



IECEX 02

Edition 5.0 2012-07

IECEX PUBLICATION

**IEC System for Certification to Standards relating to Equipment for use
in Explosive Atmospheres (IECEX System)**

**IECEX Certified Equipment Scheme covering equipment for use in explosive
atmospheres – Rules of Procedure**



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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**IECEX Certified Equipment Scheme covering equipment
for use in explosive atmospheres –****Rules of Procedure**

FOREWORD

The IECEx Management Committee (ExMC) has prepared this publication.

All of the annexes to this publication are normative.

This publication is directly related to Publication IECEx 01 containing the Basic Rules of the IECEx Certification System.

This edition of IECEx 02 takes effect immediately upon publication.

The text of this publication is based on the following documents:

Document	Report on Voting/Acceptance
ExMC/690/CD	ExMC/723A/RM

This edition of the Rules of Procedure was approved for publication during the Split 2011 ExMC meeting. Full information on the approval of this publication can be found in the documents indicated in the above table.

INTRODUCTION

The IECEX is a single global certification framework based on IEC and ISO International Standards. It caters for countries whose national standards are either identical to, or else very close to the International Standards. The IECEX is truly global in concept and practice; it reduces trade barriers caused by different conformity assessment criteria in various countries, and helps industry to open up new markets. The goal is to help manufacturers reduce costs and time while developing and maintaining uniform product evaluation to protect users against products that are not in line with the required level of safety.

The aim of the IECEX System and its Schemes is to ease international trade of Explosion Protected Equipment (termed Ex equipment) by eliminating the need for duplication of testing and certification, while preserving safety. IECEX operates as an International Certification System covering products and services associated with the Ex industries.

Where do you commonly find Ex equipment?

Flammable gases, vapours and mists, as well as combustible dusts create potentially explosive atmospheres. Ex equipment in such areas include:

- Automotive refuelling stations or petrol stations
- Oil refineries, rigs and processing plants
- Oil and gas tankers, drilling ships and FPSO (Floating Production Storage Offloading vessels)
- Chemical processing plants
- Printing industries, paper and textiles
- Hospital operating theatres
- Aircraft refuelling and hangars
- Surface coating industries
- Underground coal mines
- Sewerage treatment plants
- Gas pipelines and distribution centres
- Grain handling and storage and processing (flour-milling industry)
- Woodworking areas
- Sugar refineries
- Light metal working, where metal dust and fine particles can appear

IECEX options

The IECEX Certified Equipment Scheme provides both:

- 1) A single global Certificate of Conformity, that requires manufactures to successfully complete:
 - Testing and assessment of product samples for compliance with IEC or ISO International Standards
 - Assessment and auditing of manufacturing premises
 - On-going surveillance audits of manufacturing premises
- 2) A “fast track” process for countries where regulations still require the issuing of national Ex certification or approval by way of global acceptance of international IECEX product test and assessment reports (ExTR).

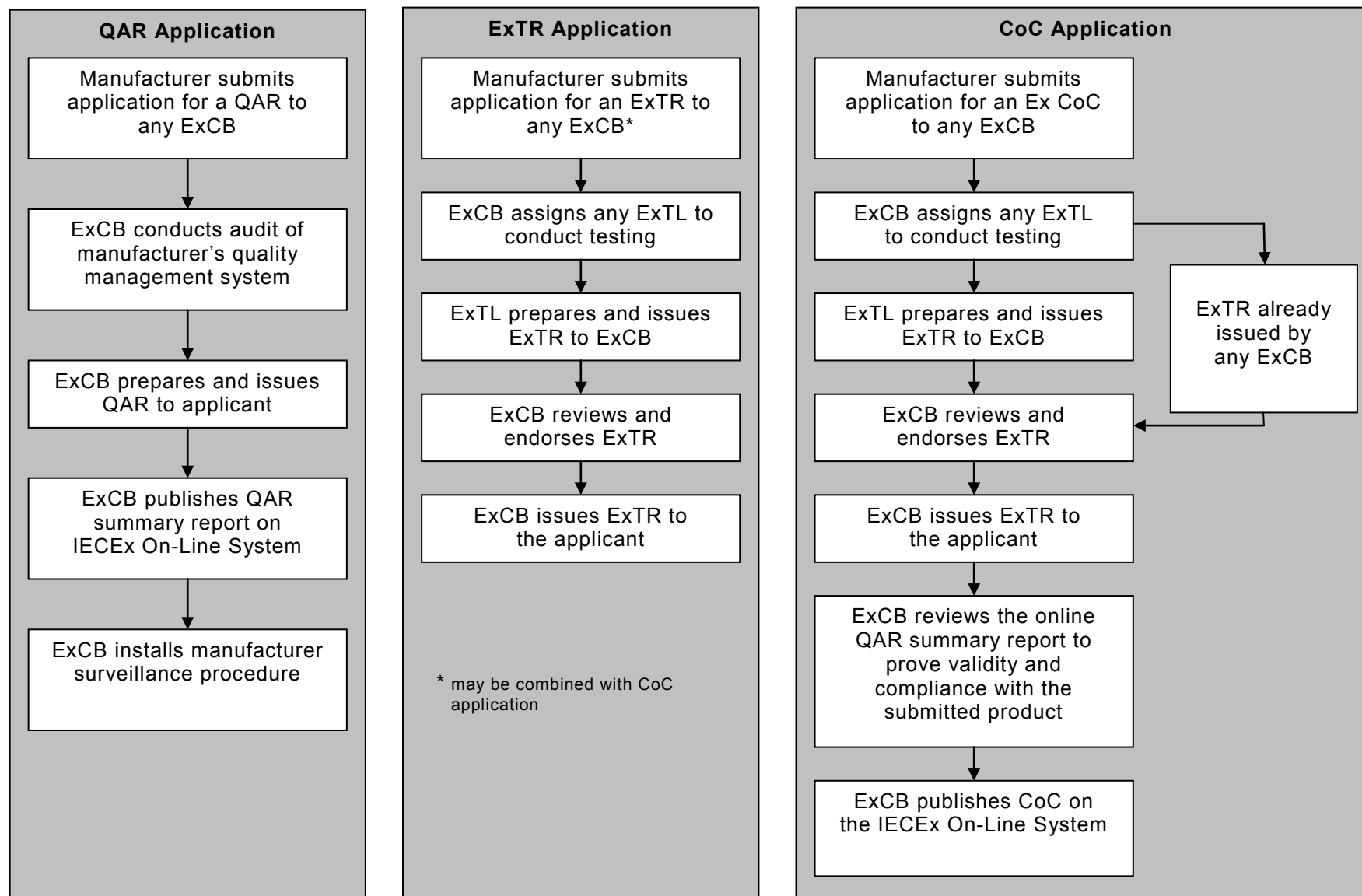
IECEX credibility

IECEX accepts the participation of Ex Certification Bodies and Ex Test Laboratories only after successful completion of the IECEX assessment process, which also includes on-going surveillance. Each Ex candidate Certification Body and Testing Laboratory is subjected to the same IECEX assessment process utilizing the internationally established ISO/IEC Standards and Guides on conformity assessment supplemented with the IECEX Technical Guidance Documents with world experts in the field of explosion protection being appointed as IECEX Assessors.

More information

Further information is available from the IECEX website: www.iecex.com, (containing free copies of the IECEX Rules and Procedures), from any of the IECEX Certification Bodies or directly from the IECEX Secretariat via the coordinates shown on the IECEX website.

Overview for issuing IECEx Certificates of Conformity, ExTRs and QARs



IECEX Certified Equipment Scheme covering equipment for use in explosive atmospheres –

Rules of Procedure

1 Scope

This publication contains the Rules of Procedure of the IECEx Certified Equipment Scheme, hereinafter referred to as the "Rules", for the certification of equipment and systems intended for use in explosive atmospheres and which complies with one or more IEC or ISO International Standards that define the types of protection against causing an explosion.

A list of current Standards in use is published on the IECEx website: www.iecex.com.

These Rules relate to the Basic Rules of the IECEx System, as given in Publication IECEx 01.

Rules covering the IECEx Certified Service Facilities Scheme and the IECEx Certificate of Personnel Competence Scheme are given in Publications IECEx 03 and IECEx 05 respectively.

NOTE The IECEx Certified Equipment Scheme is applicable to equipment conforming to International Standards.

The IECEx System also provides for the licensing of an International IECEx Mark of Conformity with the regulations and rules detailed in Publication IECEx 04 and IECEx Operational Document OD 022.

2 Normative references

The following publications contain provisions, which, through reference in this text, constitute provisions of these Rules. At the time of publication, the editions indicated were valid. The Ex Management Committee shall decide the timetable for the introduction of revised editions of the publications.

IECEX 01, *IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres (IECEX System) – Basic Rules*

IECEX 03, *IECEX Certified Service Facilities Scheme covering repair and overhaul of Ex equipment – Rules of Procedure*

IECEX 04, *IECEX Conformity Mark Licensing System – Regulations*

IECEX 05, *IECEX Scheme for Certification of Personnel Competencies for Explosive Atmospheres – Rules of Procedure*

ISO/IEC 17000, *Conformity assessment – Vocabulary and general principles*

ISO/IEC Guide 65, *General requirements for bodies operating product certification systems*

ISO 9001, *Quality management systems – Requirements*

ISO/IEC 80079-34, *Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture*

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

3 Definitions

ISO/IEC 17000 gives the basic definitions.

For the purpose of the IECEx Certified Equipment Scheme, the following definitions apply:

3.1

IECEX Certified Equipment Scheme

the IECEx Scheme for the certification of equipment intended for use in, or relating to, explosive atmospheres and applicable to equipment embodying one or more of the types of protection covered by IEC Standards or in the absence of an IEC Standard, ISO Standards

3.2

type of protection

specific measures applied to equipment to avoid ignition of a surrounding explosive atmosphere

3.3

Ex equipment

items applied as a whole or in part for the utilization of energy and incorporating one or more types of protection for potentially explosive atmospheres. These include, among others, items for the generation, transmission, distribution, storage, measurement, regulation, conversion and consumption of electrical energy and items for telecommunications. This term may apply to Ex components, Ex systems and non-electrical equipment

3.4

Ex component

a part of apparatus or a module (other than an Ex cable entry), marked with the symbol "U", which is not intended to be used alone and requires additional certification when incorporated into equipment or systems for use in potentially explosive atmospheres

3.5

Ex system

an assembly of interconnected items of Ex equipment for which the interconnection has to be carried out in accordance with the descriptive system document in order to comply with the explosion protection requirements

3.6

IECEX Certificate of Conformity (CoC)

document issued under these Rules indicating that adequate confidence is provided that a duly identified product is in conformity with a specific standard. The certificate can relate to Ex apparatus, an Ex component or an Ex system

3.7

IECEX Mark of Conformity

the IECEx Conformity Mark, licensed for use according to IECEx 04, *IECEX Conformity Mark Licensing System – Regulations*, and relevant IECEx Operational Documents (ODs)

3.8

IECEX Test Report (ExTR)

a document issued by an ExTL that includes a documented record of the obtained test and assessment results for endorsement by an ExCB, associated with the issuing ExTL, demonstrating that the examined product type is in conformity with specified Standards. An ExTR may cover complete or partial testing to the relevant Standard

3.9**IECEX Quality Assessment Report (QAR)**

a document that presents the results of an on-site assessment of a manufacturer's quality management system by an ExCB, to the requirements of the IECEx Certified Equipment Scheme. A summary of the QAR is published on the IECEx website: www.iecex.com

3.10**Ex Management Committee (ExMC)**

the body which administers the operation of the IECEx System and is responsible to the Conformity Assessment Board of the IEC

3.11**Ex Testing and Assessment Group (ExTAG)**

the body which deals with questions of practice relating to assessment and testing under the IECEx System and is responsible to the Ex Management Committee

3.12**Member Body of the IECEx System**

a body which has been accepted according to the Basic Rules of the IECEx System, Publication IECEx 01 and to these Rules of Procedure, and which is either a National Committee of the IEC or a body notified to the ExMC by the National Committee of the IEC

3.13**Ex Certification Body (ExCB)**

a body which has been accepted according to these Rules and which issues IECEx Certificates of Conformity, IECEx Quality Assessment Reports and also endorses IECEx Test Reports

3.14**Ex Testing Laboratory (ExTL)**

a testing laboratory which is accepted according to these Rules and which is either integral with, or under the complete control of, or belongs to or works under a written agreement with at least one Ex Certification Body

3.15**national differences**

those requirements or test parameters in the corresponding national standard which, when applied to equipment complying only with the IEC Standard accepted for use in the IECEx Certified Equipment Scheme, might entail non-compliance of that equipment with the relevant national standard

NOTE 1 When a requirement in the Standard is not implemented in the corresponding national standard, that is also a national difference.

NOTE 2 Those restrictive requirements in a national standard that address risk of explosion issues (i.e. other than general safety requirements that address risks such as fire, electric shock and personal injury), which do not deviate from the criteria included in the corresponding standard accepted for use in the IECEx Certified Equipment Scheme, but which limit the possibility to offer the relevant equipment for sale in the country concerned, are also considered to be national differences.

3.16**applicant**

a manufacturer or a person which acts on behalf of the manufacturer and who applies to an Ex Certification Body for obtaining an IECEx Certificate of Conformity, an IECEx Test Report or an IECEx Quality Assessment Report

3.17**manufacturer**

an organization, situated at a stated location or stated locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables

it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection

3.18

IECEX Bulletin

bulletin, issued at intervals decided by the Ex Management Committee, containing detailed information on national differences

3.19

IECEX Register

register, issued at intervals decided by the Ex Management Committee, containing information on all ExCBs and ExTLs and listing all IECEx CoCs

3.20

IECEX Newsletter

newsletter, issued at intervals decided by the Secretary of the Ex Management Committee, to promote the IECEx Schemes amongst users and prospective users of the Schemes and to inform users of significant developments of the Schemes

3.21

Unit Verification Certificate

an IECEx certificate that covers specific equipment/systems that have been produced with each being uniquely identified on the IECEx Unit Verification Certificate to allow the handling of "one-off" items or limited quantities

3.22

IECEX Technical Guidance Documents (TGDs)

technical documents approved by the ExMC and listed on the IECEx website, that act as a guide to IECEx Assessment Teams when conducting assessments of ExTLs and ExCBs according to Clause 11 of these rules

4 Governing of the IECEx Certified Equipment Scheme

The IECEx Certified Equipment Scheme (referred to throughout this document as "Scheme") shall be governed by the Ex Management Committee (ExMC), whose responsibilities in this respect are defined in the Basic Rules of the IECEx System, Publication IECEx 01.

This document, (IECEX 02) sets out the general rules and procedures of the IECEx Certified Equipment Scheme. These general rules are supplemented by the IECEx Scheme's Operational Documents. These Operational Documents are available to all IECEx Member Bodies, ExCBs and ExTLs, including candidate ExCBs and ExTLs and to manufacturers that have applied for an IECEx CoC, ExTR or QAR.

The ExMC Secretary shall be responsible for the issuing and maintenance of Operational Documents which generally fall under the following categories:

- a) Document containing explanatory guidance
- b) Document containing rules and procedures that supplement those contained in IECEx 02

The ExMC shall be kept informed on the currency of Operational Documents with ExMC agreement required for Operational Documents that fall under category b) above.

5 Principles of the IECEx Certified Equipment Scheme

5.1 IECEx Certificate of Conformity (IECEX CoC)

The IECEx Certified Equipment Scheme provides the means for manufacturers of Ex equipment to obtain certificates of conformity that are intended to be accepted in all participating countries as equivalent to their national certification. An IECEx CoC may also be accepted in other non-participating countries. An IECEx CoC may be issued by any ExCB accepted into the Scheme. The certificate will attest that the equipment's design conforms to the relevant IEC or ISO International Standards and that the manufacturer is manufacturing the product under a quality system and associated quality plan(s), meeting the requirements of this Scheme and under the surveillance of an ExCB. The IECEx quality system requirements are detailed in ISO/IEC 80079-34 being based on ISO 9001, with additional requirements specific to the design, manufacture and testing of Ex equipment.

The IECEx CoC may be issued for a product with its variety of types, including different processes and electrical connections, different temperature classes, different types of protection, etc.

Manufacturers holding IECEx CoC may apply for an IECEx Conformity Mark License to Approved ExCBs, as listed on the IECEx website: www.iecex.com to affix the IECEx Mark of Conformity to equipment that are covered by an IECEx CoC.

NOTE Details concerning the Regulations and Rules for the licensing of the International IECEx Conformity Mark are detailed in IECEx 04 and OD 022.

5.2 Method of application

ExCBs and ExTLs approved by the ExMC in accordance with these Rules and associated IECEx Operational Documents may participate in the IECEx Certified Equipment Scheme. Applications from organizations seeking ExCB or ExTL acceptance for the purpose of issuing IECEx CoCs, ExTRs or QARs can be accepted from bodies that reside in an IECEx Participating Member Country. Applications are made to the Secretary of the ExMC.

Refer to IECEx 01 regarding country membership of the IECEx System.

5.3 Acceptance

Certification bodies and assessment and testing laboratories are accepted into the IECEx Certified Equipment Scheme following satisfactory assessment of their competence by assessors appointed by the ExMC as providing adequate confidence to regulatory authority, user, manufacturer and certification body interests. Competence is judged by reference to ISO/IEC Guide 65 and ISO/IEC 17025 and IECEx Technical Guidance Documents.

5.4 Permissions

ExCBs are permitted to issue IECEx CoCs, QARs and endorsed ExTRs.

5.5 Exchange of IECEx CoCs

ExCBs located in countries that cannot yet accept IECEx CoCs or whose national standards are not yet identical to the IEC Standards, shall accept for review IECEx ExTRs and QARs for the purposes of issuing local and/or national certification, thereby providing a “fast track” path to local and/or national certification.

ExTRs may cover national differences of the accepting country where they are in addition to the requirements of the IEC Standard. An ExCB receiving an ExTR or QAR may review the documentation for completeness. Should the ExCB receiving an ExTR or QAR believe it to contain errors, the receiving ExCB shall contact the issuing ExCB before taking any action.

5.6 Objective

The final objective of the IECEx Certified Equipment Scheme is worldwide acceptance of one standard, one certificate and one mark.

5.7 Unit Verification

The IECEx Certified Equipment Scheme enables the issuing of an IECEx certificate to cover specific equipment regarded as “one-off” or production of limited quantities where the requirements for ExCBs to conduct assessment of a manufacturer’s quality system and on-going surveillance may not be relevant. ExMC shall maintain procedures for the processing of applications for Unit Verification by ExCBs.

IECEX certificates issued for Unit Verification shall require the issue of an ExTR in accordance with these Rules and shall include specific reference to the equipment covered by the IECEx certificate, e.g. serial number or numbers where more than one item is to be covered. A QAR is not required when an IECEx certificate is issued for Unit Verification.

NOTE Refer to IECEx OD 033 for procedures covering the issuing of IECEx Unit Verification CoCs.

Manufacturers and holders of an IECEx certificate issued for Unit Verification shall associate the certificate only with the equipment identified by serial number(s) indicated in the certificate. Use of the certificate to make claims about any other equipment is forbidden.

The format of IECEx Unit Verification Certificates shall be the same as certificates issued under this Scheme.

5.8 Duties and responsibilities of those participating in the IECEx Scheme

It is the duty of all parties operating in the IECEx Certified Equipment Scheme, including manufacturers and organizations that make application for an IECEx CoC, ExTR or QAR to conduct affairs in a professional and ethical manner that does not result in actions, misleading information or claims that may bring the IECEx credibility into question.

6 Confidentiality

All those participating in the IECEx Certified Equipment Scheme shall respect the confidentiality of any information that they obtain and take all reasonable steps to bind their staff and those working under contract to preserve that confidentiality. The effectiveness of such steps taken shall be evaluated as part of the IECEx assessment of the ExCB and ExTL.

7 Participating countries

7.1 Participation

In order for a country to participate in the management of the IECEx Certified Equipment Scheme the country must first be a member of the IECEx System and comply with the requirements for IECEx Membership, as detailed in IECEx 01. Countries that are existing members of the IECEx System shall be considered members of the IECEx Certified Equipment Scheme.

7.2 National differences

The candidate Member Body of the IECEx Certified Equipment Scheme shall specify national differences from the IEC Standard(s) in the application.

7.3 Changes

The Member Body of the IECEX System shall notify the ExMC of any changes in the national differences declared in its application. Notification of any changes should be made within 3 months.

7.4 Termination

The ExMC may terminate a country's participation in the IECEX Certified Equipment Scheme if the Member Body of the country persists in a breach of these Rules after due warning by the ExMC to the Member Body of the IECEX System.

7.5 Cancellation

In the event of a country's ceasing to be a participating country, the ExCBs in that country shall lose the right to issue new IECEX CoCs, ExTRs and QARs. Issued IECEX CoCs and ExTRs shall remain valid. QARs shall remain valid for a period of 6 months. Within this period the manufacturer shall seek an alternative ExCB that accepts to maintain the validity of the QARs.

8 IECEX instruments

8.1 IECEX Certificate of Conformity

8.1.1 Issue

An IECEX Certificate of Conformity is issued by an ExCB, on the basis of an ExTR and QAR. It certifies that the type of Ex equipment identified on the certificate conforms in all relevant respects with the standard(s) specified on the certificate. The manufacturer named on the certificate manufactures the product under a quality system and associated quality plan(s) complying with the requirements of ISO/IEC 80079-34, as a means of providing adequate confidence that the Ex equipment will be produced in conformity with the design of the certified equipment. An IECEX CoC may be issued to the current standard or one edition prior. An upgrading of existing CoCs after publishing of a new edition of a Standard is not required unless otherwise determined by ExMC.

NOTE The applicable latest edition is generally determined based on the issue date of the CoC.

IECEX Certificates issued under Unit Verification may be issued to any edition of the standard and may be used as an outcome of the repair and overhaul process to verify compliance with standard(s), e.g. following modifications outside those permitted by original certification. As IECEX Unit Verification Certificates apply to specific items of Ex equipment and systems, assessment of a manufacturer's compliance with ISO/IEC 80079-34 is not part of the assessment and certification process.

8.1.2 Layout

The ExMC shall decide on the layout and content of IECEX CoCs.

8.1.3 Contents

The IECEX CoC shall contain at least the following information:

- Clear description of the Ex equipment
- Name and address of the manufacturer
- The Standard, edition and amendments, if any
- Reference to the supporting ExTR
- Reference to the supporting QAR, except for Unit Verification

- Ex marking requirements
- Name of the issuing ExCB
- Conditions of safe use, if any
- IS parameters for intrinsic safety, where relevant
- Reference to manufacturers' instructions
- Serial number or other unique identifier when issued for Unit Verification

8.2 IECEx Test Report (ExTR)

8.2.1 Preparation

An ExTR is prepared and issued by an ExTL but must be endorsed by an ExCB, associated with the ExTL, recording the product design assessment, examination and assessment and testing work carried out in order to verify the conformity of Ex equipment with the requirements of the stated standards. The ExMC shall develop and maintain standard ExTR blank forms for all standards used in the IECEx Certified Equipment Scheme. An allocated part of the front cover sheet of the ExTR or a separate sheet may be used by the ExCB for endorsing the ExTR.

8.2.2 Description of equipment

The ExTR shall contain a clear description of the Ex equipment or change to already certified equipment, the name and address of the applicant and the manufacturer and the edition of the Standard, and amendments, if any. It shall give, as far as necessary, for each clause of the relevant standard a brief reference to the requirements, and the results of tests and examinations. The ExTR shall also contain the information necessary for identification of the Ex equipment such as type designation, ratings, description and photographs.

8.2.3 Layout

The ExMC shall develop the document detailing the requirements to the layout and content of ExTRs.

8.2.4 Issue

ExTRs are intended to be issued in supporting IECEx CoCs. An ExTR may be issued on its own, provided the ExTR is endorsed by the ExCB associated with the ExTL. The ExTR, may include evaluation of the Ex equipment for conformity with declared local and/or national differences, and may be used by other ExCBs when issuing their own local and/or national certification. An ExTR may be issued to cover selected clauses and test results of a Standard, with the onus on the ExCB to ensure that they are in possession of sufficient ExTRs to cover the full assessment to (a) Standard(s).

8.2.5 Restrictions

Because ExTRs form the basis for issuing an IECEx CoC, they shall not be used in any form of advertising or sales promotion in order that the information is not misrepresented.

8.2.6 Copies

When a copy of an ExTR is required, it shall be reproduced in its entirety.

8.2.7 Ensuring conformity

The manufacturer has the responsibility to ensure that all Ex equipment for which an IECEx Test Report (ExTR) is issued is in conformity with the design of the certified equipment. Failure to do so, and any other misuse of the ExTR could lead to suspension or cancellation of the associated IECEx CoC by the ExCB.

8.2.8 Testing at other locations

While it is usually expected that testing would be conducted at either the ExTL's own test premises, IECEx OD 024 covers the situations where testing is conducted at either (or a combination of) manufacturer's or end user's own location.

NOTE This may include full witness or partial witnessing of tests performed.

8.3 IECEx Quality Assessment Report (QAR)

8.3.1 Assessment of the manufacturer's quality management system

The manufacturer can apply to any ExCB for the assessment of his quality management system (QMS). The ExCB shall assess the conformity of the QMS and associated quality plan(s) relevant to the Ex equipment requested, for compliance with ISO/IEC 80079-34. In order to demonstrate how the quality system ensures that equipment is manufactured in conformity with the requirements, the manufacturer shall provide the ExCB with a copy of a quality plan for the Ex equipment or equipment categories to be listed on the QAR. The manufacturer may provide evidence of the suitability of the quality system such as certification/registration to ISO 9001 by a competent body. The ExCB shall take the evidence into account when deciding the extent of the assessment that it needs to conduct. The assessment shall include "on-site assessment" at the manufacturer's premises to confirm implementation of the quality system and associated quality plan(s).

8.3.2 Content

A QAR is intended to be issued in supporting IECEx CoCs. A QAR may be issued on its own by an ExCB recording the assessment of a manufacturer's quality system for compliance with the Ex quality system requirements of the IECEx Certified Equipment Scheme aimed at ensuring the on-going compliance of Ex products with those characteristics that are covered by the ExTR. A QAR has a limited duration (3 years) and can be withdrawn or suspended if intermediate follow-up assessments are not satisfactory. The IECEx On-Line Certificate System maintains a central register with details of issued QARs. ExCBs shall ensure that the QAR details on the central register are maintained up to date. The ExMC Secretary shall be informed, without delay, of any suspension or cancellation of QARs.

8.3.3 Layout

The ExMC shall prepare a document detailing quality requirements for the Scheme and the layout and content of QARs.

8.3.4 Issue

QARs are intended to be issued in supporting IECEx CoCs. A QAR may be issued on its own for the purpose of acceptance by other ExCBs in the national certification of the equipment. The QAR shall refer to a specific manufacturing site(s).

A QAR summary report is published on the IECEx website: www.iecex.com, containing at least the manufacturing location(s), the product type, the type of explosion protection of the equipment to be manufactured and the expiration date of the QAR.

8.3.5 Restrictions

The QARs are documents used in the preparation of IECEx CoCs and basis for on-going production; they shall not be used in any form of advertising or sales promotion in order that the information may be misinterpreted.

8.3.6 Copies

When a copy of a QAR is required, it shall be reproduced in its entirety.

8.3.7 Surveillance

Where an IECEX CoC is issued, the ExCB issuing the CoC shall either carry out or ensure that periodic surveillance of certified Ex equipment, including examination of documentation and assessment of the manufacturer's quality management system for continued compliance with ISO/IEC 80079-34, is conducted. The ExCB responsible for issuing the CoC may conduct the surveillance activities or arrange for another ExCB to carry out this work. The frequency of such surveillance, inspection and assessment and testing shall be determined by the issuing ExCB in accordance with the IECEX Certified Equipment Scheme requirements and in light of the effectiveness of the manufacturer's quality plan(s) but as a minimum shall comply with the following:

- a) Where manufacturers hold ISO 9001 certification by a body accredited by an IAF Member, not more than 18 months
- b) Manufacturers other than a) above, not more than 12 months
- c) Where changes to the manufacturer may impact on their compliance with quality management system requirements, e.g. relocation of manufacturing location, as determined by the ExCB

Such frequency shall take into account whether the manufacturer holds current ISO 9001 certification/registration by a competent body.

8.4 IECEX Mark of Conformity

Applicants in possession of IECEX CoCs, may apply for an IECEX Conformity Mark License to affix the IECEX Conformity Mark in accordance with the IECEX Conformity Mark Regulations, IECEX 04 and supporting IECEX Operational Documents, e.g. OD 022, as approved by ExMC and listed on the IECEX website: www.iecex.com.

9 Procedure to issue an IECEX Certificate of Conformity

9.1 Application

An applicant may make an application for an IECEX CoC to any ExCB for the relevant standard(s). Where the applicant is a person acting on behalf of a manufacturer, evidence shall be submitted that the applicant is authorized to act on behalf of the manufacturer for the application and that the manufacturer undertakes to abide by the Rules and obligations of the IECEX Scheme.

NOTE IECEX 02A is published as a "Guide to Applicants" to assist manufacturers when preparing an application for an IECEX Certificate of Conformity and is available from the IECEX website: www.iecex.com/guides.htm.

9.2 Documentation

The applicant shall supply the documentation necessary to specify the explosion protection features of the Ex equipment. The documentation shall also accurately identify the Ex equipment for which certification is required, the standard(s) to which certification is to be granted, and the manufacturer responsible for the conformity of production items with the design of the certified equipment.

The documents may include ExTRs and QARs issued by other ExCBs.

The documentation shall be in English or accompanied by an English translation.

ExMC shall develop and maintain a document detailing the requirements for documentation to be submitted when applying for an IECEX CoC, ExTR or QAR. Refer to IECEX 02A, *Guidance for Applicants seeking IECEX Certification under the IECEX Certified Equipment Scheme, IECEX 02*.

The documentation may be provided in paper form or electronic format. If electronic format is used, it shall be provided in a commonly used file format as determined by the ExMC, e.g. PDF or TIFF on a commonly used storage medium, e.g. CD-ROM, DVD-ROM or by any other data transfer technology.

9.3 Samples

The applicant shall supply such samples of the Ex equipment as the ExCB deems necessary.

9.4 Examination of documentation and assessment/testing of samples

The ExCB shall arrange for its associated ExTL to examine the documentation and the sample(s) to verify that the Ex equipment design is in conformity with the standard(s). The ExTL shall examine the sample(s) for compliance with the documentation, test the sample(s) as specified in the standard(s) and compile an ExTR.

Particular attention is drawn to the documentation requirements of IEC 60079-0, regarding the provision of a manufacturer's document(s) which provide(s) guidance on the use, installation, maintenance and overhaul of explosion protected equipment.

9.5 Endorsement of ExTR and QAR and issue of an IECEx CoC

Upon satisfactory completion of the work, the issuing ExCB shall review and endorse the ExTR and QAR summary report at the IECEx website: www.iecex.com. If the review is satisfactory and where the application includes a request for issuing of an IECEx CoC, the IECEx CoC shall be issued by the ExCB, in accordance with the relevant IECEx Operational Document. The manufacturer and the ExCB shall each retain a set of the documentation referred to in the certificate, including ExTR and manufacturer's documentation.

ExTRs and/or QARs may be issued on their own without the issuing of an IECEx CoC.

9.6 Changes

If the manufacturer wishes to make a change to the certified Ex equipment, controlled by the ExTR, he shall apply to the ExCB which granted the IECEx CoC, describing the change and the measures adopted to ensure continuing conformity with the relevant standard(s). The ExCB shall arrange for such work as is necessary to be carried out to verify that the Ex equipment incorporating the change will still conform to the standard(s). The ExCB shall issue an addendum to the certificate authorizing the change. The ExMC shall specify the layout and content of the addendum. The ExMC shall determine the extent of the change that can be accommodated using an addendum to the original certificate and may determine in consultation with the manufacturer that the changes require a new IECEx CoC to be issued.

9.7 Ensuring conformity

The manufacturer has the responsibility to ensure that all Ex equipment to which the IECEx Mark of Conformity is affixed and all Ex equipment that is described as "IECEx certified" is in conformity with the design of the certified equipment. Failure to do so, and any other misuse of the Conformity Mark or IECEx CoC, could lead to suspension or cancellation of the IECEx CoC by the ExCB.

9.8 Certification procedure for licensed equipment

Equipment produced or sold under license by a second manufacturer (licensee) and with a new product name can be certified in the name of the licensee based on the certificate of the original manufacturer (licensor). Based on a license agreement, the licensee can apply for the certificate referring to the technical documentation and ExTR associated with the original certificate of the licensor. Where the licensee only sells the certified product, the ExCB shall assess the relevant parts of the QMS and issue a QAR. If the licensee manufactures the product, clause 9.5 shall apply.

9.9 Documentation retained

In placing an application with an ExCB, the manufacturer authorizes the ExCB to keep for future reference photographs, technical documentation and, by agreement with the applicant, samples or, for large equipment, parts of such equipment. Such reference material shall be confidential.

9.10 Surcharges

An applicant who is not in an IECEx participating country and an applicant acting on behalf of a manufacturer in such a country shall pay a contribution to the costs of the IECEx System in the form of a surcharge, the amount to be decided by the ExMC. The surcharge is to be collected by the ExCB handling the application, and remitted to the IECEx account.

NOTE Refer to IECEx OD 019 concerning the level of surcharges.

9.11 Suspension or cancellation

An IECEx CoC may be suspended or cancelled by the issuing ExCB if

- the holder requests cancellation;
- it is used in a misleading way;
- the Ex equipment no longer corresponds to the design of the certified equipment, or the QAR no longer adequately covers the relevant Ex equipment;
- the manufacturer's quality system and associated quality plan no longer provides adequate confidence that Ex equipment will be produced in conformity with the design of the certified equipment.

The ExCB shall give due notice to the manufacturer of such suspension or cancellation and shall state the reason(s).

While a certificate is suspended or when it has been cancelled, the manufacturer shall no longer describe the Ex equipment as "IECEX certified", nor shall he affix the IECEx Conformity Mark to the Ex equipment. Equipment already supplied prior to the cancellation of the certificate is not affected.

An IECEx CoC may be also cancelled by the issuing ExCB if

- it has been issued in error;
- the assessment by an ExTL has been found to be deficient;
- the equipment design cannot be considered as explosion protected.

In that case, the ExCB shall inform immediately the ExMC Secretary and give due notice to the manufacturer of such withdrawn and shall state the reason(s). While a certificate is withdrawn, the manufacturer shall no longer describe the Ex equipment as "IECEX certified", nor shall he affix the IECEx Conformity Mark to the Ex equipment. Equipment already supplied prior to the withdrawal of the certificate is affected and need to be withdrawn from the market and from the field.

9.12 Notification of cancellation

When an IECEx CoC has been cancelled the issuing ExCB shall notify the ExMC Secretary as soon as possible. Cancellation of certificates shall be communicated to other ExCBs and published.

10 Acceptance of ExTRs and QARs for national certification

10.1 General

Where separate local and/or national certification is required, the IECEx Certified Equipment Scheme provides a fast track process through the acceptance of ExTRs and QARs. ExCBs shall accept ExTRs and QARs issued by other ExCBs according to these rules when issuing their own local and/or national certificates. This does not preclude a technical review by the receiving ExCB in accordance with ISO/IEC Guide 65. Any additional work carried out by the ExCB receiving an ExTR and QAR shall not go beyond the following, without first contacting the issuing ExCB:

- verify compliance with local and/or national differences from the IEC Standards where those local and/or national differences have not been covered by the ExCB issuing the ExTR, and
- adequately identify that the Ex equipment submitted for certification is that which is the subject of the ExTR, and
- verify compliance with local and/or national differences from IECEx reference document used for assessment of the quality system of the manufacturer where those local and/or national differences have not been covered by the ExCB issuing the QAR.

10.2 National certification

When an applicant applies to an ExCB for its national certification or approval of Ex equipment on the basis of an ExTR, a copy of the ExTR shall accompany the application. In addition, for the purposes of 10.1, the ExCB may request a sample of the Ex equipment and copies of the documentation referred to in the report for the purposes specified in 10.1.

The National Member Body shall inform the ExMC Secretary of any national certification requirements beyond those of gaining an IECEx CoC. Changes to such requirements shall be communicated to the ExMC Secretary as soon as possible, in order that such information is kept up to date.

10.3 Compliance with rules

The applicant shall follow the rules of procedure of the ExCB and shall confirm readiness to comply with all the relevant provisions regarding, for example, factory surveillance and payment of fees.

10.4 Appeals

Should the ExCB receiving an ExTR or QAR for recognition consider it to have been issued in error, the ExCB that issued the report(s) shall be informed as soon as possible. If the ExCBs involved arrive at different conclusions, the case may be referred to the IECEx Board of Appeal. Should a manufacturer or applicant be refused the issuing of an ExTR, QAR or IECEx CoC or be the subject of suspension or cancellation of an IECEx CoC and disagree with this decision, he may lodge an appeal to the IECEx Board of Appeal.

11 Acceptance of certification bodies and testing laboratories

NOTE When an application is made for acceptance of a certification body that intends to employ already accepted ExTLs, assessment is made according to this clause. Applications for acceptance of a certification body and an associated testing laboratory may be submitted together or as one combined application, and assessment according to 11.1 and 11.2 may be combined.

11.1 Acceptance of certification bodies

11.1.1 Conditions for acceptance

A certification body shall be accepted as an ExCB by the ExMC and given the right to issue IECEX CoC, ExTRs and QARs to specified standards, under the following conditions and according to the procedures stipulated in 11.1.2 to 11.1.14:

- The certification body shall be located in a participating country
- The certification body shall operate a recognized certification or approval scheme at national level for the specified types of protection
- The competence of the certification body to comply with these Rules shall be demonstrated by assessment. The general competence, efficiency, experience, familiarity with the relevant standards and the types or concepts of protection included in those standards and competence to carry out quality management system assessments as well as compliance with ISO/IEC 65 shall be assessed. Acceptance in another IEC Conformity Assessment System or IECEX Scheme or accreditation by a recognized national accreditation body shall be taken into account. In those cases, the ExMC shall decide upon the extent of the assessment that is necessary
- The certification body shall not be part of, or under the influence of, manufacturing interests associated with Ex products or services
- The certification body shall have within its organization, or have an agreement to employ, an ExTL accepted by the ExMC according to these Rules for the relevant types of protection

11.1.2 Application

The candidate certification body, via the national Member Body of the IECEX System, shall make an application for the acceptance of a certification body for one or more standards accepted for use in the IECEX Certified Equipment Scheme. Applications from candidate certification bodies require the endorsement of the Member Body of the country of operation of the candidate CB. This endorsement shall be received by the ExMC Secretary prior to the application being accepted.

The application shall be submitted to the Secretary of the ExMC and shall be accompanied by a declaration as detailed in Annex A.

Where separate national certification or approval is required in a country as a condition to supply a product for use in that country, the candidate certification body shall declare that the national certification or approval can be based on an ExTR. When national differences or other conditions have to be fulfilled, they shall be as declared by the Member Body of the IECEX System and published in the IECEX Bulletin. There shall not be more than one set of national differences for each country.

In submitting an application, the candidate certification body agrees to comply with the IECEX Scheme Rules, as amended along with an IECEX code of professional conduct which includes, at all times, to support the principles and aims of the IECEX System.

Upon application, the candidate certificate body is admitted as a member of the IECEX Conformity Assessment Bodies Committee, known as ExTAG (Ex Testing and Assessment Group), with full voting rights.

11.1.3 Recognition of ExTRs

The candidate certification body shall communicate the following information relevant to the recognition of ExTRs to the Secretary of the ExMC:

- Written information on procedures and rules for certification or approval at national level
- Whether or not a foreign manufacturer is required to make application for certification or approval through a representative resident in that country

11.1.4 Assessment

The candidate certification body shall be assessed to determine that the conditions according to 11.1.1 are fulfilled. Assessors approved by the ExMC shall carry out the assessment. The team shall be led by a Lead Assessor approved by the ExMC and shall include at least one member drawn from an ExCB.

When a testing laboratory is to be assessed on the same occasion, the assessment team may include a member from an ExTL.

Assessors with prior experience working in an ExCB or ExTL and whose knowledge of standards and certification matters is current may be used.

The candidate shall be given the names and current appointments of the assessors proposed to be appointed by the ExMC. Candidates may object "for cause" (reasons to be stated) to the appointment of the assessors.

The candidate to be assessed shall express its willingness to pay the professional fees of the assessors, the amount to be decided by the ExMC, and the reasonable travelling and living expenses arising from the assessment. An estimate of these expenses shall be provided to the candidate in advance and agreed by the candidate.

IECEX Assessment Teams shall report to the Secretary of the ExMC who shall manage all assessments, including the appointment of assessment teams from a list of assessors approved by the ExMC, to ensure assessments are carried out in a timely manner and in accordance with the requirements of the Scheme.

11.1.5 Resolution of differences

During the assessment, the assessors shall prepare a draft report that shall be discussed with the management of the candidate certification body. Efforts should be made to resolve any differences of opinion between the assessors and the candidate during this discussion.

11.1.6 Report to ExMC

The assessors shall submit to the ExMC, with a copy to the representatives of the candidate certification body, a confidential report containing their findings and recommendations, taking into account the declaration submitted together with the application. The candidate may attend an ExMC meeting or submit written comments in order to respond to enquiries regarding its application.

11.1.7 Acceptance

The ExMC shall decide upon the acceptance of the candidate certification body at a meeting or by correspondence. In the latter case, the decision shall be reported to the next meeting of the ExMC and recorded in the minutes.

11.1.8 Notification

If the decision of the ExMC is positive, the Secretary of the ExMC shall inform the candidate certification body in writing.

If the decision of the ExMC is negative, the Chairman of the ExMC may, depending on the findings, suggest to the candidate certification body

- to withdraw the application, or
- to accept a new assessment.

11.1.9 Changes

Each ExCB shall inform the Secretary of the ExMC about changes in the information given according to 11.1.2 and 11.1.3.

11.1.10 Extension of scope

When an ExCB wishes to extend its acceptance to further standards accepted for use in the IECEX Certified Equipment Scheme, an application shall be made to the Secretary of the ExMC via the Member Body of the IECEX System. When the ExCB has been assessed within the last five years, the members of the Assessment Team that assessed the ExCB should give their comments on the application.

The ExMC Secretary in consultation with the IECEX Executive shall decide whether the extension may require a full or limited assessment on the basis of the information thus available. Decisions shall be reported to the next ExMC meeting.

11.1.11 Reporting of decisions

The ExMC may delegate the decisions according to 11.1.10 to the Chairman and Vice-Chairman of the ExMC to be made by correspondence between meetings. Such a decision shall be reported to the next meeting of the ExMC and recorded in the minutes.

11.1.12 Re-assessment

By means of re-assessment to the extent and frequency deemed necessary, the ExMC shall verify whether ExCBs are still fulfilling the conditions of 11.1.1.

11.1.13 Withdrawal

An ExCB wishing to withdraw from the IECEX Certified Equipment Scheme shall notify the Secretary of the ExMC via the Member Body of the IECEX Certified Equipment Scheme at least one year in advance and shall indicate the reason for the withdrawal and the date from which the withdrawal will become effective.

11.1.14 Suspension

The acceptance of an ExCB may be suspended or withdrawn by the ExMC if that ExCB no longer fulfils the conditions of 11.1.1 or if in the opinion of the ExMC, the ExCB hampers the aim, operation or development of the IECEX Certified Equipment Scheme, fails to take action regarding misuse of IECEX CoC or the IECEX Mark of Conformity, or violates these Rules. Before such a decision is made, the ExCB shall be given the opportunity to take corrective action over a period of six months and state its own opinion on the matter.

A decision to suspend or withdraw the acceptance of an ExCB shall require agreement at a meeting of the ExMC by a majority of at least four fifths of the total number of members. Members not attending that meeting shall have the right to cast their vote in writing by registered mail, or e-mail to the Secretary of the ExMC prior to the meeting.

In case of a suspension or a withdrawal, the certification body in question shall not be allowed to claim any relationship with the IECEX Certified Equipment Scheme.

11.2 Acceptance of Ex testing laboratories

NOTE Applications for acceptance of a certification body and an associated testing laboratory may be submitted independently or as one combined application, in which case assessment according to 11.1 and 11.2 may be combined.

11.2.1 Conditions for acceptance

Acceptance of an Ex testing laboratory as an ExTL is subject to the following conditions and to the procedures stipulated in 11.2.2 to 11.2.10:

- The Ex testing laboratory shall be located in a participating country
- An Ex testing laboratory can operate as an ExTL if it is integral with an ExCB, under the complete technical and legal control of an ExCB or has a written agreement with an ExCB to undertake work with it according to these Rules
- The competence of the assessment and testing laboratory shall be demonstrated by assessment. The general competence, efficiency, experience, familiarity with the relevant standards and the types of protection included in those standards as well as compliance with ISO/IEC 17025 and the IECEx Technical Guidance Documents shall be assessed. Acceptance in another IEC Conformity Assessment System or IECEx Scheme or accreditation by a recognized national accreditation body shall be taken into account. The ExMC shall decide upon the extent of the assessment that is necessary
- The Ex test laboratory shall not be part of, or under the influence of, manufacturing interests associated with Ex products or services

11.2.2 Application

An application for the acceptance of a laboratory as an ExTL for assessment and testing according to one or more standards accepted for use in the IECEx Certified Equipment Scheme shall be made by the candidate assessment and testing laboratory, via the Member Body of the ExMC.

The application shall be submitted to the Secretary of the ExMC and shall be accompanied by a declaration as detailed in Annex B.

11.2.3 Assessment

The candidate testing laboratory shall be assessed to determine that the conditions according to 11.2.1 are fulfilled. Assessors approved by the ExMC shall carry out the assessment. The assessment team shall be led by a Lead Assessor appointed by the ExMC and shall include one member from an ExCB and one member from an ExTL.

Assessors with prior experience working in an ExCB or ExTL and whose knowledge of standards and certification matters is current may be used.

When the laboratory is integral with a candidate certification body, or is to be assessed on the same occasion as a candidate certification body, a combined assessment team of three persons may be appointed.

The candidate shall be given the names and current appointments of the assessors proposed to be appointed by the ExMC. Candidates may object "for cause" (reasons to be stated) to the appointment of the assessors.

The laboratory to be assessed shall express its willingness to pay the professional fees of the assessors, the amount to be decided by the ExMC, and the reasonable travelling and living expenses arising from the assessment. An estimate of these expenses shall be provided to the candidate in advance and agreed by the candidate.

The Secretary of the ExMC shall manage the assessment process, including the appointment of assessment teams from a list of assessors approved by the ExMC.

11.2.4 Resolution of differences

During the assessment, the assessors shall prepare a draft report that shall be discussed with the management of the candidate assessment and testing laboratory. Efforts should be made to resolve any differences of opinion between the assessors and the candidate during this discussion.

11.2.5 Report to ExMC

The assessors shall submit to the ExMC Secretary, with a copy to the representatives of the candidate assessment and testing laboratory, a confidential report containing their findings and recommendations, including the level of the ExTR review, as per 11.2.12, taking into account the declaration submitted together with the application. The candidate may attend an ExMC meeting or submit written comments to respond to enquiries regarding its application.

11.2.6 Acceptance

The ExMC shall decide upon the acceptance of the candidate Ex testing laboratory at a meeting or by correspondence. In the latter case, the decision shall be reported to the next meeting of the ExMC and recorded in the minutes.

11.2.7 Notification

If the decision of the ExMC is positive, the Secretary of the ExMC shall inform the candidate assessment and testing laboratory in writing. If the decision of the ExMC is negative, the Chairman of the ExMC may, depending on the findings, suggest to the candidate assessment and testing laboratory

- to withdraw the application, or
- to accept a new assessment.

11.2.8 Extension of scope

When an ExTL wishes to extend its acceptance to further standards accepted for use in the IECEX Certified Equipment Scheme, an application shall be made to the Secretary of the ExMC. When the ExTL has been assessed within the last five years, the members of the Assessment Team that assessed the ExTL should give their comments on the application.

The ExMC Secretary in consultation with the IECEX Executive shall decide whether the extension may require a full or limited assessment, on the basis of the information thus available. Decisions shall be reported to the next ExMC meeting.

11.2.9 Re-assessment

By means of re-assessment and comparative assessment and testing to the extent and frequency deemed necessary, the ExMC shall verify whether the ExTLs are still fulfilling the conditions of 11.2.1.

11.2.10 Suspension

The acceptance of an ExTL may be suspended or withdrawn by the ExMC if that ExTL no longer fulfils the conditions of 11.2.1 or if it violates these Rules. Before such a recommendation is made, the ExTL shall have the opportunity to take corrective action over a period of six months and state its own opinion on the matter.

In case of a suspension or a withdrawal, the assessment and testing laboratory in question shall not be allowed to claim any relationship with the IECEX Certified Equipment Scheme.

11.2.11 ExTR review

As a means of ensuring confidence among Scheme Members, newly accepted ExTLs shall submit a copy of the first completed ExTR to the ExMC Secretary who will arrange for it to be reviewed. The outcome of this review may require corrective actions to be undertaken by the ExTL and review of further ExTRs.

12 IECEx publications

12.1 Types of publications

Three publications shall be produced:

- The IECEx Register
- The IECEx Bulletin
- The IECEx Newsletter

NOTE The ExMC may decide to issue the publications in electronic format and may be contained within the IECEx website: www.iecex.com. The Register and Bulletin may be produced as one publication.

12.2 Information to be available

The following information shall be made readily available to the public:

- ExCBs and ExTLs
- Manufacturers holding IECEx CoCs
- IECEx CoCs issued
- Categories of Ex equipment covered by the IECEx Certified Equipment Scheme
- Standards accepted for use in the IECEx Certified Equipment Scheme

12.3 IECEx Bulletin

The IECEx Bulletin shall be issued at intervals decided by the ExMC. It shall contain information on

- the IEC Standards for which ExCBs in each country have declared recognition of ExTRs;
- national differences from each IEC Standard for each country as declared by the Member Bodies of the IECEx System.

NOTE Additional information relating to the operation of the IECEx System can be found by visiting the official IECEx website: www.iecex.com.

12.4 IECEx Newsletter

The IECEx Newsletter shall be used to publicise developments within the IECEx Scheme, including new ExCBs and ExTLs joining the IECEx Certified Equipment Scheme, matters relating to relevant International Standards and changes in the Rules.

12.5 Source of information

The information published in the IECEx publications is based on information given by the Member Bodies of the IECEx Certified Equipment Scheme, ExCBs and ExTLs. Neither the IEC nor the Secretary of the ExMC is therefore liable for the accuracy of that information. Publication of commercial information shall be avoided.

13 Complaints

If there are complaints concerning the actions of an ExCB or an ExTL that the ExMC cannot resolve, the ExMC or the complainant shall have the right to request the IEC Conformity Assessment Board (CAB) for appropriate action.

Annex A

Declaration by a certification body applying to become an Ex Certification Body to operate within the IECEx Certified Equipment Scheme

The declaration by a certification body applying to become an Ex Certification Body (ExCB) shall be a self-contained document including the following information:

- a) A description of the body which gives, in addition to an organization chart, information about
 - the legal status of the body;
 - the address(es) at which it carries out its operations;
 - the means by which the body will demonstrate compliance with ISO/IEC Guide 62 and ISO/IEC Guide 65;
 - any legal relationship between the body and testing laboratory(ies) used in the course of its work (including the case where the laboratory is integral with the certification body);
 - the responsibilities at national level concerning certification, and the schemes operated;
 - the arrangements for appeal;
 - the arrangements for recognition of IECEx Certificates of Conformity (IECEX CoCs), IECEx Test Reports (ExTRs) and IECEx Quality Assessment Reports (QARs) when issuing its own national or regional certificates;
 - the documents available for providing supporting information, for example with regard to existing accreditation;
 - details of senior management with competence in the certification of Ex equipment.
- b) A list of the standards accepted for use in the IECEx Certified Equipment Scheme according to which the body wishes to issue IECEx CoCs
- c) A statement that the body will recognize ExTRs and QARs produced by other ExCBs when issuing its national or regional certificates or approvals
- d) A list of the standards accepted for use in the IECEx Certified Equipment Scheme, including details of the edition and amendments if any, which are accepted in whole or in part by the body when issuing its national or regional certificates or approvals. Where national differences from the IEC Standards exist, these shall be declared for later publication in the IECEx Bulletin
- e) A statement of the number of certificates issued in the preceding two years for each type of protection covered by the standards listed in b) and d)
- f) A statement that the body will abide by the Rules

Annex B

Declaration by a testing laboratory applying to become an IECEx Testing Laboratory

The declaration by a testing laboratory applying for acceptance as an Ex Testing Laboratory shall be a self-contained document including the following information:

- a) A description of the laboratory which gives, in addition to an organization chart, information about
 - relationship between the laboratory and the relevant Ex Certification Body or accepted certification bodies;
 - the legal status of the laboratory;
 - the address(es) at which it carries out its operations;
 - the responsibilities concerning assessment and testing;
 - the means by which the laboratory will demonstrate compliance with ISO/IEC 17025;
 - the documents available for providing supporting information, for example with regard to existing accreditation.
- b) A list of the standards accepted for use in the IECEx Certified Equipment Scheme according to which the laboratory intends to conduct tests
- c) The information required in annex C
- d) A statement of the number of test reports issued in the preceding two years for each type of protection covered by the standards listed in b)
- e) A statement that the laboratory will abide by the Rules

Annex C

Additional information to be provided by a testing laboratory in applying for acceptance as an ExTL

NOTE 1 The text of this annex is taken from the annex to ISO/IEC Guide 38:1983 which is now obsolete.

NOTE 2 Throughout the text, the word "recognition" should be taken to mean "acceptance" in the context of the IECEX Scheme.

C.1 Testing laboratory contact details

Applicant's name and address.

Telephone No.

Telefax No.

C.2 ExTL site contact details

Testing Laboratory name and address (if different from paragraph 1).

Telephone No.

Telefax No.

C.3 Senior management

C.3.1 Senior executives

Names and titles of the senior executives of the Test Laboratory* and of the assessment and testing laboratories for which recognition is being sought.

C.3.2 Quality management system representatives

Name and title of the person responsible for the quality management system in the testing laboratory.

C.3.3 Principal contact

Name and title of the principal contact nominated by the testing laboratory, and of his deputy.

C.3.4 Organization chart

Operating departments of the testing laboratory for which recognition is being sought. (Show on a separate sheet to be attached either as a list or as an organization chart of the Testing Laboratory).

C.4 Employees

C.4.1 Total numbers

Total number in Testing Laboratory.

* "Test Laboratory" refers here to the corporate entity having final authority over the "testing laboratory" seeking recognition. In some cases this may be the same body.

C.4.2 Ex testing personnel

Total number in the testing laboratory for which recognition is being sought.

C.4.3 Professional qualifications

Total number of professionally qualified staff (see also ISO/IEC 17025) in the area for which recognition is being sought.

C.5 Equipment

List on a separate sheet the major items of test equipment available for use in the area for which recognition is being sought.

C.6 Test facilities and services

C.6.1 Testing services

List on a separate sheet the testing services for which recognition is being sought, indicating for each service any limits between which it will operate, and the published specifications against which the testing will be performed.

C.6.2 Existing recognitions

If recognition by other bodies or authorities is held in the area for which recognition is being sought, please give details.

C.6.3 Subcontract work

What type of testing is to be subcontracted in respect of the recognition being sought?

C.7 Other information

C.7.1 Relations with other organizations

Document, where applicable, how the testing laboratory may be related to external organizations or to components within its own parent organization.

C.7.2 Other information

Give any other information which you consider could be of assistance to the assessment team (on a separate sheet if necessary).

Yes/No	Particulars (where appropriate)
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C.8 Quality management policy

C.8.1 Quality policy

Are policy and procedures for the operation of the testing laboratory contained in a document such as a quality manual?

C.8.2 Responsibility and authority

Has the person responsible for quality management the responsibility and authority to identify quality problems and initiate effective solutions?

C.8.3 Unqualified staff

Does the quality manual contain procedures for the supervision of any unqualified staff (see also ISO/IEC 17025)?

C.8.4 Internal audits

Is there a prescribed audit procedure for checking quality management functions?

C.9 Work instructions**C.9.1 Access to documentation**

Are manuals, work instructions and regulations to be used by staff readily available?

C.9.2 Change management

Is there a system for updating, implementing and recording changes to these documents?

C.9.3 Process control

Are documents available for each assessment and testing operation?

C.9.4 Document and data control

Are documents and reference data maintained in an up-to-date condition?

C.9.5 Obsolete data

Is obsolete data promptly removed from documents, etc.?

C.10 Personnel**C.10.1 Professional standards**

Have standards of professional ability, skills and job descriptions been prescribed where necessary?

C.10.2 Training

Are training methods applied to attain and maintain skills with due attention to quality requirements?

C.11 Test equipment and calibration**C.11.1 Accuracy of measurements**

Does the quality management system specify that the equipment is of accuracy compatible with the assessment and testing undertaken?

C.11.2 List of test equipment and calibration status

Is a record maintained of all test equipment, including calibration results?

C.11.3 Test environment

Are facilities and appropriate environments provided for calibration, handling, control, storage and maintenance of all testing and measuring equipment?

C.11.4 Calibration procedures

Are there documented procedures for calibrating all equipment and reference standards which include method, periodicity, sealing after calibration, etc.?

If not, explain calibration system used.

C.11.5 Reference standards

Are reference standards used for calibration traceable to national or international standards of measurement?

C.12 Testing procedures

C.12.1

Are testing methods and procedures recorded which are not called up in specifications, manuals, etc.?

Yes/No	Particulars (where appropriate)
--------	------------------------------------

C.12.2

Are the environments in which tests are conducted and results recorded suitable to ensure their accuracy?

C.12.3

Do environmental testing facilities exist?

C.12.4

Is there control of access to the assessment and testing areas?

C.12.5

Is there a prescribed system for detecting deficiencies in testing and their causes, and for correcting unfavourable trends?

C.13 Handling and storage

C.13.1

Are work and inspection instructions prescribed and implemented for the handling, storage and return to the client of materials and samples?

C.13.2

Are appropriate storage areas arranged to prevent deterioration or damage to the products concerned?

C.13.3

Are storage methods prescribed, including special environments?

C.13.4

Are there procedures for the inspection of samples in storage?

C.13.5

Are storage areas accessible only to authorized persons?

C.13.6

Is provision made to ensure that all samples to be stored or returned to the client are adequately identified and labelled?

C.14 Records**C.14.1**

Is there a prescribed system for recording the method and results of assessment and testing activities?

C.14.2

Are observations and calculations recorded and stored as to provide a permanent test record?

C.14.3

Are there arrangements for ensuring that records are current, complete, accurate and held confidential where required?

C.15 Test reports**C.15.1**

Do test reports contain all the information required for such by ISO/IEC 17025?

C.15.2

Is the testing laboratory prepared to make arrangements to send copies of test reports to the ExCB granting recognition, where required, on a strictly confidential basis?

C.16 Preparedness for assessment**C.16.1**

Are you satisfied that you can meet all the requirements prescribed herein?

C.16.2

At what date will the assessment and testing laboratory be ready for assessment?

C.16.3

Is there any special urgency for assessment?

If so, what is the reason?

Applicant's name:

.....

Signature of person authorized to sign for the Applicant:

.....

(Title)

Date

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