IECEx OPERATIONAL DOCUMENT

IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx System)

Assessment procedures for IECEx acceptance of applicant Ex Certification Bodies (ExCBs), Ex Testing Laboratories (ExTLs) and Additional Testing Facilities (ATFs) –
Part 2: Assessment, surveillance assessment and re-assessment of ExCBs, ExTLs and ATFs operating in the IECEx 02, IECEx Certified Equipment Scheme

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INTERNATIONAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECEx Operational Document 003-2 –

Assessment procedures for IECEx acceptance of ~~Candidate Accepted~~ applicant Ex Certification Bodies (ExCBs), Ex Testing Laboratories (ExTLs) and Additional Testing Facilities (ATFs) –
Part 2: Assessment, surveillance assessment and re-assessment of ExCBs, ExTLs and ATFs operating in the IECEx 02, IECEx Certified Equipment Scheme

FOREWORD

This OD 003-2 sets out the assessment procedures for IECEx acceptance of ~~Candidate Accepted~~ applicant Ex Certification Bodies (ExCBs), Ex Testing Laboratories (ExTLs) and Additional Testing Facilities (ATFs) operating in the IECEx Certified Equipment Scheme.

This revised edition is prepared to accommodate changes arising from the ~~2016 Umhlanga~~ 2019 Dubai ExMC meeting. It also includes changes proposed by ~~ExMC WG4~~ ExAG which consider discussions at its ~~2017~~ 2020 meeting.

This redline version of IECEx OD 003-2 highlights the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

This Part 2 supplements IECEx OD 003-1, *Assessment procedures for IECEx acceptance of ~~Candidate Accepted~~ applicant Ex Certification Bodies (ExCBs), Ex Testing Laboratories (ExTLs) and Additional Testing Facilities (ATFs) – Part 1: Appointment and surveillance of assessors for IECEx certification schemes*, and supersedes OD 003-2 edition ~~1.0~~ 3.0 where the following major changes are included:

- ~~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~~ IECEx Secretariat" ~~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~~

- Addition of ATFs throughout.

- Revised title of IECEx OD 032 throughout.

- Revised step 6 of Clause 1.2 to reflect that the IECEx pool of assessors are approved by ExAG.

- Revised step 8 to add requirement that a representative of the ExCB shall be present at assessments for ExTLs that are not part of the same organization.

- Revised step 8 to add requirement that a representative of the supervising ExTL shall be present at assessments for ATFs that are not part of the same organization.

- Revised step 16 to refer to IEC CA 01.

- Replaced term "candidate" with "applicant" throughout.

- Replaced term "IECEx Secretary" with "IECEx Secretariat" throughout.

- Moved some responsibilities from IECEx Chair to ExAG Convenor and ExAG Deputy Convenor.

- Clarified Clause 3.1 that the mid-term surveillance of ExTLs is considered to cover all ATFs under their responsibility.

- Clarified Clause 3.3 that the mid-term surveillance is conducted at the ExCB premises and that when the ExCB and ExTL are not part of the same organization that it may be necessary to conduct a separate mid-term surveillance at the ExTL if the records at the ExCB are incomplete.

- Added new requirement in Clause 3.4.1 for those situations where the assessment team from the initial assessment recommends that a new ExCB has a mid-term surveillance conducted sooner than the normal 2,5 year cycle.

- Moved existing pre-assessment information to new Section 4.

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~~ applicant and existing ExCBs, ExTLs and ATFs 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.

International confidence is established by evaluating the competence of a certifying body or Ex test laboratory to comply with the IECEx System and associated scheme rules. The assessment will cover the competence, capability, experience and familiarity of personnel and the organization 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, ExTLs and ATFs)
- Section 3 – Mid-term surveillance audits of issued ExTRs and QARs
- Section 4 - Pre-assessments
- Section 5 – Notes to assessors
- Section 6 - 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 flow chart.

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~~ *Guidelines and information for IECEx assessments*.

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, e.g. email communication shall be deemed an acceptable form of formal communication and record keeping.

**Assessment procedures for IECEx acceptance of ~~Candidate Accepted~~ applicant Ex Certification Bodies (ExCBs), Ex Testing Laboratories (ExTLs) and Additional Testing Facilities (ATFs) –
Part 2: Assessment, surveillance assessment and re-assessment of ExCBs, ExTLs and ATFs operating in the IECEx 02, IECEx Certified Equipment Scheme**

Initial assessment, re-assessment and scope ~~changes~~ extensions

1.1 Scope

This section is to be applied for the initial assessment of applicant ExCBs, ExTLs and ATFs prior to their acceptance in the IECEx Certified Equipment Scheme and re-assessment and scope ~~changes~~ extensions of existing accepted ExCBs, ExTLs and ATFs.

1.2 IECEx applications

~~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.~~

Applications from applicants shall be made using the latest version of following forms, which are available from the IECEx website www.iecex.com:

- ExCB – ExMC/0047L/Q
- ExTL – ExMC/0048L/Q, and/or
- ATF – ExMC/1391A/Q

The term "applicant body" used throughout this document shall mean the applicant ExCB, applicant ExTL and/or applicant ATF, 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~~applicant ExCB, ExTL or ATF" is used this should be replaced with "accepted ExCB, ExTL or ATF".
- Where an ExCB is also an IECEx Mark License issuing ExCB, compliance with IECEx 04, IECEx OD 422 and OD 023 shall be included.

This section is also applicable for scope extensions (applied for using ExMC/251~~B~~/Q, latest version) where the IECEx ~~Secretary~~ Secretariat 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.~~

1.3 IECEx assessment procedure

The IECEx assessment flow chart should be read in conjunction with the table below.

Step	Activity	By whom	Desired outcome
Formal application submitted to IECEx ~~Secretary~~ Secretariat			
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

Step	Activity	By whom	Desired outcome
			endorsed by the IECEx Member Body. The Member Body shall provide written confirmation of their endorsement. An application for a new applicant ATF shall come from the supervising ExTL.
2	Review of application documentation for completeness and determination of the applicant's readiness for the formal IECEx assessment. The review forms used by the Secretariat are attached in Annex A.	IECEx Secretariat	IECEx Secretariat reviews the application, and for new applications, issues an Application Review Report to the applicant. This may require further information from the applicant ExCB, ExTL or ATF. 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~~ IECEx Secretariat	Invoice to applicant ExCB and/or ExTL.
Possible pre-assessment			
~~4~~	~~In conjunction with above review, IECEx Secretary informs the applicant of the potential benefit that a pre-assessment may bring.~~ ~~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.~~	~~IECEx Secretary~~	~~Recommendation to applicant regarding pre-assessment.~~
~~5~~	~~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.~~ ~~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.~~	~~IECEx Secretariat~~	~~A pre-assessment visit with confidential gap analysis report provided to the applicant body.~~
4 & 5	See Section 4.0.		
Formation of assessment team			
6	When the application is complete and any pre-assessment is finalized (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 ExAGMC~~ accepted by ExMC. For initial assessments and re-assessments, the Secretariat will appoint peers from ExCBs and ExTLs as assessment team leaders unless there are none available for the specific assessment – in this case an IECEx 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.	IECEx ~~Executive Secretary~~ Secretariat	Acceptance received from proposed members of the IECEx Assessment Team. Acceptance of proposed members of the team received from applicant.
7	Application package forwarded to members of the appointed assessment team.	IECEx Secretariat	All relevant information available for team to commence their assessment.

Step	Activity	By whom	Desired outcome
	Planning the assessment		
8	Initial planning for the assessment is carried out considering whether there is an ExCB, ExTL, ATF or ~~both~~ some combination. 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 ~~three two~~ two assessors on site for three or more days. A designated representative of the responsible ExCB shall be present during the initial assessments, re-assessments, scope extensions of the ExTLs for which the ExCB is responsible when the ExCB and ExTL are not part of the same organization, parent company, corporation, or similar legal structure. A designated representative of the supervising ExTL shall be present during the initial assessments, re-assessments, scope extensions of the ATFs for which the ExTL is responsible when the ExTL and ATF are not part of the same organization, parent company, corporation, or similar legal structure. Where the applicant body does not have its quality documents in English, it may be necessary to schedule extra time to consider the time needed for translation/interpretation during the assessment process. 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 (e.g. the quality manual) be provided with an English translation to assist the assessor in knowing the subject of the clause.	Assessment team leader in conjunction with IECEx Secretariat	Initial plan for the number of days on site and the number of assessors on site.
9	Dates for the assessment as established in consultation with the applicant body and the assessors.	Assessment team leader	Dates established
10	Preparation of a consolidated cost estimate and draft assessment programme for review by the applicant ExCB or ExTL. Work should only commence after the applicant has accepted the cost estimate. A copy of this acceptance should be provided to the IECEx Secretariat. Travel times charged for each assessment visit shall not exceed one day unless there are compelling circumstances and approval is obtained from both the IECEx Secretariat and the applicant.	Assessment team leader in conjunction with team members	A copy of the cost estimate and draft assessment plan to the applicant and IECEx Secretariat. Acceptance of the cost estimate and plan by the applicant.
11	Review of application documentation. Assessment team leader may request additional information from the ~~Candidate~~ applicant ExCB, ExTL or ATF.	Assessment team leader in conjunction with team members	Request for additional information if needed.

Step	Activity	By whom	Desired outcome
	On-site visit		
12	The assessment visit takes place. Refer to IECEx OD 032, ~~Assessor's Guide~~ *Guidelines and information for IECEx Assessments*, for more information on this process. At the closing meeting the findings will be discussed with the management of the applicant body. The documentation produced from the assessment will fall into two categories: 1) Reports that will be circulated for voting by the member bodies, or 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	Assessment team	Following reports shall be completed: • **F-004** Site Assessment Report • **OD 107** ISO/IEC 17065 checklist – required for non-accredited bodies only • **OD 018** ISO/IEC 17025 report for ExTL/ATF – required for non-accredited bodies only • **TCD~~s~~** Technical Capability Document~~s~~ • ~~Draft reports for the ExCB and ExTL for voting~~ • **F-003 IECEx** Assessment Report Form As a minimum, a first draft of F-004 and F-003 should be left with the body at the end of the assessment visit.
	Post assessment visit actions		
13	Any issues or non-compliances identified during the assessment process must be resolved by the applicant body to the satisfaction of the assessment team. NOTE 1 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 significant matter is identified the assessment team may, at its discretion, identify this as a major "non-compliance" that will need special attention. NOTE 2 The assessment team may also make "observations" and list these in the site assessment report. Observations do not require resolution. In some cases, it may be necessary for a follow-up visit by one or more members of the assessment team. 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. Where results of site visit require rectification or corrective action by the ~~candidate~~ applicant ExCB, ExTL or ATF, the assessment team leader, with input from the assessment team, shall review the corrective actions and determine whether the item(s) raised have been sufficiently addressed in order to close the issue. Where issues, identified during the site visit, remain unresolved more than 12 months beyond the site visit, the IECEx ~~Executive Secretary~~ Secretariat in consultation with the IECEx Executive shall determine whether a further site visit shall be required.	Body under assessment & assessment team Assessment team leader	Final reports for submission to the IECEx Secretariat, reviewed by all members of the assessment team. ~~Assessment Team Leader to arrange for compilation of final assessment reports for voting by ExMC.~~
14	Final IECEx Assessment Team reports reviewed by IECEx Secretariat. This review includes but is not limited to: - Ensuring all matters raised as listed in the site assessment report and TCD have been satisfactorily closed.	IECEx Secretariat	Review by IECEx Secretariat to ensure completeness of information and readiness for circulation to ExMC for voting or consideration at a meeting.

Step	Activity	By whom	Desired outcome
	- The final summary report is complete and there are no "hanging" statements. - Details of accreditation and scope are clear. Once the review is completed, the following is added at the bottom of the report: "Independently reviewed by the IECEx Secretariat".		
14A	Where review in step 14 raises questions, IECEx ~~Executive Secretary~~ Secretariat refers the matter to the IECEx Assessment Team Leader seeking additional information or revised report. The IECEx Secretariat may consult with the IECEx Executive as part of this review.	IECEx Secretariat	An acceptable report for circulation to ExMC.
15	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 Documents and associated reports for ExCB and ExTL.~~	IECEx Secretariat	ExMC document issued for voting, with a copy submitted to ~~candidate~~ applicant ExCB or ExTL.
Final approval of ExCB, ExTL or ATF by ExMC			
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 IEC ~~Ex~~ CA 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. IECEx Secretariat may consult with the IECEx ~~Chairman~~ ExAG Convenor and ExAG Deputy Convenor.
17	If voting is acceptable then IECEx Secretariat notifies the applicant body of its acceptance.	IECEx Secretariat	IECEx letter of acceptance to accepted ExCB, ExTL and/or ATF. Certificate of acceptance issued to the body. IECEx Secretariat updates the IECEx records, e.g. OD 001 and arranges access for ExCB to use IECEx On-Line Certificate system. Summary of voting results uploaded by IECEx Secretariat to IECEx website. ~~Copy of review report on voting to be forwarded to ExMCWG4 members~~ ExAG to review for information to permit them to look at ways the process might be improved based on comments from the member bodies voting. 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~~ Secretariat.
18	Appointment recorded at next ExMC meeting.	IECEx Secretariat ~~to arrange~~	Recorded in minutes.

Applicant/s

1
Application received at the IECEx Secretariat

3
Invoice sent by IECEx Secretariat to the Applicant

2
Application package reviewed by the IECEx Secretariat

2a
IECEx Secretariat issues application review to Applicant/s

19
Notification of acceptance

5
Arranged between Candidate and Assessor

Yes

4
Pre-assessment

No

12
On site Assessment takes place

12a
Draft reports by Lead assessor to applicant/s

7
Application package sent to team members

6
When the application review is complete assessment team is formed

13
Any issues or non-conformances resolved.

16
Voting by ExMC Members

8
Initial planning of assessment

14
Final assessment report sent to IECEx Secretariat for review

Voting accepted ?

No

Refer to ExMC Meeting

Yes

9
Dates for the assessment established between applicant/s and assessment team

10a
Work commences once costs and plans accepted. Acceptance notice sent to IECEx Secretariat

10
Preparation of cost estimates and draft assessment plan for review by applicant/s

Satisfactory

No

17
IECEx Secretariat notifies Applicant/s of acceptance

14a
Refer back to Lead Assessor for more inf or revision

Yes

18
Appointment recorded at next ExMC Meeting

11
Review of application documentation by Assess/team

15
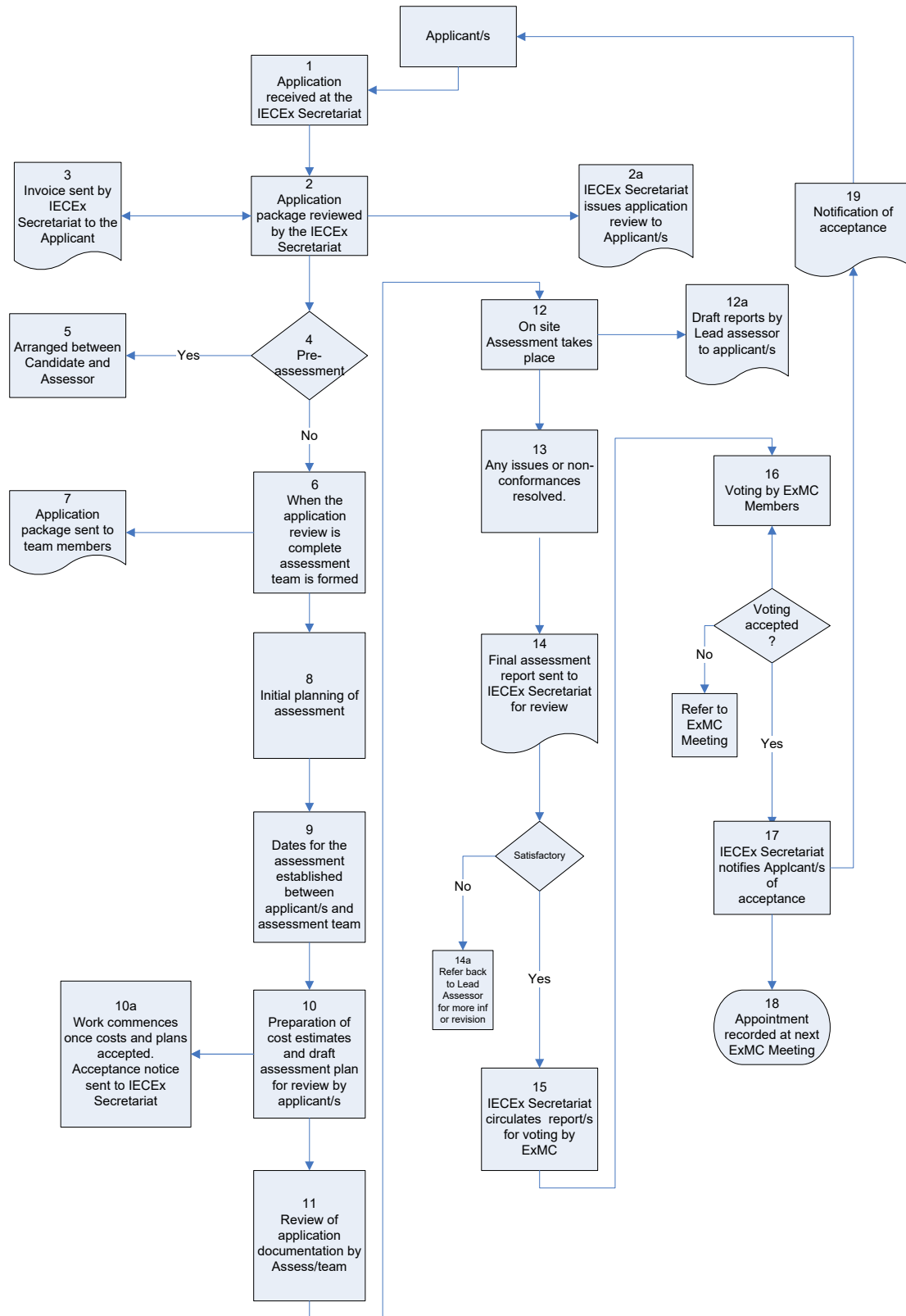IECEx Secretariat circulates report/s for voting by ExMC

Figure 1 – Process flow chart

On-going surveillance assessment of bodies (ExCBs, ExTLs and ATFs)

2.1   Scope

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

1) ExCBs, ExTLs and ATFs that maintain relevant national accreditation that is found to be acceptable by the original IECEx Assessment Team, and through the ExMC vote.

2) ExCBs, ExTLs and ATFs that do not have relevant national accreditation or whose accreditation is not acceptable to the ExMC.

2.2   Surveillance of ExCBs, ExTLs and ATFs 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, ExCBs, ExTLs and ATFs along with a call for audit reports issued by accreditation bodies and internal audit reports of the ExCBs, ExTLs and ATFs to gain evidence of compliance with ISO/IEC 17025 and ISO/IEC 17065 along with IECEx Scheme requirements. The ISO/IEC 17065 or ISO/IEC 17021, if applicable, audit reports should provide conclusive evidence that the national accreditation body is including surveillance activities in its assessment. If there is no evidence or coverage, then the IECEx Secretariat shall, if deemed necessary, arrange a witnessed assessment of surveillance activities of manufacturers at an appropriate time in the assessment cycle for the ExCB.

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

2.2.2   Review

The IECEx Secretary Secretariat shall review the information to ensure:

- ExCB, ExTL and ATF sites covered by accreditation aligns with the site previously approved by ExMC,

- All clauses of ISO/IEC 17025 for ExTLs and ATFs 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 Secretariat may consult with the IECEX Chairman ExAG Convenor, ExAG Deputy Convenor 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 ExAG Convenor and ExAG Deputy Convenor 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 ExAG Convenor and ExAG Deputy Convenor 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 Surveillance of newly accepted ExCBs and ExTLs with acceptable national accreditation

Due to the difficulty of assessing applicant ExCBs and ExTLs when they have not carried out any IECEx work and the time frame of 5 years for the re-assessment, a one-off surveillance site visit should be undertaken. The purpose for this visit is to ensure that all relevant IECEx procedures and rules are being followed. This visit will normally take place 12 months after acceptance of the body but may be deferred to a later date if no IECEx work has been undertaken during this period.

2.2.4 Re-assessment

On the fifth anniversary of the original assessment site visit or re-assessment site visit of an ExCB, ExTL or ATF, 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~~ Secretariat.

2.3 Surveillance of ExCBs, ExTLs and ATFs without acceptable national accreditation

2.3.1 Preparation

The IECEx Secretariat shall arrange for an annual on-site surveillance assessment of the ExCB, ExTL and ATF. This should normally be carried out by one member of the ~~original~~ previous IECEx assessment team. The assessor shall be appointed by the IECEx ~~Executive Secretary~~ Secretariat. 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~~ Secretariat may consult with the ~~IECEx Chairman~~ ExAG Convenor, ExAG Deputy Convenor and Executive.

The appointed assessor shall carry out an assessment for compliance with ISO/IEC 17025 for ExTLs and ATFs. 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~~ Secretariat who 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.

The IECEx Secretariat shall, if deemed necessary, arrange a witnessed assessment of surveillance activities of manufacturers at an appropriate time in the assessment cycle for the ExCB.

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~~ Secretariat may consult with the ~~IECEx Chairman~~ ExAG Convenor, ExAG Deputy Convenor 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 appeals, the ~~IECEx Chairman~~ ExAG Convenor and ExAG Deputy Convenor 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~~ ExAG Convenor and ExAG Deputy Convenor 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, ExTL or ATF 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~~ Secretariat.

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.

The mid-term surveillance of ExTLs is considered to cover all ATFs under their responsibility.

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, ExTLs and ATFs 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, ExTLs and ATFs 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, ExTLs and ATFs 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, ExTLs and ATFs 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~~ Secretariat and agreed to by the ExCB/ExTL, will focus on the technical aspects of the ExTL and ExCB. To reduce costs, and considering 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:

a) *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 organization,*

b) *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*

c) *the time needed to properly review all aspects of an organization'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 (that is, 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 one 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) 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 considered 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, for example, 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 IECEx OD 204 together with completed checklists, IECEx 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~~ Secretariat 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.

Pre-assessment

4.1   Scope

This section is to be applied for the optional pre-assessment of applicant ExCBs, ExTLs and ATFs prior to their acceptance in the IECEx Certified Equipment Scheme.

4.2   Role

The role of pre-assessment is for an applicant ExCBs, ExTL and ATFs to determine their readiness for an initial assessment. The pre-assessment may be focused on areas requested by the applicant, recommended by the IECEx Secretariat and/or the IECEx Assessor.

4.3   Procedure

Step	Activity	By whom	Desired outcome
	Request submitted to IECEx Secretariat		
1	Verify that pre-assessment is appropriate. NOTE It is possible for a pre-assessment to be done prior to an application being made to IECEx.	IECEx Secretariat	IECEx Secretariat reviews application or request from applicant body and recommends pre-assessment.

Step	Activity	By whom	Desired outcome
2	Determine scope of Pre-Assessment. NOTE It is intended that the pre-assessment use a similar approach to a normal assessment but focusing 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.	IECEx Secretariat	IECEx Secretariat recommends scope of pre-assessment.
3	Invoice prepared for the application fee.	IECEx Secretariat	Invoice to applicant ExCB and/or ExTL.
	Pre-Assessment		
4	If applicant agrees to a pre-assessment, IECEx Secretariat informs the applicant body of suitable experienced assessors.	IECEx Secretariat	Applicant body finds a suitably experienced assessor.
5	The applicant body engages the assessor directly and the assessment takes place.	IECEx Assessor	IECEx Assessor provides report of findings to applicant body and IECEx Secretariat. No formal reporting of findings is required to be retained by the IECEx Secretariat. IECEx Assessor notifies IECEx Secretariat as this may impact the composition of the assessment team for the Initial Assessment.

Notes to assessors

5.1 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 Guidelines and information for IECEx assessments*.

5.2 Instructions for assessment teams

It is recognized that assessors have been approved by ExMC based on 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.

5.3 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 contact his/her team members and the candidate applicant ExCB, ExTL and/or ATF 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, ExTL and/or ATF applications and supporting documentation for initial assessments

All team members must have the following:

- Technical capability document~~s, where available~~,

- ~~Working copy of~~ Rules and ODs applicable to the scope of the assessment, e.g. IECEx 02,

- IECEx assessment procedure, IECEx OD 003-2, ~~this document~~

- IECEx OD 032, *~~Assessor's Guide~~* *Guidelines and information for IECEx assessments*, and

- Relevant ISO/IEC Standards, particularly ISO/IEC 17025 and ISO/IEC 17065.

An assessors' package of relevant documents is available from the IECEx website at ~~http://www.iecex.com/assessors_package.htm~~ www.iecex.com/members-area/new-document-library-page/assessors-package.

~~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~~ applicant ExCB, ExTL or ATF and is responsible for all correspondence.

The team leader should liaise with the IECEx ~~Executive Secretary~~ Secretariat and ~~candidate~~ applicant ExCB or ExTL regarding the assessment programme and estimated costs (assessment fees and travel costs). The ExCB or ExTL should reach agreement with the IECEx 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 document~~s~~ and ~~IECEx 02~~ the rules and ODs are satisfied and implemented.

It is expected that most of the consultation between team members would be via ~~correspondence, fax,~~ email ~~etc~~.

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 the ExCB, ExTL and/or ATF their team have assessed.

To assist IECEx assessment teams, the IECEx Management Committee has appointed IECEx ExAG with the task acting as a reference body for assessment teams. In addition, the IECEx Secretariat and other IECEx Officers are always willing to provide assistance. Therefore, the team leader should feel free to make use of this assistance throughout the course of their assessments.

5.3.1   ExCBs, Certified Equipment Scheme

Assessments of ExCBs are aimed at demonstrating compliance with ISO/IEC 17065 and IECEx 02 for the Certified Equipment Scheme. This includes verifying:

- Declaration as per ~~Appendix~~ Annex A of IECEx 02

- An agreement between the ExCB and a recognized ExTL and/or ATF (where separate)

- An organizational chart (NOTE Where the ExCB is also an ExTL the organizational 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, IECEx OD 009)

- Procedures for assessing manufacturers quality plans, these to include the evaluation of documents that attest to a manufacturer's certification/registration to such as ISO 9001 (ISO/IEC 80079-34, IECEx 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 manufacturer's quality plans (IECEx Operational Documents OD 009, OD 025, OD 026 and 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, and

- 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 IECEx OD 025)

- A thorough understanding by the ExCB's auditors of the requirements of ISO/IEC 80079-34, IECEx OD 025 and IECEx OD 009

- Experience with operating product certification programmes 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 8007~~8~~9-34 and IECEx OD 025

5.3.2   ExTLs/ATFs, Certified Equipment Scheme

Assessments of ExTLs and ATFs 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~~ Annex B (ExTL) or Annex D (ATF) of IECEx 02

- An organizational chart (NOTE Where the ExCB is also an ExTL the organizational chart shall demonstrate independence of testing and certification up to at least manager level)

- Information as per ~~Appendix~~ Annex 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, and

- 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.~~

5.4 Assessor fees

Assessor fees (payable by the ExCB and ExTL) for mid-term assessments are defined in IECEx OD 019.

5.5 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 IECEx Lead Assessor is responsible for liaison between the assessment team and the ~~candidate~~ applicant ExCB, ExTL and ATF. 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~~ applicant ExCB, ExTL and ATF.

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 IECEx Lead Assessor immediately and advise the IECEx Secretariat.

Assessing of ExCBs, ExTLs and ATFs is an extremely important process and ~~will~~ greatly assists in establishing and maintaining the IECEx System's credibility. The ~~Assessment Panel Chairman~~ ExAG, ~~ExMC~~ IECEx Chair 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.

Proficiency testing programmes

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

For application bodies that have not been fully involved with the PTP, the following guidance is provided on how to assess them.

The following is the requirement from IECEx OD 202:

Applicant ExTLs and applicant ATFs shall, prior to completion of the assessment process

– *complete the programmes relevant to the scope of their application; or*
– *demonstrate satisfactory compliance by other means with past programmes, for example by demonstrating tests on programme artefacts as part of the assessment process.*

For demonstrating tests on programme artefacts, tests used in the PTP should be nominated by the assessment team. Attempts should be made to include tests from all relevant programmes but a complete set of tests from each programme is not likely to be practical and so is not required. However, even with a reduced number of tests, additional time is likely to be necessary for the initial assessment to address all relevant programmes.

The tests may be carried out on artefacts that are on loan from another ExTL. As a guide, the results of the tests can be compared with the assigned value where it exists in the report of the programme. But care will need to be taken in the conclusions drawn from this testing, recognising that a number of factors may affect the result, for example:

- The homogeneity of the artefact cannot be assured if it is not a new sample from PTB

- There may be fewer tests applied than required by the full programme

- The programmes provide for two rounds to permit improvement for the results, but this will not occur at an assessment

It should, however, be possible to draw useful conclusions from the testing which can provide confidence in current competence and potential areas for further improvement. Where errors in testing procedures are identified during the testing, these should be raised as formal issues for the assessment in the normal way.

Annex B provides an example of how appropriate sampling of PTP programmes may be applied. This is an example of an actual assessment which required two additional days on site for two assessors to accommodate the testing. Programmes 1 and 2 had been closed when this testing was proposed.

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

NOTE 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 programmes. The Secretariat will provide this information to the assessment team.

Auditing of the assessment process

~~It is proposed that~~ An audit of the records held by the Secretariat is to 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~~ is conducted under the oversight of the IECEx Chair.

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, ExTL and/or ATF			
– Responsibilities at 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 recognize 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 over past 2 years for standards listed in b)			
f) Statement that the ExCB will abide by the rules			

NOTE 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.

NOTE 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 organization chart about:			
– Relationship between laboratory and ExCB			
– Legal status			
– Address(es)			
– Responsibilities concerning testing			
– Demonstrate compliance with ISO/IEC 17025			
– Documents for supporting information, e.g. existing accreditation			
– Information on ATFs, as applicable			
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			

NOTE 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.

NOTE 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 Additional Testing Facility (ATF) application report

Applicant:

Prepared By: **Date:**

Information provided	Yes	No	Comments
a) Description of laboratory, including organization chart about:			
– Relationship between laboratory and ExTL			
– Legal status			
– Address(es)			
– Responsibilities concerning testing			
– Demonstrate compliance with ISO/IEC 17025			
– Documents for supporting information, e.g. existing accreditation			
b) A list of IECEx Standards which the laboratory intends to conduct tests for the relevant ExTL			
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			

NOTE 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.

NOTE 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:

Annex B

How appropriate sampling of PTP programmes may be applied

The tests from the proficiency programme are:	Additional detail on tests/assessments
1. Programme 3 – flame transmission (with nozzles that I will supply) (with reduced number of tests)	Test to be done in accordance with PTB_Ex_PTS_Procedure_Instruction_FT_2013-08-01 but tests reduced from 10 to 5 for each nozzle.
2. Programme 4 – temperature classification	Test to be done in accordance with PTB_Ex_PTS_Procedure_Instruction_TC_2013_Version_2 but with test on glass surface only.
3. Programme 5 – electrostatic charge on a two samples	Test to be done in accordance with PTB_Ex_PTS_Procedure_Instruction_EC__2016-02-05__Update but surface resistance test only to IEC 60079-0 edition 7.0 on each of the two samples.
4. Programme 6 - intrinsic safety (this is assessment, but we can review results and discuss)	Assessment to be done in accordance with PTB_Ex_PTS_Procedure_Instruction_IS_2015__2015-11-12.
5. Programme 7 – explosion pressure (with reduced number of tests)	Test to be done in accordance with PTB_Ex_PTS_Procedure_Instruction_EP2017__2017-11-28 using 3.3.1 Configuration a), Pipe A and the following tests: • Three (3) ignition tests with explosive mixture (1) (ethylene 8 % ± 0,5 %) at normal ambient temperature (ignition side 1) • Three (3) ignition tests with explosive mixture (1) (ethylene 8 % ± 0,5 %) for use at an ambient temperature of –40 °C (ignition side 1)
6. Programme 8 – pressurized enclosure (possibly with reduced number of tests)	Test to be done in accordance with PTB_Ex_PTS_Procedure_Instruction_PE_PHASE_II__2018-09-26 but with reduced testing as follows: 1. Determination of leakage flow rate according to IEC 60079-2, Clause 16.3.1 3. Filling with He until concentration of at least 70 % is reached at each measuring point. Purging with air until concentration of He is less than 1 % (IEC 60079-2, Clause A.2) according to IEC 60079-2, Clause 16.4.