IEC Ex

Secretariat

INTERNATIONAL ELECTROTECHNICAL COMMISSION

IEC SCHEME FOR CERTIFICATION TO STANDARDS FOR SAFETY OF ELECTRICAL EQUIPMENT FOR EXPLOSIVE ATMOSPHERES (IECEx SCHEME)

For Consideration by Members of the Ex Management Committee, ExMC

For the Information of Members of Ex Testing and Assessment Group, ExTAG and ExMC WG5, Manufacturers Quality Plan Requirements

DRAFT: IECEx QUALITY SYSTEM REQUIREMENTS FOR MANUFACTURERS

Introduction

This draft proposes the Quality System requirements that must form part of the manufacture's overall quality system to achieve the IECEx Certificate of Conformity (CoC) and use of the IECEx Mark.

This draft document is the result of work conducted within the ExMC Working Group 5, *Manufacturer's Quality Plans* and includes the changes to ExMC/52/CD, as agreed, during the 2000 ExMC Braunschweig meeting.

This document has adopted the internationally accepted Quality Management System principles of the ISO 9001: 2000 and is aligned with CEN draft document prEN 13980 as prepared by **CEN/TC 305/WG 4/ad hoc 2.**

Style and editorial changes to document prEN 13980 have been included in order to adapt the document for use in the IECEx Scheme, however the general intention of prEN 13980 has been maintained.

This document proposes that manufacturers implement "Production Quality Assurance". Refer to Annex C. These requirements have been aligned with the requirements contained in the European ATEX Directive.

IECEx Members acknowledge the work of CEN TC 305 and CEN/TC 305/WG4/ad hoc 2.

The principle aim of these requirements is to create confidence in the market that the manufacturer, identified on the Certificate of Conformity, has the capability to consistently produce products that comply with the nominated IEC Ex Standards.

Members of ExMC and ExTAG are requested to review this document, with their National Committees and submit comments to the ExMC Secretariat by **e-mail** by **31 August 2001.** This draft will then be considered by ExMC Working Group WG 5**,** in light of comments received, at their next meeting scheduled for October next.

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0 Introduction

This Document presents particular requirements and guidance to manufacturers providing product covered by the IECEx Scheme.

This Document needs to be read in conjunction with ISO 9001:2000 and ISO 9004:2000.

The purpose of this Document is to embrace the “good“ manufacturing practices which are appropriate to products used in potentially explosive atmospheres.

1 Scope

1.1 General

This Document specifies particular requirements and guidance on the establishment and maintenance of a quality system to meet the requirements of the IECEx Scheme. It does not preclude the use of other quality systems that are compatible with the objectives of ISO 9001:2000, subject to the acceptance of an ACB.

Therefore, ACBs assess the quality systems of manufacturers with respect to Annex C of this document. This document shall be the basis of the initial assessment and subsequent surveillance visits.

1.2 Permissible exclusions

The manufacturer may only exclude quality management system requirements within Clause 7, with the agreement of the ACB, provided that conformity of the product can still be demonstrated.

2 Normative references

This Document 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 Document only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies.

3 Terms and definitions

The definitions of IECEx 01, IECEx 02 and ISO 9001:2000 apply, as do the following definitions:

3.1
manufacturer
Refer to IECEx 02

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 IECEx Assessment and Test Report.

3.4
product
the term “product” covers equipment, protective systems, devices, components and their combinations, as well as software and service as defined in 3.4.2 of ISO 9001:2000.

3.5
schedule drawing
drawing listed in the IECEx Assessment and Test Report (ATR).

3.6
related drawing
drawing not listed in the IECEx Assessment and Test Report, but used, for example for detailed manufacture of component parts.

3.7
technical documentation
documentation that enables the conformity of the product with the requirements of the Standard(s) 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 the IECEx Assessment and Test Report, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the Standards;
- results of design calculations made, examinations carried out, etc.;
- test reports.

3.8 manufacturers documents
those documents required by a manufacturer but not subject to assessment by an ACB when making an application for either an IECEx ATR or IECEx Certificate of Conformity. 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 requirements

4.1 General requirements

4.1 of ISO 9001:2000 applies.

The quality system shall ensure compliance of the product with the type described in the IECEx Assessment and Test Report.

4.2 General documentation requirements

4.2 of ISO 9001:2000 applies.

4.2.1 General

4.2.1 of ISO 9001:2000 applies.

4.2.2 Quality manual

4.2.2 of ISO 9001:2000 applies.

4.2.3 Control of documents

4.2.3 of 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 IECEx ATR 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 IECEx ATR, 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 may 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 ACB is responsible for the each IECEx Certificate of Conformity

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 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 ISO 9001:2000 applies.

5.2 Customer focus

5.2 of ISO 9001:2000 applies.

5.3 Quality policy

5.3 of ISO 9001:2000 applies.

5.4 Planning

5.4.1 Quality objectives

5.4.1 of ISO 9001:2000 applies.

The objective shall include the manufacturer's commitment for ensuring that appropriate product and its supporting quality system shall comply with the requirements of the IEC Standard, identified in the IECEx Assessment and Test Report and the IECEx Scheme rules, IECEx 02.

5.4.2 Quality planning

5.4.2 of ISO 9001:2000 applies.

The quality system shall ensure that the product conforms to the type described in the IECEx Assessment and Test Report the technical documentation.

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 ACB 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 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 liaise with the ACB responsible for the issue of the IECEx ATR with respect to any proposed change to the design defined in the IECEx ATR and the technical documentation;

c) the need to liaise with the ACB responsible for the issuing of the IECEx Certificate of Conformity with respect to intended updating of the quality system;

NOTE: It is not practicable for the manufacturer to inform the ACB each time the quality system is updated. It is only practicable to inform the ACB 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 ACB as appropriate.

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

e) the authorising of concessions (see 8.3);

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

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

2 For each IECEx ATR it is recommended that an authorised persons be 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 ISO 9001:2000 applies.

5.5.3 Internal communication

5.5.3 of ISO 9001:2000 applies.

5.6 Management review

5.6.1 General

5.6.1 of 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 ISO 9001:2000 applies.

The review shall include the overall effectiveness of the quality management system with respect to product 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 ACB).

5.6.3 Review output

5.6.3 of ISO 9001:2000 applies.

6 Resource management

6.1 Provision of resources

6.1 of ISO 9001:2000 applies.

6.2 Human resources

6.2.1 General

6.2.1 of ISO 9001:2000 applies.

6.2.2 Competence, awareness and training

6.2.2 of ISO 9001:2000 applies.

6.3 Infrastructure

6.3 of ISO 9001:2000 applies.

6.4 Work environment

6.4 of ISO 9001:2000 applies.

7 Product realisation

7.1 Planning of realization processes

7.1 of ISO 9001:2000 applies.

NOTE Examples are given in annex A.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

7.2.1 of ISO 9001:2000 applies.

The manufacturer shall determine the product category and marking required by their customer.

7.2.2 Review of requirements related to the product

7.2.2 of ISO 9001:2000 applies.

The review shall ensure that any stated customer requirement is compatible with the IECEx ATR e.g. ambient temperature range.

7.2.3 Customer communication

7.2.3 of 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 ISO 9001:2000 applies.

a) While manufacture, test and final inspection may be sub-contracted, the responsibility for ensuring conformance with the IECEx ATR shall not be sub-contracted.

b) Suppliers providing a product, process, or service that can affect the product's compliance with the IECEx ATR shall only be selected after an evaluation has demonstrated that they have the capability of ensuring compliance with all specified requirements.

c) 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 ISO/IEC Guide 62. 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.

d) Suppliers providing calibration services shall be evaluated on their ability to meet stated requirements.

e) 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.

f) 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.

g) Requirements b) and f) are not mandatory for products, processes or services where the manufacturer fully verifies each item for conformance.

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

NOTES: 1. "review" is a process by which the manufacturer demonstrates the ongoing suitability of their suppliers e. g receiving inspection report analysis.

2. The terms "re-evaluation" and "review" are different and should not be mixed.

7.4.2 Purchasing information

7.4.2 of ISO 9001:2000 applies.

a) The purchasing documents shall clearly describe the specific requirements pertaining to subcontracted product set out in IECEx Assessment and Test Report and in the technical documentation (eg for process control, testing or inspection)

b) For items where the conformance cannot be verified after manufacture e.g. encapsulated intrinsic 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.

d) Where the manufacturer does not provide such documents with subsequent orders, then the manufacturer shall have procedures for ensuring that suppliers have current copies of documents and that they remain in good condition.

7.4.3 Verification of purchased product

7.4.3 of 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 Standards listed on the IECEx ATR, 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 their evaluation carried out under 7.4.1. The decision should reflect the competence of the supplier, including whether they have 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 has been obtained to demonstrate that the supplier is 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 IECEx Certificate of Conformity 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 circuits, 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 applicable to use in a potentially explosive atmosphere, (e.g. IECEx ATR or Certificate of Conformity), then further verification is not required unless the manufacturer considers it necessary.

7.5 Production and service operations

7.5.1 Operations control

7.5.1 of ISO 9001:2000 applies.

The manufacturer shall provide procedures, production equipment, working environments and inspection/testing facilities that together provide assurance with respect to the compliance of the product with the type as described in the IECEx Assessment and Test Report and with the requirements of IECEx Assessment and Test Report.

7.5.2 Validation of processes for production and service provision

7.5.2 of ISO 9001:2000 applies.

7.5.3 Identification and traceability

7.5.3 of 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 ISO 9001:2000 applies.

It is the responsibility of the manufacturer to verify the compatibility of customer supplied product with the requirements of the Assessment and Test Report and IECEx Assessment and Test Report.

7.5.4 Preservation of product

7.5.4 of ISO/DIS 9001:2000 applies.

The manufacturer shall provide its customer with the instructions to enable the safe use of the product. If deemed necessary by the manufacturer, such instructions shall contain special requirements for product maintenance. These may be specified in the ATR

NOTE Procedures may be required for products with limited life if they affect the type of protection e.g. batteries.

7.6 Control of monitoring and measuring devices

7.6 of ISO 9001:2000 applies.

NOTE Compliance with 7.6(a) of ISO 9001:2000 can be achieved by using 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 subjected for 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 Clause 7.6a, 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 ISO 9001:2000 applies with the following exceptions:

8.2 Measurement and monitoring

8.2.1 Customer satisfaction

8.2.1 of ISO 9001:2000 is replaced by the following requirement.

For the purpose of this Document “customer satisfaction” is in relation to the product’s compliance with the requirements of the IEC Standard and IECEx Assessment and Test Report.

8.2. 2 Internal audit

8.2. 2 of ISO 9001:2000 applies.

The audit programme shall address the effectiveness of the elements of the quality system as described in this Document to ensure that the products are in conformity with the IECEx Assessment and Test Report. The maximum period between audits should normally be 12 months and shall not exceed 14 months.

NOTES: 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 acertification 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.

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 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 ISO 9001:2000 applies.

Where routine tests are required by the IECEx Certificate of Conformity 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 nonconforming product

8.3 of 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 IEC Standard, listed on the IECEx ATR 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 ACB responsible for the issue of the IECEx Certificate of Conformity.

c) Where unsafe, non-conforming product has been supplied to a customer, the manufacturer shall, in writing,

inform its customer and the ACB responsible for the IECEx Certificate of Conformity.

NOTE It is recommended that the ACB responsible for the quality system notification liaise with other ACBs **[DRAFTING NOTE: SPECIAL CONSIDERATION TO BE GIVEN TO THIS REQUIREMENT]**

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 nonconforming 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 IECEx ATR and technical documentation are not permitted.

8.4 Analysis of data

8.4 of ISO 9001:2000 applies.

NOTE see 1.2.

8.5 Improvement

8.5.1 Continual improvement

Not in the scope of this Document.

8.5.2 Corrective action

8.5.2 of ISO 9001:2000 applies.

8.5.3 Preventive action

8.5.3 of ISO 9001:2000 applies.

Annex A
(informative)

Information relevant to particular types of protection

A.1 Introduction

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

This annex provides examples of how to meet the requirements of this Document, recognising that other methods which achieve the same objectives are equally acceptable; and draw attention to aspects of requirements that may 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 may be introduced as necessary in the future.

A.2 General

For enclosures and other components forming part of the enclosure then 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 for equipment covered by an IECEx Assessment and Test Report except where the following currently permit such techniques:

- the IEC Standard;
- IECEx TAG interpretation sheets;
- Ex TAG 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 e. g. the following should be verified:

- flatness of flanged flamepaths;
- surface roughness of all 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 effects 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, located such that it does not invalidate the test (e.g. due to pressure drop down pipe lines).

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 may 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 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 Accepted Certification Body that has issued the Assessment and Test Report. The components on this list should be verified on a 100 % basis.

This may 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 by 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 Assessment and Test Report or Certificate of Conformity, 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 Assessment and Test Report or Certificate of Conformity to ensure that other items listed in the Assessment and Test Report are selected, mounted and installed in respect to schedule drawings.

A.5 Ex e – increased safety

A.5.1 Ingress Protection

Documented procedures should ensure that the following is 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 is 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 is 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 is verified;

d) the bearing clearances are verified.

A.5.4 Windings

Documented procedures should ensure that the following is verified:

a) impregnation's are free of voids;

b) insulation materials are to the stated specification;

c) security of conductors is verified;

d) where protective devices (e. g. thermal cut-outs) are specified in the Assessment and Test Report, 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 for windings;

b) bearing insulation for rotating machines.

A.6 Ex p – Pressurised apparatus

A.6.1 Ingress protection

Documented procedures should ensure that the following is 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 IECEx Assessment and Test Report or Certificate of Conformity;

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 encapsulation.

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 IECEx Assessment and Test Report or schedule drawings.

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 aspects 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) dielectrical 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 an ACB issues an IECEx Assessment and Test Report 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 IECEx Assessment and Test Report.

B.2 Verification guidance

Three options 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 Assessment and Test Report. Typical test requirements are given in: ISO 4003: 1977 and ISO 2738:1987

The test may 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(Φ) for the sample batch,

i.e. Φ_p = the pore size standard deviation;

Φ_D = the density standard deviation.

The maximum pore size should not be exceeded and the minimum density should remain equal or greater than the value as stated in the IECEx Assessment and Test Report when 3 Φ is taken into account.

Therefore the mean value of the sample batch, plus 3 Φp (for pore size) and minus 3 ΦD (for density) should not invalidate the requirements of the IECEx Assessment and Test Report.

B.4 Test examples

The following examples are provided for guidance:

Example 1 (pore size)

Maximum permitted pore size as detailed in the

Assessment and Test Report = 150 :m

Mean value = 140 :m

Standard deviation (σp) = 2 :m

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

If standard deviation (σp) = 5 :m

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

Example 2 (density)

Minimum permitted density as detailed in the

Assessment and Test Report = 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:

$$\rho = \frac{M_1 \times \rho W}{M_2 - M_3}$$

substitute as follows:

$$\rho = \frac{(m_3 - m_1) \times \rho W}{(m_4 - m_1) - (m_5 - m_2)}$$

where

ρW 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 IECEx Assessment and Test Report eg. ISO 4003;
- the minimum density and the standard called up in the IECEx Assessment and Test Report 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 C
(Normative)

PRODUCTION QUALITY ASSURANCE

Note: This Annex is based on the requirements of Annex IV of directive 94/9/EC (OJ No. L100, 19.4.94)

1 Introduction

This annex describes the procedure whereby the manufacturer ensures that the products concerned are in conformity with the IECEx Certificate of Conformity and satisfy the requirements of the Standard which apply to them. The manufacturer shall affix the IECEx Mark to each product covered by the IECEx Certificate of Conformity and maintain a batch release register. The IECEx Mark shall be accompanied by the identification number of the Accepted Certification Body (ACB) responsible for IECEx surveillance of the quality system, as specified in Sections 4 and 5 below.

2 Quality system

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 initial assessment followed by periodic surveillance as specified in Sections 4 and 5 respectively.

3. Quality System requirements

3.1 The quality system shall ensure compliance of the product as described in the IECEx Certificate of Conformity and with the requirements of the Standard(s) 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 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 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.

4 Initial assessment of the quality system by the ACB

4.1 The manufacturer shall lodge an application for assessment of his quality system with an ACB of his choice, for the product(s) concerned. The application shall include:

- the documentation concerning the quality system;
- all relevant information for the product envisaged;
- technical documentation on the product and if available a copy of the IECEx ATR. In the absence of an ATR, the ACB reserves the right to not to proceed with the application, if this may have an adverse effect upon the assessment process. In any event, the assessment process shall not be deemed complete until a copy of the ATR is provided

The ACB shall assess the quality system to determine whether it satisfies the requirements referred to in Section 3.1, with respect to it's documentation and implementation. The auditing team shall have at least

one member with experience of evaluation in the equipment technology concerned. The assessment procedure shall include an inspection visit to the manufacturer's premises. The assessment decision shall be notified to the manufacturer in the form of an audit report and certificate. The audit report shall contain the conclusions of the examination and a reasoned assessment decision, with a list of IECEx Assessment and Test Reports.

Manufacturers operating a quality system in accordance with the requirements of this standard, which have been assessed by an ACB for an appropriate scope shall be presumed to conform with the requirements referred to in Section 3.1.

4.4 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

4.5 The manufacturer shall inform the ACB which has approved the quality system of any intended changes to the quality system.

The ACB shall evaluate the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in Section 3.1 or whether a re-assessment is required.

The ACB shall notify its decision to the manufacturer in the form of an audit report and certificate. The notification shall contain the conclusions of the examination and a reasoned assessment decision with a list of IECEx Assessment and Test Reports.

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5 Surveillance of the quality system by the ACB

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

5.2 The manufacturer shall, for inspection purposes, allow the ACB 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.

5.3 The ACB shall periodically carry out surveillance audits at intervals not greater than 1 year to ensure that the manufacturer maintains and applies the quality system. The ACB shall provide an audit report to the manufacturer.

NOTES:

1- An ACB that also provides ISO 9000 Certification services, may offer manufacturers an integrated service and have both the ISO 9000 and IECEx Surveillance audits performed during the same visit.

2- Where a manufacturer has its ISO 9000 certification carried out by a body other than the IECEx issuing ACB, the issuing ACB may subcontract the surveillance audit visit to the ISO 9000 Certification Body, providing the ISO 9000 Certification Body can demonstrate that the requirements of Section 4.1 have been met and that the audit reports are reviewed by the issuing ACB. In this case the issuing ACB accepts full responsibility for any surveillance activities performed on its behalf.

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

The manufacturer shall, for a period ending at least 10 years after the last product was manufactured, keep at the disposal of both the issuing ACB and the IECEx Secretariat:

- relevant information and technical documentation on the product, together with a copy of the IECEx Certificate of Conformity (Section 4)
- documentation concerning the quality system (Section 3.1)
- documentation concerning any changes to the quality system (Section 4.5)
- audit reports and certificates provided by the ACB (Section 4.2)
- reports and results of surveillance audits provided by the ACB (Section 5.3)
- reports and results of any unexpected visits the ACB may conduct (Section 5.4)

6 Each ACB shall notify the IECEx Secretariat where during surveillance audits, the ACB has identified a major system failure in the manufacturer's quality system that may result in the production of non-complying product being produced therefore requiring the suspension or withdrawal of the IECEx Certificate of Conformity.

End of Draft