INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Ex Management Committee, ExMC
Ex Testing and Assessment Group, ExTAG
ExMC WG5, Manufacturers Quality Plan Requirements

~~Draft - Quality system requirements for manufacturers to achieve an IECEx Certificate of Conformity and the right to use the IECEx Mark. Future IECEx Publication.~~

Introduction

This document contains the proposed changes to ExMC/52/CD, which were agreed to during the ExMC WG5 meeting held 1 September 2000. These changes are now submitted to the ExMC for consideration.

Changes as suggested by WG5 are shown as edited text.

~~**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 is submitted for consideration by Members of the Ex Management Committee, ExMC and members of the Ex Testing and Assessment Group, ExTAG.~~

~~This document has adopted the internationally accepted Quality Management System principles of the ISO DIS 9000/ 2000 and is aligned with CEN draft document~~ **~~CEN/TC 305/WG 4/ad hoc 2.~~**

~~Style and editorial changes to document CEN/TC 305/WG 4/ad hoc 2 have been included in order to adapt the document for use in the IECEx Scheme, however the general intention of CEN/TC 305/WG 4/ad hoc 2 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/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 IEC Ex Standards with which the ACB conducted the original testing and assessment.~~

~~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~~ **~~Friday 7 July 2000,~~** ~~to align with the WG5 Work Program and Timetable shown below.~~

~~**ExMC Secretariat & WG 5 Convenor = Chris Agius**~~

IEC Ex

Secretariat

~~E-Mail chris.agius@gas.com.au~~
~~Fax +61 2 9746 8460~~

~~WG 5 Work Program and Timetable~~

DATE	ACTIVITY	COMMENTS
29 March	Initial Draft circulated to WG 5 Members for their review and submission of comments to WG 5 Convenor	**Completed – ExMC WG/01/CD issued.**
24 April	Final Date for WG 5 Members to submit their comments to WG 5 Convenor (Chris Agius)	**Completed, Comments received from WG 5 Members**
24 April to 8 May	Communication between WG 5 Convenor and WG 5 Members to resolve issues	**Completed. 2nd Draft issued to WG5 members with further comments received**
12 May	Committee Draft circulated to ExMC for Comment - Comments submitted to ExMC Secretary	**Completed. ExMC/52/CD Issued 15 May**
7 July	Closing Date for ExMC Comments	
14 July	Collation of Comments circulated to ExMC	For discussion at ExMC, September Meeting
1 Sept	Meeting of WG 5, prior to the IECEx Meetings	**To be held in Braunschweig**
5-9 Sept	Consideration of comments during ExMC Meeting, Braunschweig	

0 Introduction

This Document presents particular requirements and guidance to manufacturers providing product covered by the IECEx Scheme . where a quality system in compliance with Annex C (production quality assurance) is used.

NOTE: Annex C is an adoption of Annex IV of the European Directive 94/9/EC (ATEX), with the purpose of aligning both IECEx and ATEX Quality system requirements.

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

ISO DIS 9000/2000 is issued to ExMC and ExTAG as ExMC/53/CD, for reference purposes.

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. with respect to Annex C.

It does not preclude the use of other quality systems that are compatible with the objectives of ISO/DIS 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 that are allowed by an 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

For the purposes of this Document, the equipment groups and categories concerned are defined in IEC 60079-0

The definitions of IECEx 01, IECEx 02 and ISO/DIS 9000:2000 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 electrical apparatus and Ex components and their combinations under the scope of IECEx 02 ~~equipment, protection systems, devices, components and their combinations under the scope of IEC 60079-0~~

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.

4 Quality management system requirements

4.1 General requirements

4.1 of ISO/DIS 9001:2000 applies.

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

4.2 General documentation requirements

4.2 of ISO/DIS 9001:2000 applies.

5 Management responsibility

5.1 Management commitment

5.1 of ISO/DIS 9001:2000 applies.

5.2 Customer focus

5.2 of ISO/DIS 9001:2000 applies.

5.3 Quality policy

5.3 of ISO/DIS 9001:2000 applies.

5.4 Planning

5.4.1 Quality objectives

5.4.1 of ISO/DIS 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/DIS 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 Accepted Certification Body reserves the right to audit a manufacturer's supplier evaluations, which may involve assessment at the suppliers premises, if the Accepted Certification Body considers it to be necessary. The manufacturer shall demonstrate it has established an agreement with its supplier(s) that the Accepted Certification Body may audit aspects of the suppliers operations that affect the type of protection.

~~Training needs shall also be clearly identified.~~

5.5 Administration

5.5.1 General

5.5.1 of ISO/DIS 9001:2000 applies.

5.5.2 Responsibility and authority

5.5.2 of ISO/DIS 9001:2000 applies.

Responsibilities and authority for the following shall be defined:

a) the effective co-ordination of activities with respect to the products covered by IECEx Assessment and Test Report;

b) the need to liase with the Accepted Certification Body responsible for the issue of the IECEx Assessment and Test Report with respect to any proposed change to the design defined in the IECEx Assessment and Test Report and the technical documentation;

c) the need to liase with the Accepted Certification Body responsible for the assessment of the quality system with respect to proposed changes to the quality system;

NOTE 1 It is not practicable for the manufacturer to inform the Accepted Certification Body each time a change is made to a document or procedure which forms a part of the quality system. It is only practicable to inform the Accepted Certification Body of "substantial" updating of the quality system. Similarly, it is not practicable to specify in general terms what types of changes are or are not "substantial". It is therefore recommended that the manufacturer establishes and maintains a system for categorising changes as "substantial" or not and informing the relevant Accepted Certification 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) the means by which the manufacturer informs its customer of any applicable special conditions for safe use and any schedules of limitations.

NOTE 2 Certificates with a suffix X (refer to IEC 60079-0) may contain special conditions for safe use. Component certificates, those with a suffix U (refer to IEC 60079-0), may contain schedules of limitations.

NOTE 3 For each IECEx Assessment and Test Report it is recommended that an authorised person be appointed and shall have responsibility and authority for the above activities so providing an unambiguous focal point within the company.

5.5.3 Management representative

5.5.3 of ISO/DIS 9001:2000 applies.

The management representative shall have the authority, based upon objective evidence, to veto the selection of any supplier whose ability to supply conforming products or services is in doubt.

5.5.4 Internal communication

5.5.4 of ISO/DIS 9001:2000 applies.

5.5.5 Quality manual

5.5.5 of ISO/DIS 9001:2000 applies.

5.5.6 Control of documents

5.5.6 of ISO/DIS 9001:2000 applies.

a) The following documents shall be controlled:

1) equipment documents, i.e. technical documentation such as drawings listed in the IECEx Assessment and Test Report and product / production quality assurance notifications;

2) manufacturers documents, e. g. instructions, test plans etc, related drawings, data sheets and sales literature.

b) For equipment documents there shall be a system to ensure that all such documents are within the control system.

NOTE 1 This can be achieved by having a "register" of all equipment documents.

NOTE 2 The document providing authority for changes to drawings should include a section for product covered by the IECEx Assessment and Test Report.

c) Documented procedures shall ensure that information contained within manufacturers documents is compatible with equipment documents and the IECEx Assessment and Test Report.

d) The manufacturer shall document their Quality Planning for each product, product range or series covered by an IECEx Assessment and Test Report and which Accepted Certification Body has been selected for each IECEx Assessment and Test Report.

e) Equipment documents shall be secure, in good condition, at defined locations and be readily available to authorised staff.

f) Where the required documents are produced, including those produced by electronic media, shall have a system to prevent unauthorised amendments.

g) Where equipment documents or manufacturers documents are passed to a third party, they shall be provided in a way that is not misleading.

~~h)~~The quality system shall ensure that no factor (type, characteristic, position etc) defined within the IECEx Assessment and Test Report and technical documentation is modified, ~~without the endorsement of the relevant Accepted Certification Body.~~

h)

i) Technical documentation including Schedule drawings shall not be changed without the endorsement of the relevant Accepted Certification Body.

j) The manufacturer shall not initially approve or subsequently amend related drawings unless they are in compliance with the schedule drawings.

k) There shall be a documented system which refers all related drawings to the relevant schedule drawings.

l) Where there are common schedule drawings associated with more than one IECEx ~~There shall be a documented system for all IECEx~~ Assessment and Test Report~~s~~, there shall be a documented system to ensure simultaneous supplementary action in the event of an amendment to such drawings. ~~that have common schedule drawings are subject to simultaneous supplementary action in the event of amendment to such drawings in order to assure continuing compatibility of those common schedule drawings and the relevant IECEx Assessment and Test Reports.~~

NOTE 3 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.

m) Where a manufacturer also has drawings for products not covered by IECEx Assessment and Test Report then the manufacturer shall have a system that enables both the actual related drawings and schedule drawings to be clearly identified.

NOTE 4 The following examples indicate some methods of achieving this:

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

5.5.7 Control of quality records

5.5.7 of ISO/DIS 9001:2000 applies.

The manufacturer shall, in accordance with clause 5 of Annex C, for a period ending at least 10 years after the last piece of product ~~equipment~~ was manufactured retain the following records:

- technical documentation on the approved type and a copy of the Assessment and Test Report and additions;
- the documentation concerning the quality system defined in this Document;
- updates of the quality system (see NOTE 1 of 5.5.2);
- Quality system approvals ~~notifications~~ provided by the ACBs including reports;
- test reports, where applicable, resulting from tests conducted during unexpected visits by the Accepted Certification Body.

NOTE It is in the manufacturer's interests to retain adequate quality records to demonstrate conformity of the product with IECEx Assessment and Test Report and the customers requirements. Therefore the following is provided for guidance as examples of documents requiring control and retention:

- 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).

5.6 Management review

5.6.1 General

5.6.1 of ISO/DIS 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 5.5.2 shall partic ipate in the review;

5.6.2 Review ~~Revision~~ input

5.6.2 of ISO/DIS 9001:2000 applies.
The review shall include:

- the overall effectiveness of the quality management system with respect to product covered by IECEx Assessment and Test Reports;

5.6.3 Review ~~Revision~~ output

5.6.3 of ISO/DIS 9001:2000 applies.

6 Resource management

6.1 Provision of resources ~~recourses~~

6.1 of ISO/DIS 9001:2000 applies.

6.2 Human resources

6.2.1 Assignment of personnel

6.2.1 of ISO/DIS 9001:2000 applies.

6.2.2 Training, awareness and competency

6.2.2 of ISO/DIS 9001:2000 applies.

6.3 Facilities

6.3 of ISO/DIS 9001:2000 applies.

6.4 Work environment

6.4 of ISO/DIS 9001:2000 applies.

7 Product realisation

7.1 Planning of realization processes

7.1 of ISO/DIS 9001:2000 applies.

NOTE Examples are given in annex A.

7.2 Customer-related processes

7.2.1 Identification of customer requirements

7.2.1 of ISO/DIS 9001:2000 applies.

The identification shall include the product marking~~:~~

~~a)The product category;~~

~~b)The product marking.~~

Where the customer has not provided a written statement of its requirement or the customer is not the user, e.g. a distributor, then the manufacturer shall provide to their customer a written statement detailing the parameters of the products e. g. ~~product category,~~ normal operation, product marking, and any special features or conditions.

Where product is ordered by the customer from a catalogue or data sheet using a specific description e. g. part or type number, and where the catalogue or data sheet contains the information regarding the parameters for use in potentially explosive atmospheres, then that is deemed to satisfy these requirements).

7.2.2 Review of product requirements

7.2.2 of ISO/DIS 9001:2000 applies.

The review shall ensure that any stated customer requirement is compatible with the Assessment and Test Report e. g. ambient temperature range.

7.2.3 Customer communication

7.2.3 of ISO/DIS 9001:2000 applies.

7.3 Design and/or development

Not within the scope of this document~~The following replaces this requirement of ISO/DIS 9001:2000.~~

~~**Design Changes**~~
~~All design changes and modifications shall be identified, documented, reviewed and approved by manufacturer's authorized personnel before their implementation.~~

~~**Design Hold**~~
~~On successful completion of type testing, the design of all major and critical components and materials in the product and manufacturing, assembly and testing processes shall be documented and comply with details specified in the IECEx ATR and associated Drawings, as approved by the ACB. No changes in design shall take place without approval from the ACB issuing the IECEx Certificate of Conformity. This includes labelling, packaging and instructions for use, care, installation and maintenance as applicable.~~

~~All design changes and modifications shall be identified, documented, and reviewed for possible effects on product compliance. They shall be approved by manufacturer's authorised personnel including the management representative before their implementation.~~

~~The ACB that issued the IECEx CoC shall be notified of any proposed changes which could affect compliance with the Standard and such changes shall not be implemented without written authorisation from the ACB.~~

Note: The design hold does not include minor changes that do not affect compliance of the product with the Standard. If in doubt, the Manufacturer should submit details of the proposed changes to the ACB, that issued the IECEx CoC, for consideration.

Reference Specimens
Reference specimens, drawings or photographs representative of type test specimens shall be made available as requested by the ACB. Such specimens shall be identified and retained either at the Manufacturer's premises or by the ACB.

Changes to the Product Standard
If the Standard is amended or re-issued, manufacturers must ensure that products covered by an IECEx CoC continue to comply with the new/revised Standard. To ensure the on-going validity of IECEx CoCs, ACBs are responsible for ensuring that manufacturers take appropriate action to ensure product compliance with the latest edition or amendment to the standard. Such action may include:

- manufacturers submitting details of product assessments to the ACB;
- re-submission back to the ACB and ExTL for an up dated ATR;
- manufacture notifying that their product does not comply with the latest edition/amendment of the standard and that the IECEx CoC is to be withdrawn

Changes to CoCs arising from those above will require the ACB to notify the ExMC Secretary of the changes.

To assist manufacturers prepare for changes to standards, the ExMC may nominate a period of time that manufacturers have to comply with new editions or amendments to standards

7.4 Purchasing

7.4.1 Purchasing control

7.4.1 of ISO/DIS 9001:2000 applies.

a) While manufacture and test may be sub-contracted, the responsibility for ensuring conformance to specified requirements cannot be sub-contracted.

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

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 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.

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

Note 1 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.

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 an initial and a periodic site assessment 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 2 "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 3 “review” is a process by which the manufacturer demonstrates the ongoing suitability of their suppliers e. g. receiving inspection report analysis.

NOTE 4 The terms “re-evaluation” and “review” are different and should not be mixed.

7.4.2 Purchasing information

7.4.2 of ISO/DIS 9001:2000 applies.

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

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/DIS 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 requirements of IECEx Assessment and Test Report e. g. the Assessment and Test Report, taking into account the nature of the product and the nature of the supplier.

When deciding what type of verification is required for a particular purchased product, the manufacturer shall consider the nature of the product, and the supplier and how critical it is to the type of protection used in the product in which it will be incorporated.

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 declaration of conformity according to EN 45014 that confirms it has been done.

b) The following examples indicate some of the issues to be taken into account when determining what verification arrangements are appropriate:

1) 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;

2) where the IECEx Assessment and Test Report 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;

3) where verification of a product cannot be carried out after manufacture, e. g. the internal parts of an encapsulated intrinsic 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;

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

5) 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.

c) Where the manufacturer chooses not to carry out inspections and tests at its own premises, then inspections and tests shall be performed at the suppliers premises under the responsibility of the manufacturer.

Where a supplier is providing product with an IECEx Assessment and Test Report, then the evaluation may be restricted to obtaining documentary evidence ~~(e. g. notification of the quality system)~~ that the supplier is conforming to the requirements of this scheme~~ISO 9001~~.

7.5 Production and service operations

7.5.1 Operations control

7.5.1 of ISO/DIS 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 Identification and traceability

7.5.2 of ISO/DIS 9001:2000 applies.

a) The manufacturer shall establish and maintain procedures for product identification during all stages of production, final equipment inspection and testing 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 product but not each electronic component on a PCB .

c) ~~The Manufacturer shall have a documented procedure to ensure that a finished IECEx Certified product is traceable to the relevant batch inspection or test reports on at least those items and materials which affect compliance of the product with safety aspects of the standard. The extent to which the Manufacturer can demonstrate traceability must be clearly documented.~~

d) ~~The IECEx Mark is the normal method of identifying certified product. However, if it is not possible to apply the IECEx Mark to the product, an alternative may be approved by the ACB provided that the Manufacturer submits a written request.~~

e) ~~**Approval of the form and manner in which the IECEx Mark is used**~~
~~The IECEx Mark shall only be used in a manner that has been approved in writing by the ACB. The Manufacturer shall gain approval from the ACB for:~~

~~– the form and manner in which the IECEx Mark is used on the product;~~

~~– the form and manner in which the IECEx Mark is used on promotional material, packaging, swing tags, informative labelling or instructions for use; and~~

~~– proposed references in any form to the IECEx CoC number or to certification by an ACB.~~

f) ~~Submissions for approval shall be made before the IECEx Mark is used and shall be accompanied by all qualifying words and illustrations. Manufacturers shall ensure that distributors of their certified products are aware of and observe the requirements of this clause.~~

g) ~~**Extent of marking**~~
~~The Manufacturer shall apply the IECEx Mark only to products which:~~

~~– are of the type and size specifically listed on the current Schedule to the IECEx CoC; and~~

~~– the Manufacturer warrants comply in all respects with the relevant IEC Standard and are manufactured in accordance with this IECEx Scheme.~~

h) ~~**Application at Manufacturer's premises**~~
~~The IECEx Mark shall be applied to certified products prior to dispatch from the manufacturing premises of the Manufacturer.~~

~~Where the Manufacturer wishes to incorporate an IECEx Mark on components manufactured by a sub-contractor prior to further processing or assembly, details shall be submitted to then ACB for approval. The Manufacturer shall ensure that the ACB is guaranteed access to the sub-contractors premises to determine that the IECEx Mark is applied under the conditions of the licence.~~

i) ~~**Manner of application**~~
~~The IECEx Mark shall be applied in a manner that is permanent or tamper-evident using one or more of the following methods:~~

~~– serially numbered labels available from the ACB;~~

~~– incorporation into the Manufacturer's label with wherever possible a date code or batch number; or~~

~~directly onto the product by casting, moulding, stamping, etching, etc, together wherever possible with a date code or batch number.~~

~~j) Quality of Marking~~

~~Where the IECEx Mark is applied by stamping, etching, printing, casting, moulding or other means directly onto the product, the resulting impression shall be examined at regular intervals and corrective action instigated when the visual marking quality shows signs of deterioration.~~

7.5.3 Customer property

7.5.3 of ISO/DIS 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 ~~suitable~~ instructions as specified in the ATR ~~to enable the safe assembly, installation, use, maintenance and repair of the Ex Apparatus. These instructions may include engineering drawings. Instructions shall be provided in English and the language of the country where the Ex apparatus is to be sold.~~

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

7.5.5 Validation of processes

7.5.5 of ISO/DIS 9001:2000 applies.

7.6 Control of measuring, and monitoring devices

7.6 of ISO/DIS 9001:2000 applies.

NOTE Compliance with 7.6(a) of ISO/DIS 9001:2000 can be achieved by using accredited calibration laboratory (which can demonstrate to the Accepted Certification Body that it operates in compliance with EN 45001 or ISO/IEC Guide 25 or ISO 17025 and is preferably covered by a multilateral agreement) and obtaining a certificate bearing the accreditation logo. Where such a certificate is obtained, then the laboratory may not have to be subjected to further evaluation.

If the certificate does not bear the accreditation logo of a national accreditation authority then a certificate containing all the following is an alternative:

- an unambiguous identification of the item calibrated;
- a description of the measurement standard(s) used and its calibration status;
- a statement indicating how traceability to national standards has been achieved;
- the method of calibration;
- a statement of compliance with any relevant specification;

- the calibration results;
- the uncertainty of measurement, where relevant;
- 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 issuing organisation and the date of the certificate;
- a unique identification of the calibration certificate.

A further alternative is, that the manufacturer can conduct a documented assessment of the supplier to demonstrate a valid relationship to international or national recognised standards.

Calibration laboratories shall be regarded as subcontractors which supply a service and therefore shall be included in the review of subcontactors in accordnace with 7.4.1(e). Such review shall include confirmation that any accreditation remains current and valid.

8 Measurement, analysis and improvement

8.1 Planning

8.1 of ISO/DIS 9001:2000 applies with the following exceptions:

a) Improvements are not within the scope of this Document. They may be made at the discretion of the manufacturer, but the provisions of 7.5.1 shall apply at all times.

b) The manufacturer may identify and use appropriate statistical tools for purposes other than those specified in 8.2.4.

8.2 Measurement and monitoring

8.2.1 Customer satisfaction

8.2.1 of ISO/DIS 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/DIS 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.

> NOTE A recommended 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.

8.2.3 Measurement and monitoring of processes

8.2.3 of ISO/DIS 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 demo nstrate compliance with required parameters (see also annex A).

8.2.4 Measurement and monitoring of product

8.2.4 of ISO/DIS 9001:2000 applies.

Where routine ~~individual~~ tests are required by the IECEx Assessment and Test Report and the technical documentation, then those tests shall be performed as specified in the said documents with no sampling techniques being permitted.

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

~~The manufacturer shall ensure that certified products are released by personnel who have defined responsibility and authority and that a register or batch release record showing the formal release of certified product is maintained.~~

Product may not be released with or without customer approval unless in conformity with the IECEx ATR

8.3 Control of nonconformity

8.3 of ISO/DIS 9001:2000 applies.

a) While the principle of the IECEx scheme is to prevent nonconforming product being supplied, t~~T~~he manufacturer still shall maintain a system such that in the event of product not complying with the Assessment and Test Report and having been supplied, then the manufacturers customer can be identified.

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

NOTE 1 It is recommended that the manufacturer should liase with the Accepted Certification Body responsible for the issue of the IECEx Assessment and Test Report.

c) Where unsafe non-conforming product that has been supplied to a customer, the manufacturer shall, as a minimum, in writing, inform their customer and the Accepted Certification Body responsible for issuing the IECEx CoC.

NOTE 2 It is recommended that the Accepted Certification Body responsible for the issuing the IECEx CoC should liase with the Accepted Certification Body responsible for the issue of the IECEx Assessment and Test Report(s).

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, the manufacturer shall maintain records of:

1) serial numbers or identification of product supplied;

2) the customer who received the product;

3) the action taken to inform customers and the relevant Accepted Certification Body in the case of unsafe 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 Assessment and Test Report and technical documentation are not permitted.

8.4 Analysis of data

Not in the scope of this Document.

8.5 Improvement

8.5.1 Planning for continual improvement

Not in the scope of this Document.

8.5.2 Corrective action

8.5.2 of ISO/DIS 9001:2000 applies.

8.5.3 Preventive action

8.5.3 of ISO/DIS 9001:2000 applies.

Annex A
(informative)

Guidance 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 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.

A.4.2.1.3 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 automated fabrication 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 For hand built PCB's documented procedures should be provided which 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, 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 components 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 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:

a) weld continuity;

b) fitting of gaskets and seals;

c) continuity of moulded grooves and tongues;

are all verified

A.5.2 Internal wiring and contact integrity

Documented procedures should ensure that:

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) actual wiring insulation has an appropriate temperature rating;

are all verified.

A.5.3 Rotating machines

Documented procedures should ensure that:

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:

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) restricted breathing (except luminaries);

b) dielectric tests for windings;

c) bearing insulation for rotating machines.

A.6 Ex p – Pressurised apparatus

A.6.1 Ingress protection

Documented procedures should ensure that:

a) weld continuity;

b) application of cements;

c) fitting of gaskets and seals:

are all verified

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;

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 where specified in the IECEx Assessment and Test Report should be positioned and be of the type defined.

The guidance given in A.3.3 should apply for the encapsulation process.

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.

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) ingress protection rating is maintained;

b) means of closing the enclosure.

A.9.4 Tests

All tests should be documented. Typical tests include:

a) pressure test;

b) dielectrical strength test.

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 (ó) for the sample batch,

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

óD = 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 ó is taken into account. Therefore the mean value of the sample batch, plus 3 óp (for pore size) and minus 3 óD (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 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
Assessment and Test Report = 5 gcc^{-1}

Mean value = 5,3 gcc^{-1}

Standard deviation (σD) = 0,05 gcc^{-1}

Therefore minimum value = 5,3 - (0,05 x 3) = 5.15 gcc^{-1} (PASS)

If standard deviation (σD) = 0,12

Then minimum value = 5,3 - (0,12 x 3) = 4.94 gcc^{-1} (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:

- checking 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 ~~and a copy of the IECEx Certificate of Conformity.~~

-

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.
.

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