



# **IECEX OPERATIONAL DOCUMENT**

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

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**Assessment Procedures for IECEx acceptance of Candidate Accepted Certification Bodies (ExCBs) and Ex Testing Laboratories (ExTLs) –**

**Part 2: Assessment, surveillance assessment and re-assessment of ExCBs and ExTLs operating in the IECEx 02, IECEx Certified Equipment Scheme**





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Equipment Scheme**

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## Foreword

This OD 003-2 sets out the Assessment Procedures for IECEx acceptance of Candidate Accepted Certification Bodies (ExCBs) and Ex Testing Laboratories (ExTLs) operating in the IECEx Certified Equipment Scheme.

The Revised Edition is prepared to accommodate changes arising from the 2016 Umhlanga ExMC meeting. It also includes changes proposed by ExMCWG4 which take into account discussions at its 2017 meeting.

This Part 2 supplements **IECEX OD 003-1** Assessment Procedures for IECEx acceptance of Candidate Accepted Certification Bodies (ExCBs) and Ex Testing Laboratories (ExTLs) – Part 1: Appointment and Surveillance of IECEx appointed Assessors and supersedes OD 003-2 Edition 1.0 where the following major changes are included and indicated by red margin bars:

- Replacement of references to ISO /IEC Guide 65 with ISO / IEC 17065.
- Replacement of references to IECEx OD 022 with OD 422
- General replacement of “ExMC Secretary” with “IECEX Secretary” to reflect the content of IECEx 02.
- Replacement of references to IECEx OD 005 with ISO/IEC 80079-34 in accordance with ExTAG/247A/Inf.
- Addition of details of assessor fees for mid-term assessments as supplementary to those already defined in IECEx OD 019.
- Replacement of previous two assessment report forms previously provided as Annex A and Annex B (one for ExCBs and another for ExTLs which are now replaced by the single form prepared by the WG4)
- Introduction of Section 5 on auditing of the assessment process
- Requirement where feasible to use peer lead assessor for initial assessment
- Clarification of planning for assessments where quality documents not in English
- Clarification of the terms 'issue' and 'non-compliance'
- Change of TGDs to TCDs
- Addition of a new Annex A for Application review reports for applications to join IECEx 02 Scheme

## Introduction

This OD details the assessment procedures established by the IECEX System's Management Committee, ExMC, for the purpose of ensuring a thorough assessment of candidate and existing ExCBs and ExTLs operating in the IECEX Certified Equipment Scheme. The principal aim of these procedures is to instil international confidence of manufacturers, users and regulators in the bodies' competence and capabilities for performing testing and certification of Ex equipment.

NOTE Operational Documents exist covering the assessment and surveillance of ExCBs operating in the IECEX Certified Service Facility and IECEX Certificate of Personal Competency Schemes and available from the IECEX website [www.iecex.com](http://www.iecex.com).

International confidence is established by evaluating the competence of a certifying body or Ex test laboratory to comply with the IEC Ex System and associated Scheme rules. The assessment will cover the competence, capability, experience and familiarity of personnel and the organisation with the relevant explosion protection standards, quality management systems, IECEX scheme and associated rules, ISO/IEC 17025 and ISO/IEC 17065 and IECEX Technical Capability Documents. The procedures are also aimed at ensuring a consistent approach to assessments by IECEX assessment teams.

This document provides the following five Sections:

- Section 1 – Initial Assessment, Re-Assessment and Scope Changes
- Section 2 – On-going Surveillance Assessment of Bodies (ExCBs and ExTLs)
- Section 3 - Mid Term Surveillance Audits of Issued ExTRs And QARs
- Section 4 – Notes to Assessors
- Section 5 - Auditing of the Assessment Process

The procedures are set out in table form identifying:

- Step number
- Required action
- Responsible person or party
- Desired outcome

The steps identified in the table correspond to the steps shown in the flowchart.

Further instructions are included to assist Assessment Team Members in performing their duties. More guidance for assessors can be found in IECEX OD 032 *Assessor's Guide*.

Throughout the application and assessment process, communication shall be a combination of written and oral communication, where written communication shall include paper or electronic means, eg. e-mail communication shall be deemed an acceptable form of formal communication and record keeping.

## **1 Initial Assessment, Re-Assessment and Scope Changes**

### **1.1 Scope**

This Section is to be applied for the initial assessment of ExCBs and ExTLs prior to their acceptance in the IECEX Certified Equipment Scheme and re-assessment of existing accepted ExCBs and ExTLs.

NOTE Applications from candidate ExCBs and ExTLs are made using forms ExMC/47/Q for ExCBs and ExMC/48/Q for ExTLs, as amended available from [www.iecex.com](http://www.iecex.com).

The term “applicant body” used throughout this document shall mean the Applicant ExCB and also the Applicant ExTL either together or individually.

This Section is also applicable for re-assessments with the following variations:

- Steps 1 to 5 and 16 to 18 are not applicable
- Where the term ‘Candidate ExCB or ExTL’ is used this should be replaced with ‘Accepted ExCB or ExTL’.
- Where an ExCB is also an IECEX Mark License issuing ExCB, compliance with IECEX 04, OD 422 and OD 023 shall be included.

This Section is also applicable for scope extensions (applied for using ExMC/251B/Q) where the IECEX Secretary identifies the need for a site visit with the following variations:

- Step 3 is not applicable.
- Step 15 where the assessment reports produced shall be submitted to IECEX Officers to consider approval of the scope extension and reported at the next ExMC meeting.

### **1.2 IECEX Assessment Procedure**

The IECEX Assessment Flow Chart should be read in conjunction with the table below.

| <b>Step</b>  | <b>Activity</b>  | <b>By Whom</b>    | <b>Desired Outcome</b>   |
|--|--|-------------------|--|
| <b>Formal Application Submitted to IECEX Secretary</b> |  |                   |  |
| 1  | Application received by IECEX Secretariat, in accordance with IECEX 02   | IECEX Secretariat | An application from a new applicant ExCB or ExTL, shall only be processed by the IECEX Secretariat when it has been endorsed by the IECEX Member Body. The Member Body shall provide written confirmation of their endorsement.  |
| 2  | Review of application documentation for completeness and determination of the applicant’s readiness for the formal IECEX Assessment.<br><br>The review forms used by the Secretariat are attached in Annex A | IECEX Secretariat | IECEX Secretariat reviews the application and for new application issues an Application Review Report to applicant. This may require further information from the applicant ExCB or ExTL. Close attention is paid to gauging the applicant’s experience and capability in conducting testing and certification according to Ex Standards |
| 3  | Invoice prepared for the application fee.  | ExMC Secretariat  | Invoice to applicant ExCB and/or ExTL  |

| <b>Possible Pre-Assessment</b>      |  |  |  |
|-------------------------------------|--|--|--|
| 4                                   | <p>In conjunction with above review, IECEX Secretary informs the applicant of the potential benefit that a pre-assessment may bring.</p> <p>Note: It is intended that the pre-assessment use a similar approach to a normal assessment but focussing on areas requested by the applicant. It may also include the provision of information about the Scheme and typical areas that need attention. If the pre-assessment is done in this way the assessor may be included in the initial assessment team. However, if the assessor takes on a consulting or assisting role he/she shall not be part of the IECEX assessment team.</p>                        | IECEX Secretary  | Recommendation to applicant regarding pre-assessment.  |
| 5                                   | <p>If applicant agrees to a pre-assessment, IECEX Secretary informs the applicant body of suitable experienced assessors. The applicant body engages the assessor directly and no formal reporting of findings is required to be retained by the IECEX Secretariat.</p> <p>It is also possible for a pre-assessment to be done prior to an application being made to IECEX. Assessors engaged for pre-assessments are to notify the IECEX Secretariat as this may impact the composition of the assessment team.</p>   | IECEX Secretariat  | A pre-assessment visit with confidential gap analysis report provided to the applicant body.   |
| <b>Formation of Assessment Team</b> |  |  |  |
| 6                                   | <p>When the application is considered to be complete and any pre-assessment is finalised (or for re-assessments when the date for re-assessment is about to fall due) an assessment team is formed from the IECEX pool of Assessors as approved by ExMC.</p> <p>For initial assessments and re-assessments, the Secretariat will appoint peers from ExCBs and ExTLs as Team Leaders unless there are none available for the specific assessment – in this case a Lead Assessor that is not a Peer from an ExCB or ExTL may be used. However, as required by IECEX 02 a peer assessor from another ExTL or ExCB shall be included on each assessment team</p> | IECEX Executive Secretary                                    | <p>Acceptance received from proposed members of the IECEX Assessment Team</p> <p>Acceptance of proposed members of the Team received from applicant.</p> |
| 7                                   | Application package forwarded to members of the appointed Assessment Team.   | IECEX Secretariat  | All relevant information available for team to commence their assessment.  |
| <b>Planning the Assessment</b>      |  |  |  |
| 8                                   | <p>Initial planning for the assessment is carried out taking into account whether there is an ExCB, ExTL or both. The number of on-site assessors and number of days for the assessment will then be determined. Account will be taken of relevant national accreditation. As an indication, for an assessment of a new combined ExCB and ExTL with a reasonably large scope, it is expected that it will be necessary to have</p>   | Assessment Team Leader in conjunction with IECEX Secretariat | Initial plan for the number of days on site and the number of assessors on site.   |

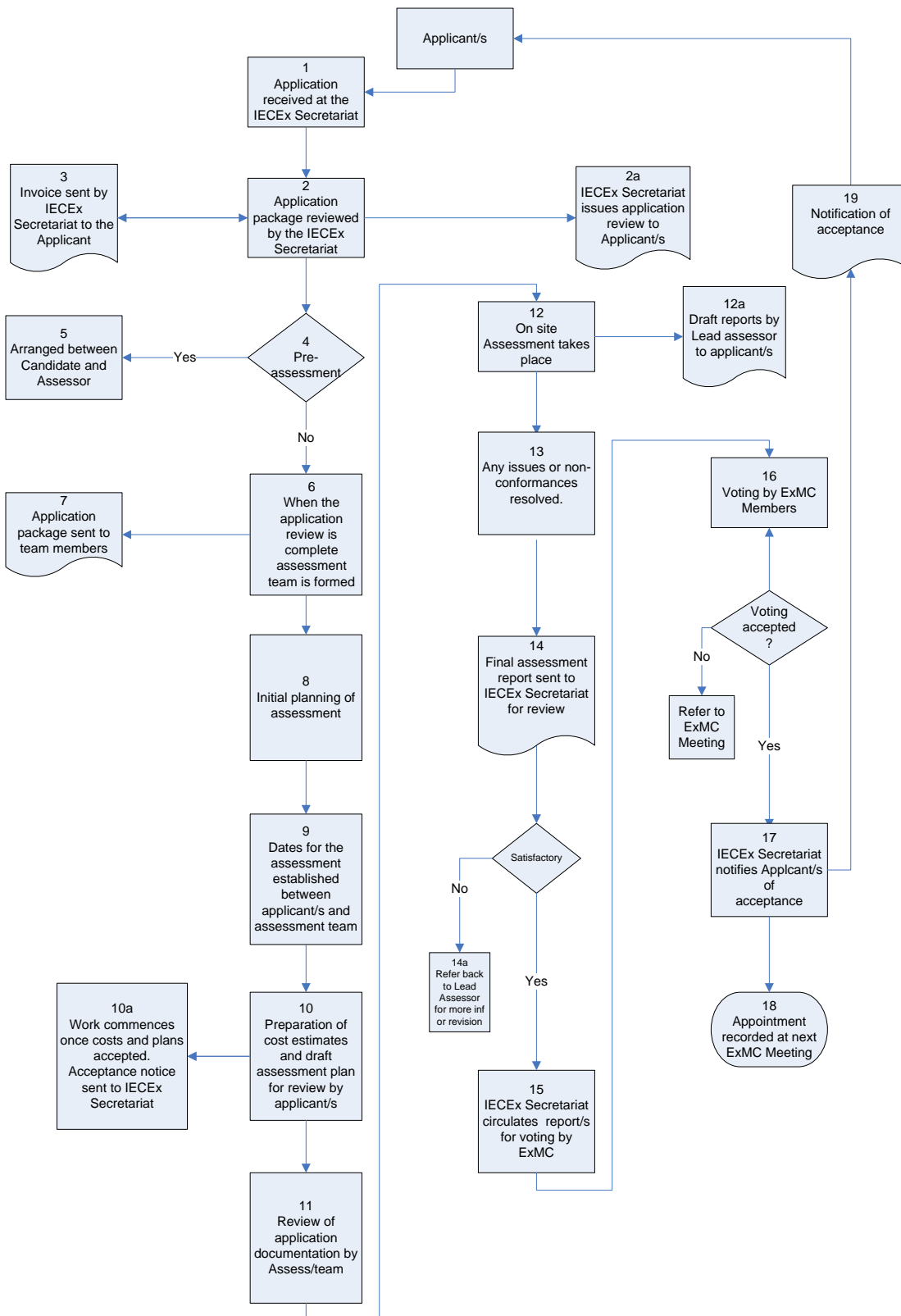


|                      |  |   |  |
|----------------------|--|---|--|
|                      | <p>three assessors on site for three days.</p> <p>Where the applicant body does not have its quality documents in English, it may be necessary to schedule extra time to take into account the time needed for translation/interpretation during the assessment process.</p> <p>NOTE: It is expected that any procedures specifically relevant to IECEX will be provided in English or be provided with an English translation. It is also recommended that the clause headings in major documents (eg the quality manual) be provided with an English translation to assist the assessor in knowing the subject of the clause.</p>                  |   |  |
| 9                    | Dates for the assessment as established in consultation with the applicant body and the assessors.   | Assessment Team Leader                                  | Dates established  |
| 10                   | <p>Preparation of a consolidated cost estimate and draft assessment program for review by the applicant ExCB or ExTL.</p> <p>Work should only commence after the applicant has accepted the cost estimate. A copy of this acceptance should be provided to the IECEX Secretariat.</p>  | Assessment Team Leader in conjunction with team members | <p>A copy of the cost estimate and draft assessment plan to the applicant and IECEX Secretariat.</p> <p>Acceptance of the cost estimate and plan by the applicant.</p>   |
| 11                   | Review of application documentation. Assessment Team Leader may request additional information from the Candidate ExCB or ExTL   | Assessment Team Leader in conjunction with team members | Request for additional information if needed.  |
| <b>On-site Visit</b> |  |   |  |
| 12                   | <p>The assessment visit takes place. Refer to IECEX OD 032 <i>Assessor's Guide</i> for more information on this process. At the closing meeting the findings will be discussed with the management of the applicant body.</p> <p>The documentation produced from the assessment will fall into two categories:</p> <ol style="list-style-type: none"> <li>1) Reports that will be circulated for voting by the member bodies</li> <li>2) Documentation that supports the findings of the assessment and how any issues have been resolved. This documentation is treated as confidential but copies will be held by the IECEX Secretariat</li> </ol> | Assessment Team   | <p>Following reports shall be completed:</p> <ul style="list-style-type: none"> <li>• <b>F-004</b> Site Assessment Report</li> <li>• <b>OD 107</b> ISO/IEC 17065 Checklist</li> <li>• <b>OD 018</b> 17025 Report for ExTL</li> <li>• <b>TCDs</b> Technical Capability Documents</li> <li>• Draft reports for the ExCB and ExTL for voting</li> </ul> |

| <b>Post Assessment Visit Actions</b> |   |  |   |
|--------------------------------------|---|--|---|
| 13                                   | <p>Any issues or non-compliances identified during the assessment process must be resolved by the applicant body to the satisfaction of the assessment team.</p> <p>NOTE1: Generally any matters requiring resolution identified by the assessment team will be identified as 'issues' and shown in the relevant annex of the site assessment report. However, if a really significant matter is identified the assessment team may, at its discretion, identify this as a major 'non-compliance' that will need special attention.</p> <p>NOTE 2: The assessment team may also make 'observations' and list these in the site assessment report. Observations do not require resolution.</p> <p>In some cases it may be necessary for a follow-up visit by one or more members of the Assessment Team.</p> <p>Results of site visit determined with a final report for submission to the IECEX Secretariat prepared using F-004. The final report shall be reviewed by all members of the assessment team.</p> <p>Where results of site visit require rectification or corrective action by the candidate ExCB or ExTL, the assessment Team Leader shall review the corrective actions and determine whether the item(s) raised have been sufficiently addressed in order to close the issue.</p> <p>Where issues, identified during the site visit, remain unresolved more than 12 months beyond the site visit, the IECEX Executive Secretary in consultation with the IECEX Executive shall determine whether a further site visit shall be required.</p> | <p>Body under assessment &amp; Assessment team</p> <p>Assessment Team Leader</p> | <p>Final reports for submission to the IECEX Secretariat, reviewed by all members of the assessment team</p> <p>Assessment Team Leader to arrange for compilation of final assessment reports for voting by ExMC.</p> |
| 14                                   | <p>Final IECEX Assessment Team reports reviewed by IECEX Secretariat. This review includes but is not limited to:-</p> <ul style="list-style-type: none"> <li>- Ensuring all matters raised as listed in the site assessment report and TCD have been satisfactorily closed</li> <li>- The final summary report is complete and there are no "hanging " statements</li> <li>- Details of accreditation and scope are clear</li> </ul> <p>Once the review is completed, the following is added at the bottom of the report:<br/>'Independently reviewed by the IECEX Secretariat'.</p>   | <p>IECEX Secretariat</p>   | <p>Review by IECEX Secretariat to ensure completeness of information and readiness for circulation to ExMC for voting or consideration at a meeting.</p>  |
| 14A                                  | <p>Where review in step 14 raises questions, IECEX Secretariat refers the matter to the IECEX Assessment Team Leader seeking additional information or revised report.</p> <p>The IECEX Executive Secretary may consult with the IECEX Executive as part of this review.</p>  | <p>IECEX Secretariat</p>   | <p>An acceptable report for circulation to ExMC</p>   |
| 15                                   | <p>IECEX Secretariat prepares a Voting Document containing the Assessment Report for voting and submits to ExMC Members for formal voting, via correspondence or at the next ExMC meeting. There are separate Voting</p>  | <p>IECEX Secretariat</p>   | <p>ExMC Document issued for voting, with a copy submitted to candidate ExCB or ExTL</p>   |

|   |   |                              |   |
|---|---|------------------------------|---|
|   | Documents and associated reports for ExCB and ExTL.   |                              |   |
| <b>Final Approval of ExCB or ExTL by ExMC</b> |   |                              |   |
| 16  | Assessment of report considered by ExMC members with members returning the completed voting form to the IECEX Secretariat as soon as possible and by due date         | ExMC Members                 | Majority acceptance vote approves application (refer to IECEX 01 regarding voting procedures)   |
| 16A   | Where voting is unsuccessful the application is then referred to IECEX Secretariat for further action which will normally involve discussion at the next ExMC meeting | IECEX Secretariat to arrange | Findings recorded in the minutes<br>IECEX Secretariat may consult with the IECEX Chairman   |
| 17  | If voting is acceptable then IECEX Secretariat notifies the applicant body of its acceptance  | IECEX Secretariat            | IECEX Letter of acceptance to accepted ExCB and ExTL<br>Certificate of Acceptance issued to the Body<br>IECEX Secretariat updates the IECEX records, eg OD 001 and arranges access for ExCB to use IECEX On-Line Certificate system<br>Copy of review report on voting to be forwarded to ExMCWG4 members for information to permit them to look at ways the process might be improved based on comments from the member bodies voting.<br>A feedback form is sent to the body that has been assessed to seek feedback on the assessment process and the performance of the assessors. The completed form is returned to the IECEX Executive Secretary. |
| 18  | Appointment recorded at next ExMC meeting   | IECEX Secretariat to arrange | Recorded in Minutes   |

Figure 1 - Process Flow chart



## 2 On-Going Surveillance Assessment of Bodies (ExCBs and ExTLs)

### 2.1 Scope

This Section applies to all ExCBs and ExTLs that have been accepted into the IECEx Certified Equipment Scheme. The purpose of ongoing assessments is to satisfy the International Ex community that ExCBs and ExTLs maintain their facilities and capabilities that enabled their entry into the Scheme. The following two different situations are addressed:

- 1) ExCBs and ExTLs that maintain relevant national accreditation that is found to be acceptable by the original IECEx Assessment Team, and through the ExMC vote.
- 2) ExCBs and ExTLs that do not have relevant national accreditation or whose accreditation is not acceptable to the ExMC.

### 2.2 Surveillance of ExCBs and ExTLs with Acceptable National Accreditation

#### 2.2.1 Procedure

The IECEx Secretariat shall, on at least an annual basis confirm the accreditation status and scope of all ExCBs holding national accreditation that are not subject to annual IECEx surveillance assessments.

This may require the IECEx Secretariat seeking confirmation from accreditation bodies and ExCBs and ExTLs along with a call for audit reports issued by accreditation bodies and internal audit reports of the ExCB and ExTLs in order to gain evidence of compliance with ISO/IEC 17025 and ISO/IEC 17065 along with IECEx Scheme requirements.

In addition to the above, ExCBs and ExTLs shall advise the IECEx Secretary of any changes in their organisation affecting the ExCB's or ExTL's operation in the IECEx Certified equipment Scheme such as the organisation of the ExCB or ExTL, its staff, facilities, quality system, operating procedures, accreditation status.

#### 2.2.2 Review

The IECEx Secretary shall review the information to ensure:

- ExCB and ExTL Sites covered by accreditation aligns with the site previously approved by ExMC;
- All Clauses of ISO/IEC 17025 for ExTLs and ISO/IEC 17065 for ExCBs, as applicable, have been covered;
- Ensure that IECEx requirements are met; and
- Any Non-Conformances are identified.

Where major Non-Conformances have been identified the IECEx Secretary may consult with the IECEx Chairman and Executive to decide on such action to be taken and report at the next ExMC meeting. Where the ExCB does not agree with the course of action, the matter may be referred to the IECEx Executive, if requested by the ExCB. During the period of referral to the Executive, the IECEx Chairman in consultation with the other members of the IECEx Executive shall decide on the status of the ExCB in question. In extreme circumstances the status of temporary suspension may be considered. The IECEx Chairman shall report at the next ExMC meeting of actions taken.

The IECEx Secretariat will retain a copy of records for a minimum of 10 years for record keeping purposes.

#### 2.2.3 Re-assessment

On the fifth anniversary of the original assessment site visit or re-assessment site visit of an ExCB or ExTL a re-assessment, in accordance with the assessment procedure detailed in Section 1, shall be performed, by an assessment team appointed by the IECEx Executive Secretary.

## **2.3 Surveillance of ExCBs and ExTLs without Acceptable National Accreditation**

### **2.3.1 Preparation**

The IECEX Secretariat shall arrange for an annual on-site surveillance assessment of the ExCB and ExTL. This should normally be carried out by one member of the original IECEX assessment team. The assessor shall be appointed by the IECEX Executive Secretary. The ExCB and ExTL shall agree to cover the costs associated with this on-site assessment and may object to the selection of the appointed Assessor, giving reasons for such objection. In such cases the IECEX Executive Secretary may consult with the IECEX Chairman and Executive.

The appointed assessor shall carry out an assessment for compliance with ISO/IEC 17025 for ExTLs. For ExCBs the assessment shall be conducted according to ISO/IEC 17065 and their ability to comply with IECEX Rules and Operational Documents. The assessor shall then report back to the IECEX Executive Secretary whom may consult with the original IECEX Assessment Team Leader.

The Assessor shall prepare a site assessment report using F-004, to the IECEX Secretariat, with copy to the ExCB or ExTL.

### **2.3.2 Procedure**

The report shall be reviewed by the IECEX Secretariat for completeness and how any issues or non-conformances have been addressed. The report shall be retained for a minimum of 10 years for record keeping purposes by the IECEX Secretariat.

If any issues or non-compliances are identified during the assessment they shall be resolved to the satisfaction of the assessor and Assessment Team Leader.

Where major Non-Conformances have been identified the IECEX Executive Secretary may consult with the IECEX Chairman and Executive to decide on such action to be taken and report at the next ExMC meeting. Where the ExCB or ExTL does not agree with the course of action, the matter may be referred to the IECEX Board of Appeals, if requested by the ExCB or ExTL. During the period of referral to the Board of Appeal, the IECEX Chairman in consultation with other Members of the IECEX Executive shall decide on the status of the ExCB in question. In extreme circumstances the status of temporary suspension may be considered. The IECEX Chairman shall report at the next ExMC meeting of actions taken.

### **2.3.3 Re-assessment**

On the fifth anniversary of the original assessment site visit or re-assessment site visit of an ExCB or ExTL a re-assessment, in accordance with the assessment procedure detailed in Section 1, shall be performed, by an assessment team appointed by the IECEX Executive Secretary.

## **3 Mid-term Surveillance Visits for the purposes of auditing Issued ExTRs and QARs**

### **3.1 Scope**

This section addresses the on-going surveillance of ExCBs and ExTLs in the IECEX Scheme via mid-term surveillance auditing of ExTRs and QARs that are issued to support an IECEX Certificate of Conformity (CoC).

Mid-term surveillance activities apply to all ExCBs and ExTLs irrespective of their Surveillance Assessment schedule determined by Section 2.

### **3.2 Role**

The role of mid-term surveillance assessments of issued ExTRs and QARs is for the international Ex industry, regulators and all IECEX Member ExCBs and ExTLs to gain confidence that IECEX Certificates of Conformity are supported by credible tests and assessments, and that the IECEX rules and procedures are followed by all IECEX Bodies.

### 3.3 Approach

The mid-term surveillance shall be conducted in accordance with the procedures outlined below and on-site at the ExCB and ExTL premises. It is expected that the assessor will be present on-site for a full day and a further half day will be sufficient for combined preparation and reporting activities.

### 3.4 The mid-term surveillance assessment schedule

#### 3.4.1 ExCBs and ExTLs with national accreditation

The mid-term surveillance assessment is scheduled to be carried out on those bodies with national accreditation presently re-assessed every 5 years with annual checking of their accreditation status by the Secretariat. The mid-term assessment to be scheduled in agreement with the relevant body/ies and is to be carried out not earlier than 2.25 years and not later than 2.75 years from the last assessment/re-assessment. The time required of an on-site mid-term assessment would normally require 1 full day on site (8 hour on site).

#### 3.4.2 ExCBs and ExTLs without national accreditation

The CoC, ExTR and QAR reviews detailed in Sections 3.7, 3.8 and 3.9 shall also be conducted on ExCBs and ExTLs that are subject to annual surveillance visits due to not holding national accreditation and shall require an additional day on site to be conducted on either the second or third annual surveillance visit.

Mid-term surveillance activities may be undertaken in conjunction with annual surveillance visits as required by Section 2.3.

### 3.5 Appointment of assessors (selected in conjunction with IECEx Secretariat).

One assessor from the ExMC approved list of Assessors, appointed by the IECEx Executive Secretary and agreed to by the ExCB/ExTL, will focus on the technical aspects of the ExTL and ExCB. In order to reduce costs, and taking into account issues of impartiality, use may be made of a suitable local Assessor who is within reasonable travel distance for the mid-term surveillance assessment.

### 3.6 Purpose of mid-term surveillance assessment

The purpose of conducting the mid-term surveillance assessment on ExCBs and associated ExTLs is to carry out a technical review of IECEx Certification files and the related ExTRs and QARs for technical integrity, completeness and compliance with IECEx Rules and Operational Documents, thereby instilling confidence within the international Ex Industry.

This includes checking that IECEx Certificates of Conformity are supported by credible tests and assessments.

The conclusion of a mid-term site surveillance assessment the IECEx Assessor will recommend whether or not the scheduled 5 year full re-assessment needs to be brought forward.

When reviewing IECEx Certification Files, the key aspects of the IECEx Certificate of Conformity, ExTR, and QAR, as listed below in Sections 3.7, 3.8 and 3.9 should be checked on a sample basis.

*The reasons for this are:*

- 1) *the 'Ex Department' may not be included in an Accreditation Body's visit as often as expected under a sampling approach applied to the whole organisation,*
- 2) *the growth in the number of IECEx Operational Documents and their increasing rate of revision may present problems in ensuring that all relevant staff are properly informed and that internal procedures and documents are reviewed with sufficient frequency, and*
- 3) *the time needed to properly review all aspects of an organisation's operations related to Ex is not always available under 'normal assessments'*

### 3.7 IECEX Certificate of Conformity (CoC)

The objective of the review is to check that the information on the sampled Certificates is correct and complete as compared to the following criteria:

#### For Certified Equipment Certificates

- a) Date of issue is appropriate (i.e. not showing in the future)
- b) A Test Report number and File Reference is included.
- c) Manufacturer name detail is consistent with the related ExTR and QAR
- d) Manufacturer's site street (not a PO Box) address is given
- e) Any attached Annex has a reference to the CoC number
- f) Referenced Annexes are attached
- g) Conditions of Certification are listed for "X" type Certificates
- h) Equipment description is clear and sufficiently detailed
- i) No major editorial mistakes (including linking to a draft ExTR)
- j) Correct links to valid ExTR and QAR
- k) Linked QAR is current
- l) Manufacturer on CoC matches QAR and QAR covers all manufacturing locations
- m) Standards listed on CoC match Standards (including Edition #) on ExTR
- n) Scope of Certificate matches QAR and ExTR ExCB capability.
- o) Type of Protection Concept on CoC matches standards and QAR
- p) Where more than 1 issue exists that they are linked and changes explained on CoC
- q) Statement of Limitations is included in CoC for Component certificates ("U" type)
- r) Unit Verification Certificates have been denoted with "V" and include Serial #(s)

### 3.8 IECEX Test and Assessment Reports (ExTRs)

The purpose of an IECEX Test Report (ExTR) is to provide a clause-by-clause documentation of the initial evaluation and testing that verified compliance of an item or product with an IEC Ex standard.

When reviewing IECEX Certification Files, at least the following key aspects of the ExTR should be checked:

- a) **Technical:** That the information contained within the ExTR is sufficient to enable a clear conclusion to be drawn that the product is in compliance with the relevant clauses of the Standards listed
- b) **Administrative:**
  - 1) Use of IECEX Blank ExTR Forms
  - 2) Evidence that the ExTL has taken into account relevant ExTAG Decision Sheets
  - 3) Product listed on related CoC matches that on the ExTR
  - 4) Standards listed on CoC matches that on ExTR and are appropriate
  - 5) ExTR registered on IECEX Website
  - 6) Drawing list is included
  - 7) All parts of the ExTR Blank form have been completed. Noting that clauses of the standard that may not apply to the product have been identified as N/A or other means and that such exclusions are appropriate for the product covered by the ExTR



- 8) Persons listed as conducting the tests and completing the ExTR are those identified by the ExTL as being competent and/or listed on their internal competency matrix.
- 9) The ExTL's associated ExCB indicates final approval of the Ex Test Report as part of the overall ExTR package on the associated ExTR Cover

### **3.9 IECEx Quality Assessment Reports (QARs)**

The purpose of an IECEx Quality Assessment Report (QAR) is to provide a clause-by-clause documentation of the manufacturing quality system compliance with the requirements of ISO/IEC 80079-34 (or OD 005 for older versions of QARs) in order to maintain confidence that the manufacturing production of product, listed on an IECEx CoC will continue to comply with the Standards listed on the CoC.

When reviewing IECEx Certification Files, at least the following key aspects of the QAR should be checked

- a) **Technical:** That the information contained within the QAR is sufficient to enable a clear conclusion to be drawn that the manufacturing production procedures are in compliance with ISO/IEC 80079-34 or OD 005
- b) **Administrative**
  - 1) Use of IECEx Blank QAR Forms
  - 2) Evidence that the ExCB has taken into account relevant ExTAG Decision Sheets
  - 3) Product or Protection Techniques listed on related CoC match those on the QAR
  - 4) Manufacturing location(s) listed on the CoC match those on the QAR
  - 5) QAR is registered on IECEx Website
  - 6) Duration between surveillance audits of the manufacturers complies with IECEx Rules, e.g. maximum 12 month intervals where the manufacturing site(s) does NOT hold ISO 9001 certification and 18 month maximum intervals where the manufacturing site(s) do hold ISO 9001 certification
  - 7) All parts and sections of the QAR Blank form have been completed. Noting that clauses of the standard that may not apply to the product have been identified as N/A or by other means and that such exclusions are appropriate
  - 8) Persons listed as conducting the audits and completing the QARs are those identified by the ExCB as being competent and or listed on their internal competency matrix.
  - 9) Audit report findings and NCRs have been closed out

### **3.10 Reporting**

A report using the format contained in OD 204 together with completed checklists, OD 205, should be forwarded to the IECEx Secretariat within six weeks of the site assessment. If there are any reasons for delay the assessor should contact the IECEx Secretariat explaining the reasons.

### **3.11 Conclusion of the Mid-term Assessment**

The IECEx Assessor submits their recommendation to the IECEx Secretariat with the IECEx Executive Secretary responsible for any follow up actions, including the re-scheduling of the planned re-assessment should this be recommended by the Assessor and agreed by the Executive Secretary. Where there is disagreement between the Assessor and ExCB and/or ExTL, the Executive Secretary shall refer the matter to the IECEx Executive for a decision on the course of action.

## 4 Notes to Assessors

### 4.1 Scope

This section provides instructions to assessment teams and assessment team leaders. Further guidance for assessors can be found in IECEX OD 032 *Assessor's Guide*.

### 4.2 Instructions for Assessment Teams

It is recognised that assessors have been approved by ExMC on the basis of their knowledge, experience and expertise and therefore ExMC relies on the wisdom and judgement of all assessors, especially lead assessors, for conducting meaningful and credible assessments.

While credibility of an assessment is paramount, the assessment process must also be mindful of containing assessment costs as well as maintaining consistency among assessments. The following guidance instructions are provided with these issues in mind.

### 4.3 Instructions for IECEX Assessment Team Leaders

Assessment Team Leaders have the additional task of coordinating the assessment process of the ExCB or ExTL under assessment by their team.

Once an assessment team has been appointed, the Team Leader should make contact with his/her team members and the candidate ExCB and ExTL Body as soon as possible. It is the Team Leader's responsibility to ensure that all team members have the following:

- Copies of the ExCB and ExTL applications and supporting documentation
- Technical Capability Documents, where available.
- Working copy of IECEX 02
- IECEX Assessment Procedure, Doc. OD 003-2, this document
- IECEX OD 032 Assessor's Guide.

An assessors' package of relevant documents is available from the IECEX Website at [http://www.iecex.com/assessors\\_package.htm](http://www.iecex.com/assessors_package.htm).

In addition, all team members must have their own working copies of the relevant ISO/IEC Standards, particularly ISO/IEC 17025 and ISO/IEC 17065.

The Team Leader generally acts as the contact between the assessment team members and candidate ExCB or ExTL and is responsible for all correspondence.

The Team Leader should liaise with the IECEX Secretary and candidate ExCB or ExTL regarding the assessment program and estimated costs (assessment fees and travel costs). The ExCB or ExTL should reach agreement with the Lead Assessor on costs before assessment work commences.

The Team Leader shall ensure that the assessment procedures, detailed in this document are followed and that the approach of assessments is one of seeking evidence of compliance with requirements. This includes reporting how the requirements of ISO/IEC Standards, the Technical Capability Documents and IECEX 02 are satisfied and implemented.

It is expected that most of the consultation between team members would be via correspondence, fax, e-mail etc.

Assessments of ExCBs are aimed at demonstrating compliance with ISO/IEC 17065 and IECEX 02. This includes verifying:

- Declaration as per Appendix A of IECEX 02
- An agreement between the ExCB and a recognised ExTL (where separate)
- An organisational chart - note where the ExCB is also an ExTL the organisational chart shall demonstrate independence of testing and certification up to at least manager level.

- Complementing the above, procedures addressing the issue that persons involved in the decision to certify should not have had any involvement in past testing and assessment for the particular product.
- Certification procedure. (IECEX 02, OD 009)
- Procedures for assessing manufacturers quality plans, these to include the evaluation of documents that attest to a manufacturers certification/registration to such as ISO9001. (ISO/IEC 80079-34, OD 025)
- Procedures for completing an independent review of ExTRs.
- Procedures for retaining, recording, filing and reporting such things as ExTRs, QARs and IECEx certificates of conformity.
- Procedures for carrying out periodic surveillance of the manufacturers quality plans (OD 009, OD025, OD026, ISO/IEC 80079-34).
- Procedures for dealing with changes to certified Ex equipment.
- Methods for ensuring impartiality in accordance with the requirements of ISO/IEC 17065
- Confidentiality procedures when keeping technical documents etc.
- Procedures for suspending or cancelling a certificate of conformity.
- Procedures for dealing with ExTRs and QARs for the purpose of issuing their own National Certification
- Procedures for national certification and approval, including whether foreign manufacturers are required to make application through a resident agent.

The IECEx Assessment Team shall also review the ExCB's ability to perform assessment of Quality Management Systems covering the manufacturer of Ex apparatus. This shall include verifying:

- Understanding of the differences between auditing of Quality management Systems to ISO 9001 and Quality Plans associated with product certification systems;
- Assessing the ExCB's system for the appointment of auditors to audit manufacturers under the IECEx Scheme (noting that IECEx require that all ExCB auditors appointed to audit manufacturers are required to have up-to- date Ex technical expertise for the types of protection in the scope - refer OD 025);
- A thorough understanding by the ExCB's auditors of the requirements of ISO/IEC 80079-34, OD 025 and OD 009;
- Experience with operating Product Certification Programs incorporating surveillance of manufacturers;
- The Assessment should also conduct a Technical interview of some or all ExCB auditors to determine their level of both Ex knowledge and requirements of ISO/IEC 80078-34 and OD 025.

Assessments of ExTLs are aimed at demonstrating compliance with ISO/IEC 17025, the Technical Capability Documents and verification of the requirements of IECEx 02. This includes verifying:

- Declaration as per Appendix B of IECEx 02
- An organisational chart (NOTE: where the ExCB is also an ExTL the organisational chart shall demonstrate independence of testing and certification up to at least manager level)
- Information as per Appendix C of IECEx 02
- A statement respecting the confidentiality of any information they obtain and how this is achieved
- Methods for ensuring impartiality in accordance with the requirements for ISO/IEC 17025
- Suitable facilities are available and the necessary test and measuring equipment for the scope are available
- That the laboratory has appropriately qualified and experienced staff with intimate knowledge of testing and assessing Ex equipment

- Implementation of IECEX Operational Documents and ExTAG Decisions into their own documentation structure.
- Implementation of testing procedures and acceptance of test facilities at national level

As part of the assessment procedure, it is the responsibility of the Team Leader to provide the IECEX Secretariat with an IECEX Assessment Report for each ExCB and ExTL their team have assessed. A separate report is required for each. Proforma Reports for both ExCBs and ExTLs including a combined ExCB/ExTL report are provided by the Secretariat.

To assist IECEX Assessment Teams, the IECEX Management Committee has appointed an IECEX Assessor Panel Chairman with the task acting as a reference body for Assessment Teams. In addition the IECEX Secretariat and ExTAG Secretary and other IECEX Officers are always willing to provide assistance. Therefore Team Leader should feel free to make use of this assistance throughout the course of their assessments.

#### **4.4 Assessor Fees**

Assessor fees (payable by the ExCB and ExTL) for mid-term assessments are currently set at CHF 1,500 per day (plus expenses).

#### **4.5 Closing Comment**

The above instructions for Team Leaders, regarding seeking evidence of compliance with requirements, apply to all assessors. Team members are reminded that the Lead Assessor is responsible for liaison between the assessment team and the candidate ExCB or ExTL. Points of non-compliance raised by any team member must be immediately brought to the Team Leader's attention who will then raise the non-conformity with the candidate ExCB or ExTL.

An effective and timely assessment requires the cooperation of all those participating in the assessment, especially all members of the assessment teams. Therefore it is most important that assessment team members respond quickly to correspondence and requests from their Team Leaders. Should any assessor have difficulty in meeting their obligations they are requested to contact their Lead Assessor immediately and advise the IECEX Secretariat.

Assessing of ExCB and ExTL is an extremely important process and will greatly assist in establishing and maintaining the IECEX System's credibility. The Assessment Panel Chairman, ExMC Chairman and Officers are all available should assessors require assistance. Assessors may contact the IECEX Secretariat if they need assistance at any stage of the assessment process.

### **5 Proficiency testing programs**

Participation in the IECEX Proficiency Testing Program, according to IECEX Operational Document OD 202 is a requirement of all existing and applicant ExTLs. Assessment teams are required to check this as part of the assessment of applicant and existing ExTLs.

#### **NOTES**

1. It is anticipated the bodies will have prior/current involvement in IECEX or similar proficiency testing programs to satisfy the requirements of ISO/IEC 17025.

2. On request, PTB will provide appropriate information to the IECEX Secretariat for bodies about to undergo assessment or re-assessment regarding the performance in completed programs. The Secretariat will provide this information to the assessment team.

### **6 Auditing of the assessment process**

It is proposed that an audit of the records held by the Secretariat be conducted by representative(s) of the IECEX Executive on a periodic basis, with the proviso that only members of the Executive who are not assessors can perform this audit. This audit would focus on the assessment process with particular reference to the records kept at the IECEX Secretariat. A report of this audit will be provided to the ExMC members. The audit and associated report will address compliance of the IECEX processes with this OD and report on areas of non-compliance, and will also report on any potential areas for improvement that may be identified during the assessment. It is proposed that the audit would be conducted under the oversight of the IECEX Chairman.

## ANNEX A

### Application review reports for applications to join IECEX 02 Scheme

(To be completed by the IECEX Secretariat)

#### IECEX Certification Body (ExCB) Application Report

**Applicant ExCB:**

**Report Prepared By:**

**Date:**

| Information Provided   | Yes | No | Comments |
|--|-----|----|----------|
|  | ✓   |    |          |
| a) Description of ExCB:  |     |    |          |
| -Legal Status  |     |    |          |
| -Address   |     |    |          |
| -Compliance with ISO/IEC 17065   |     |    |          |
| -Relationship between ExCB and ExTL  |     |    |          |
| -Responsibilities @ national level and national schemes operated   |     |    |          |
| -Arrangements for appeal   |     |    |          |
| -Recognition of IECEX TRs for issuing own certification  |     |    |          |
| -Documents available for supporting information-existing accreditation   |     |    |          |
|  |     |    |          |
| b) IEC Standards applied for.  |     |    |          |
|  |     |    |          |
| c) A statement that ExCB will recognise ExTRs from other ExCBs.  |     |    |          |
|  |     |    |          |
| d) A list of standards accepted for use in IECEX, including details of edition and amendments which are accepted in whole or part by the body when issuing its certificates or approvals. National differences shall be declared for inclusion in the IECEX Bulletin |     |    |          |
|  |     |    |          |
| e) Statement of number of certificates issued  |     |    |          |
|  |     |    |          |
| f) Statement that the ExCB will abide by the rules.  |     |    |          |
|  |     |    |          |

**Notes:**

1. This application review is limited to the extent of determining whether information has been provided as required by the application forms, which thereby enables the applicant to be listed on the IECEx system as an Applicant Body. Therefore a full assessment of documentation has not been carried out at this stage.
2. Comments made above are those that immediately come to mind during the application review and are provided for immediate feedback. Responses to those highlighted (if any) would be appreciated.

**Conclusion of Application Review:**

**IECEX Testing Laboratory (ExTL) Application Report**

**Applicant :**

**Prepared By:**

**Date :**

| Information Provided   | Yes | No | Comments |
|--|-----|----|----------|
| a) Description of laboratory, including organisation Chart about   |     |    |          |
| -Relationship between laboratory and ExCB  |     |    |          |
| -Legal Status  |     |    |          |
| -Address(es)   |     |    |          |
| -Responsibilities concerning testing   |     |    |          |
| -Demonstrate compliance with ISO/IEC 17025   |     |    |          |
| -Documents for supporting information, eg existing accreditation   |     |    |          |
| b) A list of IECEX standards which the laboratory intends to conduct tests for the relevant ExCB             |     |    |          |
| c) Information required by Annex C IECEX 02,   |     |    |          |
| d) Number of Ex Test reports for each type of protection issued over past 2 years for standards listed in b) |     |    |          |
| e) Statement that the laboratory will abide by the rules   |     |    |          |

**Notes:**

1. This application review is limited to the extent of determining whether information has been provided as required by the application forms, which enables the application to be listed on the IECEX system as an Applicant Body. Therefore a full assessment of documentation has not been carried out at this stage.
2. Comments made above are those that immediately come to mind during the application review and are provided for immediate feedback. Responses to those highlighted (if any) would be appreciated.

Conclusion of Application Review: