ATEX GUIDELINES

GUIDELINES ON THE APPLICATION OF 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

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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 referred to as ATEX ("*Atmosphères Explosibles*") Products Directive. Readers' attention is drawn to the fact that this guide is intended only to facilitate the application of Directive 94/9/EC and it is the relevant national transposition of the text of the Directive which is legally binding. However, this document does represent a reference for ensuring consistent application of the Directive by all stakeholders. The Guidelines are intended to help ensure the free movement of products[1] in the European Union[2] by consensus amongst Member States' government experts and other parties concerned.

2. These Guidelines have been prepared by the competent services of the Directorate General - Enterprise and Industry of the European Commission in collaboration with Member States, European industry, European standardisation and Notified Bodies.

3. The European Commission services will undertake to maintain this Guide. It is our goal to ensure that the information provided is both timely and accurate. If errors are brought to our attention, we will try to correct them. However the Commission accepts no responsibility or liability whatsoever with regard to the information in this Guide.

   This information is:

   - of a general nature only and is not intended to address the specific circumstances of any particular individual or entity;
   - not necessarily comprehensive, complete, accurate or up to date;
   - sometimes refers to external information over which the Commission services have no control and for which the Commission assumes no responsibility;
   - not professional or legal advice.

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.

5. Further guidance, especially concerning specific type of products, can be found on the Commission's website on EUROPA: http://ec.europa.eu/enterprise/atex/guide.htm.

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1 For the purpose of this guide the term "product" covers equipment, protective systems, safety, controlling and regulating devices, components and their combinations as they are defined in Directive 94/9/EC.

2 According to the agreement related to the European Economic Area (EEA) (Council and Commission Decision 94/1/EC of 13 December 1993 (OJ 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 EU territory. When this term, EU territory, is used in this guide, the same applies to the EEA territory.

TABLE OF CONTENTS

1 INTRODUCTION

The objective of these Guidelines is to clarify certain matters and procedures referred to in **Directive 94/9/EC**[3] 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)"[4].

These Guidelines are not only for the use of Member States' competent authorities, but also by the main economic operators concerned, such as manufacturers, their trade associations, bodies in charge of the preparation of standards as well as 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). It should be noted that the statements in these Guidelines refer only to the application of Directive 94/9/EC unless otherwise indicated. All parties concerned should be aware of other requirements, which may also apply (see chapter 6).

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 replace existing divergent national and European legislation which cover the same subjects as stipulated by Directive 94/9/EC.

As of 1 July 2003, all other relevant national regulations have been abolished and Directive 94/9/EC, as transposed into the national legislation of the Member States, is the sole legal instrument applicable.

"Use" Directives

The reader will want to be aware that where ATEX products are intended for use in a place of work, national and community legislation, intended to ensure the safety of employees will usually apply. In this respect different legislation applies to land based industries, the underground extraction of coal and other minerals, and offshore oil production[5].

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3 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. OJ L 100, 19.4.1994, p. 1. Amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003, OJ L 284, 31.10.2003, p. 1. Corrected by Corrigendum, OJ L 21, 26.1.2000, p. 42; and by Corrigendum, OJ L 304, 5.12.2000, p. 19.

4 http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm.

5 Directive 1999/92/EC of the European Parliament and of the Council of 16 December 1999 on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres (15th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC); OJ L 023 , 28.01.2000, p. 57-64.

Council Directive 92/91/EEC of 3 November 1992 concerning the minimum requirements for improving the safety and health protection of workers in the mineral- extracting industries through drilling (eleventh individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC); OJ L 348, 28.11.1992, p. 9-24.

Council Directive 92/104/EEC of 3 December 1992 on the minimum requirements for improving the safety and health protection of workers in surface and underground mineral-extracting industries (twelfth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC); OJ L 404, 31.12.1992, p. 10-25.

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[6], 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 Annex II to Directive 94/9/EC.

These Essential Health and Safety Requirements are specific with respect to:

- potential ignition sources of equipment intended for use in potentially explosive atmospheres;
- autonomous protective systems intended to come into operation following an explosion with the prime objective to halt the explosion immediately and/or limit the effects of explosion flames and pressures;
- safety devices intended to contribute to the safe functioning of such equipment with respect to ignition source and to the safe functioning of autonomous protective systems
- components with no autonomous function essential to the safe functioning of such equipment or autonomous protective system(s)

Since 1 July 2003 relevant products could only be placed on the market in the EU territory[7], freely moved and operated as designed and intended in the expected environment if they comply with Directive 94/9/EC (and other relevant legislation).

Directive 94/9/EC provides for the first time harmonised requirements for non-electrical equipment, equipment intended for use in environments which are potentially explosive due to dust hazards and protective systems. Safety 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 are also included. This is an increase in scope compared to former national regulations for equipment and systems intended for use in potentially explosive atmospheres.

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

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6 OJ No C 136, 4.6.1985 p. 1.

7 Directive 94/9/EC is also applicable in other territories where a suitable international agreement is in operation. See the DG Enterprise and Industry website for more details: http://ec.europa.eu/enterprise/atex/internationaldevelopment.htm.

3 GENERAL CONCEPTS[8]

For the purpose of this guide the term "product" covers equipment, protective systems, safety 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 products 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 which is covered, for instance, by Directives 1999/92/EC, 92/91/EC and 92/104/EC[9].

3.1 Placing ATEX products on the market

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

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

a) *new* products manufactured within the EU,

b) "as-new" products according to the section 3.3,

c) *new or used* products imported from a non-EU country,

d) new or "as-new" products labelled by a person who is not the original manufacturer.

The Directive's provisions and obligations concerning placing on the market have applied 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 been 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 should be clearly advertised in the catalogue.

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8 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.

9 See footnote 5.

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[10]. 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 neither 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 has to be made available on request of the enforcement authorities within a reasonable time (see Annexes III, VI, VIII to the Directive). 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 at the moment of first use.

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 or safety characteristics of the product with reference to the EHSRs of Directive 94/9/EC, 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 any natural or legal person who manufactures a product or has a product designed or manufactured, responsible for the design and construction of products covered by ATEX Directive 94/9/EC, and markets that product with a view to placing it on the EU market under his own name or trademark.

The manufacturer may design and manufacture the product itself, or alternatively may use bought-in items, third-party subcontractor services or components, CE marked or not, to assist in the manufacture of the product.

Whoever substantially modifies a product resulting in an “as-new” product[11], such that its health and safety characteristics (and/or performance) are in any way affected, with a view to placing it on the EU market, also becomes the manufacturer.

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[10] See Article 2.3 of the Directive. Whilst the demonstration of such non-compliant products under the above conditions is permitted national provisions ensure that such demonstrations do not result in unsafe situations.

3.3.1 Use of subcontractor services by a manufacturer

The manufacturer may have the product designed, manufactured, assembled, packaged, processed or labelled by subcontractors, with a view to placing the product on the market under its own name, and thus presenting itself as the manufacturer, disregarding its involvement in the physical/actual manufacturing processes.

Where subcontracting of this type takes place, the manufacturer must retain the overall control for the product and ensure that it receives all the information that is necessary to fulfil the responsibilities of a manufacturer according to the Directive.

In such cases, it cannot discharge itself from its responsibilities as a manufacturer, as it is responsible for the application of relevant conformity assessment procedures, including engaging a Notified Body where required to do so by the Directive, for example to approve and carry out periodic surveillance of the manufacturer's quality management system.

3.3.2 Conformity Assessment Procedures based on quality assurance (Annex IV, Annex VII)

Due to the use of subcontractors, the manufacturer may not be able to demonstrate (to a Notified Body) that its own quality assurance system ensures the product complies with the requirements of the Directive. The production quality assurance (Annex IV) or the product quality assurance (Annex VII) system at the actual manufacturing plant premises, of the manufacturer itself and/or of subcontracters, need to be the subject of an assessment by a Notified Body, including periodic audit visits.

The manufacturer may not rely on the Notified Body audits of the third-parties to discharge its responsibilities under the Directive. The Notified Body shall not issue the subcontractor with a QA Notification for this purpose, unless the subcontractor holds its own EC Type Examination certificate for the same product.

In case the manufacturer uses a subcontractor for the production or labelling of a product, which places the same product on the market under its own name, it is sufficient for the manufacturer to apply for a second certificate based on the certificate of the subcontractor. The manufacturer will be expected to submit

- 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.

See also the Consideration Paper by the ATEX Standing Committee "Certificates and CE marking without the name of the original manufacturer" (http://ec.europa.eu/enterprise/atex/withoutname.htm).

Comments:

The manufacturer bears responsibility for:

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[11] See chapter 7 of this Guide.

- 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);

- signing the Declaration or Attestation of Conformity;

- providing marking and instructions for safe use, maintenance etc. as described in Annex II to the Directive.

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.

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.

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 shall not be subject to assessment by a Notified Body, but the quality assessment system of the actual manufacturer. It would not be reasonable to assess a quality assessment system of a facility that is not producing the product. However, if the authorised representative is carrying out tests and/or verifications required by the Directive to determine conformity with the Essential Health and Safety Requirements, he shall be subject to quality assurance assessment.

Comments:

Articles 8 and 10 together with Annexes 3 - 9 to 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[12]

Equipment[13], 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 and/or the processing of material and which are capable of causing an explosion through their **own** potential sources of ignition[14].

3.7.1 Potentially explosive atmosphere

Equipment is only considered to be within the scope of the Directive if it is intended (either in whole or in part) to be used in a potentially explosive atmosphere.

If a product containing an intended potentially explosive atmosphere, for example a vessel, itself contains equipment 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 itself, which wholly or partially surrounds it, then such equipment is in effect in a potentially explosive atmosphere, and is therefore subject to the Directive.

A third scenario is that there may not only be a surrounding potentially explosive atmosphere but also a process that requires such a mixture to enter and/or be released from the product. The interface between the equipment and the process input/ output will also require consideration. This may, in some cases, lead to equipment having more than one Category, one (or more) for the external atmosphere and another for the process atmosphere.

3.7.2 "Own" ignition source

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

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12 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/she so desire.

13 Article 1.3(a) of the Directive.

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

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[15], 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 exist. Most equipment made to the Gas Appliances Directive 90/396/EEC will fall into this category.

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 to the Directive) in a potentially explosive atmosphere, it is capable of igniting the latter unless specific safety measures are taken. Therefore, equipment must ensure the required level of protection.

To ensure this required level of protection various techniques can be applied, e.g.: intrinsic safety, pressurisation, increased safety, etc.

Many common items are made from plastics (polymers) with very low electrical conductivity. These can become charged, e.g. if they are rubbed, or if dust or a liquid flows over the surface. However, in most cases this may be controlled by the user, and if they are used in hazardous areas it shall be *assessed and controlled* according to the requirements of relevant national or community legislation (e.g. Directive 1999/92/EC[16]). In any case the user of such equipment has to consider these ignition sources when undertaking a risk assessment in the workplace.

Examples are plastic containers used for transporting chemicals, polyethylene pipes, buckets and chairs.

If the only source of electrostatic charging comes from the process, such items are not considered to have their own source of ignition, and they are not in scope of Directive 94/9/EC. In these cases they should not be Ex or CE marked according to Directive 94/9/EC.

If the polymeric item is intended to be incorporated into ATEX equipment, and could become charged by the movement of the equipment (for example a fan blade) or by the intended use of the equipment, they may be classed as ordinary parts of the equipment with specific properties (e.g. to be electrostatically dissipative) or as ATEX components if they are placed on the market specifically for this intended use.

3.7.3 Non-Electrical Equipment

If non-electrical equipment has a potential ignition source, in most cases this is due to moving parts able to create a potential ignition risk either from hot surfaces, or friction sparks. Examples are: gears, fans, pumps, compressors, mixers, brakes. Mechanical equipment of this type usually has to be connected to a power source, such as an electric motor. Together placed on the market in this form, it might be an assembly, see section 3.7.5.

Mechanical equipment may be fitted with a thermocouple or similar measuring device that generates only very low voltages and currents. If these measuring devices can be considered as ‘simple apparatus’ as described in section 5.2.1 and there are no other electrical parts, the equipment should follow the conformity assessment procedures for non-electrical equipment. If the equipment contains electrical apparatus that can be clearly separated, the conformity assessment procedure for non-electrical parts can be made separately if the conditions under 3.7.4 (e.g. pump) apply. If the electrical equipment fitted to the non-electrical equipment is not "simple apparatus", the product is usually considered as an assembly (see assemblies chapter).

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[15] 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.

[16] See footnote 5.

All potential ignition sources should be considered for equipment that is within the scope. For a list of potential ignition sources, see the relevant harmonised standards for equipment. In many cases the equipment will also be machinery within scope of Directive 98/37/EC, see section 6.

Many mechanical items move very slowly, or have very low power input. Such equipment may be incapable of forming hot surfaces or other ignition sources, even in cases of rare malfunction. The manufacturer should assess if such equipment is potentially capable of igniting an explosive atmosphere, and if it is not, it shall not be classed as ATEX equipment nor be marked according to Directive 94/9/EC (see also chapter 5.2.1).

3.7.4 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 containing electrical elements, 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 does not lead to additional ignition hazards for this assembly (for further details see section 3.7.5).

3.7.5 Assemblies

From the term 'jointly' in the definition of equipment in the Directive it follows that an assembly, formed by combining two or more pieces of equipment, together with components if necessary, has to be considered as a product falling under the scope of Directive 94/9/EC (see footnote 1), 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.) shall 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 compliant 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 there are additional ignition hazards, 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 written attestation of conformity issued by their manufacturer (Article 8.3, see also chapter 10).

However, if the manufacturer of the assembly integrates parts without 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 shall cover those parts as required.

Note that the manufacturer's own risk assessment does not necessarily preclude the use of Notified Bodies in the applicable conformity assessment procedure(s).

In order to clarify the concept of “assembly” in the sense of Directive 94/9/EC, a pump/electric motor combination intended for use in potentially explosive atmospheres can be used.

1. For the purposes of Directive 94/9/EC, a *split tube motor pump* constitutes a single item of equipment with respect to the ignition hazard, i.e. the pump and electric motor cannot be considered separately for the purposes of assessing explosion risk(s). In this case, the unit as a whole has to undergo the conformity assessment procedure of electrical equipment. The same applies e.g. for an electrical ventilating fan where the fan is an integral part of the motor.

2.a) In some cases the pump and electric motor can be considered separately although they form a functional unit. If in this case there is no additional ignition hazard as a result of assembling the pump and motor, **this functional unit as a whole** does not constitute a single item of equipment which falls within the scope of Directive 94/9/EC. It is then to be considered a combination of "individual items of equipment" in terms of explosion protection. In this case, therefore, the manufacturer of pump and electrical motor must supply an EC declaration of conformity for each of both items.

2.b) A manufacturer may nevertheless choose to supply pump and motor as described in 2.a) with one declaration of conformity for the assembly as a whole. In this case further clarification is required as to the obligation of the assembler where only ATEX CE compliant products (such as equipment and autonomous protective systems) are used. Here it is clear that the assembler needs to undertake an ignition risk assessment to ensure that the nature of the incorporation and assembly has not altered the explosion characteristics of the products with respect to the Essential Health and Safety Requirements. If the assembler is in any way uncertain as to how to undertake such an assessment, **technical advice should be sought and taken into account! This might be the case, for example, if a manufacturer of mechanical equipment needs to connect different pieces of ATEX electrical equipment together as part of the assembly**. Once the assembler has successfully undertaken such an assessment and no additional ignition risk has been identified, the general agreement is that he then draws up a technical file, affixes the CE and Ex marking according to Annex II 1.0.5 of the Directive to the assembly, indicating intended use, signs the EC Declaration of Conformity covering the whole of the assembly indicating the technical specifications/ standards applied (for example, for electrical inter-connection) and provide instructions for safe use. The assembler therefore takes complete responsibility for the assembly. This procedure does not require the involvement of a Notified Body.

2.c) If there is an additional ignition hazard as a result of assembling pump and motor, or if one item is not already in full conformity with the Directive, the assembly has to undergo the complete conformity assessment procedure appropriate for the category.

Assemblies may be placed on the market in different ways:

3.7.5.1 Assemblies, which are fully specified configurations of parts

In this case 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 put together by the same person (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.

3.7.5.2 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 not necessarily put together by the manufacturer of the assembly, and placed on the market as a single functional unit, 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.

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 the parts that form the modular system are, 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 (as a minimum) by means of the assessment of those intended configurations which are the most unfavourable regarding the relevant risks (worst cases). If those configurations are considered compliant to the EHSRs of Directive 94/9/EC the manufacturer may conclude conformity of all other intended 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 case scenario again.

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

Table 1: Summary of Requirements for Assemblies

SITUATION:				
1. Parts: Assembly is composed of…	Equipment, protective systems, devices (Art. 1.2) all CE-marked (accompanied by a certificate of conformity) 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 configured to serve a specific purpose, maybe by the user/installer.	Exactly defined configuration(s)	A "modular system" of parts, to be specifically selected and configured 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. See also Note **(*)**	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. See also Note **(*)**	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) by EC-Declaration of Conformity** **b) by instructions for installation and use**	a) identification of the items in the assembly that are ATEX equipment in their own right, and which have been separately assessed; b) instructions for installation and use, sufficient to ensure that resulting assembly complies with all relevant EHSRs of Directive 94/9/EC.	a) identification of the items in the "modular system" that are ATEX equipment in their own right, and which have been separately assessed; b) instructions for the selection of parts, to be combined to fulfil 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.	a) identification of the items in the assembly that are ATEX equipment in their own right, and which have been separately assessed; b) instructions for installation and use, sufficient to ensure that resulting assembly complies with all relevant EHSRs of Directive 94/9/EC.	a) identification of the items in the "modular system" that are ATEX equipment in their own right, and which have been separately assessed; b) instructions for the selection of parts, to be combined to fulfil 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.

(*) Note: A **written attestation of conformity** for a component can not guarantee, in general, the safety of the equipment into which the component is to be incorporated, as for a component, all possible use can not be foreseen. In this case, **further investigation and evaluation by a Notified Body shall be carried out in the assembly**, when required.

3.8 Protective Systems

Protective Systems[17] means devices other than components of the equipment defined above which are intended to halt incipient explosions immediately and/or to limit the effective range of an explosion and which are separately placed on the market for use as autonomous systems.

Examples of autonomous protective systems are:

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

It is clear that certain simple products used in coal mines act as protective systems but cannot be subject to the provisions of the Directive (e.g. chalk dust on planks).

From its intended function it is obvious that a protective system will, 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[18]. 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 autonomous 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".

3.9 Components

The two defining elements for components[19]are that they,

- are essential to the safe functioning of equipment and protective systems with respect to explosion protection (otherwise they would not need to be subject to the Directive);
- 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)).

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.

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17 Article 1.3(b) of the Directive.

18 See Corrigendum to the English language version of Directive 94/9/EC (OJ L 21, 26.1.2000).

19 Article 1.3(c) of the Directive.

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

If the function of the product can be delivered without further parts then, where relevant, it cannot be considered a component.

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 standards harmonised under Directive 94/9/EC are components in the sense of the ATEX as well. **Components must not have the CE marking affixed** unless otherwise required by other directives (e.g. the EMC Directive 2004/108/EC).

Examples for items which could be placed on the market as components, if they are explicitly intended to be incorporated into ATEX products:

- terminals;
- push button assemblies;
- relays;
- empty flameproof enclosures;
- ballasts for fluorescent lamps;
- encapsulated relays and contactors, with terminals and/or flying leads;
- machinery brakes designed to be part of ATEX equipment;
- a pressurised container including suppressant powder forming part of an explosion suppression *system;*
- conveyor belting for a conveyor transporting combustible dusts;
- non-autonomous protective systems;
- suction hoses used on vacuum cleaners;
- forks for forklift trucks.

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. Some components may be assigned a category, in which case they will always be used in equipment of that category. Other components may be more widely used, and no category can be defined. In addition, components for e.g. autonomous protective systems do not need to bear a category as the protective systems themselves are not categorised. It depends on the detail that is given in any documentation provided (e.g. where relevant by means of a written attestation of conformity).

For example, drive-belts, bearings, mechanical seals, 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. increased safety 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).

If a component is subject to a conformity assessment procedure under which a Notified Body issues a Type Examination Certificate, the Certificate must detail those requirements of Annex II that have been assessed.

3.10 Safety, controlling or regulating devices as defined in Article 1.2

Devices in the scope of Article 1.2

1. **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 hazards of ignition or - respectively - with respect to the hazard of uncontrolled explosion are **subject to the Directive**;
2. These devices are covered **even if** they are intended for use **outside the potentially explosive atmosphere**. Those devices are not classified into categories according to Article 1.
3. Safety instrumented systems (e.g. a sensor, PLC and an actor) in the sense of items 1. and 2.. The whole system must be considered as a safety device in the sense of Article 1.2. Parts of this safety device may be located inside (e.g. a sensor) or outside (e.g. PLC) potentially explosive atmospheres.

For such devices, the essential requirements shall only apply so far as they are necessary for the **safe and reliable** function and operation of those devices with respect to the hazards of ignition or - respectively - with respect to the hazard of uncontrolled explosion (Annex II, Preliminary observation B).

Examples**:**

- 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 ignition hazard);
- overload protective devices for electric motors of type of protection Ex 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 on one or a small number of equipment or protective systems in terms of further avoiding an ignition hazard if dangerous levels of gas are detected;
- controller units connected to sensors measuring temperature, pressure, flow, etc, located in a safe area, used to control (in terms of further avoiding an ignition hazard) electrical apparatus, used in production or servicing operations in a potentially explosive area.

For safety and economic reasons it will be preferable in most cases to install such devices in a non-hazardous area. However, sometimes this might not be possible. 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 shall not be regarded as equipment but, evidently, the requirements resulting from Article 1.2 will still apply.

Devices outside the scope of Article 1.2

1. Devices other than safety, controlling and regulating devices.
2. **All devices**, including safety, controlling and regulating devices**, neither contributing** to **nor required** for the safe functioning with **respect to the** hazards of ignition or with respect to the hazard of uncontrolled explosion;
3. Even **safety, controlling and regulating devices** contributing to or required for the safe functioning but **with respect to hazards other than the** hazards of ignition or - respectively - with respect to the hazard of uncontrolled explosion**;**

4. **Monitoring devices** providing only an **alarm signal** to protect persons but without control of the equipment inside the hazardous area.

Examples**:**

- Switchgear, numeric controllers, etc. not related to any safety functions (with respect to the ignition hazard); see 2. above;
- Water spray systems designed to protect plant from fire;
- Blast doors designed to withstand a stated overpressure (these are designed primarily as doors, and they do no more than the walls they are placed in to protect against an explosion;
- Gas detector systems that raise an alarm but have no controlling function on the equipment;
- Emergency ventilation systems which act when gas is detected.

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 What is a potentially explosive atmosphere in the sense of 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 EU. 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. The manufacturer has to make assumptions about the intended use of his product including the contact with potentially explosive atmospheres.

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[20];

iv) in which, after ignition, the combustion spreads to the entire unburned mixture (It has to be noted that sometimes (mainly with dusts) not always the whole quantity of the combustible material 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** where they are intended for use in or in relation to mixtures which might potentially be explosive, but one or more of the **defining elements i) to iv) above are not present**.

For example:

- A product within a potentially explosive mixture without the presence of air is not in the scope of the Directive[21]. Special processes of this type require equipment that has been specially

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[20] The Directive 94/9/EC does not define atmospheric conditions. However, a surrounding temperature range of –20°C to 60°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 for use in the ambient temperature range –20°C to 40°C in conformity with the harmonised standards. Products designed for use outside of this range will require additional marking to be added and further testing as appropriate. This will normally require agreement between the manufacturer and intended user.

[21] Examples for such atmospheres could be: mixtures which are explosive without air (e.g. H_2 mixed with Cl_2), mixtures of flammable substances with other oxidants than air, pressure and/or temperature conditions outside the atmospheric range, etc.

designed for the risks, as equipment intended for use in potentially explosive atmospheres may pose an ignition hazard for mixtures under non-atmospheric conditions.

- Conveying equipment where some parts but not all are under atmospheric pressure with internal pressures different from atmospheric pressure can fall under the scope of Directive 94/9/EC. When performing a risk assessment it will become evident that although parts of the described equipment are outside the scope of Directive 94/9/EC during normal operation (pressure oscillates between too low and too high values in relation to "atmospheric conditions") some parts or spaces still are under the scope and that the whole equipment during start-up and shut-down is under the scope, at least.
  So, both the following examples fall under the scope of Directive 94/9/EC:
  a) A vapour recovery pump for petrol stations is connected at its inlet and outlet to a potentially explosive atmosphere in the sense of Directive 94/9/EC.
  b) A vacuum pump sucking from a vacuum container and conveying the mixture into a pressure vessel or pressure line. In this case the inner parts of the pump are not connected to a potentially explosive atmosphere in the sense of Directive 94/9/EC.
  Note: The manufacturer may wish to sell this equipment for use under atmospheric conditions of the inlet and outlet side additionally, and then case a) applies. In any case, the complete working cycle needs to be considered, including start-up and shut-down, which may cause an atmospheric pressure to exist. If the equipment is not intended for atmospheric use, the Directive does not apply. Risk assessment must be carried out according to Directive 1999/92/EC.

As long as the user is not able to ensure the absence of a potentially explosive atmosphere, start-up and shut-down are relevant to determine the application of the Directive.

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.

In some specific circumstances clarification is needed, in order to decide whether a certain product falls within the scope of Directive 94/9/EC or not. This will be clarified using the example of “Inerting Systems” (section 4.1.2.1) and “Paint Spray Booths” (section 4.1.2.2). In addition, two frequently arising questions concern:

- the place of installation of equipment and protective systems (section 4.1.2.3), and

- the existence of interfaces to different potentially explosive atmospheres (section 4.1.2.4).

4.1.2.1 Inerting Systems

When looking for the application of Directive 94/9/EC to inerting systems one has to consider three different cases:

1. Preventing an explosive atmosphere

Inerting systems are aimed at reducing or completely preventing the existence of an explosive atmosphere in specific areas. Inerting systems are not, however, intended to stop or restrain incipient explosions; hence they are not protective systems within the meaning of Directive 94/9/EC. The goal of inerting systems is different from those of explosion suppression systems, which may sometimes have similar parts, but are aimed at restraining an incipient explosion.

In broad terms: inerting systems **used during operation of plants** etc. are normally **not** in scope of Directive 94/9/EC.

Example:

The intended effect of an inerting system applied to inert a tank can only be assessed after knowing all operational parameters of the volume to be inerted. This assessment and the functional aspects of such systems are not covered by Directive 94/9/EC but a duty to be considered by the user and has to be laid down e.g. in the explosion protection document under the scope of the Directive 1999/92/EC and its national transpositions.

2. Inerting systems as equipment

An inerting system may (in part) also consist of parts which are intended for use **within** an explosive atmosphere and which have a potential ignition source of their own. These parts come – individually or possibly combined – under the scope of Directive 94/9/EC as "equipment". Also in this case their function of preventing an explosive atmosphere by inerting is not to be assessed within the meaning of this Directive.

3. Inerting systems as part of the ignition protection concept

In some cases, such systems may be part of the ignition protection concept of "explosion protected" equipment to fulfil the requirements of Annex II to Directive 94/9/EC, i.e. if they work as a means to protect potential ignition sources of the equipment from coming into contact with an existing potentially explosive atmosphere. This equipment, including its inerting system, comes as part of the equipment under the scope of Directive 94/9/EC. This inerting system is not a protective system according to article 1(1). Its parts may be safety, controlling and regulating devices according to article 1(2) of Directive 94/9/EC when separately placed on the market.

In broad terms: Directive 94/9/EC **applies** to an inerting system, if this system is – or is intended to be – integrated into the ignition protection concept of the equipment and thus serves to avoid ignition sources of the equipment.

Example:

Where the manufacturer of equipment intended for use in potentially explosive atmosphere wants to protect the ignition sources of this equipment, he may use the type of protection "pressurisation" according to EN 50016. This type of protection may include the use of inert gases as protective gases. In this case the inerting system is part of the equipment and as such within the scope of Directive 94/9/EC. The following case may occur in practice: Equipment according to Article 1 of Directive 94/9/EC contains an enclosure or a vessel containing sources of ignition. In order to prevent an explosive atmosphere from coming into contact with the ignition sources, an inerting system, which has been assessed in accordance with the 94/9/EC Directive as a safety device, can be applied to this equipment.

4.1.2.2 Paint Spray Booths

These products are an enclosed area, where an operator may work inside or outside, and may be described as a “simple box”. The “box”, with no ignition source and not intended for use in a potentially explosive atmosphere, does not fall within the scope of the ATEX Directive 94/9/EC.

Under operating conditions a potentially explosive atmosphere is created and the enclosed area, openings and recovery systems are normally **assessed with regard to the explosion risk**. The equipment, protective systems and components intended for use in this **assessed** potentially explosive atmosphere including safety and controlling devices outside, but contributing to their safe functioning, are within the scope of the ATEX Directive 94/9/EC.

In summary, paint spray booths, as an integral whole, do not fall under scope of the ATEX Directive 94/9/EC and as such cannot be affixed with the special marking for explosion protection and other marking detailed at Annex II, EHSR 1.0. of the Directive.

4.1.2.3 Place of intended use

Manufacturers of explosion protected equipment (e.g. in cases where potentially explosive atmospheres are conveyed) sometimes feel unsure whether and to what extent their products are covered by Directive 94/9/EC (see chapter 3.7.1). This applies especially to cases where only parts of the equipment are in contact with the explosive atmosphere.

Directive 94/9/EC deals with the special risk of explosion and has one major aim to prevent "own potential sources of ignition" (Art. 1(3)a) of equipment and protective systems (as far as it has an own potential source of ignition) from becoming active. Beside Art. 1(4) no restrictions are made with regard to local and technical conditions.

The probability of occurrence of the potential source of ignition determines the category. The technical requirements are summarised in Annex II 1.0.1; especially the 2nd indent describes the importance of the potential of the source of ignition. For this effect the place of installation is not decisive (see Art. 1(2) safety-, controlling-, regulation devices), but the possible effect of the potential source of ignition on a potentially explosive atmosphere.

In the light of these ideas the place of installation "in, at or beside" a potentially explosive atmosphere is not decisive for the application of Directive 94/9/EC. The decisive fact is whether the potential sources of ignition of an equipment are in contact – or have an interface – to a potentially explosive atmosphere, with the effect that the combustion may spread to the entire unburned mixture (see definition "explosive mixture"). In this case the potential source of ignition is in the potentially explosive atmosphere.

Equipment may have an internal explosive mixture (without limitation to dangerous quantities), which has an interface in the sense of a spreading of the combustion to a potentially explosive atmosphere even in the case it is not installed completely inside a potentially explosive atmosphere. An example could be an extraction system installed outside the potentially explosive atmosphere with a ventilator – own potential source of ignition – which exhausts explosive atmosphere out of a storage tank, or another potentially explosive atmosphere, via a pipe acting as connecting interface to the potentially explosive atmosphere.

It is important to underline in this context how machinery having a potentially explosive atmosphere inside under operating conditions, but having no interface to external potentially explosive atmospheres has to be considered. Such machines, as an integral whole, do not fall under scope of the ATEX Directive 94/9/EC (see also chapter 4.1.2.2 and 4.1.2.4).

The Machinery Directive 98/37/EC, however, requires that the manufacturer “must take steps to:

- avoid a dangerous concentration of products,
- prevent combustion of the potentially explosive atmosphere,
- minimise any explosion which may occur so that it does not endanger the surroundings.

(...)

Electrical equipment forming part of the machinery must conform, as far as the risk from explosion is concerned, to the provision of the specific Directives in force”.

It is therefore evident that equipment, protective systems and components intended for use *in this potentially explosive atmosphere* – and safety and controlling devices outside, but contributing to their safe functioning – are within the scope of the ATEX Directive 94/9/EC. It is understood that

the latter applies provided that "atmospheric conditions" in the sense of Directive 94/9/EC are present in the machine.

In this context the following questions have arisen:

1. Has the manufacturer the obligation to perform a zone classification inside this machinery?

It has been considered that:

- The manufacturer has to carry out a risk analysis, including the risk of explosion;
- Annex I to the ATEX Directive 94/9/EC contains clear and unambiguous definitions concerning the place where they are intended to be used for every single equipment-group and category;
- as opposed to the fully harmonising scope of the Machinery Directive, the zone concept applied in the framework of the ATEX "user" Directive 1999/92/EC allows member states to apply more stringent requirements than those defined in this Directive.

In order to avoid a non harmonised approach in the framework of a fully harmonised field like the Machinery Directive, it is not necessary to apply the *zone concept* as it is defined in Directive 1999/92/EC. Instead, the manufacturer should:

- Carry out the risk assessment;
- Define the requirements of the equipment to be used inside the potentially explosive atmosphere – and of safety and controlling devices outside, but contributing to their safe functioning – in order to ensure full compliance of the machinery with the requirements of the Machinery Directive;
- Purchase or produce the equipment having those requirements, i.e. intended to be used under the conditions defined during the risk analysis, and in conformity to Directive 94/9/EC.

2. Must the 'non-electrical' equipment used inside this machinery be also in conformity to 94/9/EC?

The equipment used inside must be in conformity to the applicable legislation. When the original Machinery Directive 89/392/EEC was drafted, European Directives regulated only electrical equipment for use in potentially explosive atmospheres; therefore non-electrical equipment was not mentioned.

It is nevertheless common understanding of the Standing Committee that after the date of application of Directive 94/9/EC, both electrical and non-electrical equipment used in machinery having a potentially explosive atmosphere inside must comply with Directive 94/9/EC. This position is also reflected in the revised Machinery Directive.

4.1.2.4 Interface to different potentially explosive atmospheres

This paper seeks to provide guidance on the application of ATEX Directive 94/9/EC to equipment[22] intended to operate with interfaces to different potentially explosive atmospheres.

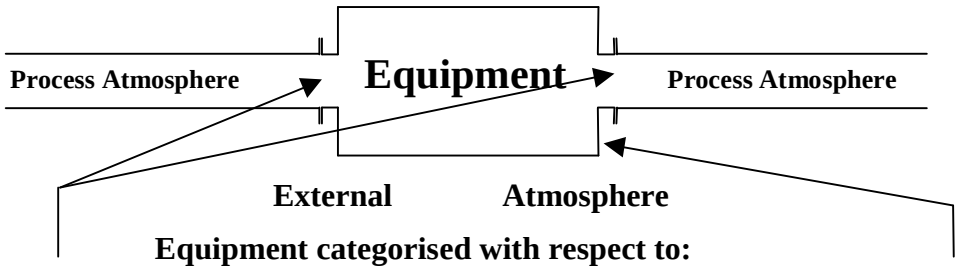
At this point it is necessary to note that equipment that contains a potentially explosive atmosphere but is neither connected to, nor intended for use in, an external or process related potentially explosive atmosphere does not fall under the scope of Directive 94/9/EC. However, any equipment

[22] Equipment here is taken to mean all products within scope of Directive 94/9/EC

inside this "container" will, so long as it fulfils the criteria for inclusion in scope, need to comply with the relevant provisions.

The categorisation of equipment is to be determined on the basis of the ignition risk assessment[23] by the manufacturer or his authorised representative and the equipment's relationship with respect to its interface with its process atmosphere and any external atmosphere.

The following diagram illustrates this point:



Equipment categorised with respect to:
connections to process atmosphere (inside) and to external atmosphere

For example, the inside or process side of a pump for flammable liquid which normally runs full but occasionally contains an explosive atmosphere may, **depending on the actual situation**, be considered Zone 1[24] if no other measures have been taken to prevent the pump running dry. If it has been decided that the surroundings or external explosive atmosphere is Zone 2 then a pump conforming to Category 2 inside and Category 3 outside must be used to meet the Essential Health and Safety Requirements.

Note: the process atmosphere zone (and the respective category) need not necessarily to be the same for the two connections to the process atmosphere.

The following guidelines may help in the selection of an appropriate category:

The category (or categories) assigned to equipment shall be determined for each part of the equipment which comes into contact with, or is connected to, a Zone with a potentially explosive atmosphere (see Directive 1999/92/EC).

The category assigned to a piece of equipment intended to contain a potentially explosive atmosphere not connected to the outside of that equipment is determined by the ignition risk associated with the outside parts of the equipment, not by its internal atmosphere i.e. only the part of the equipment which is intended to come into contact with a Zone is relevant for the assignment of the appropriate category.

The category (or categories) assigned to the process connecting points of equipment containing an explosive atmosphere cannot be higher than that appropriate to the ignition risk.

For example, consider the case of a fan conveying an explosive gas atmosphere over its rotating blades, or a powder mill producing an explosive dust atmosphere inside the mill. Each having an outlet connected to an external potentially explosive atmosphere. The ignition risk assessment for

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23 The category classification is performed by the person responsible for making the EC Declaration of Conformity according to directive 94/9/EC.

24 "Zoning" is not a concept to be found in Directive 94/9/EC but in Directive 1999/92/EC dealing with employer's obligations with respect to employees operating in hazardous atmospheres. It is not the responsibility of the manufacturer to "zone" but evidently this it is helpful to give an example of the area of intended use.

both these items of equipment has shown for these specific examples that an effective ignition source (for the explosive atmosphere connected to them) is not present in normal operation but may be present in the case of an expected malfunction. If such equipment/assembly is placed on the market without additional ignition protection or a protective system it can only be classified as category 3[25].

Such equipment can only be used when it is connected to an explosive atmosphere which is present continuously (i.e. Zone 0/20) if additional ignition protection or a protective system is fitted (see Directive 1999/92/EC).

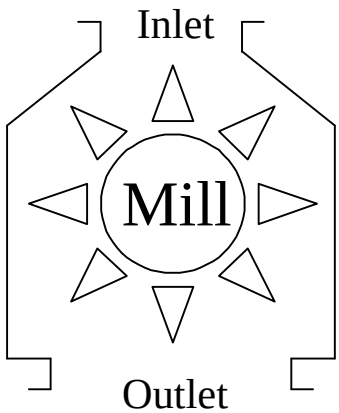
Where a piece of equipment is fitted with an autonomous protective system such as flame arresters, or a suppression system which is already compliant to Directive 94/9/EC, additional testing and conformity assessment of the resulting assembly, i.e. equipment together with the protective system, is not required provided the protective system is used within its intended design capabilities covering the specific case, is installed in accordance with the manufacturer's instructions and no new ignition hazards are introduced. However, an ignition risk assessment will be required and relevant action taken (see section 3.7.5 on assemblies) if additional hazards are identified.

Similarly, Directive 94/9/EC does not require that the pressure resistance of a vessel or container protected against the effects of an explosion by an autonomous protective system be tested, if it has been demonstrated that the autonomous protective system successfully detects and suppresses an explosion and if the vessel can withstand the residual pressure peak of the suppressed explosion.

Example

NOTE: The following is one of many examples that can be used to illustrate the above points. The assumptions made in this example should not be taken as the only possible situation. The categorisation of a particular piece of equipment will depend on the specific ignition hazard assessment that is made of the equipment and its intended use together with any ignition protection measures applied. The example only considers the inside and connecting explosive atmospheres, i.e. the process side. A separate ignition hazard assessment and categorisation must be made of the outside if the equipment is to be used in potentially explosive atmosphere.

Consider a powder mill as shown in the following figure:



The ignition hazard assessment carried out by the manufacturer has identified that in this case:

- there is no ignition source inside the mill which can become effective in normal operation[26];

[25] Additional measures to cover expected malfunctions may provide Category 2; if two faults or one rare fault are dealt with, Category 1 can be reached.

[26] It is clear that for some milling technologies an ignition source may be unavoidable.

- there is an ignition source inside the mill which can become effective during expected malfunctions.

The highest category that can be assigned to the mill is therefore Category 3 when it is placed on the market as shown. The outlet from the mill in this case produces fine dust in the form of a potentially explosive dust cloud which is continuously present in normal operation, i.e. Zone 20. The manufacturer's instructions must therefore make clear that the mill can only be used with additional explosion prevention or protection measures.

Analysis

Directive 94/9/EC defines equipment as follows:

- intended for use in potentially explosive atmospheres;

- and/ or for the processing of material;

- capable of causing an explosion through their own potential sources of ignition.

This definition applies to the grinding assembly of a mill for combustible materials of the food and fodder industry. Therefore, these are within the scope of Directive 94/9/EC.

The intended purpose of a grinding assembly in a mill is the grinding of combustible materials whereby the content of fine particles is increased considerably.

According to the risk assessment the grinding installation should fulfil the requirements for category 1, but in the best case it will meet category 3. Despite all construction measures to prevent ignition sources, the occurrence of dust explosions can not be excluded definitely. Therefore, the mill when fully installed must be provided with additional protection measures, which reduce the effect of a dust explosion for people and goods to below a dangerous level.

These measures are essential for the grinding system to fulfil the requirements of Directive 94/9/EC.

Consequently:

- all requirements on the construction of the grinding assembly *(e.g. suitable selection of material and bearings, minimum distances between rotating and fixed parts),* on certain equipment of the mill *(e.g. foreign particles separator, overload protection, temperature detector at the bearings)*

and

- all construction measures of the mill *(explosion pressure resistant design for the maximum explosion pressure, or explosion pressure resistant design for the reduced explosion pressure in combination with explosion pressure relief or explosion suppression, and in most cases additional explosion decoupling for connected installations)*

are necessary to make the grinding operation safe.

4.2 Defining Group and Category

The Directive divides equipment into two groups. 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.

Note: devices have to follow the conformity assessment procedure according to the category of the equipment or protective system they are required for or contribute to. Devices and components may be suitable for one or more category or group of equipment.

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.

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.[27]

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.[28] This normally includes also the requirement to provide equipment with a sufficient level of safety in the event of operating faults or in dangerous operating conditions which normally have to be taken into account.

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 very high level of protection 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.

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

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

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

- 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[29]

It is also considered that equipment may be classed as category 1, if the manufacturer provides a combination of protective measures to prevent an ignition source becoming active under fault conditions, and in addition an integrated protective system (see chapter 3.8) which will control the ignition hazard from a rare malfunction of the equipment.

Category 2 comprises products designed to be capable of remaining within their operational parameters, stated by the manufacturer, and based on a high level of protection 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.

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[30].

Category 3 comprises products designed to be capable of keeping within its operational parameters, stated by the manufacturer, and based upon a normal level of protection for its intended use, considering areas in which explosive atmospheres caused by mixtures of air and gases, vapours, mists or air/dust mixtures are **unlikely** 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[31].

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 PROTECTION	CATEGORY		PERFORMANCE OF PROTECTION	CONDITIONS OF OPERATION*
	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 energised 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 energised 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. If applicable also suitable for frequently occurring disturbances or for faults which are normally taken	Equipment de-energised when explosive atmosphere is recognised

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

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

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

			into account.	
High		2	Suitable for normal operation and frequently occurring disturbances or equipment where faults are normally taken into account.	Equipment remains energised and functioning in Zones 1, 2 (G) and/or 21, 22 (D)
Normal		3	Suitable for normal operation.	Equipment remains energised and functioning in Zone 2 (G) and/or 22 (D)

* *Note*: see as well the directives on minimum requirements for improving the safety and health protection of workers operating in potentially explosive atmospheres, e.g. those indicated in footnote 5. The equipment in the various categories must also comply with the relevant essential and supplementary requirements detailed in Annex II to the Directive (Essential Health and Safety Requirements).

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. However, in most cases he will not be in the position to understand the possible extent of the adverse consequences of an explosion (as part of the overall explosion risk) since this is solely dependant on the particular circumstances at the users` premises. So the manufacturer's risk assessment will in general be restricted and be focussed to the assessment of the ignition hazard (again part of the explosion risk) or the explosion control function for a protective system and safety devices. In addition, as required in Annex II, 1.0.2 to the Directive, equipment and protective systems must be designed and manufactured after due analysis of possible technical and 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, a methodology on risk assessment, i.e. here ignition hazard assessment, should not only deal with designing and construction aspects but also provide a common format or language 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. They can easily be adopted for the ignition hazard assessment explained above as follows:

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.

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

In principle the hazard assessment comprises of four steps[32]:

a) **Hazard identification**: 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.

b) **Hazard 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).

c) **Hazard evaluation**: Comparison of the hazards 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.

d) **Hazard reduction option analysis**: The final step of hazard 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.

[32] For further information on risk assessment, see EN 1127-1:1997 Explosive atmospheres - Explosion prevention and protection - Part 1: Basic concepts and methodology. For worked examples see EN 13463-1.

5 EQUIPMENT NOT IN THE SCOPE OF DIRECTIVE 94/9/EC

5.1 Exclusions based on Article 1.4 of 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. The question has also been discussed as to whether this implicitly conveys the meaning that equipment intended for use in domestic and non-commercial environments, where the leakage is not fuel gas, are included within scope. It was agreed by the ATEX Standing Committee as a general rule such types of equipment are excluded from Directive 94/9/EC as they are not intended for use in a potentially explosive atmosphere;

- personal protective equipment covered by Directive 89/686/EEC[33]. 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, as they are already covered by the IMO Convention.

- 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. **Means of transport intended for use in a potentially explosive atmosphere are not 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.

5.2 Examples for equipment not covered by Directive 94/9/EC

5.2.1 "Simple" products

For "simple" electrical products, European harmonised standards provide a good basis to assess the effectiveness of electrical ignition source and, consequently, to determine whether or not these can be considered effective or not.

In general, many simple mechanical products do not fall under the scope of Directive 94/9/EC as they do not have their own source of ignition (see chapter 3.7.2). Examples without own source of ignition are hand tools such as hammers, spanners, saws and ladders.

Other examples that in most cases have no potential ignition source are given below. However, the manufacturer will need to consider each item in turn with respect to potential ignition hazard to consider whether Directive 94/9/EC applies (see also chapter 3.7.3):

- Clockwork time pieces; mechanical camera shutters (metallic);

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[33] 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.

- Pressure relief valves, self-closing doors;

- Equipment moved only by human power, a hand operated pump, hand powered lifting equipment, hand operated valves.

The issue of hand operated valves has also been discussed. Given that these will move slowly, with no possibility of forming hot surfaces, as discussed in section 3.7.3 they are not in scope of the Directive. Some designs incorporate polymeric parts, which could become charged, but this is no different from plastic pipes. Given that it is clear that the latter is outside of the scope of Directive 94/9/EC it has been accepted that such valves do not fall within scope.

Some manufacturers have argued that their valves are specially adapted for ATEX, in that they have either selected more conductive polymers, or taken steps to ensure that no metal parts could become charged because they are unearthed. Other manufacturers state that all their valves meet this requirement simply by the way they are constructed, and they see no distinction from valves used to process non-flammable materials. To avoid confusion between those who claim correctly that their valves have no source of ignition, and are out of scope, and those who claim that they have done some very simple design change and wish to claim that their valves are now category 2 or even 1, it has been agreed that valves having characteristics as described above are out of scope. Nevertheless, as discussed in section 3.7.3, where potentially flammable atmospheres exist, users must always consider the electrostatic ignition risks.

5.2.2 Installations

The Directive does not regulate the process of installation. Installing such equipment will generally be subject to legal requirements either workplace directives (see footnote 5) or the domestic legislation of the Member States.

However, the question is frequently asked to distinguish between the responsibilities of manufacturers, building a piece of equipment or an assembly under the ATEX Directive 94/9/EC and those responsibilities of an end user, buying in equipment parts to build an installation. (One might use the analogy of the difference between the manufacturing a discreet piece of equipment which can be placed on the market, such as a television (LVD 2006/95/EC), and equipping a house with all its utilities built into which a range of products will be installed and connected, this would clearly be an installation and come under Workplace Directive 89/391/EEC or other directives concerning workplace safety.)

A common situation is that pieces of already compliant 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 3.7.5.1). 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 compliant pieces of equipment still comply when they are taken into service. For that reason he has to carefully 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.

It is understood that there is not always a clear line between an installation and an assembly.

For assemblies and installations the responsibilities will either fall on the person who places the assembly on the market, or the end-user. Each must draw up a technical file setting out how they have complied with the relevant legislation. Much of the technical content will be the same.

The plant will **usually** be an **installation** if:

- The end user, or an installer purchases parts (including ATEX components or equipment) from different manufacturers and they are installed under his responsibility after a full risk assessment has been undertaken;

- The user carries out a whole series of different processes requiring the integration of mainly ATEX compliant equipment and parts on site, and they are installed according to a unique layout;

- The end-user commissions the building of parts of his installation off-site, which may be unique, but certainly not a production run, and which is done under his direct responsibility, or indirectly through a contractor, working under contract to him;

- Commissioning tests or adjustments are needed once the plant is built and are carried out under the final responsibility of the end user.

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 provisions of each directive.

6.1 Electromagnetic Compatibility 2004/108/EC (EMC)

In the case of Directive 94/9/EC and the Directive relating to **Electromagnetic Compatibility 2004/108/EC (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 2004/108/EC 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 to Directive 94/9/EC. For example, protective systems where the performance of data acquisition and data transmission may have direct influence on explosion safety.

6.2 Low Voltage 2006/95/EC (LVD)

Products for use in potentially explosive atmospheres are explicitly excluded from the scope of the **Low Voltage Directive 2006/95/EC (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 Union with reference to Directive 2006/95/EC may be listed in the EC declaration of conformity to fulfil the requirements 1.2.7 of Annex II to 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.

6.3 Machinery 98/37/EC (MD)

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 explosion hazards (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. So equipment that complies with ATEX, and which is also a machine can be assumed to comply with the specific essential safety requirements concerning ignition risk with respect to explosive atmospheres in the Machinery Directive. For other relevant risks concerning machines, the requirements of the Machinery Directive also have to be applied.

6.4 Transport of dangerous goods by road 94/55/EC and 98/91/EC (ADR)

In order to avoid possible overlapping with **Directives 94/55/EC and 98/91/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 criteria for application of Directive 94/9/EC are that the vehicle would need to:

- be defined as an equipment, a protective system or safety device according to Article 1(2) of the Directive;
- have its own potential source of ignition;
- be intended for use in a potentially explosive atmosphere34.

In order to determine under which intended conditions both Directives will apply the exclusion at Article 1(4) of Directive 94/9/EC needs to be considered.

This exclusion explicitly determines that "means of transport" except those "intended for use in a potentially explosive atmosphere shall not be excluded".

The definition of "means of transport" is given further detail at Article 2 of Directive 98/91/EC and, in broad terms, is interpreted to be an activity on a public highway or space including unloading and loading operations.

The ATEX Standing Committee therefore considered that, as described in the Commission guidance, a vehicle under the scope of Directive 98/91/EC might also be covered by the ATEX Directive 94/9/EC.

Where such a vehicle is intended for use in a potentially explosive atmosphere both Directives will apply. However, this does not include where such environments are likely to occur solely as a result of loading and unloading operations as described in 98/91/EC. An example of this is a road tanker transporting petrol when the loading/unloading site is such that it is not initially considered to have a potentially explosive atmosphere because of its location with respect to the storage facility. As noted above, if this environment becomes potentially explosive because of the loading/unloading operation, only the requirements of Directive 98/91/EC need be applied.

In addition, it was agreed that the conformity assessment and technical requirements of 94/55/EC as further defined by 98/91/EC may not fully align with those required for compliance to Directive 94/9/EC.

In this context the question arose whether manufacturers of internal monitoring or other devices attached to or inside a vehicle such as a petrol tanker have to apply the ATEX Directive 94/9/EC and to affix CE marking? The following has been concluded:

1. Based on Article 75 of the EC Treaty and transposing the ADR, Directive 94/55/EC fully harmonises rules for the safe transport of dangerous goods by road.

2. Additionally, based on Article 95 of the EC Treaty, Directive 98/91/EC provides for full harmonisation regarding technical requirements for the following categories of vehicles intended for the transport of dangerous goods by road as follows:

- Category N: Motor vehicles having at least four wheels when the maximum weight exceeds 3.75 metric tons, or having three wheels when the maximum weight exceeds 1 metric ton, and used for the carriage of goods.
- Category O: Trailers (including semi-trailers).

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34 Unless it is a safety device as defined under Article 1(2) of Directive 94/9/EC.

According to article 4, if the requirements of the Annexes of this Directive are fulfilled for the completed vehicle, Member States may not refuse to grant EC type approval or to grant national type approval, or prohibit the registration, sale or entry into service of those vehicles on grounds relating to the transport of dangerous goods.

3. Directive 98/91/EC contains, by reference to Directive 94/55/EC, requirements covering both electrical (e.g. wiring, batteries) and non electrical equipment (e.g. heat protection of engine, combustion heaters) of vehicles designed for the carriage of dangerous goods, which may contribute towards the formation of explosive atmospheres.

4. Provided that:

- Such vehicles are not intended for use in a potentially explosive atmosphere other than that caused temporarily by loading or unloading.

- The goods, which shall be transported, are substances and articles as defined in Article 2 of Directive 94/55/EC.

- The exemptions of Annex A, paragraph 1.1.3, of Directive 94/55/EC and the ADR agreement are not pertinent.

Under these circumstances the exclusion at article 1(4) of Directive 94/9/EC applies to the WHOLE of the vehicle including ALL associated equipment necessary for the carriage of dangerous goods (e.g. “breather valves” of manhole covers, vehicle tracking systems).

In all other cases Directive 94/9/EC may apply.

Note 1: At some sites tankers may have to access a zone (e.g. zone 1). In this case users responsible for that site may demand the supplier to use tankers with ATEX compliant products.

Note 2: Even if the vehicle or parts of it are intended to be permanently used in a potentially explosive atmosphere, devices like “breather valves” of manhole covers normally would not fall within the scope of Directive 94/9/EC. Normally these devices have no own ignition source, are no safety devices in the sense of ATEX and are normally not provided with a protective system, such as a flame arrester.

6.5 Personal Protective Equipment 89/686/EEC (PPE)

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 to 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 is one way to demonstrate compliance.

6.6 Pressure Equipment 97/23/EC (PED)

Pressure Equipment Directive (PED) 97/23/EC is a single market directive similar to Directive 94/9/EC. Relatively few items of pressure equipment have their own source of ignition. There are a small number of examples of safety accessories which may be autonomous protective systems or, possibly, equipment. Flame arrestors have been judged to be pressure accessories in the sense of the PED. There are no additional requirements for the flame arrester element under the PED. PED specifically excludes from its own scope equipment classified no higher than category I under article 9 of PED but inside the scope of ATEX.

6.7 Simple Pressure Vessels 87/404/EEC

Simple Pressure Vessel Directive 87/404/EEC applies to a limited range of equipment for holding air or nitrogen under pressure. ATEX equipment may incorporate a simple pressure vessel in an assembly, but it is considered that there are relatively few occasions when both Directives will apply to the same product.

6.8 Gas Appliances 90/396/EEC (GAD)

Gas Appliances Directive (GAD) 90/396/EEC applies to equipment for domestic and non commercial use but does not apply to equipment designed for industrial processes. Most equipment within scope of GAD is capable of igniting a surrounding explosive atmosphere and cannot comply with ATEX.

It should also be noted that the Directive 94/9/EC contains the following exclusion:

"- 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;"

The question has been raised as to whether this implicitly conveys the meaning that such equipment, where the leakage is not fuel gas, are included in the scope of ATEX Directive 94/9/EC.

It was agreed that, as a general rule, such types of equipment are excluded from the Directive as they are not intended for use in a potentially explosive atmosphere.

6.9 Construction Products 89/106/EEC (CPD)

Besides the above Directives it is necessary to mention the relationship between Directive 94/9/EC and 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 using 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 ignition hazards.

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 directives with an appropriate scope.

7 USED, REPAIRED OR MODIFIED PRODUCTS AND SPARE PARTS [35]

7.1 General

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.[36]

7.2 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 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. **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 health and safety characteristics have been affected.

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.**

7.3 Reconditioned (or refurbished[37]) 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[38]. If this occurs **with no substantial modification Directive 94/9/EC does not apply.**

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35 The application of the ATEX Directive to "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.

36 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.

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

38 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

7.4 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.**

7.5 Substantially modified products

In general, the relevant text of the "Guide to the Implementation of Directives Based on New Approach and Global Approach" (Blue Guide)[39], chapter 2.1. "Products submitted to directives" applies. In the sense of Directive 94/9/EC it is any modification affecting one or more of the health and safety characteristics covered by EHSRs (e.g. temperature) or the integrity of a type protection. In this case **Directive 94/9/EC has to be applied**. **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.

7.6 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.

7.7 Spare parts

These are items 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.

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. If so, all obligations laid down in the Directive have to be fulfilled.

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.

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example, a plastic enclosure may provide much lower electrostatic protection than a metallic enclosure.

39 http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm

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. For assemblies further guidance is given in chapter 3.7.5.

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[40] (Module B)[41] followed by:

production quality assurance[42] (Module D) or,

product verification[43] (Module F);

ii) Unit verification[44](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 type[45] (Module C) or,

product quality assurance[46] (Module E)

ii) Unit verification (Module G).

For other equipment of Categories M2 and 2:

i) Internal control of production (Module A) and deposit the technical documentation[47] with a Notified Body[48,] 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,

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40 See Annex III to the Directive.

41 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)

42 See Annex IV to the Directive.

43 See Annex V to the Directive.

44 See Annex IX to the Directive.

45 See Annex VI to the Directive.

46 See Annex VII to the Directive.

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

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

ii) Unit verification (Module G).

For safety, controlling and regulating devices:

Safety, controlling and regulating devices have to comply with the requirements of Annex II, clause 1, especially clause 1.5.

The formal conformity assessment procedures of article 8 apply and the safety devices are assessed according to the equipment group and category of the system consisting of the safety device and the equipment under control. In some cases it is necessary to perform the assessment for the combination (e.g. inverter fed motors), but generally the assessment for a group of equipment and the appropriate safety devices can be done separately (e.g. type "e" motor).

Example:
A type "e" motor of category 2 is controlled by an overload protection device located outside the explosive atmosphere. The conformity assessment procedure of equipment group II and category 2 is applied for the safety device.

In brief, the different conformity assessment procedures are:

Type Examination (Annex III):

Provides a specimen of the envisaged production to a Notified Body which undertakes the necessary evaluation to determine that the "type" meets the essential requirements of Directive 94/9/EC and issues an EC Type Examination Certificate.

Production Quality Assurance (Annex IV):

Operates a quality system approved by a Notified Body for production, final equipment inspection and testing and is subject to on-going surveillance.

Product verification (Annex V):

Examination and tests by a Notified Body 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):

Tests carried out by a manufacturer on each piece of equipment manufactured to check the explosion protection aspects of the design. Carried out under the responsibility of a Notified Body.

Product Quality Assurance (Annex VII):

A quality system approved by a Notified Body for the final inspection and testing of equipment subject to on-going surveillance.

Internal Control of Production (Annex VIII):

Product and quality system assessment procedure carried out by the manufacturer and retention of documentation.

Unit verification (Annex IX):

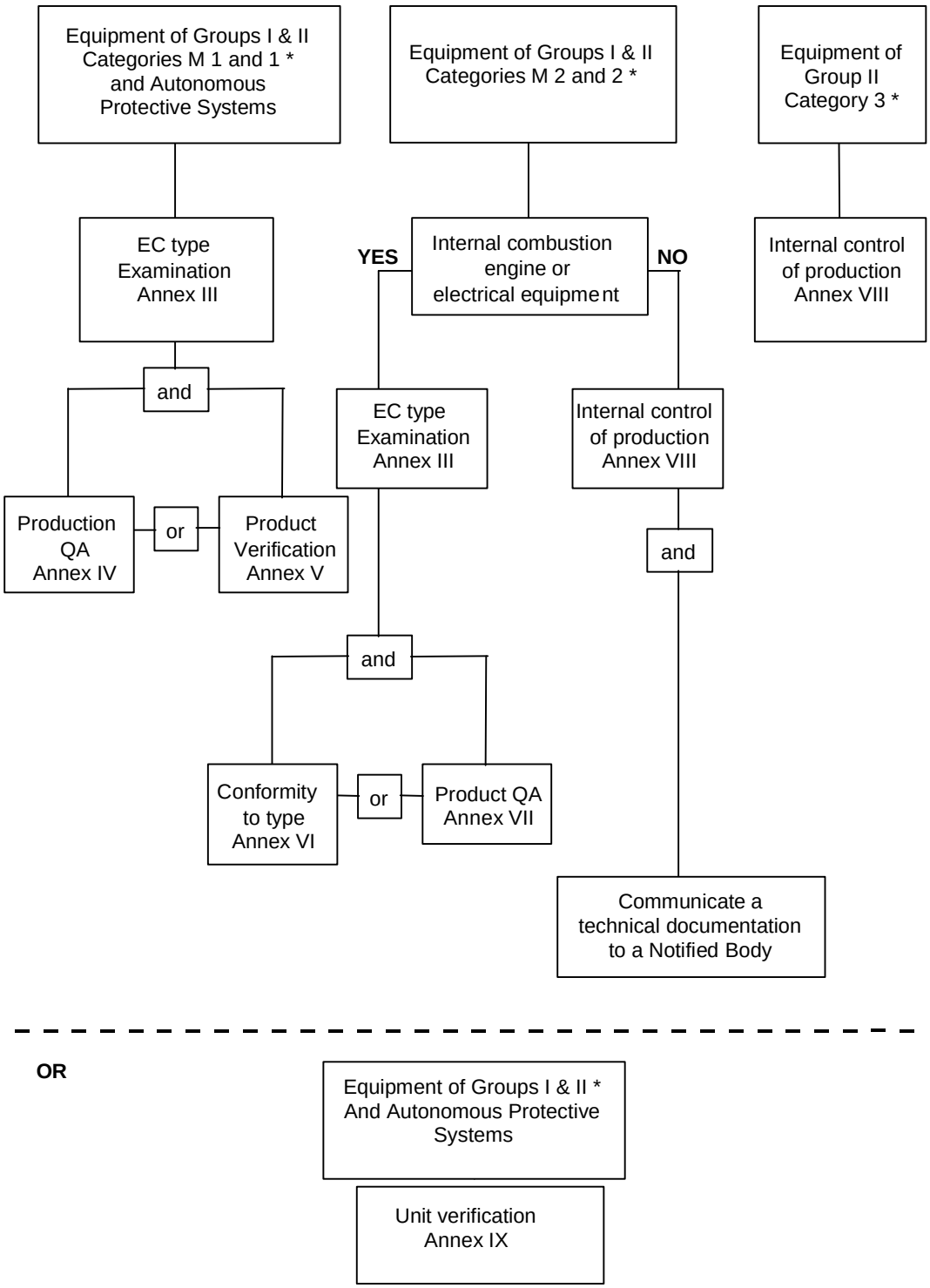
Notified Body examines individual equipment or protective system and carry out tests as defined in the harmonised standards, if they exist, or otherwise in European, international or national standards or conduct equivalent tests to ensure conformity with the relevant requirements of Directive 94/9/EC and draw up a certificate of conformity.

Internal Control of Production + Retention of documentation by a Notified Body (Article 8.1((b)(ii):

Product and quality system assessment procedure carried out by the manufacturer and retention of documentation by a Notified Body.

A chart showing the appropriate procedure is provided overleaf:

Conformity Assessment Procedures



(*) and their components and devices according to Art. 1(2), if separately assessed

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).

Which conformity assessment procedures have to be performed in the case of different categories within one product, or mixes of equipment and protective systems according to Article 1.3 b ?

If a product is made of parts which are assigned to different conformity assessment procedures it will be up to the manufacturer to decide how these parts and the whole product shall be placed on the market. The manufacturer can decide to realise the appropriate conformity assessment procedures for each part or for the whole product, even if he decides to place the product as an entity on the market. In the case of separate conformity assessment procedures for each part of the assembled equipment (called assembly in the Guidelines to Directive 94/9/EC), the manufacturer may presume conformity of these pieces of equipment and may restrict his own risk assessment of the assembly to those additional ignition and other hazards, 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.

If the manufacturer explicitly asks a Notified Body to assess the entire product, then that conformity assessment procedure has to be applied, which covers the highest requirements. The Notified Body shall include into the EC-Type examination (if relevant) all aspects of the product. Existing conformity declarations of the manufacturer for parts of the product should be given due consideration.

The Notified Body should inform the manufacturer about the possibilities of separate conformity assessment procedures for each part of the assembly as pointed out by the Guidelines to Directive 94/9/EC.

Any certificate issued by the Notified Body should make clear which aspects of the product have been assessed by the NB, and which have been assessed by the manufacturer alone.

Example: Vapour recovery pump for petrol stations

(a) The pump is sucking the petrol vapour-air mixture from the atmosphere and conveying it in pipe-work attributed to zone 0. Accordingly it is connected at its inlet and outlet to a potentially explosive atmosphere classified as zone 0. The pump itself is placed in a zone 1 environment.

With regard to the inlet and outlet connection the pump then has to comply with the requirements for category 1 equipment. The corresponding EC-type examination (equipment) has to be carried out by a Notified Body. With regard to the remaining (outer) body and integrated parts of the pump the Notified Body includes the necessary category 2 assessment into the certification, even if there are only non-electrical ignition sources to be considered.

Both categories shall be indicated in the EC-type examination certificate, making clear which aspects of the product have been assessed by the NB, and which have been assessed by the manufacturer alone, and in the marking. For those category 2 parts of the pump, which show only non-electrical ignition sources and which are placed separately on the market, and for which the technical documentation has been communicated to a Notified Body, an EC declaration of conformity (for equipment) or a written attestation of conformity (for components) of the manufacturer are sufficient.

(b) Often the pump is expected to prevent the passage of a deflagration flame from the inlet to the outlet connection, as typical vapour recovery pumps contain flame arresters in the inlet and outlet pipe. In this case the pump simultaneously may qualify as a protective system (in-line deflagration arrester).

A Notified Body – after having carried out a corresponding assessment of the flame arresting capability – may then issue a separate EC-type examination certificate for the pump as a protective system. In case that both aspects (equipment and protective system) have been assessed by the same Notified Body, only one EC-type examination certificate may be issued.

8.2 Exceptional derogations of the Conformity Assessment Procedures

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 may 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 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 NOTIFIED BODIES

9.1 Designation

Annex XI to 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 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 on 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. responsibilities, conformity assessment, testing, inspection facilities and sub-contracting, please see the "Guide to the implementation of Directives based on New Approach and Global Approach".

9.2 Co-ordination and Co-operation

All Notified Bodies are asked to participate in Notified Body co-ordination activities. The Group of Notified Bodies established under Directive 94/9/EC, the so-called ExNBG, normally meets annually and is made up of representatives of Notified Bodies with observers from the Commission, manufacturers and users trade associations, standards making bodies and other invitees. Attendance at each meeting is by invitation and any party wishing to be considered should contact the Chairman of the Group either through the Commission or via a Notified Body of your country. The group is responsible for discussing issues of a technical nature to ensure that the technical

provisions of the Directive and harmonised standards are applied in a uniform way. The group issues "Clarification Sheets" where ambiguities exist in technical procedures and also issues technical guidance documents where less detailed specifications require amplification.

Clarification Sheets and guidance documents are noted by the Standing Committee and published on the internet (http://ec.europa.eu/enterprise/atex/nb/sheets.htm).

9.3 Subcontracting

It has been agreed that Notified Bodies are to keep a register of any subcontracting to allow effective monitoring by the responsible member state in order to ensure activities are being conducted properly. The register is to be updated systematically. The register contains information about the name and location of the subcontractor, the nature and scope of work undertaken, the results of regular evaluations of the subcontractor, including evidence that details of tasks are monitored as well as evidence that the subcontractor is competent and maintains competence for the tasks specified and evidence that a direct private law contract exists.

A Notified Body may engage experts in support of its assessment activities but the experts' activities are to be controlled as if the expert were directly employed by the Notified Body under the same contractual obligations and operate within the Notified Body's own quality system.

The ExNBG has concurred that further (serial) sub-contracting by any sub-contractor is strictly prohibited.

Although assessment can be sub-contracted including assessment against the requirements of EHSRs, the Notified Body remains entirely responsible for the whole operation and shall safeguard impartiality and operational integrity.

Procedures for reviewing and accepting the work of any sub-contractor will ensure that the sub-contractor has not offered or provided consultancy or advice to the manufacturer, supplier, authorised representative or their commercial competitor with respect to the design, construction, marketing or maintenance of the products which are the subject of the sub-contracted task.

9.4 Retention of documentation

Under Article 8.1 (b)(ii) of the ATEX Directive 94/9/EC the manufacturer is required to undertake the conformity procedure at Annex VIII and then:

"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".

Bodies notified for this procedure should be so according to Article 8.1 (b)(ii) and not to Annex VIII as this latter procedure does not involve a Notified Body.

This dossier is not returned to the manufacturer on request (but may be added to), and in general it is retained for a period of ten years following the last placing of the product onto the market. The intention is that market surveillance authorities in the different member states should be given access to this dossier, in cases where there is a need to investigate the design or manufacturing details of a particular product.

With respect to the media used, it is accepted that this dossier may be in electronic format so long as it is legible and "readable" over the period concerned.

9.5 Notified Bodies having knowledge of faulty products* on the market

Also a Notified Body which gets knowledge of faulty products, but is neither engaged in the module for EC-type examination nor in a module for surveillance of the manufacture, should take some action.

If there is no immediate danger, if after contact with the responsible Notified Body for EC-Type examination and with the Notified Body responsible for surveillance of the production of the faulty product no satisfactory solution after appropriate time is reached, the Notified Body should inform his own authorities in charge of market surveillance to initiate the adequate measures.

In the case of immediate danger, the Notified Body should inform his own authority in charge of market surveillance, the Notified Body for EC-Type examination and the Notified Body for surveillance of the production without delay.

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* see Note 1 of the Guidelines

10 DOCUMENTS OF CONFORMITY

10.1 Documents issued by the manufacturer

10.1.1 EC Declaration of Conformity[49]

Once the manufacturer 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.

In respect of the Notified Bodies possibly involved in the conformity assessment procedure the EC Declaration of Conformity must contain, where appropriate, the name, identification number and address of the Notified Body and the number of the EC-Type Examination Certificate. The name and address of a Notified Body involved in the production phase, where relevant, is not a mandatory requirement.

As far as assemblies of ATEX equipment are concerned, if an assembly is to be treated as a new item of ATEX equipment the EC Declaration of Conformity needs only to identify the unit and the related information. Details of the items of equipment making up the assembly will be included on the technical file. However, there is a duty on all those in the supply chain to pass on the relevant information relating to the items of equipment where these have been previously placed on the market accompanied by their own EC Declaration of Conformity and instructions.

Annex X.B of the Directive states what the EC Declaration of Conformity must contain. Further information can be found in section 5.4 of the "Blue Guide". As a general rule, the content of the EC Declaration of Conformity contains the following:

a) Name or identification mark and the address of the manufacturer or his authorised representative in the European Union	Straightforward, noting that the name on the product places the named organisation in the position of manufacturer (or authorised representative).
b) A description of the equipment, etc.	A descriptive product designation e.g. Motor Control Unit Type ABC 123 and its intended use. For an assembly it should list the items in the assembly that are ATEX equipment in their own right, and which have been separately assessed.
c) All relevant provisions fulfilled by the equipment, etc.	The marking included on the product e.g. Equipment Group II, category 2 G (IIB T4).

continued

[49] 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.

continues

d) Where appropriate, the name, identification number and address of the Notified Body and the number of the EC-Type Examination Certificate	Name and number of the Notified Body (or Bodies) conducting the EC-type examination. In the case of Category 2 non-electrical equipment, it should refer to the Notified Body holding the copy of the technical documentation file. Where relevant, if the body responsible for oversight of the QA regime is not the same as the one issuing the original certificate, it should be named separately. However, the name and address of a Notified Body involved in the production phase is not a mandatory requirement. **There shall be no reference to a Notified Body certificate unless it is one coming within the scope of the Directive**. Certificates issued by bodies in their "private" capacity as certification bodies should be included in the technical documentation file as part of the evidence of conformity but should not be quoted on the declaration of conformity.
e) Where appropriate, reference to the harmonized standards	The harmonised standards quoted in the technical documentation file should be listed here.
f) Where appropriate, the standards and technical specifications used	Other standards and technical specifications quoted in the technical documentation file should be listed here
g) Where appropriate, references to other EU Directives which have been applied	If this is a multi-directive declaration, it should already be clear from the heading which directives the product conforms to.
h) Identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer, etc.	The signatory needs to be a responsible officer of the manufacturer or of the authorised representative.

10.1.2 Written Attestation of Conformity for Components

The EC declaration of conformity should not be confused with the written attestation of conformity for components 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 delivered for the same end user.

The product is also accompanied by instructions for safe use (see EHSR 1.0.6). The manufacturer does not have to provide the full technical file to the user.

With respect to assemblies, it is important to the safe installation, operation and maintenance of the assembled unit that all relevant information is passed to the end user. The manufacturer of the assembled unit should do this by including all related information in a package supplied to the end user.

10.1.4 Retention of documentation - Quality assurance

According to Annex IV, paragraph 5 of the ATEX Directive 94/9/EC the manufacturer, or where relevant, the authorised representative or importer) shall, for a period ending at least 10 years after the last piece of equipment was manufactured, be able to make available to the national authorities:

- the documentation of the quality system;
- updating of the quality system;
- audit reports and certificates of the Notified Body.

Larger organisations have a certified quality management system according to the ISO 9000 standards. For these manufacturers it is recognised that it is difficult to keep all quality documents and all changes to the quality system for such a long period. It is the opinion of the ATEX Standing Committee that the requirements in Annex IV, paragraph 5 of the ATEX Directive 94/9/EC are fulfilled if the manufacturer keeps at the disposal of the national authorities at least the actual quality management system documents + the following documents which have to be kept for a period ending at least 10 years after the last piece of equipment was manufactured:

- audit reports and certificates of the ISO 9000 certifier. This will be one or two audit reports per year that include the actual state at that moment of the quality system with changes;
- audit reports and notifications of the Notified Body that issued the Production Quality Assurance Notification.

The above consideration is against the background that this documentation shall always be sufficient so as to enable surveillance authorities to determine that the relevant conformity assessment procedure(s) was / were applied in a satisfactory manner and that the relevant obligations of the ATEX Directive 94/9/EC were fulfilled.

10.1.5 Acceptance of test results of manufacturers by a Notified Body

Test reports can be a part of the technical documentation the manufacturer has to present to the Notified Body and the latter may take them into consideration appropriately.

Concerning safety relevant aspects in connection with Annex III (EC-Type Examination) and Annexes V (Product verification) and IX (Unit verification) to Directive 94/9/EC, a Notified Body's independent and transparent intervention vis-à-vis the client and all interested parties (e.g. Member States, European Commission, manufacturers, Notified Bodies) is required legally. Therefore a Notified Body only may accept test reports of manufacturers under certain conditions. The requirements included in the standard EN ISO/IEC 17025:2005 “General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)” shall be used as basis for acceptance of test results.

The Notified Body has to state the acceptance of test results in his test report.

In any case the Notified Body remains fully responsible for accepted test results and for the EC-Type Examination Certificate (Annex III) or Certificate of Conformity (Annexes V and IX) based on them.

10.2 Documents issued by the Notified Body

The Notified Body issues the following documents according to the provisions of the relevant conformity assessment procedures:

- EC-Type Examination Certificate;
- product and production quality assurance notification;

- conformity to type notification;
- product verification, certificate of conformity;
- unit verification, certificate of conformity.

These documents need not accompany the product.

It is not possible to issue an EC-Type Examination Certificate for products of Category 2 nonelectrical equipment and of Category 3, as mentioned in Article 8(1)(b)(ii) and 8(1)(c). Further, it is also not permissible to list such goods on an EC-Type examination certificate issued for goods of categories other than these. This is because an EC-Type examination certificate is an attestation that the goods listed on it have undergone the necessary conformity assessment procedures that result in the issuing of an EC-Type examination certificate; it is not necessary for such goods to undergo such conformity assessment procedures.

Where a single item is covered by more than one category, it may be permissible to issue an EC-Type Examination Certificate. Under such circumstances, these items need to comply with the highest applicable conformity assessment requirements (see section 8.1). If this requirement results in an EC-Type Examination Certificate being issued, these goods are permitted to be listed on an EC-Type Examination certificate.

A typical example of this is found in the semiconductor fabrication industry where a high vacuum pump is used to extract hydrogen but cannot meet the physical clearances necessary to justify Category 2. Category 3 is adequate for the process as the pump is normally filled with pure hydrogen at low pressure, so there is no ignition risk except during the very brief transitions between operation and non-operation.

In this case, it is only the electrical part that is truly subject to EC-Type Examination but it is already established that a mechanical part can be considered along with the electrical part if they are integral with each other, rather than a mere assembly.

In such cases, it is not unreasonable to mention such items in the same set of documentation i.e. the goods have an EC-Type examination certificate issued for them.

However, where the goods are discrete items e.g. two different type categories of a hand-held radio, one of which is Category 2 and the other Category 3, a single EC-Type examination certificate should never be issued; the Category 3 goods should be listed on a separate document that in no way implied it was an EC-Type Examination Certificate. The same should be true for components of items.

However, the voluntary issue of a certificate for goods that are not permitted to be listed on an EC-Type Examination Certificate is possible. The certification body may not give an indication on the certificate that it is a Notified Body because it would not be acting in that capacity. Therefore, the number of the Notified Body must not be affixed. Further, it is not permissible to affix the CE marking to such certificates. There is no objection for the hexagon (Ex mark) to be used or to make reference to Directive 94/9/EC.

Provision of evaluation and test results with EC-Type Examination Certificates: although being a separate document, the report describing how the equipment fulfils the Essential Health and Safety Requirements of the Directive is considered to be integral to the provision of a certificate. Evaluation and test results supporting the decision to issue a EC-Type Examination Certificate should accompany the certificate from the Notified Body to the manufacturer.

10.3 EC-Type Examination Certificate and the responsibilities of stakeholders

A Type Examination Certificate attests that a specimen (including instructions, as appropriate) representative of the production envisaged by the manufacturer fulfils the relevant applicable provisions of the Directive, in particular the Essential Health and Safety Requirements (EHSRs).

The question arises as to the actions that need to be taken when the “generally acknowledged state of the art” has developed. It is clear that the original specifications applied may continue to show fulfilment of the EHSRs and the Type Examination Certificate then remains valid.

However, over time the "generally acknowledged state of the art" can develop substantively **such that the specifications originally applied no longer ensure the type examined complies with the EHSRs**. It should be noted that the question of whether there has been substantive development of the state of the art is not left to discretionary interpretation by the Notified Body, but has equally to be generally acknowledged by the technical community of the stakeholders. The publication of a revised harmonised standard would be one way to recognise a development in the state of the art: in this case, the responsible European Standardisation Organisation (ESO) shall determine whether the state of the art concerning the EHSRs has changed, and if so, in what respects. The ESO shall indicate this in the foreword of each standard.

In such cases, if the specifications and evaluation criteria originally applied to a product no longer ensure that it complies with the latest state of the art, the Type Examination Certificate is no longer valid and further action is required. Given reasonable transition periods and knowledge of current developments, it is expected that the manufacturer will have sufficient time to contact a Notified Body to undertake the necessary re-evaluation so that there is a smooth transition from one set of applied specifications to another. Notified Bodies, who are expected to maintain a good knowledge of developments in the state of the art, should make arrangements to alert the holders of their EC-Type Examination Certificates to the revision of harmonised standards.

It should be noted, however, that the issuing of a new Type Examination Certificate will have no retroactive effect and, therefore, will not affect products placed on the market and/or put into service whilst the manufacturer was in possession, where appropriate, of a valid Certificate.

It should also be re-affirmed that the overall responsibility for compliance of the product rests with the manufacturer who, where required, must ensure that a valid Certificate is in his possession, as well as that all relevant conformity documents correspond to the current state of the art. In parallel, the Notified Body must provide all the relevant information for the manufacturer in order to ensure that the existing Certificate is correct in its evaluation that the type continues to meet the EHSRs.

11 MARKING

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.

Any misleading marking in the sense of the any of these directives is forbidden.

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.

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 European Union. 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 to 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.

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). It is necessary to avoid any misleading information on equipment, for example the number of the Notified Body, **where this is not foreseen by the Directive**. Hence, the product should not have the number of a Notified Body affixed, if falling under category 3 (other than Unit verification), as well as some Category 2 equipment, and for any voluntary certification.

The CE marking and the identification number of the Notified Body do not necessarily have to be affixed within the territory of the EU. 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 (e.g. an assembly according to 3.7.5.1), 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/Specific Marking

It is the intention of Directive 94/9/EC that the design of the specific marking  follows the design, as specified 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 (see Annex to these Guidelines). 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). **User instructions shall explain in detail the meaning of the marking on the product**. However it is recommended to use the format provided in the following examples, where

" .. / .. " means the product has two different categories

".. - .. " means that a part of the product is not conforming to the Directive and not intended to be used in a potentially explosive atmosphere.

Moreover, devices according to Article 1.2 of the Directive, and separately placed on the market, shall be marked with the category of the equipment under control in round brackets, and such devices which contain an own potential ignition source intended for use in a potential explosive atmosphere shall be marked as equipment according to Annex II clause 1.0.5.

Ex I M2	Mining products, Group I, Category M2
Ex II 1 G	Non-Mining products, Group II, Category 1 for use in gas/vapour/mist – atmospheres
Ex II 1 D	Non-Mining products, Group II, Category 1 for use in dust – atmospheres
Ex	Protective system, for use in gas/vapour/mist/dust - atmospheres
Ex 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
Ex II 2 GD	Category 2 equipment for use in potentially explosive atmosphere containing gases or dust
Ex II (2)/2 (1)/1 G	An assembly, such as a gas detection system with more than one detection head, that is partly category 1 and partly category 2 formed by a safety device and an equipment. The safety device is intended for use outside the hazardous area and the equipment is intended for use inside hazardous area.
Ex II 2(1) G	Category 2 equipment containing a safety device for a category 1 equipment
Ex II 2(1) GD	Same equipment for gas or dust potentially explosive atmospheres
Ex II (2) G (1) G	A safety device alone which ensures the safety against explosion for category 1 equipment and for another category 2 equipment.
Ex II 3/3 D	a blower exhausting out of zone 22 and to be installed in zone 22

Examples for <u>marking of equipment having different categories</u> are:

Ex II 1/2 G	level gauge installed in the tank wall between zone 0 and zone 1
Ex II (2) 3 G	an electrical field bus device affecting category 2 equipment installed in zone 2
Ex II 2/- G	a ventilator exhausting out of zone 1 but to be installed outside potentially explosive atmospheres. The Directive has no provisions for marking in case of installation outside potentially explosive atmospheres.
Ex II 2/3 G	a ventilator extracting out of zone 1 but to be installed in zone 2
Ex II 3/- D	a screw conveyor conveying dust out of a zone 22 but installed outside potentially explosive atmospheres. The Directive has no provisions for marking in case of installation outside potentially explosive atmospheres.
Ex II -/2 D	blower conveying no explosive atmosphere but to be installed in zone 21

All products must be marked with the name and address of the manufacturer, designation of series or type, serial number (if any) and the year of construction. The product must be accompanied with written information explaining the different categories and the consequences for the intended use.

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.

11.3 Additional Marking for standards

Because of the special importance for the 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 to 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 European standards for electrical and non-electrical products for potentially explosive atmospheres foresee a supplementary marking. For detailed and complete information about this marking it is necessary to use these standards.

11.4 Marking of components

The person responsible for the placing on the market and/or the putting into service of a product has to mark it with the name and the address of the manufacturer, according to Annex II to Directive 94/9/EC, clause 1.0.5. The Directive leaves it free to choose between trademark and company name if there is a difference. The address must be shown on the marking. This address can be simplified if there is not really enough room on small products, as long as the responsible person can always be identified. In any event, the address on the plaque must be sufficient for mail to reach the company. An internet address is not sufficient but the postal address has to be given. In some countries a unique postal code identifies an address. The use of this postal code is sufficient with the country.

The question has arisen, whether the marking of components is mandatory.

Strictly speaking, Directive 94/9/EC explicitly requires marking in Annex II, clause 1.0.5., only for equipment and protective systems. The question, whether components should nevertheless be marked in order to facilitate the implementation to the Directive, has particular practical relevance in cases

- where it is difficult to recognise the difference between ATEX components and standard components, and
- where a manufacturer who wanted to use a component might have serious problems undertaking his risk assessment, if there is no indication about the category of the component.

Apart from the question of marking, the Directive requires an attestation of conformity for components. The latter shall give all the necessary information stating the characteristics. This normally occurs assigning to the component an explosion classification according to relevant harmonised standards, which looks like a marking (e.g. Ex II 1/2 GD cb Tx or Ex II 1 GD c Tx).

For components having an own potential ignition source or which are clearly correlated (with respect to the properties of the component) to equipment with a given category, it has been considered that without the definition of group and category, the necessary conformity procedure of the equipment, which the component will be incorporated to, cannot be performed.

In some cases the conformity procedure can only be performed, if the equipment, which the component will be incorporated to, is defined, and if this incorporation is a matter of the conformity procedure.

Therefore, it is recommended to mark components, as long as these can be assessed with respect to a certain category and group of equipment, indicating this category and group in the marking.

Moreover, it is recommended to mark components for autonomous protective systems, which can be assessed with respect to the characteristic properties of the latter, as far as reasonable indicating these characteristics in the marking.

It has also to be considered that size is a problem impeding marking on a product. In these cases, the information should be given in the accompanying documentation and on the packaging of the component subject to marking.

Finally, it is recalled that, according to Directive 94/9/EC, **ATEX components shall not bear the CE-marking**.

11.5 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.

On very small products where a reduction in the marking is unavoidable, the following information is nevertheless required:

- CE marking (not for components),
- Ex marking,

the name or registered trade mark of the manufacturer.

11.6 Marking of assemblies

The marking of assemblies is identical to the marking of equipment, in particular equipment having different categories. An assembly may consist of a large number of assessed and compliant items (equipment, protective systems, safety devices) with their own specific marking, potentially of different categories. In such cases it would not be helpful to show all of these the individual markings in the marking of the complete assembly. Nevertheless, the marking of the assembly has to display all relevant information required by Annex II, 1.0.5, of Directive 94/9/EC necessary for the intended use of the assembly as a whole. The marking shall be placed in such a way – e.g. on the outer housing of the assembly – so that there is no doubt that it shows the characteristics of the whole assembly and not just one part.

Assemblies may consist of parts of different categories and be intended for potentially explosive atmospheres having different physical characteristics. The marking of the assembly as a whole with group, categories and additional information essential for the safe use of the assembly (temperature class, etc.) may fall under one of the two following scenarios:

Case 1: The assembly as a whole is intended for use in one potentially explosive atmosphere of one specific zone

Where the individual parts of the assembly are marked for potentially explosive atmospheres having different characteristics, the part with the lowest level of safety defines the marking of the whole assembly. That means that the category, temperature class, explosion group etc with the lowest requirement for the equipment has to be used for the marking of the whole assembly.

Case 2: Parts of the assembly are intended for use in potentially explosive atmospheres having different physical characteristics and/or different zones

If it is essential for that intended use, the marking of the assembly shall contain all groups, categories and additional markings (temperature class, etc.) necessary for the intended atmospheres.

In this case, the instructions for use, installation etc. will indicate the different atmospheres/zones intended (and/or provided by constructional measures) in or around different parts of the equipment.

Examples (only categories and additional markings essential for safe use are given in these examples):

Examples for case 1:

- An assembly consisting of parts marked with T3 and other parts with T6 shall be marked T3 to indicate, that it is, as a whole, intended for use in T3 atmospheres.
- A pump unit consisting of a liquid pump (non flammable liquid) and driving electric motor. The pump is marked II 2 G T6, the motor II 2 G IIB T4. The whole assembly shall be marked II 2 G IIB T4, as the motor is the part that meets the lower requirements.
- A similar pump unit with a pump conveying hot liquid (non flammable). The pump is marked II 2 G T3, the motor II 2G IIB T4. In this case the assembly shall be marked II 2 G IIB T3.

Examples for case 2:

- A fan conveying a IIA T3 explosive atmosphere (zone 1), the fan fitted with an electric motor and some control devices placed in a zone 2, the fan accordingly marked II 2/3 G IIA T3. The motor is marked II 3 G T3, the intrinsic safe control device II 2 G IIC T6. As the intrinsic safe control device is placed in the same atmosphere as the motor, the part meeting the lower requirements (in this case the motor) is the decisive item. Accordingly the marking of the whole assembly is II 2/3 G IIA T3.
- A similar fan assembly, but with the motor placed outside the hazardous area. The marking of the whole assembly is II 2/3/- G IIA T3.

12 SAFEGUARD CLAUSE[50] 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 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 re-establish 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.[51]

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”.

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50 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.

51 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. 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.

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[52]. 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 whether or not it is necessary to withdraw the references to those standards from the published information.

[52] 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, as amended by Directive 98/48/EC.

13 EUROPEAN HARMONISED STANDARDS[53]

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 OJEU. 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 Union.

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.

Voluntary harmonised standards are the only documents the application of which provides for presumption of conformity. Manufacturers may also decide to use existing European, national and other technical standards and specifications regarded as important or relevant to cover the relevant essential health and safety requirements, together with additional controls addressing those other requirements not already covered.

Standards are amended and updated in response to new technical knowledge. During the process of updating, a manufacturer may continue to use a current harmonised standard to claim full compliance with the Directive, even though it is clear that the standard will change in time.

13.1 European Harmonised Standards published in the Official Journal

By way of information, a reference list of European Harmonised Standards can be found on the European Commission's website[54].

European standards for ATEX are available from the European Standardisation Organisations:

- CEN: avenue Marnix 17, B-1000 Bruxelles; tel. (32-2) 550 08 11; fax (32-2) 550 08 19 (http://www.cen.eu)

- CENELEC: avenue Marnix 17, B-1000 Brussels; tel. (32-2) 519 68 71; fax (32-2) 519 69 19 (http://www.cenelec.org)

National transpositions of Harmonised Standards are available from the national standardisation bodies.

13.2 Standardisation Programme

Two standardisation programmes addressed to the European standardisation bodies. Each one is the subject of a standardisation mandate drawn up by the European Commission.

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53 See also http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm ("Blue Guide")

54 http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist/atex.html

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 technical committee CEN/TC 305 "Potentially explosive atmospheres - Explosion prevention and protection". Several 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.

14 USEFUL WEBSITES

Equipment intended for use in Potentially Explosive Atmospheres (ATEX) website on EUROPA:
http://ec.europa.eu/enterprise/atex

Text of Directive 94/9/EC:
http://ec.europa.eu/enterprise/atex/direct/newapproach.htm

"How to apply the Directive", further Considerations by the ATEX Standing Committee's Working Group:
http://ec.europa.eu/enterprise/atex/standcomm.htm

References of national measures transposing Directive 94/9/EC:
http://ec.europa.eu/enterprise/atex/direct/trans94-9.htm

List of competent authorities known to the Commission regarding Market Surveillance of Directive 94/9/EC in Member States, candidate countries EEA countries:
http://ec.europa.eu/enterprise/atex/listcomp.htm

Central contact points in charge of implementation of Directive 94/9/EC in Member States, candidate countries and EEA countries:
http://ec.europa.eu/enterprise/atex/centrcont.htm

International organisations:
http://ec.europa.eu/enterprise/atex/intern_org.htm

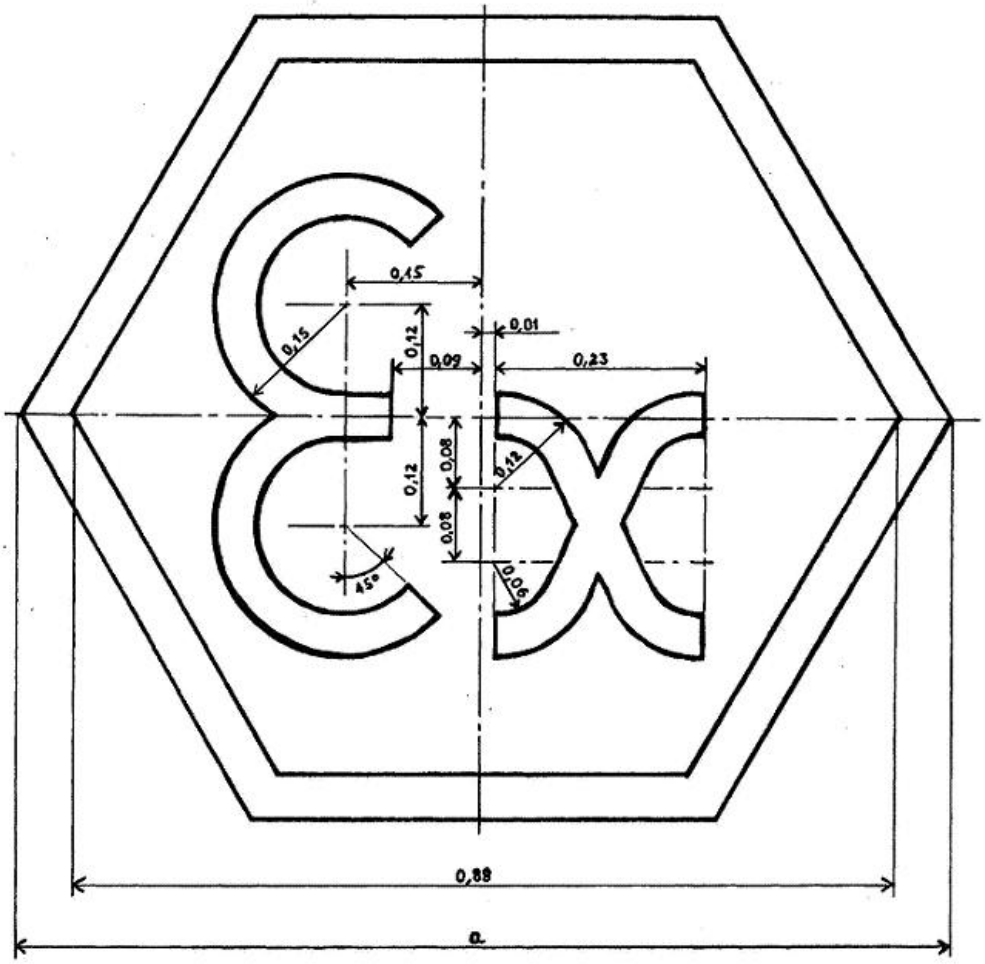
Notified Bodies:
http://ec.europa.eu/enterprise/atex/nb/nblist.htm

ATEX standardisation:
http://ec.europa.eu/enterprise/atex/stand.htm

ATEX Directive interest group in CIRCA:
http://circa.europa.eu/Members/irc/enterprise/atex/home

ATEX Administrative Co-operation (ADCO) interest group in CIRCA:
http://circa.europa.eu/Members/irc/enterprise/atexms/home

ANNEX I: DISTINCTIVE COMMUNITY (EX) MARK DRAWN FROM DIRECTIVE 84/47/EEC



All values related to ‘a’

ANNEX II: BORDERLINE LIST - ATEX PRODUCTS

BORDERLINE LIST - ATEX PRODUCTS

The List has been confirmed during the Directive 94/9/EC ATEX Working Group meeting 25 June 2008

Note that the list is not complete, it only clarifies some common inquires and provide examples of products within or outside the scope of the "ATEX" Directive 94/9/EC. The List does not replace the vital risk assessment of each product and in addition ignition sources and explosion hazards related to the use of all the products shall also always be considered.

Equipment	Scope of 94/9/EC	Examples of equipment	Comments
Equipment	(El. = Electrical)		
Clockworks	-		See 5.2.1 in ATEX Guidelines.
Computers	Yes (El.)		
Earthing clamps with and without cord	No/Yes		Should be assessed on a case-by-case basis to determine if the design of the equipment contains any potential ignition sources.
Electrical motors	Yes (El.)		El. equipment with potential ignition sources like heat and sparks of electrical origin (e.g. windings, connections) and mechanical origin (e.g. bearings).
Electrical pump with integrated electrical motor (e.g. canned or split tube motor pump, petrol pump/dispensers for petrol filling)	Yes (El.)		El. equipment with potential ignition sources like heat and sparks of electrical origin (e.g. motor circuit) and mechanical origin (e.g. pump impeller).
Electrical fan with integrated electrical motor (e.g. electrical axial fan)	Yes (El.)		El. equipment with potential ignition sources like heat and sparks of electrical origin (e.g. motor circuit) and mechanical origin (e.g. fan blades).
Non-electrical fan with integrated air motor (e.g. non-electrical axial fan)	Yes (Non El.)		Non-el. Equipment with potential ignition sources like frictional heat and sparks of mechanical origin (e.g. bearings, fan blades).
Hand operated valves	No		See 5.2.1 in ATEX Guidelines.
Heating cables	Yes (El.)		Heating cables transforms electricity into heat while cables "only" transports electricity
Mechanical brakes	Yes (Non El.)		Non-el. Equipment with potential ignition sources like frictional heat of mechanical origin.
Mechanical gears	Yes (Non El.)		Non-el. Equipment with potential ignition sources like frictional heat and sparks of mechanical origin.
Phones and similar equipment e.g. walkie-talkies, head phones etc.	Yes (El.)		El. equipment with potential ignition sources like heat and sparks of electrical origin.
Plugs and socket outlets	Yes (El.)		El. equipment with potential ignition sources like sparks of electrical origin (e.g. when connected or disconnected). Note that all countries have special requirements on plugs and socket outlets for domestic use.
Switches for fixed electrical installations	Yes (El.)		El. equipment with potential ignition sources like sparks of electrical origin (e.g. when switched on or off).
Torch	Yes (El.)		El. equipment with potential ignition sources like heat and sparks of electrical origin (e.g. sparks from a switch or heat in a bulb or battery).
Protective Systems			
Fire extinguisher	No		Intended to be used after an explosion.
Vent panels (for explosion pressure relief)	Yes		Intended to be used to limit the effects of an explosion.

Components			
Cables / Cable ladder systems for cable management	No		No autonomous function; not essential to safe functioning of ATEX equipment or protective system.
Conduits/pipes: e.g. Fume extraction arms and conduits for electrical installations (except for conduits intended to be used between the flameproof enclosures and the conduit sealing devices)	No		No autonomous function; not essential to safe functioning of ATEX equipment or protective system.
Cable lugs/shoes with and without cord	No		No autonomous function; not essential to safe functioning of ATEX equipment or protective system.
Electro Static Discharge (ESD) - Protections: e.g. wrestles, shoes, standing mats, antistatic bags	No		No autonomous function; not essential to safe functioning of ATEX equipment or protective system.
Enclosures	Yes (El.)		Intended to be used for electrical equipment with potential ignition sources.
Magnetic catches for doors etc.	No		No autonomous function; not essential to safe functioning of ATEX equipment or protective system.
PT 100 sensor	No/Yes		No when used in a intrinsic safe system together with e.g. a barrier. In all other situations is it to be decided on a case by case assessment.
Spark arrestor	Yes (Non El.)		Intended to prevent an explosion; not to limit it. It is an ATEX component if intended to be built into ATEX equipment or protective systems.
Safety, Controlling or Regulating devices			
Devices controlling the regular safety limits of an industrial process handling flammables, like pressure, level and temperature transmitters	No		Shall be protected as potential ignition sources themselves if placed inside hazards areas, but safety devices with respect to risks other than ignition hazards + monitoring devices providing only an alarm signal, but without direct control function, are outside scope of the directive (with respect to reliability and functional requirements acc to ESHR clause 1.5. and 1.6.)
Overload or temperature protective devices, inhibiting ignition sources from becoming active (e.g. current-dependent device for Exe motor) + Initiator devices for explosion protective equipment systems, i.e. suppression systems (trigging)	Yes (El.)		Both categories of devices are within 94/9/EC article 1.2., with respect to functional and reliability requirements according to the ESHR, clause 1.5. and 1.6.
Other products			
Doors	No		No own source of ignition.
Ladders, irrespective of the material	No		No own source of ignition.
Paint	No		No own source of ignition.
Tank	No		No own source of ignition.
Tools: e.g. hammers, tongs	No		No own source of ignition.

Note 1: Additional information can be obtained in the second edition of ATEX Guidelines and Standing Committee Considerations to directive 94/9/EC but also in the Non-binding guide to directive 1999/92/EC.

Note 2: Equipment, protective systems, components, safety, controlling, regulating devices and/or other products indicated as not falling within the scope of ATEX 94/9/EC, ignition sources and explosion hazards related to the use shall be considered. Friction impacts and abrasion processes involving rust and light metals (e.g. aluminium and magnesium) and their alloys may initiate an aluminothermic (thermite) reaction, which can give rise to particularly incentive sparking.