



IECEX OD 009

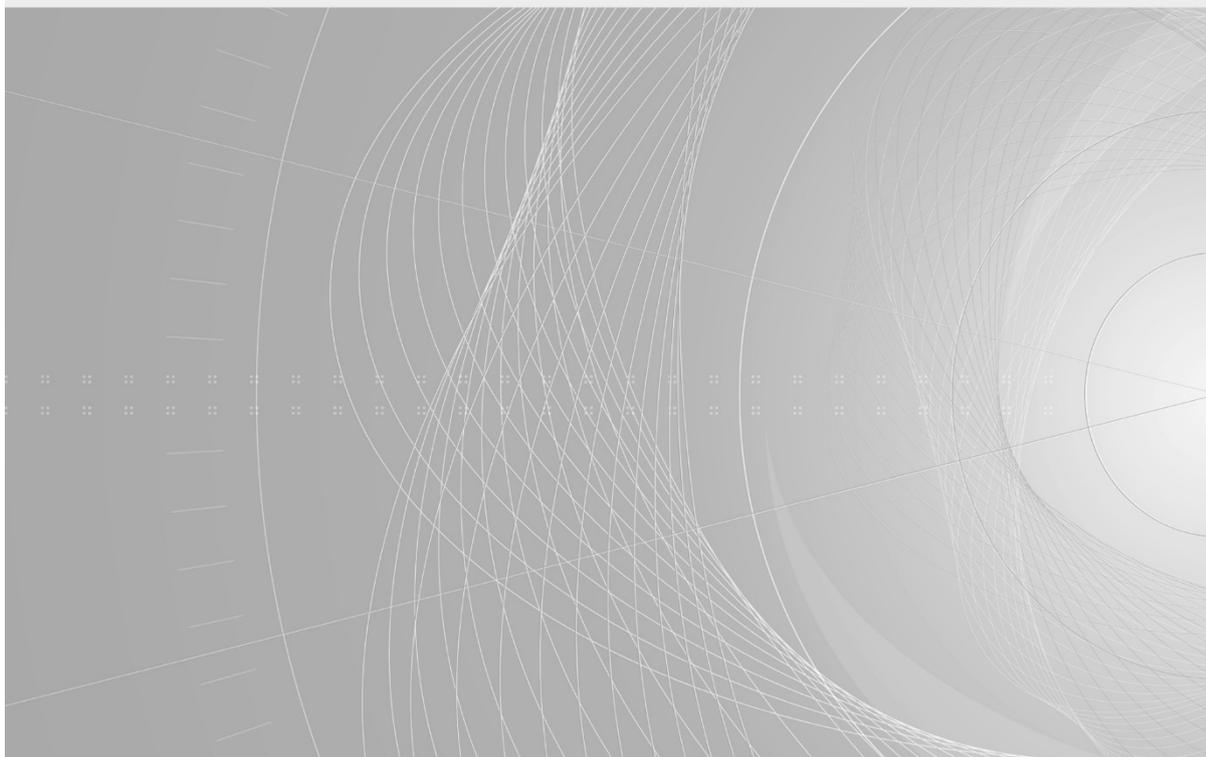
**Edition 4.2
2018 – 10**

IECEX Operational Document

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

**Operational Document - Procedures for the Issuing of
IECEX Certificates of Conformity, IECEx Test Reports
and IECEx Quality Assessment Reports**

OD 009 :2018(e)





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IECEX OD 009

**Edition 4.2
2018 -10**

IECEX OPERATIONAL DOCUMENT

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

**IECEX Certified Equipment Scheme – Procedures for the Issuing of IECEx
Certificates of Conformity, IECEx Test Reports and IECEx Quality
Assessment Reports**

**INTERNATIONAL
ELECTROTECHNICAL
COMMISSION**

INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECEX OPERATIONAL DOCUMENT

IECEX Certified Equipment Scheme

Ex OD 009 Edition 4.2

IECEX Operations Manual – IECEX Certified Equipment Scheme - Procedures for the Issuing of IECEX Certificates of Conformity, IECEX Test Reports and IECEX Quality Assessment Reports

This Operational Document, OD 009 sets out the procedures for the processing of applications for IECEX Certificates of Conformity (CoC), IECEX Test Reports (ExTRs), IECEX Quality Assessment Reports (QARs), in accordance with the Rules and Procedures IECEX 02.

Attention is drawn to IECEX Operational Document OD 033 for the procedures to be used when issuing IECEX Unit Verification Certificates of Conformity.

Document History

| Date | Summary |
|---------|--|
| 2003 06 | Original Issue (Version 1) |
| 2010 08 | Edition 2 includes: <ul style="list-style-type: none"> • clarification over the situation of applications for CoCs where manufacturers already hold IECEX Certification for other products and valid QARs • Inclusion of Section 3 “Changes to Certification” • Clarification of IECEX On-Line Registration of ExTRs and QARs |
| 2012 05 | Edition 3 includes: <ul style="list-style-type: none"> - Updated references to new ISO/IEC 80079-34 - Clarification of various stages |
| 2016 | Edition 4.0 as approved for publication via ExMC Decision 2016/42 regarding ExMC/1154/DV includes a number of text changes that have been included to improve clarity and in response to ExMC Decision 2016/41 regarding ExMC/1152/CD |
| 2017-10 | Edition 4.1 as approved via ExMC Decision 2017/36 regarding ExMC/1250/DV that incorporates changes to Step 6 of Section 1 as recommended by ExMC WG1 from their May 2017 meeting. |
| 2018-10 | Edition 4.2 as approved via ExMC Decision 2018/37 regarding ExMC/1392/DV and additional edits agreed during the 2018 ExMC Meeting. |

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Introduction

This document is supplementary to the Operational manuals and procedures operated by IECEX Certification Bodies (ExCBs) and IECEX Test Laboratories (ExTLs) for the purpose of ensuring a thorough and consistent assessment of applications for either an:

- IECEX Certificate of Conformity
- IECEX Test Report (ExTR)
- IECEX Quality Assessment Report (QAR)

The IECEX Certified Equipment Scheme of the IECEX System is modelled on an ISO Type 5 Certification System with the rules, IECEX 02, requiring that both an ExTR (covering product testing) and a QAR, covering the same product, be issued in order that an ExCB may then issue an IECEX Certificate of Conformity. This is shown in the flowchart contained in Section 1.

This IECEX Operational Document comprises 5 Sections:-

- **Section 1*** – Procedures for the Issuing of an IECEX Certificate of Conformity
- **Section 2** – Procedures for the Issuing of an IECEX Test and Assessment Report (ExTR)
- **Section 3** – Procedures for the Issuing of an IECEX Quality Assessment Report (QAR)
- **Section 4** – Surveillance Audits - Procedures for maintaining validity of an IECEX Certificate of Conformity
- **Section 5** – Procedures for the processing of changes to issued IECEX Certificates of Conformity

The procedures are set out in table form identifying:

- Step number showing the link between flowcharts and table
- Description of the activity
- Related documents
- Responsible person or party
- Additional comments and remarks where appropriate

This operational document also captures previous decisions of the IECEX Management Committee concerning the use of “previously obtained” test data and the procedures for the compiling and issuing of ExTRs.

The preparation of this document has been done so with the aim of alignment with various ISO/IEC International Standards and Guides, including but not limited to the following:

- ISO /IEC Guide 28 General rules for a model third-Party certification System for products
- ISO/IEC Guide 27 Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
- ISO/IEC Guide 53 Conformity assessment — An approach to the utilization of an organization's quality management system in product certification
- ISO/IEC 17065 General requirements for bodies operating product certification systems
- ISO 10011 series Guidelines for auditing quality systems

SECTION 1 – Procedures for the Issuing of an IECEX Certificate of Conformity

This Section is to be applied by ExCBs and ExTLs when processing new applications for:

- IECEX Certificate of Conformity

These steps are in line with the requirements of ISO/IEC 17065, *General requirements for bodies operating product certification systems*, in addition to the requirements as laid down in the IECEX Scheme rules, IECEX 02.

Section 1 also refers to Annex A for the criteria for use of previous test data and Annex B for criteria concerning the use of quality system assessment and audit results obtained prior to the application for an IECEX Certificate of Conformity being lodged.

The procedures detailed in IECEX OD 033 are to be followed when issuing an IECEX Unit Verification Certificate of Conformity.

IECEX OD 017 , Drawing and documentation Guidance for IEC Ex Certification – for use by Manufacturers and ExTLs is also a useful reference document in the application of IECEX OD 009.

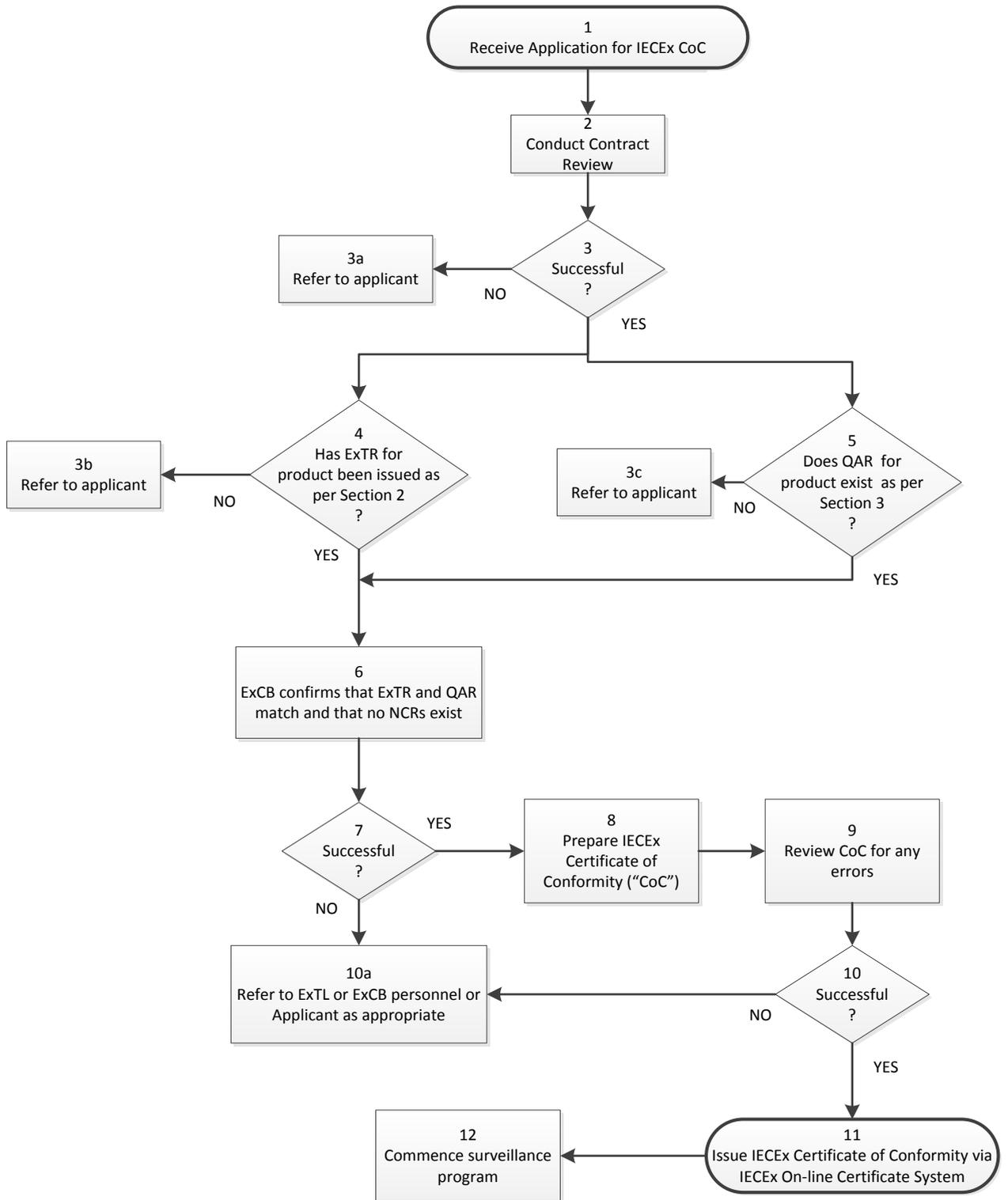


Figure 1. Process for issuing an IECEx Certificate of Conformity

| Step | Section 1- Procedures for the Issuing of an IECEx Certificate of Conformity under the Equipment Certification Program of the IECEx Scheme - Description of Activity | Related Documents | By Whom | Notes/Comments |
|------|--|---|--------------------------------|---|
| 1 | Application received in accordance with IECEx 02. For applications for IECEx Unit Verification Certificates of Conformity, refer to IECEx OD 033. | IECEX 02 | ExCB | Applications for an IECEx Certificate of Conformity can only be made for an IEC or ISO International Standards and shall be made for the current edition or one edition prior. It should be noted that an IECEx Certificate of Conformity may be issued for Unit Verification, the procedures for which are detailed in OD 033 |
| 2 | Contract review to be conducted by the ExCB receiving the application, in accordance with the ExCB's own Quality System and as required by ISO/IEC 17065. Contract review shall include: <ul style="list-style-type: none"> • A review to ensure that the application is within the scope of acceptance of the ExCB and associated ExTL • Whether the manufacturer has an established quality management system • Whether a surcharge applies for manufacturers from non-member countries (Refer to OD 019, IECEx System Fees) • Estimation of costs and time to complete project • Determination of any special requirements, eg travel for site audit etc. • Agreement on method and system of payment by applicant, in accordance with ExCB's own policy and quality system | ExCBs own Certification procedures as included in their Quality System as required by ISO/IEC 17065 | ExCB | The results of the contract review shall be documented and recorded. |
| 3 | ExCB shall only proceed where the contract review has been successfully completed | | ExCB | |
| 3a | Where unsuccessful, ExCB shall communicate in writing to the applicant with the applicant free to amend their application or select another ExCB, when the ExCB's scope of IECEx acceptance does not cover the application. | | ExCB | |
| 3b | Where successful, ExCB shall provide in writing to the applicant an offer describing the scope of work involved, the applicable technical and IECEx | | ExCB receiving the application | |

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| | system requirements, testing and certification costs and time until issuing the ExTR and/or CoC, provided all tests passed satisfactorily. | | | |
| 4 | An ExTR(s) covering the product(s) that are to be listed on the CoC must exist and be in the possession of the ExCB. Where an ExTR does not exist then the process of Section 2 of this OD 009 shall be followed. When completed the IECEX CoC application process may proceed according to this Section 1 | | | A single ExTR may only cover partial assessment testing therefore it may not be uncommon for a single CoC to make reference to more than one ExTR |
| 5 | A valid (with respect to the "Valid until:" date) IECEX QAR covering the product(s) / technology (e.g. Types of Protection and where necessary Ex performance related standards) and the manufacturing locations that are to be listed on the CoC must exist with at least the QAR Summary being in the possession of the ExCB. Where a QAR does not exist or does not cover either the Ex protection technique or any of the manufacturing locations, then the process of Section 3 of this OD 009 shall be followed. When completed the IECEX CoC application process may proceed according to this Section 1 | | | It is not intended that an assessment covered by a QAR is repeated by a receiving ExCB |
| 6 | <p>The ExCB to whom the application for an IECEX Certificate of Conformity was made shall conduct a certification review, in accordance with their quality management system, ensuring among others</p> <ul style="list-style-type: none"> • ExTR(s) relate to the same product(s) listed on the Certificate • Any major Non Conformances have been successfully closed • All stages of the certification process have been documented and followed, including those contained in this manual • The ExCB has signed a commitment to abide by the rules of the IECEX Scheme and ExCB's certification conditions • The applicant and the manufacturer, if different from the applicant, are aware of their obligations under the scheme, including ensuring that any promotional material does not contain misleading information that may infer products NOT covered by IECEX certification <p>and also ensuring that the person(s) conducting this review of the ExTR have NOT been involved in evaluation work for this particular certification project.</p> <p>The ExCB shall review the manufacturer's QAR Summary Report <u>and QAR Summary Report(s) of all Manufacturing Locations and Production Site(s)</u>, ensuring that</p> <ol style="list-style-type: none"> a) type of protection b) applicable Ex performance standards c) product type d) manufacturing location / production site e) validity date | IECEX 02 ISO/IEC 80079-34 OD 005 OD 025 OD 026 | ExCB | <p>ISO/IEC 80079-34 replaces OD 005.</p> <p>Refer ExTAG/247A/Inf for the transitional arrangements concerning the withdrawal of OD 005 and introduction of ISO/IEC 80079-34</p> |

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| | f) issuing ExCB still competent/approved of the product to be certified are covered and valid. | | | |
| 7 | Where Step 6 is not successful then the matter may be referred to the ExCB responsible for the ExTR and QAR. Once matters are resolved then the process may continue according to this Section 1 | | | |
| 8 | IECEX Certificate of Conformity shall be compiled using the IECEX On-Line Certificate system via the password protected system. OD 011 Part 2 provides step by step guidance on creating a CoC via the On-Line Certificate system. | Refer IECEX website OD 011 Part 2 | The person authorised to issue IECEX Certificates of Conformity within the ExCB to whom the original application was made | OD 011 Part 2 provides a detailed step by step guide to creating IECEX On-Line CoCs Contact the IECEX Secretariat for any questions or concerns |
| 9+10 | A draft of the IECEX Certificate of Conformity is to be reviewed for errors. It may be beneficial to pass a draft copy to the applicant for them to assist in the final review prior to issuing the certificate. Every attempt shall be made to correct errors prior to issuing the certificate | Original application form submitted by the applicant. | The person authorised to issue IECEX Certificates of Conformity within the ExCB to whom the original application was made The applicant should also be given the opportunity to review | Contact the IECEX Secretariat for any questions or concerns |
| 10a | Where questions are raised during the final certification review these need to be raised with the relevant ExTL and or ExCB personnel and resolved prior to issuing the Certificate | ExCB and ExTL internal procedures | ExCB staff conducting certification review | |
| 11 | Once the Certificate is considered correct, a Certification Review record shall be created, signed and dated. The IECEX Certificate is issued by setting status = "Current" on the IECEX On-Line Certificate System when logged in with the Level 2 username and passwords allocated by the IECEX Secretariat (refer to IECEX OD 011-2 for details) This will be regarded as making the certification decision as defined by ISO/IEC 17065. The applicant being informed in writing by the ExCB, via letter, fax or E-mail | | The person authorised to issue IECEX Certificates of Conformity within the ExCB to whom the original application was made (noting that an ExCB may establish procedures that permit a deputy to sign in the absence of the 'authorised person'. | Contact the IECEX Secretariat for any questions or concerns NOTE: there is a period of two weeks within which changes to an issued Certificate can be made by the ExCB. After this period please contact the IECEX Secretariat to arrange for corrections |

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| <p>12</p> | <p>Certification Maintenance begins, with the ExCB issuing the IECEX Certificate of Conformity being responsible for the on-going maintenance of the certificate which shall include:-</p> <ul style="list-style-type: none"> • Conducting of surveillance assessments / audits is covered by the QAR process. • Responding to public inquiries regarding the certificate • Taking necessary action when aware of possible breaches by the applicant, eg claims that product not the subject of IECEX Certificate of Conformity are being claimed as "IECEX Certified" | <p>IECEX 02 OD 025 ISO/IEC Guide 62 ExCB's own quality management system</p> | <p>Management of the ExCB that issued the IECEX Certificate of Conformity in coordination with the original ExCB</p> | <p>Contact the IECEX Secretariat for any questions or concerns</p> |
|------------------|---|--|--|--|

SECTION 2 – Procedures for the Issuing of an IECEx Test and Assessment Report (ExTR)

This Section is to be applied by ExCBs and ExTLs when processing new applications for:

- IECEx ExTR according to the IECEx 02 Rules

These steps are in line with the requirements of ISO/IEC 17065, *General requirements for bodies operating product certification systems*, in addition to the requirements as laid down in the IECEx Scheme rules, IECEx 02.

This Section 2 also refers to Annex A for the criteria for use of previous test data.

2.1 DEFINITIONS

To be read in conjunction with Clause 8.1.1 and Section 8.2 of IECEx 02.

ExTR

Abbreviation of “IECx Test Report”.

A document that provides “clause –by-clause” evidence of conformity of equipment with all relevant requirements of a particular Standard and Edition thereof.

ExTR Package

An ExTR Package comprises an ExTR Cover Sheet and one or more associated ExTR documents (which may include ExTRs, ExTR Addendums and ExTR of National Differences).

All ExTR Package documents are compiled and reviewed by the ExTL and are then endorsed by an issuing ExCB on an ExTR Cover Sheet to indicate final approval of the overall ExTR Package

ExTR Cover Sheet

An ExTR Cover is the sole top-level document that shall be used by ExCBs to associate together all other parts of an IECEx Test Report (ExTR) Package and shall be used for all IECEx ExTRs.

ExTR Addendum

An ExTR Addendum can be used to supplement an already issued Ex Test Report and is to be accompanied by a single ExTR Cover Sheet, which is to be approved by the ExCB following compilation and review by an ExTL.

Only those clauses applicable to the supplemental issue being addressed are to be tabulated and remarked upon as part of this document. An ExTR Report of National Differences may also supplement this ExTR Addendum.

ExTR of National Differences

This type of document can be used to supplement an Ex Test Report or ExTR Addendum, with a separate such document issued for each intended country / region. All National Differences of the intended country / region are to be tabulated and remarked upon as part of this document. An Ex Test Report of National Differences is compiled and reviewed by an ExTL.

ExTR of Partial Testing

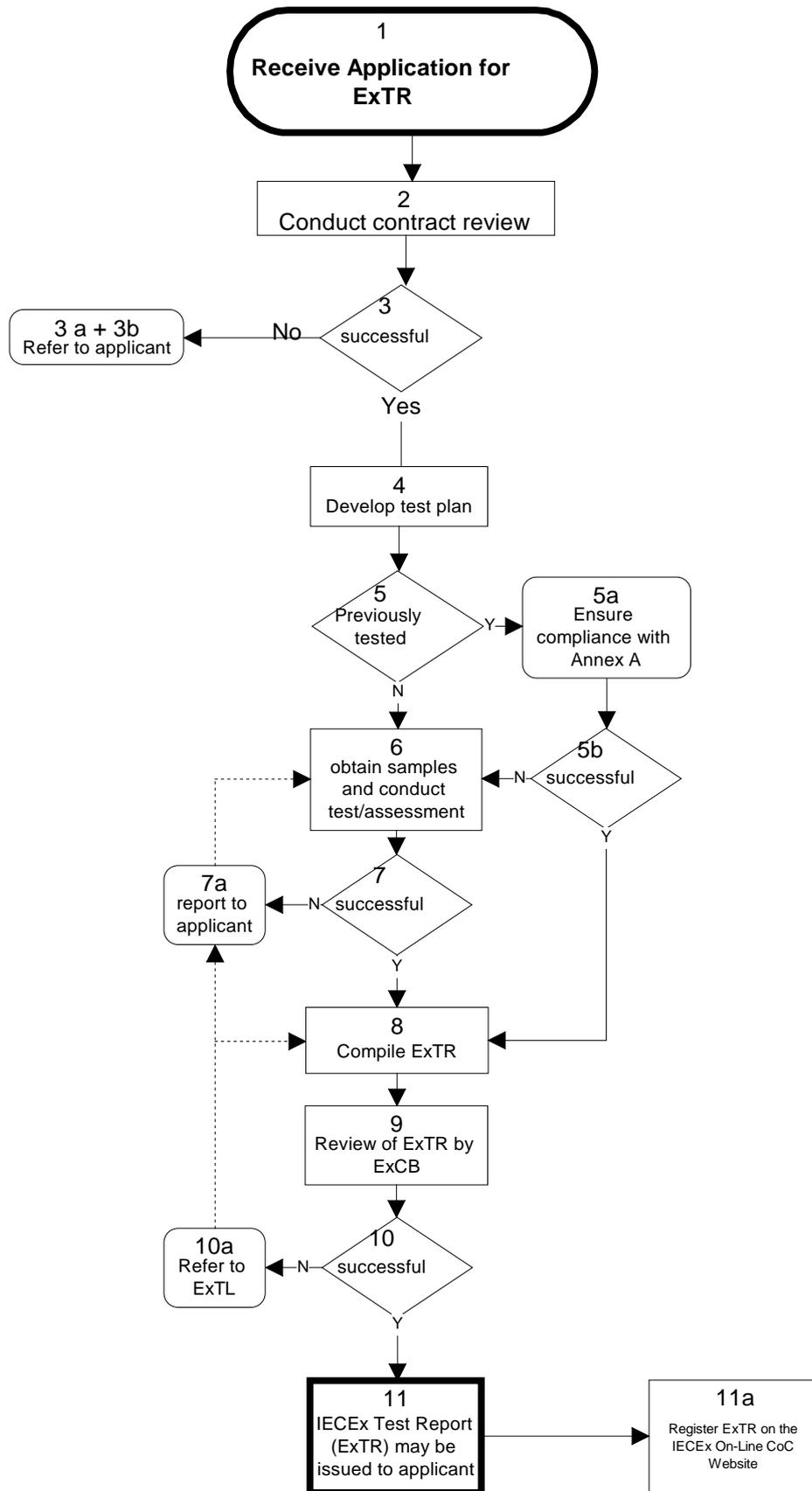
An ExTR of Partial Testing provides a clause-by-clause documentation of the initial evaluation and testing that verified compliance of an item or product with only select requirements from an IEC Ex standard. This ExTR of Partial Testing can form part of an ExTR Package that may include other Ex Test Report, Addendum and National Differences documents, along with a single ExTR Cover Sheet. An ExTR of Partial Testing is to be compiled and reviewed by the ExTL. The Issuing ExCB indicates final approval of the ExTR of Partial Testing as part of the overall ExTR Package on the associated ExTR Cover Sheet.

ExTR Summary

An electronic document published on the IECEx On-line Certificate System to indicate that an ExTR has been endorsed by an ExCB and registered on the IECEx On-line Certificate System for the use in preparing IECEx Certificates of Conformity. This electronic document contains only a summary of some key elements of the ExTR.

ExTR Blank Report Forms

Official templates prepared and maintained by IECEx Working Groups that shall be used by accepted IECEx Certification Bodies and Ex Test Laboratories to prepare ExTRs. These are available from www.iecex.com



Process for Issuing and IECEX Test and Assessment Report (ExTR)

| Step | Section 2- Procedures for the Issuing of an IECEX Test and Assessment Report (ExTR) under the Certified Equipment Program of the IECEX Scheme - Description of Activity | Related Documents | By Whom | Notes/Comments |
|------|---|--|--|--|
| 1 | Application received in accordance with IECEX 02. The scope of testing and assessment covered by an ExTR can cover all or partial requirements of an International Standard | IECEX 02 | ExCB | Applications for an IECEX ExTR can be made for an International IEC or ISO Standard |
| 2 | <p>Contract review to be conducted by the ExCB receiving the application, in accordance with the ExCB's own Quality System and as required by ISO/IEC 17065. Contract review shall include:</p> <ul style="list-style-type: none"> • A review to ensure that the application is within the scope of acceptance of the ExCB and associated ExTL • Whether a surcharge applies for manufacturers from non- member countries (Refer OD 019) • Estimation of costs and time to complete project • Agreement on method and system of payment by applicant, in accordance with ExCB's own policy and quality system | ExCBs own Certification procedures as included in their Quality System and required by ISO/IEC 17065 | ExCB | The results of the contract review shall be documented and reported to the applicant. |
| 3 | ExCB shall only proceed where the contract review has been successfully completed | | ExCB | |
| 3a | Where unsuccessful, ExCB shall communicate in writing to the applicant with the applicant free to amend their application or select another ExCB, when the ExCB's scope of IECEX acceptance does not cover the application | | ExCB | |
| 3b | Where successful, ExCB shall provide in writing to the applicant an offer describing the scope of work involved, the applicable technical and IECEX system requirements and certification costs and time until issuing the ExTR and / or CoC, provided all tests passed satisfactorily. | | ExCB receiving the application | |
| 4 | <p>Develop Test and assessment plan, especially where model ranges are involved in the application. The ExCB in conjunction with its associated ExTL need to be satisfied that samples selected for testing are representative of models covered by the application.</p> <p>The ExTL shall apply all relevant EXTAG Decisions Sheets, IECEX Operational Documents, relevant Standards and corrigenda, amendments and I-SHs that apply to the product or Standard relevant to the application</p> | | ExCB in conjunction with its associated ExTL | A test plan is required for each application even where it is intended to utilise previously obtained test data to ensure that the original test plan is still relevant for this new application |

| Step | Section 2- Procedures for the Issuing of an IECEx Test and Assessment Report (ExTR) under the Certified Equipment Program of the IECEx Scheme - Description of Activity | Related Documents | By Whom | Notes/Comments |
|--------|--|--|---|--|
| 5 | Where products, components or systems are covered by the application, have been previously tested without ExTR being issued and the applicant wishes to utilise these tests then steps 5a and 5b may be applied | Annex A to this document | ExCB and ExTL | IECEX OD 010 may also be of assistance |
| 5a | <p>A review of the previous test data shall include:</p> <ul style="list-style-type: none"> • Determination whether the test requirements, methods and pass/fail criteria used previously are the same as those contained in the standard for which application is made • Facilities and methods previously used are still appropriate | Annex A to this document | ExTL | Note that it is still essential that an ExTR be completed and registered on the IECEx On-Line Certificate system even when using previously obtained test data |
| 5b | <p>A file note is required to act as a record to demonstrate the outcome of the assessment to Annex A</p> <p>Such file note shall be retained on the ExTL's records for possible review by an IECEx Assessment Team conducting surveillance or re-assessment of the ExTL</p> | | ExTL | |
| 6 | <p>Samples to be obtained by the ExTL and tests and assessments conducted as required by the Standard.</p> <p>The requirements of both IECEx 02 and IECEx Operational Document OD 010 shall be followed.</p> | IECEX 02 IECEX OD 010 | ExTL | Note: The ExTL should check the list of ExTAG Decision Sheets to see if there are any that relate to the product under test. |
| 7 + 7a | Where testing and assessments are unsuccessful, then such results and any non-conformances identified during the assessment shall be reported to the applicant, in writing, requesting corrective action. Such action may include modification of the design and provide new samples for testing or amend their original application or withdrawing their application. | | ExTL but will need to consult with the ExCB for instances where the original application is amended | |
| 8 | <p>The relevant IECEx Test Report (ExTR) Blank Report Forms for the relevant Standard(s) and Edition(s) thereof shall be used to prepare and compile an ExTR.</p> <p>An ExTR shall also be compiled by the ExTL when utilising previously obtained test data. This may mean transferring information from a previously issued test report into the ExTR format</p> | IECEX Standard ExTR Blank Forms available from the IECEx Website | ExTL | Note: ExTRs were previously called ATRs. Old ATR blanks can still be used while they are being updated to reflect the new terminology |

| Step | Section 2- Procedures for the Issuing of an IECEX Test and Assessment Report (ExTR) under the Certified Equipment Program of the IECEX Scheme - Description of Activity | Related Documents | By Whom | Notes/Comments |
|-------------|---|------------------------------------|--|---|
| 9 | ExTR to be reviewed by the ExCB prior to being issued by the ExCB, with whom the ExTL is associated. If successful, the ExCB shall prepare the ExTR cover sheet and compile the ExTR package encompassing all ExTRs | | ExCB | |
| 10 + 10a | Where the review by the ExCB is unsuccessful, this shall be referred to the ExTL for correction or may be referred back to the applicant for their action, similar to step 7 and 7a, depending on the nature of the problem detected during the ExCB's review | | ExCB The applicant should also be given the opportunity to review | When ExCBs and ExTLs are within the one organisation, the ExTR review shall be conducted by a staff member not involved or responsible for the tests/ assessments |
| 11 | The ExTR Package may now be issued to the applicant or retained for duration of the IECEX CoC procedure. Where the manufacturer or the applicant is located in a non-member country, the ExCB shall, arrange for payment to the IECEX account of the surcharge, refer to OD 019, IECEX System Fees | | ExCB | Where a valid ExTR already exists, this may be used for the purpose of issuing an IECEX CoC without the repeating the tests. ExTRs issued prior to the date of application for an IECEX CoC may only be used where it has been confirmed that the testing requirements are the same as those of the Standard for which a CoC is to be issued and that the product has not included any change in design that may affect the Ex protection |
| 11a | ExCB to register the ExTR via the creation of an ExTR Summary on the IECEX On-Line Certificate System on the IECEX Website @ www.iecex.com The On-Line Certificate System provides a reference source of key information that can be searched by Manufacturer, ExTL, ExTR reference Number, Standards and so on. This enables the future use of the ExTR for the purpose of issuing an IECEX Certificate of Conformity by linking it and the relevant QAR Summary to the Certificate, Refer to OD 011 Parts 1 and 2 for further information | OD 011 Part 2 IECEX Website | ExCB | OD 011 Part 2 provides a detailed step by step guide to registering an ExTR on the IECEX On-Line Certificate System Contact the Secretariat for any assistance |

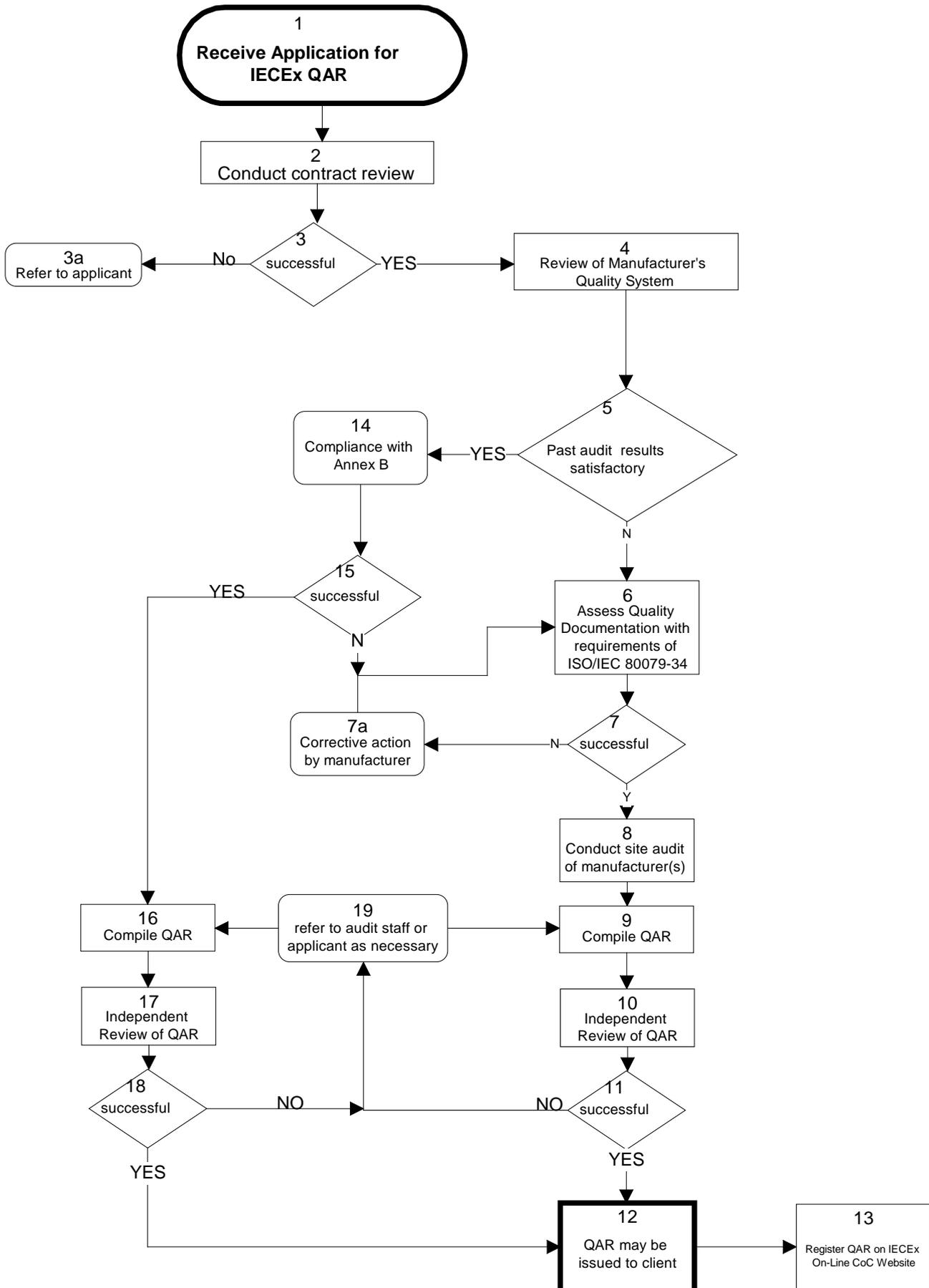
SECTION 3 – Procedures for the Issuing of an IECEx Quality Assessment Report (QAR)

This Section is to be applied by ExCBs when processing new applications for :

- o IECEx QAR according to the IECEx 02 Rules

These steps are in line with the requirements of ISO/IEC 17065, *General requirements for bodies operating product certification systems*, in addition to the requirements as laid down in the IECEx Scheme rules, IECEx 02.

This Section 3 also refers to Annex B for criteria concerning the use of quality system assessment and audit results obtained prior to the application for an IECEx Certificate of Conformity being lodged.



Process for Issuing an IECEX Quality Assessment Report (QAR)

| Step | Section 3- Procedures for the Issuing of an IECEx Quality Assessment Report (QAR) under the Certified Equipment Program of the IECEx Scheme - Description of Activity | Related Documents | By Whom | Notes/Comments |
|------|--|--|---------|--|
| 1 | Application received in accordance with IECEx 02 | IECEX 02 | ExCB | Applications for an IECEx Certificate of Conformity can only be made for an IEC or ISO International Standard. |
| 2 | <p>Contract review to be conducted by the ExCB receiving the application, in accordance with the ExCB's own Quality System and as required by ISO/IEC 17065. Contract review shall include:</p> <ul style="list-style-type: none"> • A review to ensure that the application is within the scope of acceptance of the ExCB and associated ExTL • Whether the manufacturer has an established quality management system • Whether a surcharge applies for manufacturers from non-member countries (Refer to OD 019) • Estimation of costs and time to complete project • Determination of any special requirements, eg travel for site audit etc. • Agreement on method and system of payment by applicant, in accordance with ExCB's own policy and quality system | ExCBs own Certification procedures as included in their Quality System and ISO/IEC 17065 | ExCB | <p>The results of the contract review shall be documented and recorded.</p> <p>ISO/IEC 80079-34 replaces OD 005. Refer ExTAG/247A/Inf for the transitional arrangements concerning the withdrawal of OD 005 and introduction of ISO/IEC 80079-34</p> |
| 3 | ExCB shall only proceed where the contract review has been successfully completed | | ExCB | |
| 3a | Where unsuccessful, ExCB shall communicate in writing to the applicant with the applicant free to amend their application or select another ExCB, when the ExCB's scope of IECEx acceptance does not cover the application | | ExCB | |
| 4 | <p>The ExCB must review the manufacturer's quality management system to ensure compliance with ISO/IEC 80079-34 by either:</p> <ol style="list-style-type: none"> 1) Conduct a site audit of the manufacturing location(s); or 2) For manufacturers previously audited, conduct a document review of past audits and other documentation to cover new products, review the QAR summary report at the IEC Ex WEB site to ensure, that the product type, type of protection and manufacturing locations and all IECEx CoCs are covered by a valid QAR. | OD 025 ISO/IEC 80079-34 | ExCB | <p>The previous OD 005-1, Part 1 has been replaced by ISO/IEC 80079-34 However OD 005-2, Part 2 provides a checklist for the requirements listed in ISO/IEC 80079-34</p> <p>ExTAG/247A/Inf sets out the transitional arrangements from OD 005-1 to</p> |

| Step | Section 3- Procedures for the Issuing of an IECEx Quality Assessment Report (QAR) under the Certified Equipment Program of the IECEx Scheme - Description of Activity | Related Documents | By Whom | Notes/Comments |
|--------|---|--------------------------------------|---|--|
| | <p>Situation 2) above takes into account where the manufacturer has been previously audited for the purposes of a previous IECEx application. When conducting a review according to situation 2) above, the ExCB receiving the application must consider at least the following:-</p> <ul style="list-style-type: none"> • The scope and product types covered by the previous audit; • The time since the previous audits and where more than 1 year ago should consider that a new audit may be required • The results of the past audits • Any changes in management, manufacturing etc since the last audit | | | ISO/IEC 80079-34 |
| 5 | <p>Where an audit of the manufacturer has taken place by the ExCB for a related program and within the last 18 months, such results may be used where the applicant wishes to do so.</p> <p>To rely on past audits, for new applications, it is necessary to demonstrate that the production of equipment, to be covered by new Certificates, was included as part of the previous audit.</p> | Refer Annex B | ExCB | |
| 6 | <p>Assessment of the manufacturer's quality management system procedures that relate to the manufacture of Ex products to be covered by new IECEx Certificates of Conformity. Generally this will relate to the detailed product quality plans. The assessment shall ensure that all requirements contained in ISO/IEC 80079-34, as they relate to the product, are adequately addressed by the Manufacturer's quality system procedures and work instructions.</p> <p>This step may also be termed the "Documentation Review"</p> | ISO/IEC 80079-34 OD 025 OD 026 | ExCB or by another ExCB working under direction by the ExCB to which the original application was made. | The document review may be conducted prior to the on-site audit, at the ExCB premises or on-site at the manufacturers premises as part of the on-site audit. Where different manufacturing sites are involved the ExCB should satisfy itself that the same quality plans are used. If not then each manufacturing location must be treated separately with separate assessments and site audits for each location. |
| 7 + 7a | Relevant manufacturer's quality system documentation is to be reviewed to verify that documentation complies with the requirements of ISO/IEC 80079-34 | ISO/IEC 80079-34 OD 025 | ExCB or by another ExCB working under direction by the ExCB to which the original | OD 025 includes a checklist of ISO/IEC 80079-34's documentation requirements. |

| Step | Section 3- Procedures for the Issuing of an IECEx Quality Assessment Report (QAR) under the Certified Equipment Program of the IECEx Scheme - Description of Activity | Related Documents | By Whom | Notes/Comments |
|------|---|--|--|---|
| | <p>Where serious deficiencies in the manufacturer's documented quality plans may give rise to non-complying product being produced, these shall be raised by the ExCB as major non-conformances and the applicant and manufacturer are required to take action to correct this situation (usually by the introduction or amendment of quality plans), prior to proceeding with the issue of an IECEx Certificate of Conformity.</p> <p>Where non-compliance with various clauses of ISO/IEC 80079-34 are judged to be of a minor nature by the ExCB, the process of on-site auditing may continue</p> | OD 026 | application was made, for manufacturers located in different countries | |
| 8 | <p>The ExCB conducts on-site audit This on-site audit shall seek to verify that relevant quality system procedures and work instructions are in place and that there are records and evidence to demonstrate that the requirements of ISO/IEC 80079-34 are being met by the manufacturer(s)</p> <p>OD 025 provides guidance in the management of assessments of manufacture's quality system and shall be used by all ExCBs</p> <p>OD 026 provides guidelines for the qualification of ExCB auditors conducting IECEx audits.</p> <p>F-001 and F-002 are IECEx QAR forms and Nonconformity Report Forms respectively, available from the IECEx website at http://www.iecex.com/QAR_Forms.htm</p> | ISO/IEC 80079-34 OD 025 OD 026 F-001 F-002 | ExCB , for manufacturers located in different countries | Where the Ex product is manufactured in different locations, especially different countries each location shall be audited |
| 9 | <p>A Quality Assessment Report (QAR) of the assessment/audit of the manufacture's quality system, including site audit, shall be compiled by the ExCB</p> <p>Where serious deficiencies in the manufacturer's documented quality plans may give rise to non-complying product being produced, these shall be raised by the ExCB as major non-conformances and the applicant and manufacturer are required to take action to correct this situation (usually by the introduction or amendment of quality plans), prior to proceeding with the issue of an IECEx Certificate of Conformity.</p> <p>Where non-compliance with various clauses of ISO/IEC 80079-34</p> | ISO/IEC 80079-34 OD 025 F-001 F-002 | ExCB conducting the audit/assessment | Generally this will be the ExCB to whom the application has been made, but may be compiled by another ExCB requested to conduct the audit |

| Step | Section 3- Procedures for the Issuing of an IECEx Quality Assessment Report (QAR) under the Certified Equipment Program of the IECEx Scheme - Description of Activity | Related Documents | By Whom | Notes/Comments |
|------|---|--|--|--|
| | are judged to be of a minor nature by the ExCB, the process may continue | | | |
| 10 | <p>An independent review of the QAR shall be conducted within the ExCB to whom the original application was made.</p> <p>The independent review shall be conducted by a staff member of the ExCB that is not responsible for the audit.</p> | In accordance with the ExCBs own quality management system | | This independent review is to ensure that a complete assessment and audit has taken place and that the recommendations are in line with the audit findings and any NCRs and related corrective actions |
| 11 | <p>The ExCB to which the application for an IECEx CoC or QAR has been made shall determine that the QAR is complete and complies with the following:</p> <ul style="list-style-type: none"> • IECEx rules and procedures • ExCBs own quality management system • All NCRs provide a clear description of their nature • Shows a clear relationship to the products covered by the ExTR(s), which are the subject of the IECEx Certificate of Conformity, where part of the original application <p>Where discrepancies are identified they shall be immediately raised within the ExCB and a further review of steps 14 – 17 are conducted by the ExCB to confirm all details remain relevant.</p> <p>The applicant and or IECEx Secretary may need to be informed where errors or discrepancies are of a major nature, eg incorrect audit personnel conducting the audit or insufficient audit depth revealed.</p> | <p>ISO/IEC 80079-34</p> <p>OD 025 ExCB's own quality management system</p> | Final decision being taken by the ExCB to which the original application has been made | The review should also ensure that the principles and guidelines of OD 025 have been followed |
| 12 | The final Quality Assessment Report (QAR) shall be issued, by the ExCB to whom the original application was made, to the applicant and a copy retained on the ExCB file. | F-001 | ExCB to whom the original application was made | F-001 provides the QAR report format while F-002 provides the format for Non Conformity Reports |
| 13 | <p>ExCB to register the QAR on the IECEx On-Line Certificate System on the IECEx Website @ www.iecex.com by creating a QAR Summary Report which is an electronic document that summarises some key elements of information from the QAR.</p> <p>The publishing of a QAR Summary Report on the On-Line Certificate System creates a reference source for key information such as</p> | <p>OD 011 Part 2</p> <p>IECEX Website</p> | ExCB | OD 011 Part 2 provides a detailed step by step guide to registering a QAR on the IECEx On-Line CoC System by creating a QAR Summary Report |

| Step | Section 3- Procedures for the Issuing of an IECEx Quality Assessment Report (QAR) under the Certified Equipment Program of the IECEx Scheme - Description of Activity | Related Documents | By Whom | Notes/Comments |
|---------|---|----------------------------|------------|--|
| | <ul style="list-style-type: none"> • Manufacturer and sites audited • ExCB performing the site audit • Protection Techniques • Ex Performance related standards • Product Type • Related CoCs • Other. <p>This enables the future use of the QAR for the purpose of issuing an IECEx Certificate of Conformity, through a Linked Database with IECEx CoCs and QARs,</p> <p>Refer to OD 011 Parts 1 and 2 for further information</p> | | | Contact the Secretariat for any assistance |
| 14 + 15 | The ExCB shall review past audit / assessment results for compliance with Annex B | | | |
| 16 | Where the past audit / assessment results are acceptable the ExCB shall compile an IECEx QAR | F-001 | | |
| 17 + 18 | The independent review of Step 10 shall be conducted by a staff member of the ExCB that has not undertaken the quality assessment. | | | |
| 19 | Where this review is successful then the procedures according to step 16 or 9, as appropriate, shall be conducted by the ExCB issuing the QAR | ExCB's internal procedures | ExCB staff | |

SECTION 4 – Surveillance Audits - Procedures for Maintaining an IECEX Certificate of Conformity

This Section is to be applied by ExCBs to ensure that IECEX Certificates of Conformity, issued under the IECEX Equipment Certification Program of the IECEX Scheme remain valid, through surveillance audits according to IECEX 02.

These steps are in line with the requirements of ISO/IEC 17065, *General requirements for bodies operating product certification systems*, in addition to the requirements as laid down in the IECEX Scheme rules, IECEX 02.

In addition, they follow the general concepts of ISO/IEC Guide 53 *Conformity assessment — An approach to the utilization of an organization's quality management system in product certification*

Once an ExCB has issued an IECEX CoC they are responsible to ensure that surveillance assessment visits to the manufacturing location(s) are conducted in accordance with IECEX OD 025, either

- By conducting the surveillance visits
- Confirming that surveillance visits have been conducted by another ExCB, by confirming the details on the IECEX QAR registration area of the IECEX CoC website

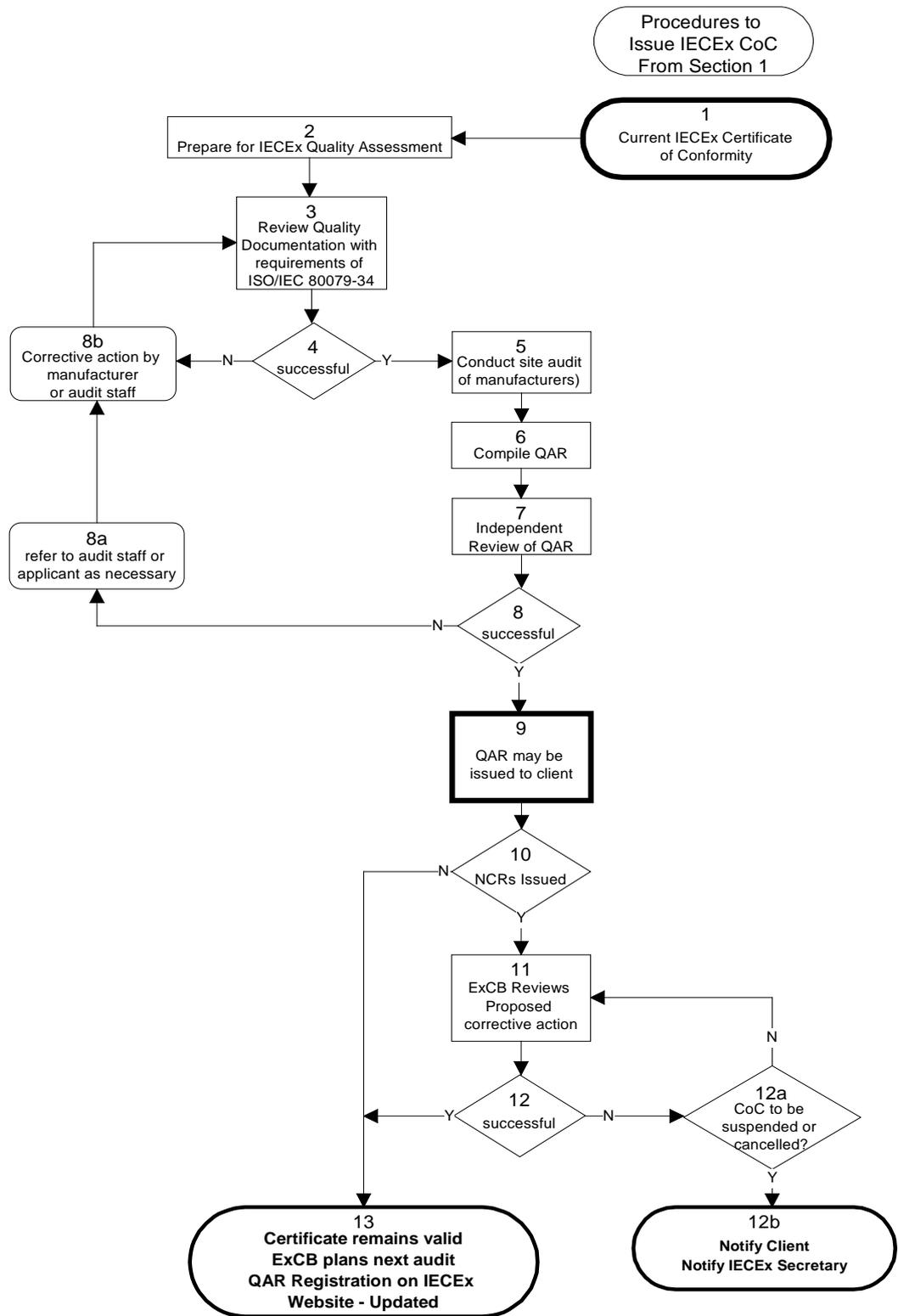
IECEX CoC holders may choose to use the ExCB that issued the IECEX CoC or another ExCB (with the Ex Technique within their IECEX scope) to conduct the surveillance assessment visits.

While this Section provides guidance to ExCBs when arranging for surveillance audits of manufacturers by the QAR issuing ExCB, there may be times where possible non-compliance of Ex products, covered by an IECEX Certificate of Conformity, are suspected not to be in compliance with the International Standard nominated on the IECEX Certificate of Conformity. ExCBs have the responsibility to act when this is a likelihood or where IECEX Certificates of Conformity, issued by them, are being misused or misrepresented.

Such action may include conducting unscheduled visits of the manufacturer, “check testing” of samples for serious cases, or even noting such instances on the ExCBs files for raising at the next surveillance audit.

Where a Certificate Holder wishes to transfer their surveillance audits to another ExCB, the new ExCB shall treat such a transfer as a new/initial audit and assessment.

At any time during the maintenance of an IECEX Certificate of Conformity, the IECEX Secretariat, Officers and Management Committee are available to provide assistance with the understanding of the process and expectation of outcomes of such surveillance activity.



IECEX Surveillance Operations - Overview

| Step | Section 4- Surveillance Audits - Procedures for Maintaining an IECEx Certificate of Conformity - Description of Activity | Related Documents | By Whom | Notes/Comments |
|------|---|---|--|---|
| 1 | <p>IECEX Certificate of Conformity verified as valid by the ExCB that issued the IECEx CoC (ExCB #1) and confirms details on IECEx Certificate website are current and correct, eg manufacturing location(s), product identifier etc.</p> <p>In principle, the procedures detailed in Section 3 apply when conducting surveillance audits of manufacturers with those detailed in this Section 4, providing additional information.</p> | IECEX 02 IECEX CoC | ExCB that issued the IECEx CoC (ExCB #1) | <p>The previous OD 005-1, Part 1 has been replaced by ISO/IEC 80079-34 However OD 005-2, Part 2 provides a checklist for the requirements listed in ISO/IEC 80079-34</p> <p>ExTAG/247A/Inf sets out the transitional arrangements from OD 005-1 to ISO/IEC 80079-34</p> |
| 2 | <p>ExCB that issued the IECEx CoC (ExCB #1) shall arrange to conduct the surveillance audit.</p> <p>Where the previously issued QAR, which is linked to the IECEx CoC, was issued by another ExCB, then (ExCB #1) shall request that the other ExCB conducts a surveillance audit.</p> <p>As an alternative, the holder of the IECEx CoC may arrange for another ExCB (ExCB #2) to conduct the surveillance audit by informing the ExCB that issued the IECEx CoC (ExCB #1), providing that the scope of the alternative ExCB matches the scope of the IECEx CoC. In such cases changing to another ExCB for the purposes of surveillance audits require the issue of a new QAR and a Supplementary (New Issue) of the IECEx CoC by the ExCB that issued the original IECEx CoC, showing the change in ExCB conducting the surveillance audit as the reason for the new Issue of the IECEx CoC. In such instances the new ExCB conducting the surveillance visit shall treat the “transfer” as a new/initial assessment. This ensures full traceability of the system</p> | ExCBs own Quality System and OD 025 F-001 | ExCB that issued the IECEx CoC (ExCB #1) | |
| 3 | Review of the manufacturer’s quality documentation to ensure that any changes since the last audit complies with the requirements of ISO/IEC 80079- | ISO/IEC 80079-34 | ExCB conducting the audit (ExCB #2) | In most cases it is more productive to conduct this |

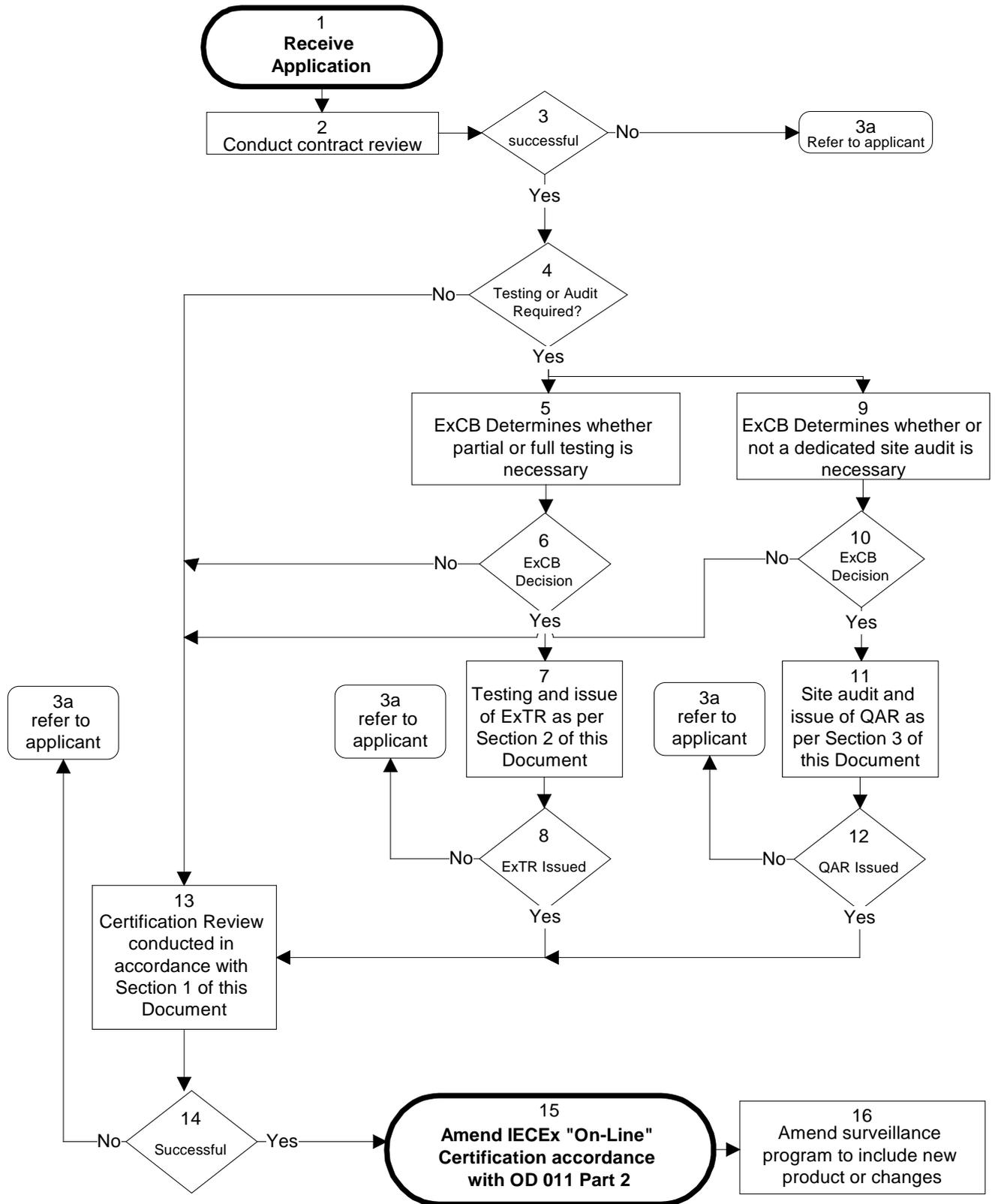
| Step | Section 4- Surveillance Audits - Procedures for Maintaining an IECEx Certificate of Conformity - Description of Activity | Related Documents | By Whom | Notes/Comments |
|--------------|---|--|--|--|
| | 34. This review of documentation may take place either prior to the site visit or as part of the site visit and audit of the manufacturer's premises | OD 025 | | document review at the manufacturer's premises as part of the on-site audit |
| 4+8a 4+8b | Where the document review reveals non-compliance with the requirements of ISO/IEC 80079-34, the ExCB shall determine whether the non-conformance is such that they need correction prior to continuing with the site audit. Corrective action by the manufacturer or audit staff shall be documented. | ISO/IEC 80079-34 OD 025 | ExCB #2 | |
| 5 | Following the document review, the ExCB shall carry out the site audit in accordance with OD 025 | OD 025 ISO/IEC 80079-34 | ExCB #2 | |
| 6 | A Quality Assessment Report, QAR shall be completed by the ExCB conducting the audit (ExCB #2) | OD 025 F-001 | ExCB conducting the audit (ExCB #2) | F-002 provides a format for issuing NCRs |
| 7 | The ExCB that issued the IECEx CoC (ExCB #1) shall conduct an internal independent review of the prepared QAR by a person not conducting the assessment. This review shall verify among other items: <ul style="list-style-type: none"> • That a complete audit as planned had been conducted • Necessary documentation and records available • Confirmation that the auditor/team was appropriate, especially where another ExCB is involved in the audit | OD 025 ISO/IEC 80079-34 IECEX 02 | ExCB that issued the IECEx CoC (ExCB #1) | |
| 8, 8a, 8b | Where the QAR reveals that the audit was incomplete, not conducted in accordance with OD 025 or contains errors, the matter is to be raised with the audit staff and applicant listed on the IECEx Certificate of Conformity, as appropriate. The purpose of the QAR review is for the ExCB to be assured that they have sufficient objective evidence that the manufacturer's quality system and associated quality plans enable Ex products (as listed on the IECEx CoC) to be produced in compliance with the International Standards listed on the IECEx CoC | OD 025 IECEX 02 ISO/IEC 80079-34 | ExCB that issued the IECEx CoC (ExCB #1) | Where a subsequent audit is required due to errors on the part of the ExCB, such audits may need to be conducted at the ExCB's own expense |

| Step | Section 4- Surveillance Audits - Procedures for Maintaining an IECEX Certificate of Conformity - Description of Activity | Related Documents | By Whom | Notes/Comments |
|------------|--|--|--|---|
| | This review may require a revised QAR to be issued or even a subsequent audit of the manufacturer where it is identified that the audit was incomplete or insufficient or unqualified auditor(s) used. | | | |
| 9 | QAR may be issued to the applicant listed on the IECEX CoCs. | OD 025 | ExCB that issued the IECEX CoC | |
| 10, 11 +12 | <p>The ExCB that issued the IECEX CoC (ExCB #1) shall review proposed corrective actions relating to Non Conformance Reports (NCRs) in terms of:</p> <ul style="list-style-type: none"> • The time to implement such action is appropriate • Whether a follow up audit is necessary or can verification be handled at the next scheduled surveillance audit <p>It should be noted that where Major NCRs are raised consideration must be given to the likelihood of non-complying product being released to the market</p> | <p>ISO/IEC 80079-34</p> <p>OD 025</p> | ExCB that issued the IECEX CoC (ExCB #1) | Contact the IECEX Secretariat for any questions or concerns |
| 12a+12b | The ExCB that issued the IECEX CoC (ExCB #1) will need to determine whether the IECEX CoC needs to be suspended or cancelled. Given the seriousness of the situation, prompt action by the ExCB is required. This includes, notifying the applicant listed on the IECEX CoC in writing and the IECEX Secretariat requesting that the IECEX CoC be suspended or withdrawn | IECEX 02 | ExCB that issued the IECEX CoC (ExCB #1) | Contact the IECEX Secretariat for any questions or concerns |
| 13 | <p>Where ExCB is satisfied that a full and complete surveillance assessment/audit has been completed demonstrating compliance with the requirements of ISO/IEC 80079-34 and OD 025, the ExCB that issued the IECEX CoC (ExCB #1) shall confirm that the details of the IECEX CoC as recorded on the IECEX website are accurate and up to date.</p> <p>The ExCB (ExCB #2) shall up-date the QAR registration on the IECEX website. OD 011 Part 2 provides step by step guidance for registering surveillance audits on the IECEX On-Line Certificate System. The ExCB (ExCB #2) shall then schedule the next surveillance audit visit, in accordance with OD 025.</p> | <p>IECEX 02</p> <p>OD 025</p> <p>OD 011 Part 2</p> | ExCB that issued the IECEX CoC (ExCB #1) | <p>Contact the IECEX Secretariat for any questions or concerns</p> <p>Only QARs that indicate compliance with IECEX requirements, even if minor NCRs are issued, shall be registered on the IECEX Website.</p> <p>QARs that show Major or significant problems shall NOT be registered on the IECEX website</p> |

SECTION 5 – Procedures for the Processing of changes to issued IECEx Certificates of Conformity

This Section is to be applied by ExCBs when processing applications for changes to IECEx Certificates of Conformity.

These steps are in line with the requirements of ISO / IEC 17065, *General requirements for bodies operating product certification systems*, in addition to the requirements as laid down in the IECEx Scheme rules, IECEx 02



Process for dealing with changes to IECEx Certification - Overview

| Step | Section 5- Procedures for Assessing applications for changes to IECEx Certificates of Conformity Description of Activity | Related Documents | By Whom | Notes/Comments |
|------|---|---------------------------------------|--|---|
| 1 | Manufacturer lodges an application for Changes to the ExCB responsible for issuing the IECEx Certificate | IECEX 02 Certificate | IECEX Certificate Holder | |
| 2 | ExCB that issued the IECEx Certificate shall conduct a contract review to determine, among others, that: <ul style="list-style-type: none"> • The application is within the Scope of the IECEx Scheme • All necessary information has been provided by the applicant • The requested changes, are within the area of operation of the ExCB, eg scope of ExCB acceptance • Whether the requested changes should be treated as a new Certificate, in consultation with the manufacturer | ExCBs own Quality System and IECEx 02 | ExCB that issued the IECEx Certificate | For technical changes that incorporate a significant change to the product, the ExCB may determine that this be best dealt with by a new certificate. Both manufacturer and ExCB may consult with the IECEx Secretariat |
| 3 | The ExCB shall inform the applicant of the results and shall record the contract review outcomes within their documented record system Where unsuccessful, the ExCB shall immediately inform the applicant in writing. | IECEX 02 OD 025 | ExCB receiving the application | |
| 3a | Where the results of any of the stages are unfavourable to the application, the ExCB must immediately inform such outcome to the applicant who shall decide on whether to proceed by way of correcting any non-conformity or to amend or even withdraw their application. It is expected that in such situations the ExCB should work with the applicant in the interests of maintaining good customer relations | ExCB and Applicant | | Where a dispute arises between the ExCB and applicant, the applicant must use the ExCB's internal appeals process before seeking to use the IECEx Appeals procedure |
| 4 | The ExCB receiving the application for change shall determine whether the requested change is of a technical nature or administrative. Examples of administrative changes may be: <ul style="list-style-type: none"> • Change to product identification • Change of company name, with no change to systems or personnel • Model redesignation | ExCB's own quality procedures | ExCB | |

| Step | Section 5- Procedures for Assessing applications for changes to IECEx Certificates of Conformity Description of Activity | Related Documents | By Whom | Notes/Comments |
|------|---|---|------------------------------|---|
| | <p>Even for administrative changes identified above the ExCB shall satisfy itself that changes of company name and ownership and the like ensure that previous controls over production are maintained. This may require the submission of documentation to the ExCB</p> <p>The addition of another manufacturing location or change thereof is regarded as a technical change and requires an audit of that additional site.</p> | | | |
| 5 | The ExCB shall in consultation with the ExTL determine the level of testing of samples required (in the case of a technical change) where the changes are of a technical nature. The ExCB shall review this situation in light of Section 1 of this Operational Document | Section 1 of this OD 009 OD 010 | ExCB | |
| 6 | The decision by the ExCB and its ExTL on the level of testing or omission of such testing shall be documented and recorded within the ExCB's and the ExTL's job files including the reason why any testing or evaluation may have been omitted | ExCB's own quality documentation | ExCB and its associated ExTL | |
| 7 | On satisfactory completion of testing an ExTR shall be prepared and issued. This ExTR may be issued as an annex to an existing ExTR. | Section 2 of this OD 009 OD 010 | ExCB and its associated ExTL | |
| 8 | <p>The ExTR shall only be issued where all requirements have successfully met. Where this is not the case the ExCB or its associated ExTL shall notify the applicant as per step 3a</p> <p>The issuing of an ExTR shall only be considered complete once it has been registered on the IECEx website</p> | OD 011 Part 2 Section 2 of this OD 009 | ExCB or its associated ExTL | Refer to OD 011 Part 2 for guidance regarding Registration of ExTRs |
| 9 | The ExCB shall determine whether or not a dedicated site audit or visit is necessary and the scope of such audit. The ExCB shall review this situation in light of Section 3 of this Operational Document | Section 3 of this OD 009 OD 025 | ExCB | |

| Step | Section 5- Procedures for Assessing applications for changes to IECEx Certificates of Conformity Description of Activity | Related Documents | By Whom | Notes/Comments |
|------|--|--|---|--|
| 10 | The decision by the ExCB whether or not a dedicated site audit or visit is necessary shall be documented and recorded within the ExCB's job files including the reasons why or why not. Refer to step 9 for guidance, | Section 3 of this OD 009 OD 025 | ExCB | Contact the IECEx Secretariat for any questions or concerns |
| 11 | If a site visit is necessary, a QAR shall be prepared and issued according to Section 3, upon completion. | Section 3 of this OD 009 OD 025 | ExCB | |
| 12 | The QAR shall only be issued where all requirements have successfully met. Where this is not the case the ExCB shall notify the applicant as per step 3a The issuing of a QAR is only considered complete once it is registered on the IECEx website | OD 011 Part 2 | ExCB that issued the QAR | Refer to OD 011 Part 2 for guidance regarding Registration of QARs |
| 13 | The ExCB responsible for issuing the original IECEx Certificate shall be responsible for conducting a final Certification Review in accordance with Section 1 of this OD and their own quality management system, ensuring among others that: <ul style="list-style-type: none"> • ExTR and QAR relate to the same product(s) • Any major Non Conformances have been successfully closed • All stages of the certification process have been documented and followed, including those contained in this manual • The ExCB have a signed commitment by the applicant to abide by the rules of the IECEx Scheme and ExCB's certification conditions, eg agreement to have the ExCB undertake or arrange for surveillance audits • The applicant is aware of his/her obligations under the scheme, including ensuring that any promotional material does not contain misleading information that may infer products NOT covered by IECEx certification are certified | ExCB own quality system procedures Section 1 of this OD 009 | ExCB that issued the original IECEx Certificate | The Certification review step is required even where the application change is of an administrative nature |

| Step | Section 5- Procedures for Assessing applications for changes to IECEx Certificates of Conformity Description of Activity | Related Documents | By Whom | Notes/Comments |
|------|---|--|--|--|
| 14 | The process to issue a new issue (change to existing CoC), known as Issue 1 or higher, shall only proceed where all requirements have been successfully met. Where this is not the case the ExCB shall notify the applicant as per step 3a. | | ExCB that issued the original IECEx Certificate | <p>Note that the first time a certificate is issued is identified as Issue 0, otherwise known as Original Issue.</p> <p>Any revisions to that original CoC are known as Issue 1 or higher. See OD 011 Part 1 + 2 for further explanations.</p> |
| 15 | <p>IECEX Certificate of Conformity shall be compiled using the IECEx “On-Line” system via the password protected system</p> <p>A draft of the IECEx Certificate of Conformity is to be reviewed for errors. It may be beneficial to pass a draft copy to the applicant for them to assist in the final review prior to issuing the certificate.</p> <p>Every attempt shall be made to correct errors prior to issuing the certificate</p> | <p>Section 1 of this OD 009</p> <p>OD 011 Part 2</p> | <p>ExCB that issued the original IECEx Certificate</p> <p>The applicant should also be given the opportunity to review</p> | |
| 16 | The ExCB shall review their surveillance program to ensure that the program covers any changes resulting from the new Issues of the certificate, eg the addition of new manufacturing locations for future surveillance visits. | | ExCB that issues the IECEx Certificate | |

ANNEX A

Acceptance of Test/Assessment Data Obtained prior to the Application for an IECEx Test Report or IECEx Certificate of Conformity

A1 Introduction

This Annex sets out the conditions upon which test or assessment data, obtained prior to the ExCB receiving an application for an IECEx Test Report (ExTR) or IECEx Certificate of Conformity (CoC).

A2 Acceptable use

A2.1 Acceptance of test data obtained prior to the acceptance of an ExTL by the IECEx Management Committee

ExTLs may use test or assessment data obtained prior to the ExTL's acceptance into the IECEx Scheme only when ALL of the following criteria have been met, noting that ExCBs receiving ExTRs, may refuse to accept such results where the test were conducted more than 3 years prior to the acceptance of the ExTL:

- a) Data from tests/assessments are not from such test facilities, equipment or processes that were the subject of a Major non-compliance raised at the time of the IECEx Assessment, such that corrective action by way of new/modified test apparatus, test/assessment processes or new personnel were required in order to gain acceptance as an ExTL. Test results falling into this category cannot be used and the test or assessment to be repeated; and
- b) The test parameters, procedures, process used to obtain the previous test or assessment data are the same as those concerning the Standard to which application has been made; and
- c) The previously obtained test or assessment data is from test samples that are identical to the test samples that would now be selected as representative of the product(s) to which are the subject of an ExTR or IECEx CoC application.

A2.2 Acceptance of test data obtained after an ExTL has been accepted by the IECEx Management Committee but yet obtained prior to the application for an ExTR or IECEx CoC

ExTLs may use test or assessment data obtained prior to receiving an application for an ExTR only when ALL of the following criteria have been met:

- a) The test parameters, procedures, process used to obtain the previous test or assessment data are the same as those concerning the Standard to which application has been made;
- b) The previously obtained test or assessment data is from test samples that are identical to the test samples that would now be selected as representative of the product(s) to which are the subject of an ExTR or IECEx CoC application

A2.3 Manufacturer's test Data

Test results obtained from manufacturer's testing facility are ONLY permissible where such tests have been conducted under the supervision of the ExTL, according to OD 024, and in accordance with the ExTL's own quality management system. The requirements of A2.2 above shall also be met.

NOTE: IECEx are currently developing a guide covering the use of manufacturer's test data. Proposals for inclusion in this guide may be submitted by ExCBs, ExTLs, Member Bodies and industry and government stakeholders via their IECEx Member Body or direct to the IECEx Secretariat

A2.4 Method and format for reporting by ExTLs and ExCBs

A2.4.1 Background

As in many cases the ExTR will be used by other Certification and Approval Bodies to issue their own certification/approval, the quality and completeness of the information, such to assist the body receiving an ExTR is most important.

Time and money spent getting the ExTR right, before it is issued, prevents problems for manufacturers and sellers down the track and also possible rejection by bodies receiving ExTRs. The credibility of the issuing ExTL can also be judged on the quality and completeness of the test/assessment information.

The IECEx Management Committee also recognise that the IECEx blank Test Report format requires a greater level of reporting than an ExTL, operating within their own national certification, may normally have been required, as much of the detailed test and assessment data remains on the laboratory's own files. As bodies receiving ExTRs are required to make judgement on the ExTR information alone, the more complete the information and easier to show compliance with each clause of the standard, the smoother will be the acceptance by the body receiving the ExTR and hence their issuing of certification or approval. The end result will be reduced overall costs and quicker time to market for by the seller.

Therefore in light of the above, the IECEx Management Committee have decided on the following requirements when completing and issuing an ExTR using test data from information.

A2.4.2 Reporting requirements

In ALL cases the IECEx Test Blank Report Forms shall be used. An ExTL is permitted to attach their a complete test report or evaluation record, to an ExTR/ATR format providing the Section 1 of the ExTR provides a clear linkage to the test data and results contained within the attached report.

Copies of related drawings, duly endorsed by the ExTL, shall form part of the overall ExTR.

ExTRs shall clearly identify those test/assessments results that were obtained previously.

ExTRs shall be registered on the IECEx On-Line Certificate of Conformity System. Refer to OD 011 Part 2 for guidance by creation of an ExTR Summary.

ANNEX B

Acceptance of Quality Assessment and Audit Data Obtained prior to the Application for an IECEX Quality assessment Report

B1 Introduction

This Annex sets out the conditions upon which quality assessment data relating to a manufacturer applying for an IECEX Quality Assessment Report (QAR) may be accepted.

B2 Acceptable use

B2.1 Acceptance of quality assessment and audit data obtained prior to the acceptance of an ExCB by the IECEX Management Committee

ExCBs may use quality assessment or audit data obtained prior to the ExCB's acceptance into the IECEX Scheme only when ALL of the following criteria have been met:

- a) Quality assessments and audits were conducted by the ExCB's personnel with competencies in the Ex field;
- b) No Non-conformances were raised at the time of the IECEX Assessment, such that corrective action by way of new/modified processes or new personnel were required in order to gain acceptance as an ExCB;
- c) The ExCB can demonstrate that the general requirements of ISO/IEC 80079-34 have been met;
- d) The previously obtained assessment and audit data are for test samples that are identical to the test samples that would now be selected as representative of the product(s) to which are the subject of an ExTR or IECEX CoC application; and
- e) The ExCB shall conduct a site visit as part of a surveillance audit, in accordance with OD 025, prior to the issue of a QAR.

B2.2 Acceptance of quality assessment and audit data obtained after an ExCB has been accepted by the IECEX Management Committee but yet obtained prior to the application for an IECEX QAR or IECEX CoC

ExCBs may use quality assessment and audit data obtained prior to receiving an application for a QAR when ALL of the criteria specified in B2.1 above have been met.