of the vessel.

Does such a vessel as a complete unit fall within the scope of 94/9/EC?

**Example 1**: Suppose ventilation ducts are transporting flammable mixtures sufficient to lead to classification of the interior of the ducts. The duct walls are constructed as barriers and isolate the potentially explosive atmosphere inside the duct from the surroundings. The surroundings of the duct thus are unclassified, and the duct is installed in an unclassified area.

**Example 2**: Petrol pumps at petrol filling stations are mainly surrounded by unclassified areas. However, the exterior is classified in the region of the nozzle boot. The interior is in part or entirely classified volume.

**Example 3**: A distillation tower distilling flammable liquids.

#### Answer (see as well chapter 4.1.2):

In general terms, to fall within the scope of directive 94/9/EC, the following conditions must be fulfilled:

- a potentially explosive atmosphere must be present;
- the atmosphere must consist of flammable substances mixed with air;
- the atmosphere is under atmospheric conditions;
- the product must have its own potential sources of ignition (see 4.1.2 a).

As the directive is a risk-related directive, a risk assessment has to be made related to the degree of the above mentioned conditions and if they constitute a dangerous explosion risk. In conjunction with the above conditions please see Table 2 on page 18 of the application guide to check if a product is within the scope of the directive:

1. Situation C - not in the scope of the directive

Example 1: situation C, remark (a) possible

Example 2: A petrol dispenser may be considered as an assembly within the scope of directive

94/9/EC, both if it is built of CE-marked and of non-CE-marked parts. It is a widely supported opinion that a CE marking for the whole equipment is in both cases necessary. When assembling a petrol dispenser a manufacturer may use only CE-marked parts. In this case only additional hazards due to the fact that such parts are connected have to be assessed for the CE-marking of the entire dispenser. In case a manufacturer uses partly or fully non-CE-marked products for the assembly an

assessment of the whole assembly has to be done.

Example 3: perhaps situation C, but to answer properly more information would be required.

#### **Question 2:**

Is an apparatus, which contains explosive atmospheres inside but is not surrounded by explosive atmospheres inside the scope of the directive 94/9/EC?

In addition, there are questions from manufacturers and Notified Bodies about the classification of equipment-groups into categories. If e.g. an apparatus is used in areas in which explosive atmospheres are likely or unlikely to occur or even do not occur but inside the apparatus under normal operating conditions an explosive atmosphere (for example air/dust mixtures in crushing mills, dryers, dust separators) is always present.

Which conformity assessment procedure for which category is to be used in such cases? For choosing the right procedure is it important to attend to the atmosphere around the apparatus? The confusion in this case comes from the heading in the directive "intended for use <u>in</u> potentially explosive atmospheres".

#### Answer (see as well chapter 4.1.2):

Situation C, if apparatus has its own ignition source

Situation E, if apparatus has no ignition source

E.g. A vessel, which is not surrounded by a potentially explosive atmosphere but has a potentially explosive atmosphere inside is, in general, not in the scope of the directive. Nevertheless, all the equipment inside the vessel with own sources of ignition is inside the scope of the directive

#### **Question 3:**

We understand from the definitions of potentially explosive atmospheres and atmospheric conditions that a process vessel operating under other than atmospheric conditions is not covered by 94/9/EC. However, process vessels for chemical reactions are frequently operating with a pressure of several atmospheres. Also in storage tanks for liquefied gas the pressure normally is several atmospheres.

#### Answer (see as well chapter 4.1.2 and 4.3):

If a product is not intended for use under atmospheric conditions it is not in the scope of directive 94/9/EC, but an explosive atmosphere could form inside under atmospheric conditions during startup, shut-down or maintenance periods. This would form part of the user's risk assessment and could lead to the specification of ATEX equipment to be installed in or on the vessel. This is common practice.

#### **Question 4:**

Equipment should be "capable of causing an explosion", otherwise it is not covered by directive 94/9/EC. Suppose a simple sheet metal or glass container (vessel or equivalent equipment) which does, or does not, contain a potentially explosive atmosphere, is used in a classified area. The container does not contain mechanical or electrical equipment. Does such a container fall within the scope of directive 94/9/EC?

**Example 1**: Ventilation ducts are unclassified inside (e.g. a fresh air duct) but are installed in a classified area. No damper or other equipment, mechanical or electrical, is installed in the ducting.

**Example 2**: Ventilation ducts are classified inside and installed in a classified area, but there are no dampers or other equipment, mechanical or electrical, installed in the ducting.

#### Answer (see as well chapter 4.1.2):

If a product has no own potential ignition source it is not in the scope of the directive (see table on page 18).

Example 1: situation G, no source of ignition Example 2: situation B, no source of ignition

#### **Question 5:**

We understand from 94/9/EC that the presence of air is required, otherwise the directive does not apply. Some mixtures of gases are however explosive without the presence of air. Is it necessary that the explosive properties of the mixture are based on air and the oxygen content of the air?

In chlorine production cells hydrogen is also produced, but separated. Suppose that chlorine and hydrogen are mixed in such cells (or by other means) in the presence of air in negligible quantities. The mixture is still explosive over a vast concentration range.

#### Answer (see as well chapter 4.1.1):

One of the conditions to be inside the scope of the directive is that the potentially explosive atmosphere consists of a mixture with air. Therefore a product within a potentially explosive atmosphere without the presence of air is not in the scope of the directive.

Excluded from the scope of the directive because explosion hazard results exclusively from the presence of explosive or unstable substances [Art 1(4)]

#### **Question 6:**

Article 1(3): Are incomplete items of electrical equipment (current designation "U") components or equipment?

Example: A pressure-proof encapsulated built-in probe that must be installed in a housing of ignition-protection type Ex-e.

#### Answer (see as well chapters 3.10 and 4.1.2):

It depends on the intended use. If they do not have an autonomous function they can be considered as components.

## **Question 7:**

Article 8(I)(b)(ii)

Is this section to be applied to all appliances and components that can constitute an ignition hazard, more particularly as a result of frictional heat, impact or frictional sparking or electro-static charges?

If this were the case the procedure would, under certain circumstances, also have to be applied to the following components:

- vee-belts;
- fork prongs (tines);
- fans (at least the mechanical part);
- · wheels.

## Answer (see as well chapters 4.2.1 c):

Yes, the procedures have to be applied if a component is necessary for the safe functioning of equipment and protective systems and is placed on the market separately, with the explicit intention to be integrated to such equipment and protective system.

## **Question 8:**

In relation to the classification of stacker trucks/ industrial trucks and of other appliances consisting of electrical and mechanical components that could constitute ignition hazards (Article 8(1)(b))

If the procedure in accordance with Article 8(1)(b)(ii) were to be applied to such composite units this would mean that such appliances could incorporate both electrical equipment and internal combustion engines to which the more onerous procedure in accordance with Article 8(1)(b)(ii) would not be applied.

The following problems would thus arise:

- appliances (better to say "units") such as forklift trucks operate under particularly rough
  conditions. Nevertheless the conformity assessment procedure would be of a simpler type than
  that for stationary equipment. Experience has shown this not to be justified since it is precisely
  fork lift trucks that are often used where the probability of the presence of a dangerous potentially
  explosive atmosphere is particularly great, as in the pouring of flammable liquids into mobile
  containers:
- the procedure generates particular problems for the operator and can represent a barrier to competition, since in practice only the manufacturer is able to supply spare parts and conduct routine tests. This applies particularly to wearing parts such as batteries, wheels, tines, motors, switches etc. Any change to the piece of equipment means that the CE logo becomes invalid, the unit becomes a special product and must be completely re-certified by the examining expert.

## Answer (see as well chapters 4.1.2):

For clarification, for example, one may consider a forklift containing an internal combustion engine and some electrical equipment:

The internal combustion engine and the electrical equipment have to undergo the conformity assessment according to Article 8(1)(b)(i).

The combined equipment (the forklift) is neither electrical equipment nor an internal combustion engine, therefore Article 8(1)(b)(ii) applies. There is no difference between mobile and fixed equipment regarding conformity assessment.

The second indent seems to reveal a fundamental misunderstanding: The whole directive does apply to placing on the market and taking into service (as defined in the Blue Guide). Maintenance and/or repair has no influence on the conformity of the product at the time of placing on the market and taking into service is therefore not harmonised and has to follow other regulations (if any).

## **Question 9:**

Is a manufacturer who draws up an EC declaration of conformity under directive 94/9/EC allowed to refer in this declaration also to the Low Voltage directive in view of the elimination of electrical risks of Ex-equipment?

If not, how can electrical safety be confirmed? Is it possible to refer in the ATEX declaration of conformity to the standards which are used to guarantee electrical safety under the LVD (EN 61010)?

## Answer (see as well chapter 6):

The principle of applying other directives, based on point 1.2.7 of Annex II of the ATEX directive 94/9/EC, can not be extended to the risks covered by the Low Voltage directive 73/23/EEC. This is due to the fact that Annex II of directive 73/23/EEC clearly excludes ex-products from the scope of this directive. The wording in the directive 94/9/EC cannot overrule this precise provision in directive 73/23/EEC. The consequence is that the EC declaration of conformity of ATEX products can not state that directive 73/23/EEC has been applied. The manufacturer has to follow the procedures of Article 8(4) of directive 94/9/EC regarding other risks.

To enable the manufacturer to place ATEX products on the Community market without obstacles, he could indicate in the ATEX declaration of conformity, that the standards published in the OJEC with reference to directive 73/23/EC (e.g. EN 61010) have been used to fulfil 1.2.7 of Annex II of directive 94/9/EC to eliminate electrical risks.

## **Question 10:**

Annex I, Section 2b

What are "frequent equipment malfunctions or defect situations which are normally to be expected"? What is "the necessary measure of safety"?

## Answer (see as well chapters 4.2.1 and 4.2.2):

It is difficult to give a general definition of "frequent equipment malfunctions or defect situations which are normally to be expected" because this depends to a large extent on the specific equipment.

Malfunctions or defects resulting from normal wear could be considered as "frequent equipment malfunctions or defect situations, which are normally to be expected" but there are also other possibilities.

The "necessary measure of safety" will also depend on the specific equipment. One general approach could be the following:

In normal operation there will always be a certain safety margin. Under the condition of "frequent equipment malfunctions or defect situations which are normally to be expected" the equipment needs only to be safe without a safety margin.

## **Question 11:**

Annex II, Essential requirement 1.2.6 - Historically there were three levels of "safe opening" permitted, there is now only "special fastenings". The effect of this needs consideration for Group II.

## **Answer:**

The three historic levels of "safe opening" are not precluded by the essential requirement 1.2.6 and it is not the intention of directive 94/9/EC to require a level of safety higher than that required by the third editions of EN 50014 series of standards for the equivalent zone of risk.

<u>Level 1</u>, the use of "Special Tools" e.g. on fasteners with hexagonal socket heads can still be used as specifically described by 1.2.6.

<u>Level 2</u>, the use of fasteners which require some form of tool to open the door e.g. a simple screwdriver, an adjustable spanner, or a key, are allowed in 1.2.6 where the additional "appropriate protection measure" would be the presence of a warning label requiring the operator to "De-energise before opening" or similar text.

Note: To qualify for Level 2 a "key" operated fastener (if used) should be used in conjunction with a lock mechanism that automatically locks the door in the closed position when the door is closed. The use of a lock which requires the use of a key to lock it in the closed position is not allowed for Level 2 since the operator may choose not to lock the door again when the door is closed and the additional protection required is no longer provided.

<u>Level 3</u>, the use of a door fastener which would allow the operator to open the door of the enclosure without the use of any tool i.e. with the "bare hands", is also not prevented by 1.2.6. However because of the increased personal and explosion risk additional measures have to be applied e.g. the use of an electrical or mechanical interlock to de-energise automatically the interior of the enclosure as well as the conspicuous presence of the warning label used in Level 2 above.

## **Question 12:**

Is it possible to give further clarification to EHSR 1.5.5, 1.5.6 and 1.5?

## **Answer:**

Requirements in respect of devices with a measuring function for explosion protection have been included in Annex II to make it obvious that measuring equipment is in the scope of the directive and to emphasize its double task due to safety.

Measuring devices have to be safe in potentially explosive atmospheres and it is necessary that they work properly because the measuring results are important for the evaluation of a potentially explosive atmosphere. False measuring can cause a safety problem. This could also include devices measuring the temperature of bearings or motor windings.

## **Question 13:**

Is it possible to issue trade agent certificates without the name of the original manufacturer?

If yes, how can the local surveillance body follow the line of quality management and which number is to be put behind the CE Mark?

## Answer (see as well chapter 3.3):

#### Case 1:

The manufacturer applies for assessment and the certificate, if granted, is in the name of the manufacturer.

The EC declaration of conformity and the application of the CE marking may be effected either by the manufacturer or his authorised representative, but not by both. Required marking shall show the manufacturer's name and the number of the notified body involved in the manufacturer's production phase shall appear be placed after the CE marking.

A trade agent who is not an authorised representative is not allowed to issue an EC declaration of conformity or to apply the CE marking.

A trade agent, who is also an authorised representative, is assimilated with and regarded as an extension of the manufacturer's operation. The name of the manufacturer shall be on the rating plate.

#### Case 2:

A trade agent may apply for assessment and, if successful, have the certificate granted in his name and puts his name on the rating plate

- provided he can satisfy the chosen notified body that he is fully responsible and has control over the design of the saleable product.

Irrespective of where the product is manufactured, the trade agent can issue the EC declaration of conformity, affix the CE marking and add the number of the notified body concerned with the approval of the production phase

- provided the trade agent is fully responsible for and in control of the production.

In this case, the trade agent is the "de facto" manufacturer of the product. The agent can show full responsibility by, for example, placing a sub-contract for production with the actual manufacturer. The trade agent, in this case, is also responsible for engaging a notified body to approve and carry out periodic surveillance of the quality management system used in production, whether in the EU or elsewhere in the world.

The number to be applied after the CE marking is that of the notified body appointed by the trade agent to assess the quality management system.

## Case 3:

A manufacturer A, whose quality management system is approved according to directive 94/9/EC by a Notified Body x, produces and sells equipment for which he holds an EC-Type examination certificate issued in his own name. A trade agent/manufacturer B, whose quality management system is approved according to directive 94/9/EC by another notified body y, applies for an EC-Type certificate in his name, B, based on the certificate previously granted to manufacturer A. On receipt of the certificate he then manufactures the product, issues his own declaration of conformity, affixes the CE-mark with the identification number of the notified body y and sells the equipment in his own name.

Alternatively, trade agent B may choose to have the equipment manufactured under sub-contract. In this case the trade agent must ensure that the quality system used by the sub contractor is in compliance with the relevant requirements of directive 94/9/EC. If the quality system is again approved by notified body y the trade agent can issue his own declaration of conformity, affix the CE-mark together with the identification number of the notified body y and sell the product in his own name.

Note. Although the procedure for issuing a second EC-type certificate in a second manufacturer's name is not explicitly covered by 94/9/EC, it would appear justifiable in order to support established commercial practices, e.g. manufacturing or selling under licence.

In applying for the second certificate, manufacturer B will be expected to submit to the appropriate notified body:

- the original certificate,
- a declaration by the original manufacturer that the equipment to be produced under the name of the trade agent will be identical with the originally certified equipment,
- a declaration by the trade agent that the equipment brought to the market will be identical to that originally certified, and
- a copy of the contractual agreement between A and B.

The line of quality management could then be followed back to the original CE-type assessment.

## **Question 14**

Conveyer systems like bucket elevators, move material (e.g. food and feeding-stuffs) between fixed feeder- and delivery stations. In the cores of bucket elevators and particularly in the head and bottom areas combustible dust air mixtures are likely to occur during operation.

How are bucket elevators to be treated within the framework of directive 94/9/EC, especially in respect that in the surrounding area of bucket elevators potentially explosive areas are not necessarily present?

## Answer (see as well chapter 4.1.2):

The intention of directive 94/9/EC is to avoid the ignition of potentially explosive atmospheres by equipment, protective systems and components. According to the potential hazards and the prevention measures the products are divided into categories.

Directive 94/9/EC defines a potentially explosive atmosphere as an atmosphere, which could become explosive due to local and operational conditions. This means that the potentially explosive atmosphere is either present from the beginning or develops during the working process (e.g. in relation with the conversion of energy or the processing of materials). To that extent the zoning concept for operational areas is not applicable.

In bucket elevators the potentially explosive area is limited in general by housings and/or sheathings, whereby a multiplicity of potential ignition sources can become effective due to construction, for example by rubbing and flapping sparks or by inadmissible heating.

A manufacturer of bucket elevators has to analyse all potential ignition sources (e.g. belts, buckets, angle wheels, drive units, regulating devices) and preventive measures according to design, transported material, transport speed etc. under the aspect of the intended use of the equipment. According to the necessary level of safety, depending on their incorporation in the housing and the disturbances or equipment faults which have normally to be taken into account, special components (presenting a higher risk) might be assigned to categories different to the entire category of the bucket elevator.

# USEFUL ADDRESSEES (correct as at \*\*.9.99)

Annex 9

## **European Commission**

Directorate-General Enterprise

Directorate G: Conformity and standardisation, new approach, industries under new approach Mechanical and electrical engineering and radio and telecom terminal equipment industries

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