



INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Ex Management Committee (ExMC)

Draft Rules of Procedure of the IEC Scheme for Certification to Standards for Electrical Equipment for Explosive Atmospheres (IECEx Scheme), Publication IECEx 02.

Introduction

The IECEx Scheme's Management Committee, ExMC had previously agreed to revise the IECEx Scheme's Rules of Procedure document, IECEx 02, in light of experience with the Scheme now operating at the Transitional phase. ExMC also established WG1 for the purpose of managing this revision.

A first draft has been prepared by the ExMC Chairman and WG1 Convenor, Mr Ian Cleare and the ExMC Secretary and submitted to WG1 members for comment.

This draft incorporates comments from WG1 members and is now submitted to ExMC and ExTAG for comment. Comments received will be collated and issued for discussion at the next ExMC meeting, Bern October 2001.

Proposed changes, to the current edition, include:

- Introduction of a Quality Assessment Report (QAR)
- Deletion of the requirement that ATRs are to be withdrawn should an ACB leave the Scheme (previous comment submitted by FR)
- Clarification of the ACB and ExTL Assessment process
- Allowing ACBs from countries whose national standards are harmonised with IEC, to issue IECEx Certificates of Conformity (Clause 5.4)
- Others

You are requested to consider the Draft and submit any comments to the ExMC Secretary by **31 August 2001**. Any comments submitted should include proposed new text, where appropriate.

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The timetable for work on this document is as follows

- Issue initial Draft to WG1 **Completed.**
- Comments on initial draft submitted by WG1 members **Completed**
- Revised draft incorporating comments from WG 1 members submitted to ExTAG and ExMC for comment **Completed**
- Comments to be received from ExTAG and ExMC members by 31 August 2001
- Issue collated comments to ExMC
- WG 1 meets Saturday 6 October 2001 (in Berne Switzerland) to consider collated comments and propose response for ExMC meeting
- WG1 Reports to ExMC meeting 10-12 October 2001 (Berne Switzerland)
- Desired outcome from ExMC meeting, a Final Draft for postal voting by ExMC.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

Rules of Procedure of the Scheme of the IEC for Certification to Standards for Electrical Equipment for Explosive Atmospheres (IECEx Scheme)

FOREWORD

This publication has been prepared by the Ex Management Committee.

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 Scheme.

INTRODUCTION

NOTE - This INTRODUCTION provides an overview of the IECEx Scheme and is not part of the Rules.

The aim of the IECEx Scheme is to facilitate international trade in electrical equipment intended for use in explosive atmospheres (Ex equipment) by eliminating the need for multiple national certification while preserving an appropriate level of safety.

The Scheme has a two-path approach with two objectives in mind:

- a) to accommodate the needs and concerns of today and the immediate future, through a well-defined and practical transitional period;
- b) to provide a route to the ultimate aim of using one international certificate and mark accepted in all participating countries.

The Scheme has a clear long term objective, with the means for achieving it, while also providing a mechanism for recognizing and dealing with the obstacles that lie in the way of its achievement. The figure on the next page illustrates the two paths available to any country for participation in the Scheme.

The IECEx Scheme provides the means for manufacturers of Ex equipment to obtain certificates of conformity that will be accepted at national level in all participating countries. A certificate of conformity may be obtained from any certification body accepted into the Scheme. The certificate will attest that the equipment design conforms to the relevant IEC standards and that the product is manufactured under a quality plan assessed by an ACB. Manufacturers holding certificates of conformity may affix the IECEx Mark of Conformity* to equipment that they have verified as complying with the certified design.

An application for a country to participate in the IECEx Scheme is made on a standard by standard basis by the candidate Member Body of the IECEx Scheme for that country. The application is made to the Secretary of the Ex Management Committee. Certification bodies and testing laboratories wishing to be accepted into the IECEx Scheme must reside in a participating country. Their application to be accepted into the Scheme is made through the Member Body of the IECEx Scheme for the country in which they reside.

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

For the IECEx Scheme to achieve its long term objective, each national standard for which application is made by participating countries will need to be identical to the corresponding IEC standard, and the IECEx Certificates of Conformity issued by all accepted certification bodies will need to be recognized in all participating countries as equivalent to their own national certification.

For countries whose national standards are not yet identical to the IEC standards, a transitional period will be necessary. The transitional period, which could be different for different standards, is to allow time for

* under development

- the IEC standards and the national standards to be made identical, and
- national acceptance of IECEEx Certificates of Conformity and the IECEEx Mark of Conformity*.

Convergence of standards will be assisted by agreements between regional and international standards bodies, such as that between CENELEC** and IEC, to co-ordinate their work.

A candidate Member Body of the IECEEx Scheme, when making an application to participate in the IECEEx Scheme, will provide an undertaking to the ExMC that it will use its best endeavours to assist in the achievement of the objectives of identical standards and national acceptance within the transitional period. If at the end of the transitional period the objectives have not been achieved, the ExMC will review the position with the Member Body of the IECEEx. If, at the time of the review, there is no prospect of the objectives' being achieved in the near future, the country of the Member Body of the IECEEx will withdraw from the Scheme.

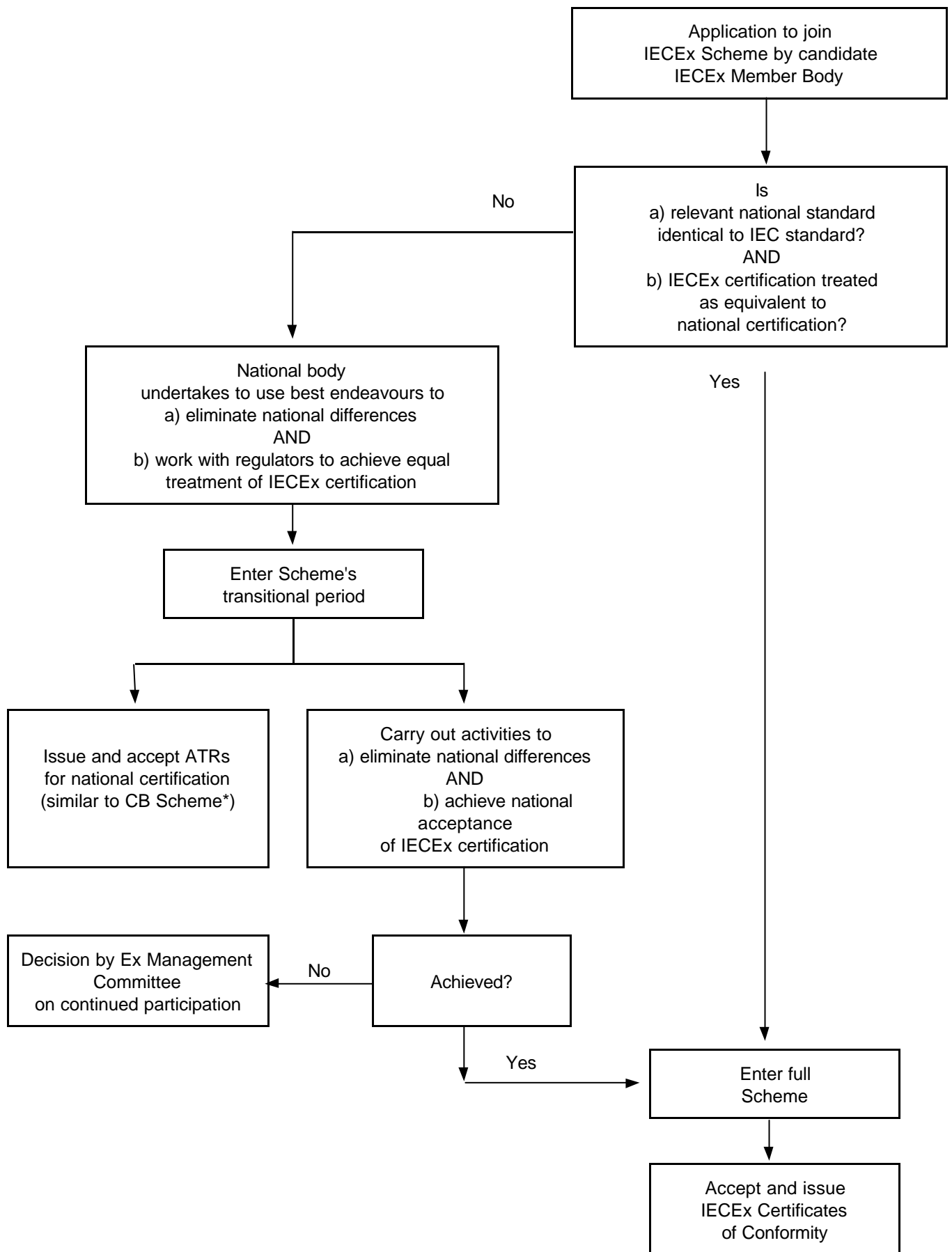
Accepted certification bodies in participating countries during the transitional period will be required to accept IECEEx Assessment and Test Reports produced by other accepted certification bodies for the purpose of issuing their own national certification which may include national differences as listed in the IECEEx Bulletin.

The final objective of the IECEEx Scheme is world-wide acceptance of one standard, one certificate and one mark.

The Rules and Procedures governing the scheme are detailed in IEC Publications IECEEx 01 and 02.

 * under development

** European Committee for Electrotechnical Standardization



* Scheme of the IECEE for Mutual Recognition of Test Certificates for Electrical Equipment

Figure 1 - Alternatives for participation on a standard by standard basis

**Rules of Procedure of the Scheme of the IEC
for Certification to Standards for Electrical Equipment for
Explosive Atmospheres (IECEx Scheme), Publication IECEx 02**

1 Scope

This publication contains the Rules of Procedure of the Scheme of the IEC, hereinafter referred to as the "Rules", for the certification of electrical equipment which is intended for use in explosive atmospheres and which complies with one or more of the IEC standards defining the types of protection against causing an explosion (IECEx Scheme).

The IECEx Scheme becomes operative for each type of protection as soon as at least three certification bodies from different countries have been accepted for that type of protection. . Once operative each participating country may choose to participate at either the Transitional or Full Levels. Countries seeking participation at the Full Level must also satisfy Clause 5.4

The list of accepted standards is published in the IECEx Bulletin (see 12.3).

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

NOTE - The IECEx Scheme is applicable to equipment conforming to standards prepared by IEC TC 31 and its subcommittees, which currently include the following:

- flameproof enclosures (IEC 60079-1)
- type of protection 'p' (IEC 60079-2)
- sand-filled apparatus (IEC 60079-5)
- oil-immersed apparatus 'o' (IEC 60079-6)
- increased safety 'e' (IEC 60079-7)
- intrinsic safety 'i' (IEC 60079-11)
- electrical apparatus with type of protection 'n' (IEC 60079-15)
- encapsulation 'm' (IEC 60079-18)

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: 1999, *Basic Rules of the IECEx Scheme*.

ISO/IEC Guide 2: 1996, *Standardization and related activities - General vocabulary*.

ISO/IEC 17025 1990, *General requirements for the competence of calibration and assessment and testing laboratories*.

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

3 Definitions

ISO/IEC Guide 2 gives the basic definitions.

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

3.1

IECEx Scheme

Scheme of the IEC for the certification of electrical equipment intended for use in explosive atmospheres and applicable to equipment embodying one or more of the types of protection covered by IEC standards prepared by IEC technical committee No 31

3.2

type of protection

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

[IEC 60079-0:2000]

3.3

Ex apparatus

items applied as a whole or in part for the utilization of electrical 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

3.4

Ex component

a part of electrical 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 electrical apparatus or systems for use in potentially explosive atmospheres

3.5

Ex system

an assembly of interconnected items of Ex apparatus 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

Ex equipment

a general term applying to Ex apparatus, Ex components and Ex systems

3.7

IECEx Certificate of Conformity

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

[ISO/IEC Guide 2: 1996, term 15.5 modified]

3.8

IECEx Mark of Conformity*

* under development

3.9

IECEX Assessment and Test Report (ATR)

a document that presents product design assessment and test results and other relevant information, demonstrating that a product design is in conformity with a specified standard

3.10

Ex Management Committee (ExMC)

the body which administers the operation of the IECEx Scheme 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 Scheme and is responsible to the Ex Management Committee

3.12

Member Body of the IECEx Scheme

a body which has been accepted according to the Basic Rules of the IECEx Scheme, 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

Accepted Certification Body (ACB)

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

3.14

IECEX Assessment and Testing Laboratory (ExTL)

an assessment and 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 for an Accepted 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 standard accepted for use in the IECEx Scheme, might entail non-compliance of that equipment with the relevant national standard

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

2 Those restrictive requirements in a national standard, which do not deviate from the criteria included in the corresponding standard accepted for use in the IECEx 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

transitional arrangements

arrangements for each standard under which Accepted Certification Bodies from countries whose national standard is not identical with the IEC standard and in which IECEx Certificates of Conformity are not accepted, recognize IECEx Assessment and Test Reports, which may include assessment and assessment and testing to national differences, issued by other Accepted Certification Bodies when issuing their own national certificates

3.17

transitional period

period for each standard agreed by the Ex Management Committee and the Member Body of the IECEx Scheme by the end of which the national standard will be identical to the IEC standard and IECEx Certificates of Conformity will be accepted in the Member Body's country

3.18

applicant

a firm or a person who applies to an Accepted Certification Body for obtaining an IECEx Certificate of Conformity or an IECEx Assessment and Test Report

3.19

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

3.20

IECEx Bulletin

bulletin, issued at intervals decided by the Ex Management Committee, containing detailed technical and procedural information about the IECEx Scheme

3.21

IECEx Register

register, issued at intervals decided by the Ex Management Committee, containing information on all Accepted Certification Bodies and IECEx Assessment and Testing Laboratories and listing all IECEx Certificates of Conformity

3.22

IECEx Newsletter

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

3.23

IECEx Quality Assessment Report (QAR)

a document that presents the results of an on-site assessment of a manufacturer's quality control system, by an ACB, to the requirements of the IECEx Scheme

4 Governing of the IECEx Scheme

The IECEx Scheme shall be governed by the Ex Management Committee (ExMC), whose responsibilities in this respect are defined in the Basic Rules of the IECEx Scheme, Publication IECEx 01.

5 Principles of the IECEx Scheme

5.1 The IECEx Scheme provides the means for manufacturers of Ex equipment to obtain certificates of conformity that will be accepted in all participating countries as equivalent to their national certification. A certificate of conformity may be obtained from any certification body accepted into the Scheme. The certificate will attest that the equipment design conforms to the relevant IEC standards and that the manufacturer is manufacturing the product under a quality plan meeting the

requirements of this Scheme. Manufacturers holding certificates of conformity may affix the IECEx Mark of Conformity* to equipment that they have verified as complying with the certified design.**5.2**

An application for a country to participate in the IECEx Scheme is made on a standard by standard basis by the candidate Member Body of the IECEx Scheme for that country. The application is made to the Secretary of the ExMC. Certification bodies and assessment and testing laboratories wishing to be accepted into the Scheme must reside in a participating country. Their application to be accepted is made through the Member Body of the IECEx Scheme for the country in which they reside.

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

5.4 Only ACBs in countries where IECEx Certificates of Conformity are accepted and whose national standards are harmonised to the corresponding IEC Standards can issue IECEx Certificates of Conformity.

5.5 For countries that do not accept IECEx Certificates of Conformity or whose national standards are not yet identical to the IEC standards, a transitional period will be necessary. The transitional period, which could be different for different standards, is to allow time for

- a) the IEC standards and the national standards to be made identical, and
- b) the IECEx Certificates of Conformity to be accepted as equivalent to national certificates.

5.6 A candidate Member Body of the IECEx Scheme, when making an application to participate in the IECEx Scheme, shall provide an undertaking to the ExMC that it will use its best endeavours to assist in the achievement of the objectives of identical standards and national acceptance within the transitional period. If at the end of the transitional period the objectives have not been achieved, the ExMC will review the position with the Member Body of the IECEx Scheme. If, at the time of the review, there is no prospect of the objectives' being achieved in the near future, the country of the Member Body of the IECEx will withdraw from the Scheme.

5.7 ACBs in countries participating in accordance with transitional arrangements shall accept ATRs and QARs, produced by other ACBs, for the purpose of issuing their own national certification. Such ATRs may cover any national differences of the accepting country. An ACB receiving an ATR or QAR may review the documentation for completeness.

5.8 The final objective of the IECEx Scheme is world-wide acceptance of one standard, one certificate and one mark.

6 Confidentiality

All those participating in the IECEx 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.

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7 Participating countries

7.1 In order for a country to participate in the IECEx Scheme, the candidate Member Body of the IECEx Scheme shall make an application to the Secretary of the ExMC in the form of annex A.

7.2 The Member Body of the IECEx Scheme and the ExMC shall agree on the length of any necessary transitional period for the specified standard(s). Separate transitional periods may apply for each standard. The national differences from the IEC standard(s) shall be specified in the application.

7.3 The transitional periods shall end when both

- a) the national standards are identical to the corresponding IEC standards, and
- b) the IECEx Certificates of Conformity are accepted as equivalent to national certificates.

7.4 Once the application has been approved by the ExMC, the country shall be deemed to be a participating country.

7.5 The Member Body of the IECEx Scheme shall notify the ExMC of any changes in the national differences declared in its application.

7.6 At the end of the transitional period the ExMC shall review the situation with the Member Body of the IECEx Scheme to ascertain whether the conditions have been met. If they have not been met but there is the prospect that they will be met in the near future, a further transitional period may be agreed. If there is no reasonable prospect of the conditions' being met, the country shall withdraw from the IECEx Scheme.

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

7.8 In the event of a country's ceasing to be a participating country, the ACBs in that country shall lose the right to issue new IECEx Certificates of Conformity and ATRs. IECEx Certificates of Conformity shall remain valid for a period of 6 months following which they shall be withdrawn.

ATRs and QARs, previously issued shall remain valid.

8 IECEx instruments

8.1 IECEx Certificate of Conformity

8.1.1 An IECEx Certificate of Conformity is issued by an ACB, on the basis of an ATR and QAR, certifying that the type of Ex equipment identified on the Certificate conforms in all relevant respects with the IEC standard(s) specified on the Certificate and that the manufacturer named on the Certificate manufactures the product under quality plans complying with the requirements of this Scheme, as a means of providing adequate confidence that the Ex equipment will be produced in conformity with the design of the certified equipment.

8.1.2 The ExMC shall decide on the layout and content of IECEx Certificates of Conformity.

8.2 IECEx Assessment and Test Report (ATR)

8.2.1 An ATR is prepared by an ExTL and endorsed and issued by an ACB 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.

8.2.2 The ATR shall contain a clear description of the Ex equipment, the name and address of the applicant and the manufacturer and the edition of the IEC 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 ATR shall also contain the information necessary for identification of the Ex equipment such as type designation, ratings, description and photographs.

8.2.3 The ExMC shall decide on the layout and content of ATRs.

8.2.4 During the transitional period, the ATR may include evaluation of the Ex equipment for conformity with declared national differences, and may be used by other ACBs in the national certification of the equipment.

8.2.5 Because ATRs are transitory documents used in the preparation of IECEx Certificates of Conformity, they shall not be used in any form of advertising or sales promotion in order that the information is not misrepresented.

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

8.3 IECEx Quality Assessment Report

8.3.1 A QAR is prepared and issued by an ACB recording the assessment of a manufacturer's quality control system used to ensure the on-going compliance of Ex products with that covered by the ATR. The assessment includes assessing conformity of the manufacturer's quality control system with the requirements of the IECEx Scheme in addition to assessing the implementation of the quality controls by the manufacturer.

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

8.3.3 The QAR shall contain details of the name and address of the manufacturer. It shall give as far as necessary, a brief reference to and identification of examples that provide evidence of compliance for each IECEx quality requirement.

8.3.4 During the transitional period, the QAR may be issued by ACBs for the purpose of acceptance by other ACBs in the national certification of the equipment. The QAR shall refer to a specific manufacturing site.

8.3.5 Because QARs are transitory documents used in the preparation of IECEx Certificates of Conformity, they shall not be used in any form of advertising or sales promotion in order that the information is not misrepresented.

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

8.4 IECEx Mark of Conformity*

9 Certification procedure

9.1 An application for an IECEx Certificate of Conformity may be made by an applicant to any ACB for the relevant standard(s). The applicant may be a manufacturer or may act on behalf of a manufacturer. In the latter case, 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. The Certificate shall be issued in the name of the manufacturer.

9.2 The documentation submitted by the applicant shall 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.

9.3 The applicant shall supply the documentation necessary to specify the explosion protection features of the Ex equipment. The applicant shall supply such samples of the Ex equipment as the ACB deems necessary.

9.4 The ACB shall arrange for an 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 ATR.

* under development

9.5 The ACB shall assess the conformity of the manufacturer's quality plan(s), associated with the quality system, with the requirements of the IECEx Scheme. Refer to IECEx XXXXX . In order to demonstrate how the quality system ensures that equipment is manufactured in conformity with the design of the certified equipment, the manufacturer shall provide the ACB with a copy of a quality plan for the equipment. The manufacturer may provide evidence of the suitability of the quality system such as certification/registration to ISO 9001 by a competent body. The ACB shall take the evidence into account when deciding the extent of the assessment which it needs to conduct. The ACB shall issue an IECEx QAR.

9.6 Upon satisfactory completion of the work, the ACB shall endorse the ATR and QAR which together with an IECEx Certificate of Conformity shall be issued to the applicant, with a copy of each being retained by the ACB. The manufacturer and the ACB shall each retain a set of the documentation referred to in the certificate. The ACB shall send a copy of the Certificate to the Secretary of the ExMC.

9.7 the ACB shall carry out, or arrange for another body to carry out on its behalf, periodic surveillance of the manufacturer's quality system and quality plan(s) as well as periodic examination and, if appropriate, assessment and testing of representative samples of certified Ex equipment. The frequency of such surveillance, inspection and assessment and testing shall be determined by the ACB in the light of the effectiveness of the manufacturer's quality plan(s), but shall not be less than once every year. Such frequency shall take into account whether the manufacturer holds current ISO 9001 certification/registration by a competent body.

9.9 If the manufacturer wishes to make a change to the certified Ex equipment, he shall apply to the ACB which granted the IECEx Certificate of Conformity, describing the change and the measures adopted to ensure continuing conformity with the relevant standard(s). The ACB 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 ACB shall issue an addendum to the Certificate authorizing the change. The layout and content of the addendum shall be specified by the ExMC. The ExMC shall determine the extent of the change which can be accommodated using an addendum to the original Certificate. Major changes could require a new Certificate to be issued.

9.10 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 Mark, could lead to suspension or withdrawal of the IECEx Certificate of Conformity by the ACB.

9.11 The ACB has the right 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.

9.12 An applicant who is not in a 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 Scheme in the form of a surcharge for each application.

9.13 An IECEx Certificate of Conformity may be suspended or withdrawn by the issuing ACB if

- it has been issued in error,
- 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 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 ACB shall give due notice to the manufacturer of such suspension or withdrawal and shall give the reason(s).

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

9.14 When an IECEx Certificate of Conformity has been withdrawn, the Secretary of the ExMC shall be notified as soon as possible by the issuing ACB. Withdrawal of Certificates shall be published in the IECEx Bulletin.

10 Transitional arrangements

10.1 If, during a transitional period, IECEx Certificates of Conformity are not recognized in a participating country, ACBs in such a country shall accept ATRs issued by other ACBs. An ACB may also chose to accept QARs issued by other ACBs when issuing their own national certificates. The work carried out by the ACB receiving an ATR and QAR shall be limited to that which is necessary to

- a) verify compliance with national differences from the IEC standards where those national differences have not been covered by the ACB issuing the ATR, and
- b) adequately identify that the Ex equipment submitted for certification is that which is the subject of the ATR.

10.2 When an applicant applies to an ACB for its national certification or approval of Ex equipment on the basis of an ATR, the application shall be accompanied by a copy of the ATR. In addition, the ACB 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.

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

10.4 The ACB may refuse to recognize the ATR when the standard(s) or the amendments or editions of the standard(s) according to which it was issued is (are) no longer valid in the country of the ACB. Such a change in validity shall have been notified in accordance with 7.5 and listed in the IECEx Bulletin as a national difference.

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10.5 Should the ACB receiving an ATR or QAR for recognition consider it to have been issued in error, the ACB that issued the report shall be informed as soon as possible. If the ACBs involved arrive at different conclusions, the case may be referred to the Board of Appeal.

11 Acceptance of certification bodies and assessment and testing laboratories

NOTE - When an application is made for acceptance of a certification body that intends to employ already accepted IECExTLs, assessment is made according to this clause. Applications for acceptance of a certification body and an associated assessment and 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 A certification body shall be accepted as an ACB by the ExMC and given the right to issue IECEx Certificates of Conformity, ATRs and QARs to specified standards, under the following conditions and according to the procedures stipulated in 11.1.2 to 11.1.15:

- a) the certification body shall be located in a participating country;
- b) the certification body shall operate a recognized certification or approval scheme at national level for the specified types of protection;
- c) 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 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 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;
- d) 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 An application for the acceptance of a certification body for one or more standards accepted for use in the IECEx Scheme shall be made by the candidate certification body, via the national Member Body of the IECEx Scheme.

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

When, during the transitional period, certification or approval is needed 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 ATR. When national differences or other conditions have to be fulfilled, they shall be as declared by the Member Body of the IECEx Scheme and published in the IECEx Bulletin. There shall not be more than one set of national differences for each country.

11.1.3 The candidate certification body shall communicate the following information relevant to the recognition of ATRs 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 The candidate certification body shall be assessed to determine that the conditions according to 11.1.1 are fulfilled. The assessment shall be carried out by three assessors appointed by

the ExMC. The assessment team shall be led by a Lead Assessor appointed by the ExMC and shall include at least one member drawn from an ACB.

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

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.

The Secretary of the ExMC shall manage all assessments to ensure assessments are carried out in a timely manner and in accordance with the requirements of the Scheme.

11.1.5 During the assessment, the assessors shall prepare a draft report which 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 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 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 If the decision of the ExMC is positive, the Secretary of the ExMC shall inform the candidate certification body in writing.

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

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

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

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

The ExMC shall decide whether the extension can be accepted on the basis of the information thus available, or whether a full or limited assessment will be needed.

The matter shall either be submitted to a meeting of the ExMC for decision or handled according to 11.1.12.

11.1.12 The ExMC may delegate the decisions according to 11.1.11 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.

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

11.1.14 An ACB wishing to withdraw from the IECEx Scheme shall notify the Secretary of the ExMC via the Member Body of the IECEx 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.

11.1.15 The acceptance of an ACB may be suspended or withdrawn by the ExMC if that ACB no longer fulfils the conditions of 11.1.1 or if in the opinion of the ExMC, the ACB hampers the aim, operation or development of the IECEx Scheme, fails to take action regarding misuse of IECEx Certificates of Conformity or the IECEx Mark of Conformity*, or violates these Rules. Before such a decision is made, the ACB 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 ACB 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 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 Scheme.

11.2 Acceptance of assessment and testing laboratories

NOTE - Applications for acceptance of a certification body and an associated assessment and 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 Acceptance of a assessment and testing laboratory as an ExTL is subject to the following conditions and to the procedures stipulated in 11.2.2 to 11.2.12:

- a) the assessment and testing laboratory shall be located in a participating country;
- b) an assessment and testing laboratory can operate as an ExTL if it is integral with an ACB, under the complete technical and legal control of an ACB or has a written agreement with an ACB to undertake work with it according to these Rules;
- c) 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 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.

11.2.2 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 Scheme shall be made by the candidate assessment and testing laboratory, via the Member Body of the IECEx Scheme.

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

* under development

11.2.3 The candidate assessment and testing laboratory shall be assessed to determine that the conditions according to 11.2.1 are fulfilled. The assessment shall be carried out by three assessors appointed by the ExMC. The assessment team shall be led by a Lead Assessor appointed by the ExMC and shall include one member from an ACB and one member from an ExTL.

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.

11.2.4 During the assessment, the assessors shall prepare a draft report which 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 The assessors shall submit to the ExMC, with a copy to the representatives of the candidate assessment and testing laboratory, 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 to respond to enquiries regarding its application.

11.2.6 The ExMC shall decide upon the acceptance of the candidate assessment and 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 If the decision of the ExMC is positive, the Secretary of the ExMC shall inform the candidate assessment and testing laboratory in writing.

11.2.8 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

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

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

The ExMC shall decide whether the extension can be given on the basis of the information thus available, or whether a full or limited assessment will be needed.

The matter shall be submitted to the ExMC for decision at a meeting or handled according to 11.2.10.

11.2.10 The ExMC may delegate the decisions according to 11.2.9 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.

11.2.11 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.

11.2.12 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 Scheme.

12 IECEx publications

12.1 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 an IECEx Internet Website. The Register and Bulletin may be produced as one publication.

12.2 The IECEx Register shall be issued at intervals decided by the ExMC. It shall contain a complete listing of

- ACBs and ExTLs,
- manufacturers holding IECEx Certificates of Conformity,
- IECEx Certificates of Conformity issued,
- categories of Ex equipment covered by the IECEx Scheme, and
- standards accepted for use in the IECEx Scheme.

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

- the standards for which ACBs in each country have declared recognition of ATRs,
- national differences for each standard and country as declared by the Member Bodies of the IECEx Scheme,
- important rules in addition to the content of the standards which have to be fulfilled in the countries during the transitional period,
- the standards for which ACBs in each country are authorized to issue IECEx Certificates of Conformity,
- the operation of the IECEx Scheme, to assist the applicants, and

– IECEx Certificates of Conformity withdrawn.

12.4 The IECEx Newsletter shall be used to publicise developments within the IECEx Scheme, including new ACBs and ExTLs joining the IECEx Scheme, matters relating to relevant IEC standards and changes in the Rules.

12.5 The information published in the IECEx publications is based on information given by the Member Bodies of the IECEx Scheme, ACBs 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 ACB or an ExTL that the ExMC cannot resolve, the ExMC or the complainant shall have the right to request the CAB to take appropriate action.

Annex A
(normative)

Application from a candidate Member Body of the IECEx Scheme to become a participating country in the IECEx Scheme

The application from a candidate Member Body of the IECEx for its country to become a participating country in the IECEx Scheme shall be a self-contained document including the following information:

- a) the name of the country;
- b) the name and address of the candidate Member Body of the IECEx Scheme;
- c) the legal status of the candidate Member Body of the IECEx Scheme;
- d) the IEC standard(s) for which participation is sought;
- e) the national standard(s) corresponding to the IEC standard(s) listed in d);
- f) any national differences from the IEC standard(s);
- g) whether or not IECEx Certificates of Conformity are accepted in the country;
- h) where national differences exist or where IECEx Certificates of Conformity are not accepted in the country, a proposed transitional period during which national standards and IEC standards would become identical and acceptance of IECEx Certificates of Conformity would be achieved;
- i) an undertaking that the applicant will abide by the Rules and use its best endeavours to assist in the achievement of the aims and objectives of the IECEx Scheme.

Annex B
(normative)

**Declaration by a certification body applying to become an
Accepted Certification Body**

The declaration by a certification body applying to become an Accepted Certification Body (ACB) 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 Guides 62 and 65,
 - the legal relationship between the body and the assessment and testing laboratory(ies) used in the course of its work (including the case where the assessment and testing 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 Assessment and Test Reports (ATRs) and IECEx Quality Assessment Reports (QARs) when issuing its own national or regional certificates, during the transitional period, and
 - 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 Scheme according to which the body wishes to issue IECEx Certificates of Conformity;
- c) a statement that the body will recognize ATRs produced by other ACBs when issuing its national or regional certificates or approvals, during the transitional period;
- d) a list of the standards accepted for use in the IECEx 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 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 C
(normative)

**Declaration by a assessment and testing laboratory applying for acceptance
as an IECEx Assessment and Testing Laboratory**

The declaration by an assessment and testing laboratory applying for acceptance as an IECEx Assessment and 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 Accepted 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, and
 - 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 Scheme according to which the laboratory intends to conduct tests;
- c) the information required in annex D;
- 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 D

(normative)

Information to be provided by an assessment and testing laboratory in applying for acceptance

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

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

1 Applicant's name and address:

Telephone No:

Telefax No:

2 Test Laboratory* name and address (if different from paragraph 1):

Telephone No:

Telefax No:

3 Senior management

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

3.2 Name and title of the person responsible for the Quality Management System in the assessment and testing laboratory:

3.3 Name and title of the principal contact nominated by the assessment and testing laboratory, and of his deputy:

3.4 Operating departments of the assessment and 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 Test Laboratory*.):

4 Employees

4.1 Total number in Test Laboratory*:

4.2 Total number in assessment and testing laboratory for which recognition is being sought:

4.3 Total number of professionally qualified staff (see also ISO/IEC Guide 25) in the area for which recognition is being sought:

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.

6 Test facilities and services

6.1 List on a separate sheet the assessment and 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 assessment and testing will be performed.

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

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

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

7 Other information

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

7.2 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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8 Quality Management Policy

8.1 Are policy and procedures for the operation of the assessment and testing laboratory contained in a document such as a Quality Manual?

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

8.3 Does the Quality Manual contain procedures for the supervision of any unqualified staff (see also ISO/IEC Guide 25)?

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

9 Work instructions

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

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

9.3 Are documents available for each assessment and testing operation?

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

9.5 Is obsolete data promptly removed from documents, etc.?

10 Personnel

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

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

11 Test equipment and calibration

11.1 Does the Quality Management System specify that the equipment is of an accuracy compatible with the assessment and testing undertaken?

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

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

11.4 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:

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

12 Test procedures

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

Yes/No Particulars
(where appropriate)

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

12.3 Do environmental test facilities exist?

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

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

13 Handling and storage

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

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

13.3 Are storage methods prescribed, including special environments?

13.4 Are there procedures for the inspection of samples in storage?

13.5 Are storage areas accessible only to authorized persons?

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

14 Records

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

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

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

15 Test reports

15.1 Do test reports contain all the information required for such by ISO/IEC Guide 25?

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

16 Preparedness for assessment

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

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

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

Application for assessment as a recognized assessment and testing laboratory

Name of applicant: Name and address of assessment and testing laboratory if different:

Address:

.....

.....

.....

Name of contact: Name of contact:

Title: Title:

Test or series of tests for which recognition is sought:

.....

.....

.....

The assessment and testing laboratory hereby agrees to undertake

- a) to conform to the requirements for a recognized assessment and testing laboratory;
- b) to pay all costs connected with assessment and administration in the pre-recognition stage irrespective of whether or not recognition is granted.

Signed:
(Title)

Date:
