BRITISH STANDARD

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13980:2002

Potentially explosive atmospheres — Application of quality systems

The European Standard EN 13980:2002 has the status of a British Standard

ICS 03.120.10; 13.230

BSI
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National foreword

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The UK participation in its preparation was entrusted to Technical Committee FSH/23, Fire precautions in industrial and chemical plant, which has the responsibility to:

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Potentially explosive atmospheres - Application of quality systems

Atmosphères explosibles - Application des systèmes qualité

Explosionsgefährdete Bereiche - Anwendung von Qualitätsmanagementsystemen

This European Standard was approved by CEN on 12 September 2002.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Contents

Foreword

This document EN 13980:2002 has been prepared by Technical Committee CEN/TC 305 "Potentially explosive atmospheres - Explosion prevention and protection", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2003, and conflicting national standards shall be withdrawn at the latest by April 2003.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this document.

In this European Standard the annexes A and B are informative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard is complementary to EN ISO 9000 and EN ISO 9001 and is applicable to products intended for use in potentially explosive atmospheres. Its purpose is to embrace manufacturing practices that are appropriate to these products.

It does not preclude the use of other quality systems that are compatible with the objectives of EN ISO 9001.

1 Scope

1.1 General

This European Standard specifies particular requirements and information for establishing and maintaining a quality system in accordance with the requirements of Annex IV and Annex VII of Directive 94/9/EC.

It is intended for use by manufacturers, notified bodies and regulatory authorities.

Therefore, when notified bodies assess the quality systems of manufacturers this document is intended to be the basis of the initial assessment and subsequent visits.

1.2 Application

Only those requirements in clause 7 of this European Standard pertaining to the difference between Annex IV and VII of the Directive may be excluded, provided that conformity of the product can still be demonstrated.

Permissible exclusions with respect to Annex VII of Directive 94/9/EC are as follows:

7.1 Planning of product realisation;
7.2.3 Customer communication;
7.4 Purchasing;
7.5.1 Control of production and service provision;
7.5.2 Validation of processes for production and service provision;
7.5.3 Identification and traceability.

No explicit requirements in Annex IV and VII relate to the concept of “continuous improvement”. As a consequence, references in this European Standard to the requirements of EN ISO 9001:2000 exclude this concept.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

prEN 13237-1, *Potentially explosive atmospheres – Explosion prevention and protection — Part 1: Terms and definitions for equipment and protective systems intended for use in potentially explosive atmospheres.*

EN 45012, *General requirements for bodies operating assessment and certification/registration of quality systems (ISO/IEC Guide 62:1996).*

EN 45014, *General criteria for suppliers declaration of conformity (ISO/IEC Guide 22:1996).*

EN ISO 9000:2000, *Quality management system - Concepts and vocabulary (ISO 9000:2000).*

EN ISO 9001:2000, *Quality management system – Requirements (ISO 9001:2000).*

3 Terms and definitions

For the purposes of this European Standard the terms and definitions given in prEN 13237-1 and EN ISO 9000:2000 and following apply.

3.1
manufacturer
organisation, situated at a stated location or locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection

NOTE The term “manufacturer” is used instead of “organisation” as used in EN ISO 9001:2000. For the purposes of this standard they are interchangeable.

3.2
contract
requirements forming an agreement between a manufacturer and a customer and transmitted by any appropriate means

3.3
customer complaint
any reported written or verbal allegation made by a customer which concerns the identity, quality, durability, safety, security, conformity or performance of any equipment or protective system or component as defined in the EC type-examination certificate

3.4
product
equipment, protective systems, devices, components and their combinations, as well as software and service as defined in 3.4.2 of EN ISO 9000:2000

3.5
schedule drawing
drawing referenced in the EC type-examination certificate (e.g. in the schedule or the report)

3.6
related drawing
drawing not referenced in the EC type-examination certificate, but used for example, for detailed manufacture of component parts

3.7
equipment document
technical documentation as defined in Annex III of the Directive and product/production quality assurance notifications

3.8
manufacturers document
those documents required by a manufacturer but not subject to assessment by a notified body when making an application for either an EC type-examination certificate or product/production quality assurance notification. For example, instructions, related drawings, data sheets and sales literature

3.9
type of protection
specific measures applied to product to avoid ignition of a surrounding explosive atmosphere

4 Quality management system

4.1 General requirements

4.1 of EN ISO 9001:2000 applies.

The quality system shall ensure compliance of the product with the type described in the EC type-examination certificate.

4.2 Documentation requirements

4.2.1 General

4.2.1 of EN ISO 9001:2000 applies.

4.2.2 Quality manual

4.2.2 of EN ISO 9001:2000 applies.

4.2.3 Control of documents

4.2.3 of EN ISO 9001:2000 applies.

a) Equipment documents and manufacturer's documents shall be controlled;

b) Documented procedures shall ensure that information contained within manufacturer's documents is compatible with equipment documents. The manufacturer shall not initially approve or subsequently amend related drawings unless they are in compliance with the schedule drawings;

c) The quality system shall ensure that no factor (type, characteristic, position etc.) defined within the EC type-examination certificate and technical documentation (e.g. schedule drawings) is modified;

d) There shall be a documented system that refers all related drawings to the relevant schedule drawings,

e) Where there are common schedule drawings associated with more than one EC type-examination certificate, there shall be a documented system to ensure simultaneous supplementary action in the event of an amendment to such drawings;

NOTE Some manufacturers use common components with common drawing numbers on more than one product. Some of these products can have different persons responsible for them. Therefore, if one product with a common component and drawing number is revised to meet a need and the necessary supplementary certificate obtained, there needs to be a system for ensuring that any other certificates that call up such components are also subject to supplementary certification in order to avoid those products not being in compliance with their equipment documents.

f) Where a manufacturer also has drawings for products not intended for use in potentially explosive atmospheres then the manufacturer shall have a system that enables both the related drawings and schedule drawings to be clearly identified

NOTE The following examples indicate some methods of achieving this:

- the use of visual markers;
- the use of a unique series of drawing numbers, e.g. all drawings concerning a certified product have an Ex prefix to the drawing number.

g) The manufacturer shall document which notified body is responsible for the quality system notification for each EC type-examination certificate;

h) Where equipment documents or manufacturer's documents are passed to a third party, they shall be provided in a way that is not misleading.

4.2.4 Control of quality records

4.2.4 of EN ISO 9001:2000 applies.

NOTE It is in the manufacturer's interests to retain adequate quality records to demonstrate conformity of the product. Examples of documents requiring control and retention are:

— those arising from regulatory requirements;

— customer order;

— contract review;

— training records;

— inspection and test data (per batch);

— calibration data;

— sub-contractor evaluation;

— delivery data (customer, delivery date and quantity, including serial numbers where available).

5 Management responsibility

5.1 Management commitment

5.1 of EN ISO 9001:2000 applies.

5.2 Customer focus

5.2 of EN ISO 9001:2000 applies.

5.3 Quality policy

5.3 of EN ISO 9001:2000 applies.

5.4 Planning

5.4.1 Quality objectives

5.4.1 of EN ISO 9001:2000 applies.

5.4.2 Quality management system planning

5.4.2 of EN ISO 9001:2000 applies.

The quality system shall ensure that the product conforms to the type described in the EC type-examination certificate. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of quality programmes, plans, manuals and records.

The manufacturer shall facilitate an arrangement whereby the notified body may audit aspects of the suppliers operations that affect the type of protection.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

5.5.1 of EN ISO 9001:2000 applies.

Responsibilities and authority for the following shall be defined:

a) the effective co-ordination of activities with respect to products intended for use in potentially explosive atmospheres;

b) the need to liase with the notified body responsible for the issue of the EC type-examination certificate with respect to any proposed change to the design defined in the EC type-examination certificate and the technical documentation;

c) the need to liase with the notified body responsible for the assessment of the quality system with respect to intended updating of the quality system;

NOTE It is not practicable for the manufacturer to inform the notified body each time the quality system is updated. It is only practicable to inform the notified body of “substantial” updating of the quality system relevant to the type of protection. Similarly, it is not practicable to specify in general terms what types of updating are or are not “substantial”. It is therefore recommended that the manufacturer establishes and maintains a system for categorising updates as “substantial” or not and informing the notified body as appropriate.

d) the authorising of initial approval and changes to related drawings, where appropriate;

e) the authorising of concessions (see 8.3 f));

f) informing its customer of any applicable special conditions for safe use and any schedules of limitations;

NOTE 1 Certificates with a suffix X can contain special conditions for safe use. Component certificates, with a suffix U can contain schedules of limitations.

NOTE 2 For each EC type-examination certificate it is recommended that an authorised person is appointed who should have responsibility and authority for the above activities so providing an unambiguous focal point within the organization.

5.5.2 Management representative

5.5.2 of EN ISO 9001:2000 applies.

5.5.3 Internal communication

5.5.3 of EN ISO 9001:2000 applies.

5.6 Management review

5.6.1 General

5.6.1 of EN ISO 9001:2000 applies.

a) the maximum intervals between reviews should normally be 12 months and shall not exceed 14 months;

b) top management shall chair the review;

c) the person(s) responsible for the activities as detailed in 5.5.1 shall participate in the review.

5.6.2 Review input

5.6.2 of EN ISO 9001:2000 applies.

The review shall include the overall effectiveness of the quality management system with respect to products intended for use in potentially explosive atmospheres.

NOTE Results of audits should include both internal audits and those conducted by other parties (e.g. the notified body).

5.6.3 Review output

5.6.3 of EN ISO 9001:2000 applies.

6 Resource management

6.1 Provision of resources

6.1 of EN ISO 9001:2000 applies.

6.2 Human resources

6.2.1 General

6.2.1 of EN ISO 9001:2000 applies.

6.2.2 Competence, awareness and training

6.2.2 of EN ISO 9001:2000 applies.

6.3 Infrastructure

6.3 of EN ISO 9001:2000 applies.

6.4 Work environment

6.4 of EN ISO 9001:2000 applies.

7 Product realisation

7.1 Planning of product realisation

7.1 of EN ISO 9001:2000 applies.

NOTE Examples are given in annexes A and B.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

7.2.1 of EN ISO 9001:2000 applies.

The product category and marking shall be included.

7.2.2 Review of requirements related to the product

7.2.2 of EN ISO 9001:2000 applies.

The review shall ensure that any stated customer requirement is compatible with the EC type-examination certificate e.g. ambient temperature range.

7.2.3 Customer communication

7.2.3 of EN ISO 9001:2000 applies.

7.3 Design and development

Not within the scope of this standard.

7.4 Purchasing

7.4.1 Purchasing process

7.4.1 of EN ISO 9001:2000 applies.

a) While manufacture, test and final inspection may be sub-contracted, the responsibility for ensuring conformance with the EC type-examination certificate shall not be sub-contracted;

b) Suppliers providing a product, process, or service that can affect the product's compliance with the EC type-examination certificate shall only be selected after an evaluation has demonstrated that they have the capability of ensuring compliance with all specified requirements;

   1) The evaluation shall be made by one or more of the following methods:

      — the supplier has third party quality system certification to the appropriate standard and scope issued by an accredited body which can demonstrate that it operates in compliance with EN 45012. This can be achieved by an accredited certification;

      — a documented evaluation which provides objective evidence that the supplier can provide product, process or service that are fit for purpose;

      — a documented site assessment to ensure that all relevant controls are available, documented, understood and effective.

      NOTE The evaluation should take the following into account:

      — criticality of the product, process or service;

      — degree of difficulty, or variability in the manufacturing process;

      — location of the supplier and hence the effectiveness of communications;

      — does the supplier, in turn sub-contract the product, process or service;

   2) Suppliers providing calibration services shall be evaluated on their ability to meet stated requirements;

   3) Where the features affecting the type of protection can not be verified at a later stage e. g. encapsulated intrinsically safe circuits, then the evaluation shall include initial and periodic site assessments at the suppliers premises to ensure relevant controls are available, documented, understood and effective;

c) Suppliers not used for a period exceeding one year shall be re-evaluated prior to the placing of the contract;

NOTE "re-evaluation" means to treat the supplier as a new supplier and therefore 7.4.1 b) is applicable.

d) Requirements b) and c) are not mandatory for products, processes or services where the manufacturer fully verifies each item for conformance;

e) The ongoing ability of the supplier to provide conforming product, process or service shall be reviewed at periods not exceeding one year.

NOTE 1 “review” is a process by which the manufacturer demonstrates the ongoing suitability of their suppliers e. g. receiving inspection report analysis.

NOTE 2 The terms “re-evaluation” and “review” are different and should not be mixed.

7.4.2 Purchasing information

7.4.2 of EN ISO 9001:2000 applies.

a) The purchasing documents shall clearly describe the specific requirements pertaining to subcontracted product set out in the EC type-examination certificate and the equipment documents (e.g. for process control, testing or inspection);

b) For items where conformance cannot be verified after manufacture (e.g. encapsulated intrinsically safe circuits), the purchasing information shall set out the specific quality procedures, resources and sequence of activities relevant to the particular item;

c) The manufacturer shall define the method by which documents e. g. technical specifications, stated in a particular purchase order remain traceable to the order.

7.4.3 Verification of purchased product

7.4.3 of EN ISO 9001:2000 applies.

a) For purchased products that can compromise the type of protection the manufacturer shall determine and implement verification arrangements which demonstrate the product’s compliance with the EC type-examination certificate, taking into account the nature of the product and the nature of the supplier;

b) When deciding what type of verification is required for a particular purchased product, the manufacturer shall consider the nature of the purchased product, the supplier, and how critical it is to the type of protection.

NOTE In considering whether the supplier should carry out the verification, the manufacturer should take into account the results of his evaluation carried out under 7.4.1. The decision should reflect the competence of the supplier, including whether he has a quality system that covers the activity, the resources, e. g. equipment, and the people with sufficient skill and experience to do it. This latter point is particularly significant when judgement is required, such as when inspecting a flameproof casting. When the manufacturer elects to have the supplier carry out test or inspection that is relevant to the type of protection, the product should be supplied with a declaration of conformity according to EN 45014 that confirms it has been done.

c) where the supplier has been evaluated and documented objective evidence demonstrate the supplier to be fully capable of producing and verifying the product or service, no further verification of the product or service is required, if a declaration of conformity according to EN 45014 is supplied with each batch or product;

d) where the EC type-examination certificate specifies routine tests or inspections these shall be carried out on each and every product. They may be carried out by either the supplier or the manufacturer. When carried out by the supplier they shall be specified on the purchasing documents, e. g. by a quality plan, and confirmed by the supplier e. g. declaration of conformity according to EN 45014;

e) where verification of a product cannot be carried out after manufacture, e. g. the internal parts of an encapsulated intrinsically safe circuit, then the product shall only be accepted if supplied with a declaration of conformity according to EN 45014. This shall specifically state compliance to the purchase documents, e. g. a quality plan, that lists the factors that together demonstrate conformity of the product;

f) where sample inspections or tests are permitted they shall be conducted in a manner which demonstrates conformity of the entire batch;

g) where either the supplier or the manufacturer requires training or specialist skill or knowledge to carry out a verification they shall be documented and training records maintained;

h) where the manufacturer chooses not to carry out inspections and tests at its own premises, then inspections and tests shall be performed on the suppliers premises under the responsibility of the manufacturer;

i) where a supplier provides product with evidence of conformity, (e.g. EC type-examination certificate, quality assurance notification), then further verification is not required unless the manufacturer considers it necessary.

7.5 Production and service provision

7.5.1 Control of production and service provision

7.5.1 of EN ISO 9001:2000 applies.

The manufacturer shall consider the requirements contained in the EC type-examination certificate.

7.5.2 Validation of processes for production and service provision

7.5.2 of EN ISO 9001:2000 applies.

7.5.3 Identification and traceability

7.5.3 of EN ISO 9001:2000 applies.

a) The manufacturer shall establish and maintain procedures for product identification during all stages of production, testing, final inspection and placing on the market;

b) Traceability is required with respect to the final product and its significant parts.

NOTE Significant parts are, for example, a printed circuit board (PCB) of an intrinsically safe, circuit, but not each electronic component on a PCB.

7.5.4 Customer property

7.5.4 of EN ISO 9001:2000 applies.

It is the responsibility of the manufacturer to verify the compatibility of customer supplied product with the requirements of the EC type-examination certificate.

7.5.5 Preservation of product

7.5.5 of EN ISO 9001:2000 applies.

The manufacturer shall provide its customer with the instructions as described in Annex II of the Directive 94/9/EC.

7.6 Control of monitoring and measuring devices

7.6 of EN ISO 9001:2000 applies.

NOTE Compliance with 7.6(a) of EN ISO 9001:2000 can be achieved by using an accredited calibration laboratory (which can demonstrate to the notified body that it operates in compliance with an internationally recognised standard and is preferably covered by a multilateral agreement) and obtaining a certificate bearing the accreditation logo. Where such a certificate is obtained, the laboratory need not be subject to further evaluation.

a) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority, each calibration certificate shall include at least the following information:

— an unambiguous identification of the item calibrated;

— evidence that the measurements are traceable to international or national measurement standards;

— the method of calibration;

— a statement of compliance with any relevant specification;

— the calibration results;

— the uncertainty of measurement, where necessary;

— the environmental conditions, where relevant;

— the date of calibration;

— the signature of the person under whose authority the certificate was issued;

— the name and address of the issuing organisation and the date of issue of the certificate;

— a unique identification of the calibration certificate.

b) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority or does not contain the information listed in a), the manufacturer shall demonstrate a valid relationship to international or national measurement standards by other means (e.g. a documented site assessment).

8 Measurement, analysis and improvement

8.1 General

8.1 of EN ISO 9001:2000 applies with the following exceptions:

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

8.2.1 of EN ISO 9001:2000 shall be replaced by the following requirement.

For the purposes of this European Standard “customer satisfaction” shall be in relation to the product’s compliance with the EC type-examination certificate.

8.2.2 Internal audit

8.2.2 of EN ISO 9001:2000 applies.

The audit programme shall address the effectiveness of the elements of the quality system as described in this standard to ensure that the products are in conformity with the EC type-examination certificate. The maximum period between audits should normally be 12 months and shall not exceed 14 months.

NOTE 1 One method of demonstrating effectiveness is the use of vertical auditing whereby a product awaiting despatch is used to prove the system. The auditor examines all aspects of the system associated with the production of that product from a certification viewpoint. This should include appropriate documentation (drawings, inspection checklists, test records, material certificates etc.), product identification, handling, storage, training of staff and any other elements of the system which can affect the compliance of the product to the certification parameters.

NOTE 2 For those manufacturers that employ checklists to assist in their internal audit programmes then the inclusion of the requirements of this European Standard into the appropriate checklists and the retention of internal audit records is another alternative method of addressing this requirement.

Manufacturers may at their own discretion employ both methods or some other equivalent method.

8.2.3 Monitoring and measurement of processes

8.2.3 of EN ISO 9001:2000 applies.

Where a process can affect the integrity of a type of protection, and where the resulting integrity cannot be verified after manufacture (e. g. the environmental conditions required for curing an encapsulant), that specific process shall be measured or monitored and documentary evidence shall be maintained to demonstrate compliance with required parameters (see also annex A).

8.2.4 Monitoring and measurement of product

8.2.4 of EN ISO 9001:2000 applies.

Where routine tests are required by the EC type-examination certificate and the equipment documents, then those tests shall be performed as specified with no sampling techniques being permitted.

Where practicable, the label bearing the marking data, shall not be affixed until the final inspection and testing has been satisfactorily completed.

8.3 Control of non-conforming product

8.3 of EN ISO 9001:2000 applies.

NOTE One of the purposes of this standard is to prevent nonconforming product being supplied.

a) The manufacturer shall maintain a system such that in the event of product not complying with the EC type-examination certificate and having been supplied, then the manufacturers customer can be identified;

b) The manufacturer shall take action, appropriate to the degree of risk, where non-conforming product has been supplied to a customer;

NOTE It is recommended that the manufacturer liaise with the notified body responsible for the issue of the EC type-examination certificate.

c) Where unsafe, non-conforming product has been supplied to a customer, the manufacturer shall, in writing, inform its customer and the notified body responsible for the quality system notification;

NOTE It is recommended that the notified body responsible for the quality system notification liaise with the notified body responsible for the issue of the EC type-examination certificate.

d) Where it is not possible to trace unsafe product (e.g. product supplied via a distributor, or for high volume products such as cable glands) then a notice shall be placed in appropriate publications providing recommended action to be taken;

e) For all non-conforming product that has been supplied to a customer, the manufacturer shall maintain, for a minimum period of 10 years, records of :

   1) serial numbers or identification of products supplied;

   2) the customer who received the product;

   3) the action taken to inform customers and the relevant notified body in the case of unsafe non-conforming product;

4) the action taken to implement corrective and preventative action;

f) Concessions for product that take the product outside the design as defined in the EC type-examination certificate and technical documentation are not permitted.

8.4 Analysis of date

8.4 of EN ISO 9001:2000 applies.

For continual improvement, see 8.2.

8.5 Improvement

8.5.1 Continual improvement

Not in the scope of this standard.

8.5.2 Corrective action

8.5.2 of EN ISO 9001:2000 applies.

8.5.3 Preventive action

8.5.3 of EN ISO 9001:2000 applies.

Annex A
(informative)

Information relevant to particular types of protection

A.1 Introduction

This annex provides information on those aspects that the quality system needs to address with respect to particular types of protection. It does not add to or otherwise change the requirements of this European Standard.

This annex provides examples of how to meet the requirements of this European Standard, recognising that other methods which achieve the same objectives are equally acceptable; and draws attention to aspects of requirements that can not be readily apparent to those unfamiliar with quality systems for products intended for use in potentially explosive atmospheres. Examples of other types of protection including non-electrical equipment can be introduced as necessary in the future.

A.2 General

For enclosures and other components forming part of the enclosure the manufacturer should verify the material composition (e.g. declaration of conformity, in compliance with EN 45014 from the supplier).

Sampling techniques are not appropriate to routine tests required by the EC type-examination certificate except where the following currently permit such techniques:

— the European Standard;

— CENELEC and CEN interpretation sheets;

— EX notified bodies group decisions.

A.3 Ex d-flameproof enclosures

A.3.1 Castings

Castings should be subject to verification which demonstrates conformity, e.g.:

— wall thickness (including those parts not subject to machining);

— flaws, inclusions, blow holes and porosity (by either a visual or test method depending upon the criticality);

Recovery of porous castings by impregnation methods, e. g. silicon is not recommended. In the event that a casting is recovered by welding it will become subject to the requirements applicable to fabricated enclosures, e. g. routine pressure testing.

A.3.2 Machining

Machining should be subject to verification which demonstrates conformity. For example:

— flatness of flanged flamepaths;

— surface roughness of non-threaded flamepaths;

— fit of all threaded flamepaths (e.g. cable entries and threaded access covers);

— depth of drilling and tappings to ensure adequate residual wall thickness;

— dimensional requirements of all flamepaths.

A.3.3 Cemented joints and potted assemblies

Documented procedures should address the following:

a) shelf life and storage of cement, potting compounds;

b) mixing;

c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion);

d) application e. g. filling instructions, freedom from voids and temperature conditions;

e) curing, which should include: curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period.

A.3.4 Routine pressure testing

The purpose of the test is to check that the enclosure does not suffer damage or permanent deformation and that there is no leakage from the enclosure during the test other than through constructional gaps, e.g. flamepaths.

Leakage through cemented joints or potted assemblies would constitute a failure.

The test can be a single test conducted on a complete assembly, or a series of tests on each sub-assembly or component part. For enclosures that contain more than one discrete compartment, each compartment should be tested individually. The method used should ensure that the assembly, sub-assembly or component parts are subjected to representative stress patterns e.g. actual fastening facilities are used. Clampings that effect the mechanical properties of the type of protection would invalidate the test.

Due to safety considerations and difficulty in detecting leakage, hydraulic rather than pneumatic methods are recommended.

The test facility should be adequate to readily provide the required pressure during the test period. Leakage from flamepaths can be reduced by the use of gaskets or ‘O’ rings.

The pressure gauge should be calibrated, of suitable resolution and range, and located such that its location does not invalidate the test (e.g. due to pressure drop down pipelines).

The method of test should enable any leakage to be monitored during the test period.

The verification of the routine pressure test should include verification of the product for damage or deformation, e.g. flange flamepaths are still within stated tolerances and fastenings are not stretched.

A.3.5 Flanged joints

Flanged joints should be verified after final assembly to ensure the specified gap is not exceeded.

A.3.6 Sintered components

For product containing sintered components, see annex B.

A.4 Ex i - intrinsic safety

A.4.1 Components for intrinsically safe products

The following features should be verified with respect to the following components for use in intrinsically safe apparatus and associated apparatus. This normally means verifying the marking on the components or packaging and can be achieved by using statistical techniques where appropriate:

Resistors:	value, power, type.
Capacitors:	value, tolerance, type.
Piezo-electric devices:	manufacturer, type, capacitance.
Inductive components:	type, inductance, d.c. resistance, number of turns, wire gauge and material, material specification of core and bobbin where appropriate.
Transformers:	type, manufacturer, isolation, voltage.
Semi-conductors	
Diodes Zener Diodes Transistors Integrated Circuits Thyristors	} type number and where appropriate, the manufacturer
Cells and batteries:	manufacturer and type number, or IEC designation.
Fuses:	manufacturer, type, value.
Insulating materials:	specification, dimensions and where appropriate type number.
Connectors (e.g. plugs/ sockets and terminals):	type number and where appropriate, the manufacturer.

A.4.2 Printed circuit boards (PCB)

A.4.2.1 Non-populated PCB’s

A.4.2.1.1 For high volume or complex PCB’s e.g. multilayer PCB's, the batch can be accepted with a declaration of conformity in accordance with EN 45014. The declaration should state compliance to the purchase documents e.g. a quality plan, that lists the factors that together demonstrate conformity of the product.

A.4.2.1.2 For simple single or double sided PCB's, the copper artwork should be visually verified using photographic negative (transparency), certified drawing or controlled inspection sample.

Purchase documents should specify copper thickness, PCB thickness and CTI values.

A.4.2.2 Populated PCB's

A.4.2.2.1 Varnish and coatings should be controlled with respect to the specification of material, effectiveness of cover and where required application of two independent coverings, i.e. the first covering is allowed to cure or to dry for a time suitable for overcoating before application of the second.

A.4.2.2.2 For PCB's the manufacturer should maintain a list of safety critical components used in production (e.g. resistors and zener diodes) which have been agreed with the notified body that has issued the EC type-examination certificate. The components on this list should be verified on a 100 % basis.

This can be conducted by:

— a visual verification; or

— for surface mount components, by ensuring correct loading of the "pick and place" machines and a visual verification of correct placement;

— by automatic test equipment (ATE) provided that the ATE addresses each individual safety critical component and that a visual verification is conducted to verify type number of components in shunt zener diode/diode assemblies.

NOTE Where the surface mount component "pick and place" machine selects the component reel based on measuring the component value, the measuring function should be calibrated.

A.4.2.2.3 Documented procedures should be provided that ensure that workmanship standards are defined with respect to component mounting and soldering.

A.4.2.2.4 Specified segregation for hand build PCB's should be verified on a 100 % basis.

A.4.3 Sub-assemblies and assemblies

A.4.3.1 Documented procedures should ensure that production documentation includes all relevant variations to the product design.

A.4.3.2 Production documentation should address all safety critical components, and in the case of encapsulated parts, the encapsulant manufacturer, type, mix and depth.

A.4.3.3 Documented procedures should ensure that segregation of related parts (e. g. terminals) and wiring/cabling is maintained and that specified colours and/or labels are fitted.

A.4.3.4 Sealing arrangements should be verified for compatibility with the product's ingress protection rating.

A.4.4 Tests

Any tests specified in the EC type-examination certificate, e.g. high voltage tests on complete assemblies or individual components such as transformers, should be controlled by documented procedures and conducted on a 100 % basis unless otherwise permitted.

A.4.5 Intrinsically safe circuits and assemblies housed in Ex d, Ex p or Ex q enclosures

Where Ex d, Ex p or Ex q enclosures contain intrinsically safe circuits then precautions should be taken as stated in the EC type-examination certificate to ensure that other items listed in the EC type-examination certificate are selected, mounted and installed in accordance with schedule drawings.

A.5 Ex e - increased safety

A.5.1 Ingress Protection

Documented procedures should ensure that the following are verified:

a) weld continuity;

b) fitting of gaskets and seals;

c) continuity of moulded grooves and tongues;

d) application of cements.

A.5.2 Internal wiring and contact integrity

Documented procedures should ensure that the following are verified:

a) wiring is effectively clamped;

b) wiring is correctly terminated, e. g. excessive insulation is not removed from connecting wires (normally within 1 mm of terminal metal);

c) wiring insulation has an appropriate temperature rating

A.5.3 Rotating machines

Documented procedures should ensure that the following are verified:

a) rotor end connections and fixing bars are correctly tightened and not subject to undue stress;

b) the air gap is verified (rotor to stator) or calculated from the tolerances defined;

c) the fan clearance;

d) the bearing clearances.

A.5.4 Windings

Documented procedures should ensure that the following are verified;

a) impregnation's are free of voids;

b) insulation materials are to the stated specification;

c) security of conductors;

d) where protective devices (e.g. thermal cut-outs) are specified in the EC type-examination certificate, they should be of the type and in the location specified.

A.5.5 Tests

All tests should be documented. Typically tests include:

a) dielectric tests;

b) bearing insulation for rotating machines.

A.6 Ex p - Pressurised apparatus

A.6.1 Ingress protection

Documented procedures should ensure that the following are verified:

a) weld continuity;

b) fitting of gaskets and seals;

c) continuity of moulded grooves and tongues;

d) application of cements.

A.6.2 Tests

All tests should be documented. Typical tests include:

a) an overpressure test, at the pressure stated in the EC type-examination certificate;

followed by

b) a leakage test, to ensure the specified leakage rate is not exceeded.

A.7 Ex m - Encapsulation

A.7.1 Production documentation

Thermal protection (e.g. thermal fuses) should be positioned according to and be of the type specified in the schedule drawings.

The guidance given in A.3.3 should apply to the encapsulant.

A.7.2 Tests

All tests should be documented. Typical tests include:

a) visual examination;

b) dielectric characteristics verification.

A.8 Ex o - Oil immersion

All tests should be documented. Typical tests include:

a) reduced pressure test (sealed enclosures only);

b) overpressure test (sealed and unsealed enclosures).

A.9 Ex q - Powder filling

A.9.1 Material control

The material should be of defined size and type.

Evidence should exist as to the flammability verification of enclosure materials and these materials should align with those specified in the EC type-examination certificate.

A.9.2 Filling

Filling should be made without voids. Care is clearly needed to ensure that voids are not created after filling by shaking, down. The process for filling should be documented and the documentation should include verification criteria.

A.9.3 Ingress protection

Documented procedures should ensure that the following are verified:

a) weld continuity;

b) fitting of gaskets and seals;

c) continuity of moulded grooves and tongues;

d) application of cements.

A.9.4 Tests

All tests should be documented. Typical tests include:

a) pressure test;

b) dielectric strength test of filling material.

Annex B
(informative)

Verification criteria for sintered components used as an integral part of a type of protection

B.1 Introduction

Sintered material is used in many products, such as gas detectors and loud speakers.

When a notified body issues an EC type-examination certificate involving such components, then the design parameters for the sintered component normally covers three factors

— maximum pore size;

— minimum density;

— diameter and thickness of sinter.

Therefore the purpose of this annex is not to add any technical requirements but to provide manufacturers with guidance as to how they can demonstrate that the actual sintered components comply with the design requirements as detailed in the EC type-examination certificate.

B.2 Verification guidance

Three options are available:

— the manufacturer conducts the verification examination and tests;

— the manufacturer conducts a pre-contract and follow-up periodic documented assessment of the sinter supplier and accepts sinters with a “Declaration of conformity”, that is in accordance with EN 45014;

— the manufacturer accepts sinters with a “Declaration of conformity” that is in accordance with EN 45014 from a sinter manufacturer, who has a certified quality management system with an appropriate scope.

B.3 Tests

The tests. for all verification options should be performed in accordance with the requirements of the EC type-examination certificate. Typical test requirements are given in ISO 4003 and ISO 2738.

The test can be conducted on a sample basis provided that the sample size is not less than 1 % of the batch size or 10 units, whichever is the greater.

Where tests to determine pore size and density are conducted on a sample basis, then the results should be calculated to establish the standard deviation (σ) for the sample batch,

i.e. σ_p is the pore size standard deviation;

σ_D is the density standard deviation.

The maximum pore size should not be exceeded and the minimum density should remain equal to or greater than the value as stated in the EC type-examination certificate when 3 σ is taken into account. Therefore the mean value of the sample batch, plus 3 σ_p (for pore size) and minus 3 σ_D (for density) should not invalidate the requirements of the EC type-examination certificate.

B.4 Test examples

The following examples are provided for guidance:

Example 1 (pore size)

Maximum permitted pore size as detailed in the

EC type-examination certificate = 150 µm

Mean value = 140 µm

Standard deviation (σp) = 2 µm

Therefore maximum value = 140 + (2 x 3) = 146 µm (PASS)

If standard deviation (σp) = 5 µm

Then maximum value = 140 + (5 x 3) = 155 µm (FAIL)

Example 2 (density)

Minimum permitted density as detailed in the

EC type-examination certificate = 5 gcm^{-3}

Mean value = 5,3 gcm^{-3}

Standard deviation (σD) = 0,05 gcm^{-3}

Therefore minimum value = 5,3 - (0,05 x 3) = 5,15 gcm^{-3} (PASS)

If standard deviation (σD) = 0,12

Then minimum value = 5,3 - (0,12 x 3) = 4,94 gcm^{-3} (FAIL)

NOTE In some cases the sinter is formed directly in a solid housing. To establish the density value, the following formula should be used:

$$\rho = \frac{M_1 \cdot \sigma_W}{M_2 - M_3}$$

substitute as follows:

$$\rho = \frac{(m_3 - m_1) \cdot \rho_W}{(m_4 - m_1) - (m_5 - m_2)}$$

where

ρ_W is the density of water;

m_1 is the housing only, weight in air;

m_2 is the housing only, weight in water;

m_3 is the housing and sinter (assembly), weight in air;

m_4 is the coated assembly, weight in air;

m_5 is the coated assembly, weight in water.

B.5 Purchase information

The manufacturer should ensure that the purchase documents include the following:

— the sinter material specification;

— the dimensional requirements;

— the maximum pore size and the standard called up in the EC type examination certificate e.g. ISO 4003;

— the minimum density and the standard called up in the EC type examination certificate e.g. ISO 2738.

B.6 Pre-tested components

Where the manufacturer does not conduct their own tests then the “Declaration of Conformity” should be in accordance with EN 45014, and should also include the following:

— the manufactured batch size;

— the sample size taken to establish the maximum pore size and the minimum density;

— the number of components supplied;

— the calculated maximum pore size and minimum density, e. g. the mean values and standard deviation should be stated.

B.7 Measurement and monitoring

Upon receipt of the components, the manufacturer should:

— check the “Declaration of Conformity” against the requirements of B.3;

— check the compatibility of the purchase order requirements with the “Declaration of Conformity” (if not testing on site and giving special attention to the stated pore size and density data to ensure that when taking the stated tolerance into account the specification is not exceeded;

— conducting the tests (if testing on site);

— conducting a statistical check on the overall size of the sintered component e. g. diameter and thickness.

Annex ZA
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of the following EU Directive:

> 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.

WARNING Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The clauses of this standard are likely to support requirements of the above mentioned Directive. The following table establishes the relationships between the relevant requirements of the respective Directive and the clauses of this European Standard dealing with them:

Table ZA.1 — Relationship between Directive 94/9/EC and clauses of this standard

Essential requirement of Directive 94/9/EC	Dealt with in this European Standard in clause
Annex IV and Annex VII	4 to 8

Compliance with this standard provides one means of conforming with the specific essential requirements of Directive concerned and associated EFTA regulations.

Bibliography

EN 45001, *General criteria for the operation of testing laboratories.*

EN 45011, *General requirements for bodies operating product certification systems (ISO/IEC Guide 65:1996).*

ISO 2738, *Sintered metal materials, excluding hardmetals - Permeable sintered metal materials - Determination of density, oil content and open porosity.*

ISO 4003, *Permeable sintered metal materials - Determination of bubble test pore size.*

ISO/IEC 17025, *General requirements for the competence calibration and testing laboratories.*

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