

IECEx OD 501

Edition 3.1 2017

IECEX OPERATIONAL DOCUMENT

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

IECEx Scheme for Certification of Personnel Competence for Explosive Atmospheres –

Assessment procedures for IECEx acceptance of Certification Bodies (ExCBs) for the purpose of issuing and maintaining IECEx Certificates of Personnel Competence (CoPCs)





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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Assessment procedures for IECEx acceptance of Certification Bodies (ExCBs) for the purpose of issuing and maintaining IECEx Certificates of Personnel Competence (CoPCs)

This Operational Document, OD 501 sets out the procedures for the assessment and acceptance of Certification Bodies seeking to become ExCBs for the purpose of operating under the IECEx Certification of Personnel Competence Scheme, IECEx 05.

Document History

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April 2013 Edition 2	
Sept 2016	Edition 3 as per ExMC Decision 2016/35
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INTRODUCTION

This document details the assessment procedures established by the IECEx System'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 maintaining IECEx Certificates of Personnel Competence whom seek IECEx Certification.

The assessment is to cover the competence, experience and familiarity of ExCB personnel and the organisation with the relevant explosive atmosphere standards, quality management systems, IECEx System and associated rules ISO/IEC 17024 and IECEx Operational Documents. The procedures are also aimed at ensuring a consistent approach to assessments by IECEx assessment teams and therefore establishing confidence in the scheme.

This document provides the following sections:

Section A – Initial Assessment and Re-Assessment of ExCBs

Section B – On going Assessment of ExCBs

NOTE A simple change of scope for an ExCB already accepted in another IECEx Scheme is not seen as viable due to the entirely different requirements used for Certification of Personnel Competence.

The procedures are set out in Tabular form identifying:

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

with the steps identified in the table correspond to the steps shown in the flowchart presented as Figure 1.

Assessment Procedures for IECEx acceptance of Certification Bodies (ExCBs) for the purpose of issuing and maintaining IECEx Certificates of Personnel Competence

SECTION A - 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 Certification of Personnel Competence 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.

Steps 1 – 4 of Figure 1 following are applicable to new applications.

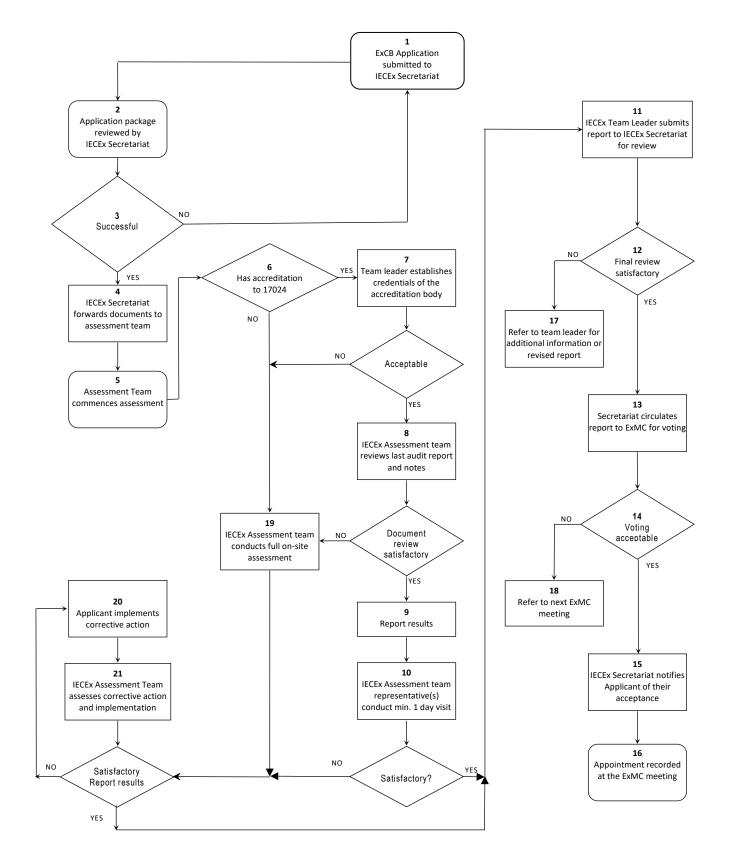


Figure 1: IECEx Assessment Process Flow Chart

(Refer to table for details of each step)

Step	Activity	By whom	Desired outcome	
Formal	Formal application submitted to IECEx Secretariat			
1	Application endorsed by Member Body prior to being received by IECEx Secretariat, in accordance with IECEx 05	IECEx Secretariat	Candidate ExCB	
2	Application assessed for completeness and Assessment Team appointed.	IECEx Secretariat	Assessment team proposed by IECEx Secretariat	
3	IECEx Secretariat reviews application documentation for completeness. IECEx Secretariat may request further information from the Candidate. IECEx Secretariat to report findings to Candidate ExCB	IECEx Secretariat		
4	IECEx Secretariat forwards Application Documentation package to Members of the appointed IECEx Assessment Team	IECEx Secretariat	All relevant information available for team to commence their assessment	
Docum	entation review stage			
5	IECEx Assessment Team commences assessment. Team Leader, in conjunction with team members reviews application documentation to satisfy steps 6 to 8. Team Leader may request additional information from the Candidate ExCB. The application documentation shall include copies of all relevant procedures and sufficient and suitable (refer to IECEx 05, Clause 9.1 and OD 503, Table 2) assessment questions and answers for each unit included in the scope nominated in the application. Details of artefacts for the practical assessments shall also be included in the application documentation. The questions and answers submitted for use in the assessment of knowledge for each clause of the "Critical Aspects of evidence" (refer to OD 504) specified for each unit of competence shall be assessed for suitability and sufficiency. The artefacts for use in the practical assessment of competence for each performance requirement shall be assessed Knowledge and practical assessment methods shall be designed to avoid short term memory responses. The assessment of candidates shall not be integrated with training activities (such as in a 'topic by topic' approach) Similarly there shall be a clear separation between the management of any training services and the management of any training services (this includes personnel working as invigilators and examiners)	Team Leader to manage	Team Leader notifies Candidate of successful review of documentation and then prepares to arrange site visit. Assessment knowledge questions accepted and passed to the Question Bank WG Following acceptance by the Assessment Team the Assessment knowledge questions and answers are passed to ExPCC WG3 or a group formed by ExPCC WG3 for independent verification prior to sending to the IECEx Secretariat for addition to the IECEx Question Bank.	
6	Assessment Team Leader, in conjunction with team members determines whether the applicant ExCB has Accreditation to ISO/IEC 17024	Team Leader or his designate	Formal notification of accreditation, with a copy being submitted by the applicant	

Step	Activity	By whom	Desired outcome
7	Assessment of the accreditation and credentials of the accreditation body. For example determining: *Whether the body has Mutual Recognition Agreements with other accreditation 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. The assessment of the documentation shall establish that the CB has the competence related to the particular aspects of hazardous area competence they will be issuing. This will include any facilities provided for demonstration of craft skills" NOTE This may need to provide CV's of particular people used in competence assessment activities.	Team Leader	*Verification of MRAs *Notification of Government recognition *Use of : IECEx Basic Rules ISO/IEC Guide 2, Standardization and related activities - General vocabulary. ISO/IEC 17000 Conformity Assessment – Vocabulary and general principles ISO/IEC 17024 Conformity Assessment – General requirements for bodies operating certification of persons *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 05, and Documents, ISO/IEC Guide 2, ISO/IEC 17000 and ISO/IEC 17024 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 05, ISO/IEC Guide 2 and ISO/IEC 17024
9	Notification of results of step 6-8 to Candidate ExCB	Team Leader	Letter, Fax or e-mail to Candidate ExCB. Copy to IECEx Secretariat

Step	Activity	By whom	Desired outcome
On-site	e visit		
10	A minimum of one representative of the IECEx Assessment Team visits Candidate to conduct a minimum one day site visit for each ExCB application according to IECEx Basic Rules and IECEx 05. This visit is to verify implementation of certification or auditing procedures	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 decide if more than 1 man day visit is necessary.
11	Results of site visit determined with a final report for submission to the IECEx Secretariat prepared in the format as outlined in OD505. 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 a	pproval 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 approves application (re IECEx Basic Rules)
15	If voting is acceptable then IECEx Secretariat 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 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 Basic Rules 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 are 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 Basic Rules and IECEx 05 and Technical Guidance Documents, ISO/IEC Guide 2, ISO/IEC 17000 and ISO/IEC 17024 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	Decision by Assessment team	Team Leader	Details including in Assessment Report

SECTION B – ON GOING ASSESSMENT OF ExCBs

This Section applies to ExCBs that have been accepted into the IECEx Certification of Personnel Competence Scheme for the scope of issuing of IECEx Certificates of Personnel Competence (CoPC) to provide cross-industry competence needed for work associated with equipment for hazardous areas. The purpose of on-going assessments is to satisfy the International Ex community that ExCBs maintain their facilities relating to assessing demonstration of craft skills and capabilities that enabled their entry into the Scheme.

1 Surveillance of ExCBs with Accreditation to ISO/IEC 17024 acceptable to ExMC

1.1 Scope

This section covers ExCBs that maintain Accreditation to ISO/IEC 17024 found to be acceptable by the original IECEx Assessment Team, and subsequently accepted by way of ExMC voting on the initial assessment report. The procedures detailed below are general and ALL ExCBs are reminded of their obligations to notify the IECEx Secretariat of any changes within their organisation that may impact on 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.

1.2 Review

The IECEx Secretariat shall, on at least an annual basis, confirm the accreditation status and scope of all ExCBs continuation of holding accreditation to ISO/IEC 17024 acceptable to the ExMC.

Such a review shall ensure that

- ExCB sites covered by accreditation aligns with the site previously approved by ExMC
- All Clauses of ISO/IEC 17000 and ISO/IEC 17024, as applicable, have been covered

This review may require the IECEx Secretariat seeking confirmation from accreditation bodies and ExCBs along with a call for audit reports issued by accreditation bodies and internal audit reports of the ExCB in order to gain evidence of compliance with ISO/IEC 17024 and IECEx requirements.

In addition to the above, ExCBs shall advise the IECEx Secretariat of any changes in their organisation affecting the ExCB's operation in the IECEx CoPC Scheme such as the organisation of the ExCB, its staff, facilities, quality system, operating procedures, accreditation status.

The IECEx Secretariat shall review the information to ensure:

- IECEx requirements continue to be met
- Any Non-Conformances are identified

1.3 Re-assessment

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

2 Surveillance of ExCBs <u>without</u> Accreditation to ISO/IEC 17024 acceptable to ExMC

2.1 Scope

This section covers ExCBs that <u>do not</u> have Accreditation to ISO/IEC 17024 acceptable to the ExMC but who have been accepted in to the IECEx System by way of a full on-site assessment, by the IECEx Assessment Team.

2.2 On-site Surveillance Audit

The IECEx Secretariat shall arrange for a surveillance assessment on-site audit not more than 2.5 years after the last site visit to ensure that:

- IECEx requirements continue to be met
- Any Non-Conformances are identified

The assessor shall be appointed by the IECEx Secretariat whom may consult with the IECEx Assessment Team Leader responsible for the original assessment. The ExCB shall agree to bear the costs associated with this on-site audit.

The appointed assessor shall carry out an assessment for compliance with ISO/IEC 17000 and ISO/IEC 17024 and IECEx CoPC Scheme Rules. The appointed assessor shall issue a report.

The report shall be forwarded to the IECEx Secretariat who shall review it for completeness and any non-conformances. Where non-conformances have not been identified the report shall be retained, for a minimum of 10 years, for record keeping purposes, by the IECEx Secretariat.

2.3 Non-conformances

Where major Non-Conformances have been identified the report shall be referred to the IECEx Secretariat who shall consult with the IECEx Officers on non-conformances that remain outstanding, whom 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 IECEx Board of Appeal. During the period of referral to ExMC, the IECEx Chairman in consultation with the other IECEx Officers 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.

2.4 Fifth anniversary

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