



EUROPEAN POWER SUPPLY MANUFACTURERS ASSOCIATION
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Guideline for the Safety Requirements of AC / DC Power Supplies

Part 2: Requirements for power supplies intended to be used in hazardous locations

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This guideline summarises the requirement of approvals for power supplies to EN 60079-15:2005 (applicable for Zone2/Cat3 only).

It illustrates the specialities required by a development engineer for the design and application of power supplies in hazardous or potentially hazardous environments.

THIS PAPER DOES NOT INTEND TO BE A STANDARD

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The European Power Supply Manufacturers Association was established in 1995, to represent the European power supply industry.

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INNOVA Product Service		Application Note
EN 60079-15	Electrical apparatus for explosive gas atmospheres – Type of protection “n”	15/09/2006

1.0 THE DIRECTIVE

The directive 94/9/CE covers the European regulations concerning equipment and protective systems intended for use in potentially explosive atmospheres.

Guideline:

<http://europa.eu.int/comm/enterprise/atex/guide/index.htm>

Directive:

<http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist.html>

SUMMARY:

In order to approve power supplies to the hazard location directive the standard EN60079-15 has to be applied.

The directive applies to equipment and protective systems intended for use in potentially explosive atmospheres.

The directive does not differentiate between explosive atmosphere and potentially explosive atmosphere.

Excluded from the directive are:

- Medical devices
- Equipment and protective systems where the explosion hazard results from the presence of explosive substances or chemicals (for example a measuring equipment for chemicals)
- Equipment intended for use in domestic, non commercial environments
- Personal protective equipment
- Seagoing vessels and mobile offshore units
- Means of transport vehicles intended to transport passengers

Equipment has to be delivered with a CE declaration of conformity and the CE marking. A component has to be delivered with a certificate of conformity.

Group (Annex 1)	Use for	Comment	Approval to Annex	Approval to Module (described in article 8)
Group I Cat: M1	Underground mines, firedamp,	Stay safe in the event of rare incidents relating to this equipment, with explosive atmosphere present. In event of failure of one protection a second independent protection has to be still functional. Two faults independent of each other are covered by the protection (redundancy, two failures should not cause hazard)	Annex II 2.0.1	Annex III and Annex IV or V (notified body)
Group I Cat. M2		Protection is achieved by switching the unit off in case of explosive atmosphere	Annex II 2.0.2	Annex III with Annex VI or VII (notified body)
Group II Cat 1 (Zone 0, Dust zone 20)	Explosive atmosphere caused by mixtures of air and gases, vapours or mists or by air/ dust are presently cont.	Event of two failure no danger, a second means provides the requisite level of protection (REDUNDNACE)	Annex II 2.1	Annex III and Annex IV or V (notified body)
Cat 2 (Zone 1, Dust Zone 21)	Explosive atmosphere caused by mixtures of air and gases, vapours or mists or by air/ dust are likely to occur	Level of protection, even in the event of frequently occurring disturbances or equipment faults which normally taken into account (protection is one error in case of regular disturbances)	Annex II 2.2	Annex III with Annex VI or VII (notified body)
Cat 3 (Zone 2, Dust Zone 22)	Explosive atmosphere caused by mixtures of air and gases, vapours or mists or by air/ dust are unlikely to occur, if they occur, then only for short time	Level of protection during normal use	Annex II 2.3	Annex III (Quality system and production inspection)

The standard electrical apparatus for explosive gas atmospheres – Part 15:
Type of protection – “n” EN60079-15 (May 2006)

2.0 TEMPERATURES

A hot spot is a potential ignition source. Temperature rating of the component is not relevant. If not otherwise mentioned on the type label, the hazard location temperature index refers to ambient 40 °C.

Voltage has to be +/-10% of the rated voltage. Measurement has to be done at the maximum specified ambient temperature.

The unit must be marked with the temperature class of Table 1 (EN 60079-0).

Small components can exceed the limits of the rated temperature class as follows:

Table 1.

Class T4	<20mm ²	Surface temperature max. 275°C
Class T4	≥ 20mm ²	Maximum loss ≤ 1,3 W (for an ambient of 60 °C reduced to 1,2 W or for ambient 80 °C reduced to 1,0 W)
Class T4	≥ 20mm ² ≤1000mm ²	Surface temperature max. 200°C
Class T5	<1000mm ²	Surface temperature max. 150°C

Temperature class	Maximum surface temperature
T1	450
T2	300
T3	200
T4	135
T5	100
T6	85

3.0 ENCLOSURE

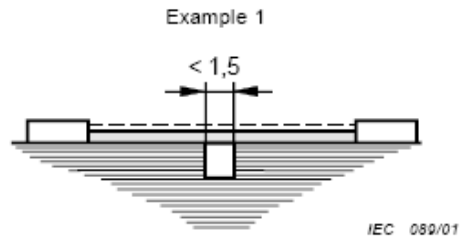
IP54 for non insulated parts, IP44 for insulated parts must be provided for final applications.

For build-in components min. IP4X or IP2X must be provided. “U” has to be marked on the type label and an adequate comment must be within the documentation. IP44/54 enclosure must be provided in the final installation.

4.0 SPACINGS

EN60079-15 does not mention alternative methods for functional insulation as for example IEC60950. Therefore Table 2 assumes pollution degree III has to be applied.

IEC60950 does not count for creepage, if the air gap is >1mm. IEC60079-15 requires an air gap of 1.5mm to be counted as non-creepage.



Condition: Path under consideration includes a parallel-or converging-sided groove of any depth with a width less than 1,5 mm. Rule: Creepage distance and clearance are measured directly across the groove as shown.

There is no requirements for circuits that are <math>< 20\text{W}</math> and <math>< 60\text{Vac}</math> and <math>< 75\text{Vdc}</math>. An IP54 enclosure must be provided.

Power supplies which fulfil the requirements of IEC60950: 2003 will pass for areas requiring reinforced insulation in IEC60950 also the requirements of the standard IEC60079-15. The main issue is the functional insulation.

For functional insulation on switch mode power supplies the standard allows the following alternatives/exceptions:

Possible solution for the functional insulation alternative 1:

- Conformal coating: min. two layers of coating (solder mark might count as one layer), no requirement for thickness of coating (reduced spacing). If the unit is conformal coated (for USA us UL approved coating to category QMJU2) the spacing has to be verified, but the requirements are much lower (see table below)

7.4 A conformal coating, if applied, shall have the effect of sealing the conductors in question against ingress of moisture. It shall adhere to the conductive parts and the insulating material. If the conformal coating is applied by spraying then two separate coats are to be applied. Other methods of application require only one coat, for example dip coating, brushing, vacuum impregnating, but the intention is to achieve an effective, lasting, unbroken seal. A solder mask is considered as one of two coatings, provided it is not damaged during soldering.

Where bare conductors emerge from the coating, the requirements given in table 2 shall apply taking account of the comparative tracking index (CTI) applicable to both insulation and conformal coating.

Alternative method 2 for functional insulation:

The standard requires an enclosure to clause 5.1 (IP4x or IP54). Therefore the spacing for a built in power supply could be defined for pollution degree II. The table 2 refers to IEC60664.

- The standard at table 2 refers to IEC60664. IEC60664 allows reduced spacing on PCB boards. This allows using the reduced spacing described in IEC60664 for PCB boards. The distances on semiconductors like switch mode transistors are treated in the same way.
- The spacing for functional insulation has to comply with the spacing requirement of IEC60664. (alternative methods like shorts or dielectric testing as allowed by IEC60950 is not accepted)

Attention: The working voltage from trace to trace has to be measured and the spacing verified accordingly. This is a major effort. Either IEC60664 is used (pollution degree II) or Table 2 of IEC60079-15 (pollution degree II). For functional insulation the actual working voltage has to be considered to determine the spacing.

Inner Layer spacing of PCB (Printed circuit board)

The standard does not define the required amount of layers as in IEC60950. Either three layers of preprag or the distance in accordance to table 2 “encapsulated or sealed parts” has to be applied. The inner distance for example for 250 Vac has to be 0.6 mm. IEC60950 does only require 0.4 mm.

CSA limitation written in the CSA reports by approval of built in power supply without coating:

“For class I, Zone 2, EXnCIIC /AEXnCIIC , the unit is to be installed in final enclosure, dust proof, IP66 or enclosure Type 4X minimum; alternatively printed wiring boards are coated with suitable sealing compound/ conformal coating (two coats); to be evaluated in the final installation.”

This interpretation is not in accordance with our understanding of the standard.

Table 2 – Minimum creepage distances, clearances and separations

Voltage a.c. r.m.s. or d.c. (note 1)	Minimum creepage distance (note 2) mm				Minimum clearances and separation mm		
	Material group				In air	Sealed (note 3)	Encapsulated or solid insulation (note 4)
	I	II	IIIa	IIIb			
≤10 (see note 5)	1	1	1	1	0,4	0,3	0,2
≤12,5	1,05	1,05	1,05	1,05	0,4	0,3	0,2
≤16	1,1	1,1	1,1	1,1	0,8	0,3	0,2
≤20	1,2	1,2	1,2	1,2	0,8	0,3	0,2
≤25	1,25	1,25	1,25	1,25	0,8	0,3	0,2
≤32	1,3	1,3	1,3	1,3	0,8	0,3	0,2
≤40	1,4	1,6	1,8	1,8	0,8	0,6	0,3
≤50	1,5	1,7	1,9	1,9	0,8	0,6	0,3
≤63	1,6	1,8	2	2	0,8	0,6	0,3
≤80	1,7	1,9	2,1	2,1	0,8	0,8	0,6
≤100	1,8	2	2,2	2,2	0,8	0,8	0,6
≤125	1,9	2,1	2,4	2,4	1	0,8	0,6
≤160	2	2,2	2,5	2,5	1,5	1,1	0,6
≤200	2,5	2,8	3,2	3,2	2	1,7	0,6
≤250	3,2	3,6	4	4	2,5	1,7	0,6
≤320	4	4,5	5	5	3	2,4	0,8
≤400	5	5,6	6,3	6,3	4	2,4	0,8
≤500	6,3	7,1	8	8	5	2,4	0,8
≤630	8	9	10	10	5,5	2,9	0,9
≤800	10	11	12,5	–	7	4	1,1
≤1 000	11		13	–	8	5,8	1,7
≤1 250	12		15	–	10	–	–
≤1 600	13		17	–	12	–	–
≤2 000	14		20	–	14	–	–
≤2 500	18		25	–	18	–	–
≤3 200	22		32	–	22	–	–
≤4 000	28		40	–	28	–	–
≤5 000	36		50	–	36	–	–
≤6 300	45		63	–	45	–	–
≤8 000	56		80	–	56	–	–
≤10 000	71		100	–	70	–	–
≤11 000	78		110	–	75	–	–
≤13 800	98		138	–	97	–	–
≤15 000	107		150	–	105	–	–

NOTE 1 Voltage steps up to 10 000 V are based on the R10 series. For working voltages up to 1 000 V, the actual working voltage may exceed the value given in the table by up to 10 %.

NOTE 2 Values for creepage distances are derived from IEC 60664-1. Up to 800 V, creepage distances are based on Pollution degree 3; values between 2 000 V and 10 000 V are based on Pollution degree 2. Other values are interpolated or extrapolated.

NOTE 3 Sealed by a conformal coating, see 7.4.

NOTE 4 Completely encapsulated in compound to a minimum depth of 0,4 mm, or separation through solid insulating material, for example the thickness of a printed wiring board.

NOTE 5 At 10 V and below, the value of CTI is not relevant and materials not meeting the requirements for material group IIIb may be acceptable.

5.0 CONSTRUCTION AND COMPONENTS

Fuses and connectors must be secured to prevent unintentional disconnection. Internal connectors must withstand 15N pull test. Components must withstand pull test 100 times their own weight.

External plug-connectors must be mechanically secured and the warning “Do not disconnect under if powered” must be provided. Cable ducts must be provided with strain relief.

The use of relays is allowed, but the relays have to be tested for thickness to clause 7.2

6.0 MARKING

The following marking must be provided:

EN 60079-15

- a) Manufacturer or Trademark
- b) Type
- c) Electrical parameter
- d) Symbol Ex
- e) Type of protection (nA, nC, nL, nR)
- f) Group (I, II)
- g) Temperature class (TX) and ambient temperature (Tamb)
- h) U for built in or X for special precaution required.
- i) Serial Nr.
- j) X (if required)

Directive (additional):

- a) Manufacturers address
- b) Year of manufacture
- c) Ex (-Symbol), Group, Cat., G for Gas or D for Dust or both

For example:



II 3 G
Ex nAC IIC T4 U

If required, several warning markings must be provided. For example “Do not disconnect if powered”.

7.0 MANUAL/DOCUMENTATION

Declaration of Conformity:

- ATEX Marking
- Applied standards with date (like EN60079-15:2005 + EN60079-15:2004)
- Model name
- Ambient temperature for hazard location
- ATEX directive
- Name of manufacturer
- Special considerations (like for built in use)

Manual:

The same information as marking, but in addition:

- The Installation and start date of use
- Mounting and demounting instructions
- Information for training
- Electrical data and pressure, maximum surface temperature
- Standards

ANNEX I: CRITERIA DETERMINING THE CLASSIFICATION OF EQUIPMENT-GROUPS INTO CATEGORIES

1. Equipment-group I

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

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

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

- either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,
- or the requisite level of protection is assured in the event of two faults occurring independently of each other.

Equipment in this category must comply with the supplementary requirements referred to in Annex II, 2.0.1.

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

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

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

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

Equipment in this category must comply with the supplementary requirements referred to in Annex II, 2.0.2.

2. Equipment-group II

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

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

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

- either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,
- or the requisite level of protection is assured in the event of two faults occurring independently of each other.

Equipment in this category must comply with the supplementary requirements referred to in Annex II, 2.1.

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

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

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

Equipment in this category must comply with the supplementary requirements referred to in Annex II, 2.2.

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

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

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

Equipment in this category must comply with the supplementary requirements referred to in Annex II, 2.3.

ANNEX II

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES

Preliminary observations

A. Technological knowledge, which can change rapidly, must be taken into account as far as possible and be utilized immediately.

B. For the devices referred to in Article 1 (2), the essential requirements shall apply only in so far as they are necessary for the safe and reliable functioning and operation of those devices with respect to the risks of explosion.

1. COMMON REQUIREMENTS FOR EQUIPMENT AND PROTECTIVE SYSTEMS

1.0. General requirements

1.0.1. Principles of integrated explosion safety

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

In this case, the manufacturer must take measures:

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

1.0.2. Equipment and protective systems must be designed and manufactured after due analysis of possible operating faults in order as far as possible to preclude dangerous situations.

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

1.0.3. Special checking and maintenance conditions

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

1.0.4. Surrounding area conditions

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

1.0.5. Marking

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

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

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

1.0.6. Instructions

(a) All equipment and protective systems must be accompanied by instructions, including at least the following particulars:

- a recapitulation of the information with which the equipment or protective system is marked, except for the serial number (see 1.0.5.), together with any appropriate additional information to facilitate maintenance (e.g. address of the importer, repairer, etc.);
- instructions for safe:
 - putting into service,
 - use,
 - assembling and dismantling,
 - maintenance (servicing and emergency repair),
 - installation,
 - adjustment;
- where necessary, an indication of the danger areas in front of pressure-relief devices;
- where necessary, training instructions;
- details which allow a decision to be taken beyond any doubt as to whether an item of equipment in a specific category or a protective system can be used safely in the intended area under the expected operating conditions;
- electrical and pressure parameters, maximum surface temperatures and other limit values;
- where necessary, special conditions of use, including particulars of possible misuse which experience has shown might occur;
- where necessary, the essential characteristics of tools which may be fitted to the equipment or protective system.

(b) The instructions must be drawn up in one of the community languages by the manufacturer or his authorized representative established in the community.

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

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

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

(c) The instructions must contain the drawings and diagrams necessary for the putting into service, maintenance, inspection, checking of correct operation and, where appropriate, repair of the equipment or protective system, together with all useful instructions, in particular with regard to safety.

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

1.1. Selection of materials

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

1.1.2. Within the limits of the operating conditions laid down by the manufacturer, it must not be possible for a reaction to take place between the materials used and the constituents of the potentially explosive atmosphere which could impair explosion protection.

1.1.3. Materials must be so selected that predictable changes in their characteristics and their compatibility in combination with other materials will not lead to a reduction in the protection afforded; in particular, due account must be taken of the material's corrosion and wear resistance, electrical conductivity, impact strength, ageing resistance and the effects of temperature variations.

1.2. Design and Construction

1.2.1. Equipment and protective systems must be designed and constructed with due regard to technological knowledge of explosion protection so that they can be safely operated throughout their foreseeable lifetime.

1.2.2. Components to be incorporated into or used as replacements in equipment and protective systems must be so designed and constructed that they function safely for their intended purpose of explosion protection when they are installed in accordance with the manufacturer's instructions.

1.2.3. Enclosed structures and prevention of leaks

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

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

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

1.2.4. Dust deposits

Equipment and protective systems which are intended to be used in areas exposed to dust must be so designed that deposit dust on their surfaces is not ignited.

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

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

The thickness of deposit dust must be taken into consideration and, if appropriate, means must be taken to limit the temperature in order to prevent a heat build up.

1.2.5. Additional means of protection

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

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

1.2.6. Safe opening

If equipment and protective systems are in a housing or a locked container forming part of the explosion protection itself, it must be possible to open such housing or container only with a special tool or by means of appropriate protection measures.

1.2.7. Protection against other hazards

Equipment and protective systems must be so designed and manufactured as to:

- (a) avoid physical injury or other harm which might be caused by direct or indirect contact;
- (b) assure that surface temperatures of accessible parts or radiation which would cause a danger, are not produced;
- (c) eliminate non-electrical dangers which are revealed by experience;
- (d) assure that foreseeable conditions of overload shall not give rise to dangerous situations.

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

1.2.8. Overloading of equipment

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

1.2.9. Flameproof enclosure systems

If parts which can ignite an explosive atmosphere are placed in an enclosure, measures must be taken to ensure that the enclosure withstands the pressure developed during an internal explosion of an explosive mixture and prevents the transmission of the explosion to the explosive atmosphere surrounding the enclosure.

1.3. Potential ignition sources

1.3.1. Hazards arising from different ignition sources

Potential ignition sources such as sparks, flames, electric arcs, high surface temperatures, acoustic energy, optical radiation, electromagnetic waves and other ignition sources must not occur.

1.3.2. Hazards arising from static electricity Electrostatic charges capable of resulting in dangerous discharges must be prevented by means of appropriate measures.

1.3.3. Hazards arising from stray electric and leakage currents

Stray electric and leakage currents in conductive equipment parts which could result in, for example, the occurrence of dangerous corrosion, overheating of surfaces or sparks capable of provoking an ignition must be prevented.

1.3.4. Hazards arising from overheating Overheating caused by friction or impacts occurring, for example, between materials and parts in contact with each other while rotating or through the intrusion of foreign bodies must, as far as possible, be prevented at the design stage.

1.3.5. Hazards arising from pressure compensation operations

Equipment and protective systems must be so designed or fitted with integrated measuring, control and regulation devices that pressure compensations arising from them do not generate shock waves or compressions which may cause ignition.

1.4. Hazards arising from external effects

1.4.1. Equipment and protective systems must be so designed and constructed as to be capable of performing their intended function in full safety, even in changing environmental conditions and in the presence of extraneous voltages, humidity, vibrations, contamination and other external effects, taking into account the limits of the operating conditions established by the manufacturer.

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

1.5. Requirements in respect of safety-related devices

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

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

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

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

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

1.5.3. Emergency stop controls of safety devices must, as far as possible, be fitted with restart lockouts. A new start command may take effect on normal operation only after the restart lockouts have been intentionally reset.

1.5.4. Control and display units Where control and display units are used, they must be designed in accordance with ergonomic principles in order to achieve the highest possible level of operating safety with regard to the risk of explosion.

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

In so far as they relate to equipment used in explosive atmospheres, devices with a measuring function must be designed and constructed so that they can cope with foreseeable operating requirements and special conditions of use.

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

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

1.5.8. Risks arising from software In the design of software-controlled equipment, protective systems and safety devices, special account must be taken of the risks arising from faults in the programme.

1.6. Integration of safety requirements relating to the system

1.6.1. Manual override must be possible in order to shut down the equipment and protective systems incorporated within automatic processes which deviate from the intended operating conditions, provided that this does not compromise safety.

1.6.2. When the emergency shutdown system is actuated, accumulated energy must be dispersed as quickly and as safely as possible or isolated so that it no longer constitutes a hazard.

This does not apply to electrochemically-stored energy.

1.6.3. Hazards arising from power failure Where equipment and protective systems can give rise to a spread of additional risks in the event of a power failure, it must be possible to maintain them in a safe state of operation independently of the rest of the installation.

1.6.4. Hazards arising from connections Equipment and protective systems must be fitted with suitable cable and conduit entries.

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

1.6.5. Placing of warning devices as parts of equipment Where equipment or protective systems are fitted with detection or alarm devices for monitoring the occurrence of explosive atmospheres, the necessary instructions must be provided to enable them to be provided at the appropriate places.

2. SUPPLEMENTARY REQUIREMENTS IN RESPECT OF EQUIPMENT

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

2.0.1. Requirements applicable to equipment in category M 1 of equipment-group I

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

Equipment must be equipped with means of protection such that:

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

- or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

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

It must remain functional with an explosive atmosphere present.

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

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

2.0.1.4. Equipment must be so designed that the opening of equipment parts which may be sources of ignition is possible only under non-active or intrinsically safe conditions. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

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

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

2.0.2.1. Equipment must be equipped with means of protection ensuring that sources of ignition do not become active during normal operation, even under more severe operating conditions, in particular those arising from rough handling and changing environmental conditions.

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

2.0.2.2. Equipment must be so designed that the opening of equipment parts which may be sources of ignition is possible only under non-active conditions or via appropriate interlocking systems. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

2.0.2.3. The requirements regarding explosion hazards arising from dust applicable to category M 1 must be applied.

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

2.1.1. Explosive atmospheres caused by gases, vapours or hazes

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

It must be equipped with means of protection such that:

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

- or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

2.1.1.2. For equipment with surfaces which may heat up, measures must be taken to ensure that the stated maximum surface temperatures are not exceeded even in the most unfavourable circumstances.

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

2.1.1.3. Equipment must be so designed that the opening of equipment parts which might be sources of ignition is possible only under non-active or intrinsically safe conditions. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

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

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

It must be equipped with means of protection such that - either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

- or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

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

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

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

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

2.2. Requirements for category 2 of equipment-group II

2.2.1. Explosive atmospheres caused by gases, vapours or mists

2.2.1.1. Equipment must be so designed and constructed as to prevent ignition sources arising, even in the event of frequently occurring disturbances or equipment operating faults, which normally have to be taken into account.

2.2.1.2. Equipment parts must be so designed and constructed that their stated surface temperatures are not exceeded, even in the case of risks arising from abnormal situations anticipated by the manufacturer.

2.2.1.3. Equipment must be so designed that the opening of equipment parts which might be sources of ignition is possible only under non-active conditions or via appropriate interlocking systems. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

2.2.2. Explosive atmospheres caused by air/dust mixtures

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

2.2.2.2. With regard to surface temperatures, requirement 2.1.2.3 applies.

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

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

2.3. Requirements applicable to equipment in category 3 of equipment-group II

2.3.1. Explosive atmospheres caused by gases, vapours or mists

2.3.1.1. Equipment must be so designed and constructed as to prevent foreseeable ignition sources which can occur during normal operation.

2.3.1.2. Surface temperatures must not exceed the stated maximum surface temperatures under intended operating conditions. Higher temperatures in exceptional circumstances may be allowed only if the manufacturer adopts special additional protective measures.

2.3.2. Explosive atmospheres caused by air/dust mixtures 2.3.2.1. Equipment must be so designed and constructed that air/dust mixtures cannot be ignited by foreseeable ignition sources likely to exist during normal operation.

2.3.2.2. With regard to surface temperatures, requirement 2.1.2.3 applies.

2.3.2.3. Equipment, including cable entries and connecting pieces, must be so constructed that, taking into account the size of its particles, dust can neither develop explosive mixtures with air nor form dangerous accumulations inside the equipment.

3. SUPPLEMENTARY REQUIREMENTS IN RESPECT OF PROTECTIVE SYSTEMS

3.0. General requirements

3.0.1. Protective systems must be dimensioned in such a way as to reduce the effects of an explosion to a sufficient level of safety.

3.0.2. Protective systems must be designed and capable of being positional in such a way that explosions are prevented from spreading through dangerous chain reactions or flashover and incipient explosions do not become detonations.

3.0.3. In the event of a power failure, protective systems must retain their capacity to function for a period sufficient to avoid a dangerous situation.

3.0.4. Protective systems must not fail due to outside interference.

3.1. Planning and design

3.1.1. Characteristics of materials

With regard to the characteristics of materials, the maximum pressure and temperature to be taken into consideration at the planning stage are the expected pressure during an explosion occurring under extreme operating conditions and the anticipated heating effect of the flame.

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

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

3.1.4. The reactions caused by pressure in peripheral equipment and connected pipe-work must be taken into consideration in the planning and design of protective systems.

3.1.5. Pressure-relief systems

If it is likely that stresses on protective systems will exceed their structural strength, provision must be made in the design for suitable pressure-relief devices which do not endanger persons in the vicinity.

3.1.6. Explosion suppression systems

Explosion suppression systems must be so planned and designed that they react to an incipient explosion at the earliest possible stage in the event of an incident and counteract it to best effect, which due regard to the maximum rate of pressure increase and the maximum explosion pressure.

3.1.7. Explosion decoupling systems

Decoupling systems intended to disconnect specific equipment as swiftly as possible in the event of incipient explosions by means of appropriate devices must be planned and designed so as to remain proof against the transmission of internal ignition and to retain their mechanical strength under operating conditions.

3.1.8. Protective systems must be capable of being integrated into a circuit with a suitable alarm threshold so that, if necessary, there is cessation of product feed and output and shutdown of equipment parts which can no longer function safely.

ANNEX III

MODULE EC-TYPE EXAMINATION

1. This module describes that part of the procedure by which a notified body ascertains and attests that a specimen representative of the production envisaged meets the relevant applicable provisions of the directive.

2. The application for the EC-type examination shall be lodged by the manufacturer or his authorized representative established within the community with a notified body of his choice.

The application shall include:

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

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

3. The technical documentation shall enable the conformity of the product with the requirements of the directive to be assessed. It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product and shall to that extent contain:

- a general type-description;
- design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;

- descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the product;
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards referred to in Article 5 have not been applied;
- results of design calculations made, examinations carried out, etc.;
- test reports.

4. The notified body shall:

4.1. Examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as the components which have been designed without applying the relevant provisions of those standards;

4.2. Perform or have performed the appropriate examinations and necessary tests to check whether the solutions adopted by the manufacturer meet the essential requirements of the directive where the standards referred to in Article 5 have not been applied;

4.3. Perform or have performed the appropriate examinations and necessary tests to check whether these have actually been applied, where the manufacturer has chosen to apply the relevant standards;

4.4. Agree with the applicant the location where the examinations and necessary tests shall be carried out.

5. Where the type meets the provisions of the directive, the notified body shall issue an EC-type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination and the necessary data for identification of the approved type.

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

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

Provision shall be made for an appeals procedure.

6. The applicant shall inform the notified body which holds the technical documentation concerning the EC-type-examination certificate of all modifications to the approved equipment or protective system which must receive further approval where such changes may effect conformity with the essential requirements or with the prescribed conditions for use of the product. This further approval is given in the form of an addition to the original EC-type-examination certificate.

7. Each notified body shall communicate to the other notified bodies the relevant information concerning the EC-type-examination certificates and additions issued and withdrawn.

8. The other notified bodies may receive copies of the EC-type-examination certificates and/or their additions. The annexes to the certificates shall be kept at the disposal of the other notified bodies.

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

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

ANNEX IV

MODULE: PRODUCTION QUALITY ASSURANCE

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned are in conformity with the type as described in the EC-type-examination certificate and satisfy the requirements of the directive which apply to them. The manufacturer, or his authorized representative established in the community, shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for EC monitoring, as specified in Section 4.

2. The manufacturer shall operate an approved quality system for production, final equipment inspection and testing as specified in Section 3 and shall be subject to monitoring as specified in Section 4.

3. Quality system

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

The application shall include:

- all relevant information for the product category envisaged;
- the documentation concerning the quality system;
- technical documentation on the approved type and a copy of the EC-type-examination certificate.

3.2. The quality system shall ensure compliance of the equipment with the type as described in the EC-type-examination certificate and with the requirements of the directive which apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of quality programmes, plans, manuals and records.

It shall contain, in particular, an adequate description of - the quality objectives and the organizational structure, responsibilities and powers of the management with regard to equipment quality;

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

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

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to uphold the system so that it remains adequate and efficient.

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

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

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

4. Surveillance under the responsibility of the notified body

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

4.2. The manufacturer shall, for inspection purposes, allow the notified body access to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular - the quality system documentation - the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

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

4.4. Furthermore, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may carry out tests, or arrange for tests to be carried out, to check that the quality system is functioning correctly, if necessary. The notified body shall provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer shall, for a period ending at least 10 years after the last piece of equipment was manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the second indent of Section 3.1;
- the updating referred to in the second paragraph of Section 3.4;
- the decisions and reports from the notified body which are referred to in Section 3.4, last paragraph, Section 4.3 and Section 4.4.

6. Each notified body shall apprise the other notified bodies of the relevant information concerning the quality system approvals issued and withdrawn.

ANNEX V

MODULE: PRODUCT VERIFICATION

1. This module describes the procedure whereby a manufacturer or his authorized representative established within the community checks and attests that the equipment subject to the provisions of point 3 are in conformity with the type as described in the EC-type-examination certificate and satisfy the relevant requirements of the directive.

2. The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees conformity of the equipment with the type as described in the EC-type-examination certificate and with the requirements of the directive which apply to them. The manufacturer or his authorized representative established in the community shall affix the CE marking to each piece of equipment and shall draw up a declaration of conformity.

3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the equipment, protective system or device referred to in Article 1 (2), with the relevant requirements of the directive, by examining and testing every product as specified in Section 4.

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

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

4.1. All equipment shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equipment tests shall be carried out in order to verify their conformity with the type as described in the EC-type-examination certificate and the relevant requirements of the directive.

4.2. The notified body shall affix or have affixed its identification number to each approved item of equipment and shall draw up a written certificate of conformity relating to the tests carried out.

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

ANNEX VI

MODULE: CONFORMITY TO TYPE

1. This module describes that part of the procedure whereby the manufacturer or his authorized representative established within the community ensures and declares that the equipment in question is in conformity with the type as described in the EC-type-examination certificate and satisfy the requirements of the directive applicable to them. The manufacturer or his authorized representative established within the community shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity.

2. The manufacturer shall take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured equipment or protective systems with the type as described in the EC-type-examination certificate and with the relevant requirements of the directive.

3. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last piece of equipment was manufactured. Where neither the manufacturer nor his authorized representative is established within the community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the equipment or protective system on the community market.

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

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

ANNEX VII

MODULE: PRODUCT QUALITY ASSURANCE

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of Section 2 ensures and declares that the equipment is in conformity with the type as described in the EC-type-examination certificate. The manufacturer or his authorized representative established within the community shall affix the CE marking to each product and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for surveillance as specified in Section 4.

2. The manufacturer shall operate an approved quality system for the final inspection and testing of equipment as specified in Section 3 below and shall be subject to surveillance as specified in Section 4 below.

3. Quality system

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

The application shall include:

- all relevant information for the product category envisaged;

- documentation on the quality system;
- technical documentation on the approved type and a copy of the EC-type-examination certificate.

3.2. Under the quality system, each piece of equipment shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to ensure its conformity with the relevant requirements of the directive. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instruments. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

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

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

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

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

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

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

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

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

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

4. Surveillance under the responsibility of the notified body

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

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

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

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

4.4. Furthermore, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or arrange for tests to be carried out in order to check the proper functioning of the quality system, where necessary; it shall provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer shall, for a period ending at least 10 years after the last piece of equipment was manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the third indent of Section 3.1;
- the updating referred to in the second paragraph of Section 3.4;
- the decisions and reports from the notified body which are referred to in Section 3.4, last paragraph, Section 4.3 and Section 4.4.

6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

ANNEX VIII

MODULE: INTERNAL CONTROL OF PRODUCTION

1. This module describes the procedure whereby the manufacturer or his authorized representative established within the community, who carries out the obligations laid down in Section 2, ensures and declares that the equipment satisfy the requirements of the directive applicable to it. The manufacturer or his authorized representative established within the community shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity.

2. The manufacturer shall establish the technical documentation described in Section 3 and he or his authorized representative established within the community shall keep it at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last piece of equipment was manufactured.

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

3. Technical documentation shall enable the conformity of the equipment with the relevant requirements of the directive to be assessed. It shall, to the extent necessary for

such assessment, cover the design, manufacture and operation of the product. It shall contain:

- a general description of the equipment,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the equipment,
- a list of the standards applied in full or in part, and descriptions of the solutions adopted to meet the safety aspects of the directive where the standards have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

4. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity with the technical documentation.

5. The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees compliance of the manufactured equipment with the technical documentation referred to in Section 2 and with the requirements of the directive applicable to such equipment.

ANNEX IX

MODULE: UNIT VERIFICATION

1. This module describes the procedure whereby the manufacturer ensures and declares that the equipment or protective system which has been issued with the certificate referred to in Section 2 conforms to the requirements of the directive which are applicable to it. The manufacturer or his authorized representative in the community shall affix the CE marking to the equipment or protective system and draw up a declaration of conformity.

2. The notified body shall examine the individual equipment or protective system and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, to ensure its conformity with the relevant requirements of the Directive.

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

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

The documentation shall contain:

- a general description of the product;
- conceptual design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the equipment or protective system;

- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied;
- results of design calculations made, examinations carried out, etc.;
- test reports.

ANNEX X

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

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

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

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

B. Content of the EC declaration of conformity The EC declaration of conformity must contain the following elements:

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

ANNEX XI

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

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of equipment, protective systems, or devices referred to in Article 1 (2) which they inspect, nor the authorized representative of any of these parties. They shall become involved neither directly nor as authorized representatives in the design, construction, marketing or maintenance of the

equipment, protective systems or devices referred to in Article 1 (2) in question. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

2. The body and its inspection staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which may influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.

3. The body shall have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it shall also have access to the equipment required for special verification.

4. The staff responsible for inspection shall have:

- sound technical and professional training;
- satisfactory knowledge of the requirements of the tests which they carry out and adequate experience of such tests;
- the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.

6. The body shall take out liability insurance unless its liability is assumed by the state in accordance with national law or the member state itself is directly responsible for the tests.

7. The staff of the body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the state in which its activities are carried out) under this directive or any provision of national law giving effect to it.