

IECEX OPERATIONAL DOCUMENT

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

**IECEX Certified Service Facilities Scheme –
Part 2: Selection of Ex equipment and design of Ex installations**

Assessment procedures for IECEX acceptance of Candidate Certification Bodies (ExCBs) for the purpose of issuing IECEX Certificates to Ex Service Facilities providing selection of Ex equipment and design of Ex installations related services



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**IECEx Certified Service Facilities Scheme –
Part 2: Selection of Ex equipment and design of Ex installations**

**Assessment procedures for IECEx acceptance of Candidate Certification Bodies
(ExCBs) for the purpose of issuing IECEx Certificates to Ex Service Facilities
providing selection of Ex equipment and design of Ex installations related
services**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

Operational Document IECEX 316-2**IECEX Certified Service Facilities Scheme –
Part 2: Selection of Ex equipment and design of Ex installations****Assessment procedures for IECEX acceptance of Candidate Certification
Bodies (ExCBs) for the purpose of issuing IECEX Certificates to
Ex Service Facilities providing selection of Ex equipment and
design of Ex installations related services****FOREWORD**

This document is the Operational Document IECEX OD 316-2 Assessment Procedures for the Acceptance of Applicant ExCBs seeking to participate in the IECEX Certified Service Facilities Scheme – Part 2: Selection of Ex equipment and design of Ex installations in order to issue IECEX Certificates to Service Facilities providing selection of Ex equipment and design of Ex installations related services.

A listing of currently approved ExCBs is maintained on the IECEX website: www.iecex.com.

Document History

Date	Summary
2013-03	This original issue Edition 1.0 of IECEX OD 316-2 supersedes IECEX OD 016 Version 1.0 in part and represents the application of a new numbering system.
2018-10	This Edition 2.0 was approved for publication by the 2018 ExMC Meeting via ExMC Decision 2018/54 and supersedes Edition 1.0 of IECEX OD 316-2 upon publication.

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INTRODUCTION

This Operational Document details the assessment procedures established by the IECEx Scheme's Management Committee, ExMC, for the purpose of ensuring a thorough assessment of candidate ExCBs.

The principle aim of these procedures is to instil international confidence in the ExCB's competence and capabilities for performing assessment and auditing of Ex Service Facilities covering selection of Ex equipment and design of Ex installations and who seek IECEx Certification.

International confidence is established by evaluating the competence of a certifying body. The assessment is to cover the competence, experience and familiarity of ExCB personnel and the organization with the relevant explosion protected standards, quality management systems, IECEx Scheme and associated rules and ISO/IEC 17065 and IECEx Technical Capability Documents (TCD).

The procedures are also aimed at ensuring a consistent approach to assessments by IECEx assessment teams.

This Operational Document provides the following three Sections:

- Section 1 – Initial assessment and re-assessment of ExCBs
- Section 2 – On going surveillance of ExCBs
- Section 3 – Assessment of existing ExCBs seeking to extend their scope of acceptance to cover the IECEx Certified Service Facilities Scheme for design of Ex installations and selection of Ex equipment

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.

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

NOTE Although this IECEx Operational Document makes reference to IEC 60079-14 and IEC 60079-17, it is also relevant in determining ability to work with other international, national or regional requirements of a similar nature, such as IEC 61892-7 - Mobile and fixed offshore units – electrical installations – Part 7: Hazardous areas.

IEC CA 01, *IEC Harmonised Basic Rules*

IECEX 01-S, *IECEX Supplement to IEC CA 01*

IECEX 03-0, *IECEX Certified Service Facilities Scheme – Part 0: General Rules of Procedure*

IECEX 03-2, *IECEX Certified Service Facilities Scheme – Part 2: Selection of Ex equipment and design of Ex installations – Rules of Procedure*

IEC 60079-14, *Explosive atmospheres – Part 14: Electrical installations design, selection and erection*

IEC 60079 Series as relevant or as referenced from IEC 60079-14 (for example IEC 60079 – Parts 10-1, 10-2, 13, 19, 26, 28, 29-1, 29-4, 30-1, 30-2, 32-1, 43 or 46)

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

ISO/IEC 17011, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*

ISO/IEC 17020, *Conformity assessment – Requirements for the operation of various types of bodies performing inspection*

ISO/IEC 17021-1, *Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements*

ISO/IEC 17065, *Conformity assessment – Requirements for bodies certifying products, processes and services*

ISO 19011, *Guidelines for auditing management systems*

ISO Guide 27, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*

ISO Guide 28, *Conformity assessment – Guidance on a third-party certification system for products*

ISO/IEC Guide 53, *Conformity assessment – Guidance on the use of an organization's quality management system in product certification*

Operational Document IECEX OD 316-2

IECEX Certified Service Facilities Scheme – Part 2: Selection of Ex equipment and design of Ex installations

Assessment procedures for IECEX acceptance of Candidate Certification Bodies (ExCBs) for the purpose of issuing IECEX Certificates to Ex Service Facilities providing selection of Ex equipment and design of Ex installations related services

Section 1 – Initial assessment and re-assessment of ExCBs

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

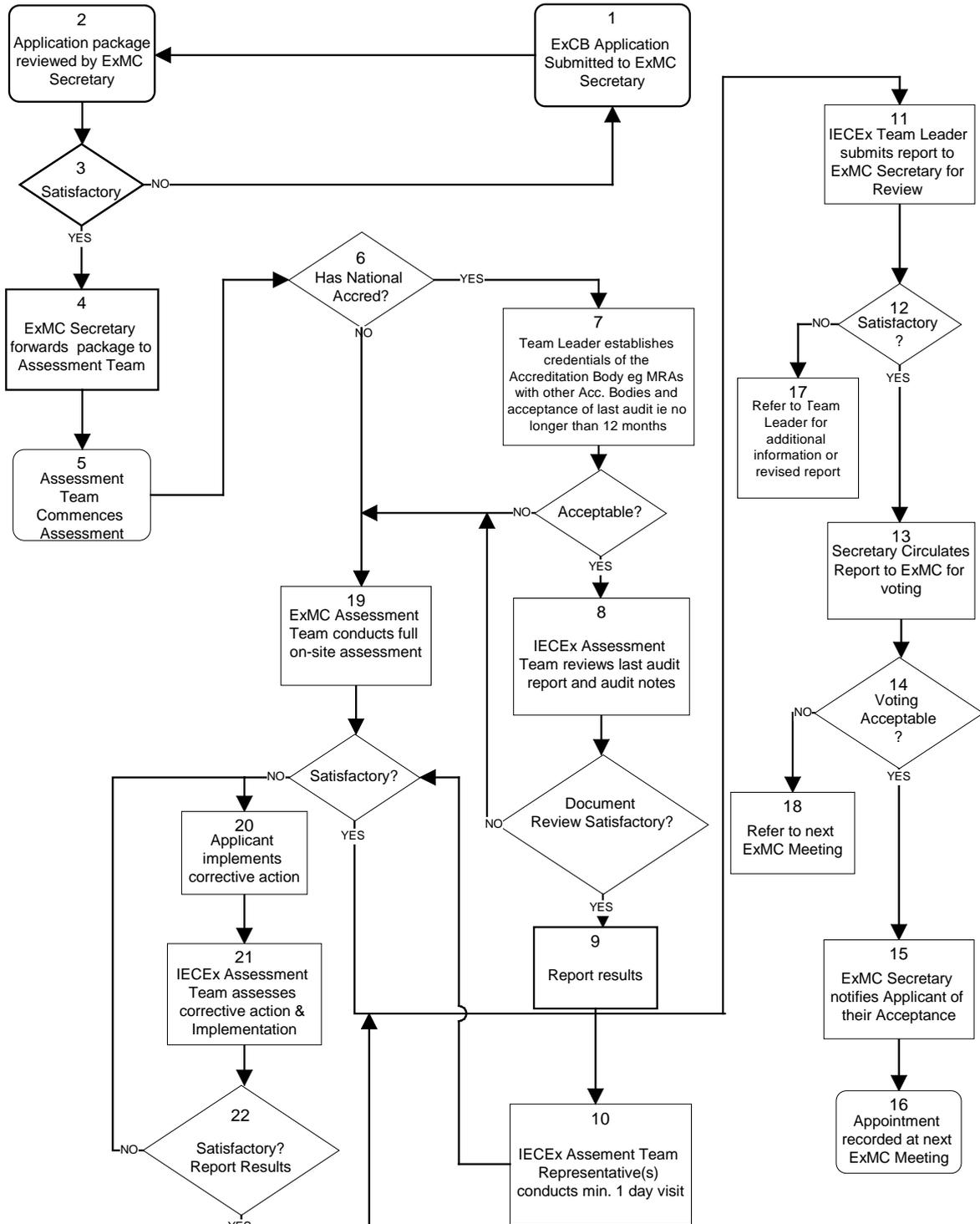
The term Lead Assessor, as used throughout this document, shall mean the IECEX Assessment Team Leader appointed by the IECEX Secretariat and endorsed by ExMC.

This Section does not apply to ExCBs already accepted in the IECEX Certified Equipment Scheme. Refer to Section 3.

The ExCB shall use application forms that include a statement by which the applicant declares any previous or existing applications made to other ExCBs.

Step	Activity	By Whom	Desired Outcome
Formal Application Submitted to ExMC Secretary			
1	Application received by IECEX Secretariat, in accordance with IECEX 03-2. The application shall include details of the proposed ExCB assessors to undertake IECEX 03-2 audits.	IECEX Secretariat	Candidate ExCB
2	Application assessed for completeness. Appointed Assessment Team accepted by ExMC.	IECEX Secretariat	Assessment team proposed by IECEX Secretariat and accepted by ExMC
3	IECEX Secretariat reviews application documentation for completeness. IECEX Secretariat may request further information from the candidate. ExMC Secretary to report findings to candidate ExCB.	IECEX Secretariat	
4	IECEX Secretariat forwards Application package to Members of the appointed Assessment Team.	IECEX Secretariat	All relevant information available for team to commence their assessment
Documentation Review Stage			
5	IECEX Assessment Team commences assessment. Team Leader, in conjunction with team members reviews application documentation to satisfy Steps 6 to 8. The ExCB shall provide a filled-out TCD 60079-14. Team Leader may request additional information from the Candidate ExCB.	Team Leader to manage	Team Leader notifies candidate of successful review of documentation and then prepares to arrange site visit
6	Team Leader, in conjunction with team members determines whether the applicant ExCB has Independent Accreditation.	Team Leader or his designated	Formal notification of accreditation, with a copy being submitted by the applicant
7	Assessment of the accreditation and credentials of the accreditation body. For example determining: – Whether the body has Mutual Recognition Agreements with other bodies – Whether the body has National Government recognition – What Standards or Guides are used IECEX Assessment Team Leader may obtain information directly from accreditation body or candidate ExCB and circulate to other IECEX Assessment team members for review via correspondence. NOTE ExCB should obtain all necessary information from accreditation body for presentation to IECEX Assessment Team Leader.	Team Leader	<ul style="list-style-type: none"> – Verification of MRAs – Notification of Government recognition – Use of ISO/IEC 17065 – Frequency of surveillance audits
8	Review of past audit reports, issued by the accreditation body, by Assessment Team to establish compliance with the requirements of IECEX 03-2, and Documents, ISO/IEC 17021-1 and ISO/IEC 17065 as relevant.	Assessment Team managed by Team Leader	Acceptance by IECEX Assessment Team of information and audit reports as evidence of compliance to the requirements of IECEX 03-2 and ISO/IEC 17065
9	Notification of results of Step 6 to 8 to candidate IECEX 03-2 ExCB.	Team Leader	Letter, fax or e-mail to Candidate ExCB. Copy to IECEX Secretariat

On-site Visit			
10	A minimum of one representative of the IECEX Assessment Team visits candidate to conduct a site visit for each ExCB application. This visit is to verify the applicant ExCBs ability to comply with IECEX 03-2 requirements. The Assessment shall include a review of the ExCB's system for allocating auditors as competent to undertake IECEX Service Facility Assessments.	At least one person from IECEX Assessment Team (usually Team Leader)	Visit notes to be included in assessment file Team Leader in consultation with his Team shall determine the duration of the visit
11	Results of site visit determined with a final report for submission to the IECEX Secretariat prepared in the format as outlined in Annex A. Final report to be reviewed by all members of the assessment team.	Team Leader	Team Leader to commence arrange for a final assessment report compiling a Report
12	Final IECEX Assessment Team Report Reviewed by IECEX Secretariat.	IECEX Secretariat	Review by IECEX Secretariat to ensure completeness of information and ready for circulation to ExMC for voting
13	IECEX Secretariat prepares Report for voting and submits to ExMC Members for formal voting, via correspondence or at the next ExMC meeting.	IECEX Secretariat	ExMC Document issued for voting, with a copy submitted to candidate ExCB
Final Approval of ExCB by ExMC			
14	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 (approval $\geq 67\%$) approves application (IECEX 01)
15	If voting is acceptable then ExMC Secretary notifies applicant of their acceptance.	IECEX Secretariat	ExMC letter to accepted ExCB
16	Appointment recorded at next ExMC meeting.	IECEX Secretariat to arrange	Recorded in the minutes
17	Where review in Step 12 is unsatisfactory, IECEX Secretariat refers the matter to the IECEX Assessment Team Leader seeking additional information or revised report.	IECEX Secretariat	An acceptable report for circulation to ExMC
18	Where a positive vote, in accordance with IECEX 01 is not achieved the application is then referred to the next ExMC meeting for discussion.	IECEX Secretariat to arrange	Findings recorded in the minutes
19	If at the conclusion of the "Document Review Stage", the Assessment Team is not satisfied with the information presented, the Team Leader shall inform the candidate ExCB and IECEX Secretariat of the Assessment team's views. In order for the assessment to proceed, the IECEX Assessment Team may be required to conduct a full on site assessment in accordance with IECEX 03-2 and Technical Guidance Documents (TCD 60079-14), ISO/IEC 17065 and ISO/IEC 17021-1, as applicable.	Team Leader to manage	Assessment report by Team Leader
20	Where non-conformances are identified during the assessment process the candidate ExCB implements corrective action if they wish to proceed with their application.	Candidate ExCB	Implementation of corrective actions
21	Assessment team assesses corrective action. This may be performed by either the full team or a partial team or even one member of the team.	Team Leader to manage	Report on assessment of corrective actions
22	Notification of results of step 5 to candidate IECEX 03-2 ExCB.	Team Leader	Letter, fax or e-mail to Chairman of Assessing Panel



IECEX Assessment FlowChart
(Refer to table for details of each step)

Figure 1 – IECEX Assessment Flowchart (refer to table for details of each step)

Section 2 – On going surveillance of ExCBs

This Section applies to ExCBs that have been already accepted into the IECEX Certified Service Facilities Scheme for issuing IECEX Certification to Ex Service Facilities involved in selection of Ex equipment and design of Ex installations.

The purpose of on-going assessments is to satisfy the International Ex community that ExCBs maintain their facilities and capabilities that enabled their entry into the Scheme.

2.1 Surveillance of ExCBs with National Accreditation acceptable by ExMC

2.1.1 Scope

This section covers ExCBs that maintain national accreditation found to be acceptable by the original IECEX Assessment Team, and by way of ExMC voting on the initial assessment report.

Acceptable National Accreditation according to this Clause means accreditation to ISO/IEC 17065 or ISO/IEC 17024 for Ex Product Certification or Ex Personnel Competence Certification by an accreditation body that is a member of the International Accreditation Forum (IAF). No limitations to Ex types of protection can apply.

The procedures detailed below are general and ALL ExCBs are reminded of their obligations to notify the IECEX Secretariat of any changes within their organization that may affect their ability to deliver IECEX Certification Services in accordance with IECEX Rules and Operational Documents and in the spirit of a timely and professional service delivery.

2.1.2 Procedures

Each year, prior to the anniversary date of acceptance into the IECEX Scheme, ExCBs shall submit to the IECEX Secretariat a report containing the following information:

a) Any changes in the organization

Description of changes in the organization of the ExCB, its staff, facilities, quality system, operating procedures, or other similar changes, that relate to the ExCB's operation under IECEX 03-2.

AND

b) Annual audit report

Copy of a National Accreditation Body's audit report issued during the preceding 12 months. This report should show:

- Site that was audited by the accreditation body;
- Date and duration of the audit;
- Audit scope;
- ISO/IEC Guides, Standards and IECEX Technical Capability Documents (TCD) used during the audit;
- Observation notes;
- Details of any non-conformances raised;
- Copy of any audit report summary.

OR

c) Report by the ExCB based on its own internal audit(s) carried out during the preceding 12 months. A standardised report format should be used for this purpose. Once every two

years, the report, prepared by the ExCB shall be endorsed by the National Accreditation Body

Item a) is mandatory and either of b) or c).

2.1.3 Review

The IECEX Secretariat shall review the information to ensure:

- Site assessed aligns with the site previously approved by ExMC;
- All Clauses of ISO/IEC 17021-1, ISO/IEC 17065, as applicable, have been covered;
- Ensure that Technical Capability Documents (TCD) have been used (where available);
- Any Non-conformances are identified.

Where major Non-conformances have been identified the ExMC Secretary in consultation with the IECEX Assessor panel Chairman shall propose appropriate action to be taken, with the IECEX Executive to decide on such action and report at the next ExMC meeting.

Where the ExCB does not agree with the course of action, the matter may be referred for appeal in accordance with IEC Harmonised Basic Rules (IEC CA 01) and IECEX Supplement to IEC CA 01 (IECEX 01-S).

During the period of referral to the Board of Appeal, the ExMC Chairman in consultation with the other IECEX Executive shall decide on the status of the ExCB in question.

In extreme circumstances, the status of temporary suspension may be considered. The ExMC is to decide on the final action to be taken.

The IECEX Secretariat will retain a copy of the report, for a minimum of 10 years, for record keeping purposes.

2.1.4 Re-assessment

On or before the fifth anniversary of the acceptance of the ExCB or the last re-assessment of an ExCB a re-assessment, in accordance with the assessment procedure detailed in Section 1, shall be performed by an IECEX Assessment Team appointed by IECEX Secretariat.

2.2 Surveillance of ExCBs without National Accreditation acceptable by ExMC

2.2.1 Scope

This section covers ExCBs that do not have national accreditation but who have been accepted in to the IECEX Scheme by way of a full on-site assessment, by the IECEX Assessment Team.

2.2.2 On-site audit

The IECEX Secretariat shall arrange to have one member of the original IECEX assessment team conduct an annual on-site audit. The assessor shall be appointed by the IECEX Assessment Team Leader responsible for the original assessment.

The ExCB shall agree to bear the costs associated with this on-site audit prior to the site visit based on an estimate prepared and submitted to the ExCB by the Team Leader.

The appointed assessor shall carry out an assessment for compliance with ISO/IEC 17065 and IECEX Scheme Rules. The Team Leader will then issue a report.

These reports shall be forwarded to the IECEX Secretariat who shall review them for completeness and any non-conformances.

2.2.3 Non-conformances

Where Non-conformances have been identified the reports shall be referred to IECEX Secretariat who shall consult with IECEX Executive who shall propose appropriate action to be taken and report at the next ExMC meeting.

Where the ExCB does not agree with the course of action, proposed, the matter may be referred to the ExMC or appealed according to IECEX Basic Rules (IECEX 01).

During the period of referral to ExMC, the ExMC Chairman in consultation with the other IECEX Executive shall decide on the status of the ExCB in question.

In extreme circumstances, the status of temporary suspension may be considered. The ExMC will then decide on the final action to be taken.

2.2.4 Fifth anniversary

On or before the fifth anniversary of the original acceptance or the last re-assessment of an ExCB a reassessment, in accordance with the assessment procedure detailed in Section 1, shall be performed by an IECEX assessment team appointed by ExMC, on recommendation from the IECEX Secretariat.

Section 3 – Assessment of existing ExCBs seeking to extend their scope of acceptance to cover the IECEx certified Service Facilities Scheme for selection of Ex equipment and design of Ex installations

3.1 Scope

This Section covers the situation where an ExCB already accepted in the IECEx Certified Equipment Scheme wishes to extend their acceptance to include the ability to assess and issue IECEx Certification to Ex Service Facilities involved in selection of Ex equipment and design of Ex installations services.

3.1.1 Assessment procedures within scope

ExCBs seeking acceptance to issue IECEx Service Facility Certification, WITHIN the Ex Types of Protection and existing field of their current scope of acceptance as ExCB in the IECEx Certified Equipment Scheme shall be subjected to the following assessment procedures.

3.1.2 Internal procedures

In general, a site assessment visit is not required when an ExCB already accepted in the IECEx Certified Equipment Scheme wishes to be accepted for issuing IECEx Certification for Service Facilities, within their current scope of IECEx Certified Equipment Scheme acceptance if the ExCBs submits suitable copies of their internal procedures for dealing with applications for Ex Service Facilities and for the maintenance of certification of Ex Service Facilities (refer to IECEx 03-2 Annex A and ExMC/417x/Q for guidance) to the IECEx Secretary.

The IECEx Secretary will assess or arrange to have the procedures reviewed for compliance with IECEx Operational Document IECEx OD 313-2. The candidate IECEx 03-2 ExCB application shall include details of the proposed ExCB assessors that will conduct IECEx 03-2 audits of applicant service facilities seeking certification.

The ExCB shall use application forms that include a statement by which the applicant declares any previous or existing applications made to other ExCBs. If after the IECEx Executive Secretary's review and report to the IECEx Executive (refer 3.1.4 following), the IECEx Executive Secretary or the IECEx Executive feel that a site assessment visit is necessary, this shall be arranged by the IECEx Secretariat.

In general, a site assessment visit is not required when an ExCB wishes to be accepted for issuing IECEx Certification for Service Facilities, within their current scope of IECEx acceptance, providing ExCBs submit a copy of their internal procedures for dealing with applications for Ex Service Facilities and for the maintenance of certification of Ex Service Facilities to the ExMC Secretary who will assess or arrange to have the procedures assessed for compliance with the relevant IECEx Operations Manual e.g. OD 313-2, OD 313-4.

3.1.3 Cost estimate

The ExCB shall be provided with a cost estimate for the documentation assessment and must agree with the cost prior to the assessment proceeding.

3.1.4 Report

Following the documentation review the IECEx Secretariat shall prepare a report for consideration by the IECEx Executive. Where any one IECEx Officer disagrees with the extension of acceptance for the ExCB this shall be documented and consultation conducted with the ExCB in an effort to resolve the concerns raised.

Upon finalising the application the ExCB's acceptance into the IECEX 03-2 Scheme shall be published and reported to the IECEX Management Committee. Alternatively, the IECEX Chairman may elect to refer the matter to a vote by ExMC via correspondence or at a meeting.

3.2 Assessment procedures outside scope

ExCBs already accepted as ExCB in the IECEX Certified Equipment Scheme that are seeking appointment for issuing IECEX selection of Ex equipment and design of Ex installations services Certification, OUTSIDE the Types of Protection and existing field of their current scope of acceptance as ExCB in the IECEX Certified Equipment Scheme, shall be assessed according to the procedures of Section 1 of this IECEX OD 316-2 Operational Document.

Annex A

IECEX Assessment Report Form for IECEX 03-2 ExCB (IECEX Certification Body – Certified Service Facilities Program) – Selection of Ex equipment and design of Ex installations

Type of Assessment:

- Initial Assessment for Candidate IECEX 03-2 ExCB
- Surveillance Assessment for existing ExCB

A.1 OBJECT AND FIELD OF APPLICATION

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A.1.1 Country

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A.1.2 Name of candidate IECEX 03-2 ExCB

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A.1.3 Members of the assessment team

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A.1.4 Place and date of assessment

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A.1.5 Assessment references

Document (current editions):

- i) IECEX 03-2;
- ii) IECEX OD 316-2
- iii) IECEX OD 013-2 and IECEX OD 314-2
- iv) ISO/IEC 17065;
- v) ISO/IEC 17021-1;
- vi) ExCB application documents;
- vii) IEC 60079-14 (Also IEC 61892-7 for Ex Services Facilities performing selection of Ex equipment and design of Ex installations in offshore Ex installations);
- viii) TCD 60079-14;

A.1.6 Scope of application

Indicate whether this is an extension of scope for an already accepted ExCB (include details of existing acceptance).

A.1.7 Candidate ExCB persons interviewed

Name	Position
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A.1.8 Legal entity of the candidate ExCB

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A.1.9 Associated certification functions

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A.1.10 National marks and certificates

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A.1.11 Financial support

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A.1.12 History

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A.1.13 Standards accepted

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A.1.14 National differences to IEC Standards

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A.2 ORGANIZATION

A.2.1 Names, titles and experience of the senior executives

Name	Title	Experience
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A.2.2 Name, title and experience of the quality management representative

Name	Title	Experience
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A.2.3 Name and title of nominated principal contact

Name	Title	Comments
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A.2.4 Name and title of signatories for certification

Name	Title	Comments
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A.2.5 Name and title of IECEx 03-2 assessors

Name	Title	Responsibility
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A.2.6 Other employees in ExCB activity

Name	Title	Responsibility
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A.2.7 Organizational structure

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A.2.8 Administration

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A.2.8.1 Administrative structure

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A.2.8.2 Terms of reference of the governing board

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A.3 RESOURCES

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A.4 COMMITTEES

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A.5 CERTIFICATION OPERATIONS

A.5.1 National approval/certification methods

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A.5.2 Certification policy

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A.5.3 Staff Work instructions

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A.5.4 Application for certification

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A.6 STATISTICS

Detail experience in assessment and certification of Ex related Service Facilities for selection of Ex equipment and design of Ex installations under this application during the past 2 years:

A.7 DOCUMENTATION

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A.8 RECORDS

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A.9 CONFIDENTIALLY

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A.10 PUBLICATIONS

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A.11 APPEALS

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A.12 NATIONAL ACCREDITATION

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A.13 RECOGNITION AND AGREEMENTS

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A.14 QUALITY MANAGEMENT SYSTEM (QMS) MANUAL

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A.15 INTERNAL AUDIT AND PERIODIC REVIEW

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A.16 COMPLAINTS

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A.17 WITHDRAWAL AND CANCELLATION OF CERTIFICATES

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A.18 SPECIAL FACTS TO BE NOTED

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A.19 RECOMMENDATION

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A.20 LIST OF ANNEXES

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