



INTERNATIONAL ELECTROTECHNICAL COMMISSION SCHEME FOR CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE IN EXPLOSIVE ATMOSPHERES (IECEx SCHEME)

Title: Draft Operational Document OD xxxC- Assessment Procedures for IECEx acceptance of Certification Bodies (ExCBs) for the purpose of issuing and maintaining IECEx Certificates of Personnel Competencies

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Circulation: IECEx Management Committee (ExMC)

INTRODUCTION

In line with the Report from WG 12 (ExMC/464/R) this draft Operational Document has been prepared by the ExMC Working Group WG 12 as proposed assessment procedures for for IECEx acceptance of Certification Bodies (ExCBs) for the purpose of issuing and maintaining IECEx Certificates of Personnel Competencies.

This draft is issued for consideration during the ExMC Paris October 2008 Meeting.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

Draft IECEx OPERATIONAL DOCUMENT**IEC Scheme for Certification of
Personnel Competency for Explosive Atmospheres –****Ex OD 0xxC Version 1 – draft 02**

**Title: Assessment Procedures for IECEx acceptance of Certification
Bodies (ExCBs) for the purpose of issuing and maintaining
IECEx Certificates of Personnel Competencies**

This Operational Document, OD xxxC sets out the procedures for the assessment and acceptance of Certification Bodies seeking to become ExCBs for the purpose of operating under the IECEx Certificates of Personnel Competencies Program, IECEx 05.

Document History

Date	Summary
2008 05	Original Issue (Version 1 draft 01)
2008 08	Original [revised] issue (Version 1 draft02) incorporating comments from Task Team members

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INTRODUCTION

This 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 maintaining IECEx Certificates of Personnel Competencies whom 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 organisation with the relevant explosion protected standards, quality management systems, IECEx scheme and associated rules, ISO/IEC guide 65, ISO/IEC 17024 and IECEx technical guidance documents. The procedures are also aimed at ensuring a consistent approach to assessments by IECEx assessment teams.

This document provides the following three Sections:

Section 1 Initial Assessment and Re-Assessment of ExCBs

Section 2 On going Surveillance of ExCB

NOTE: A simple change of scope for an existing ExCB is not seen as viable due to the entirely different requirements used for Personnel Certification.

The procedures are set out in table form identifying:

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

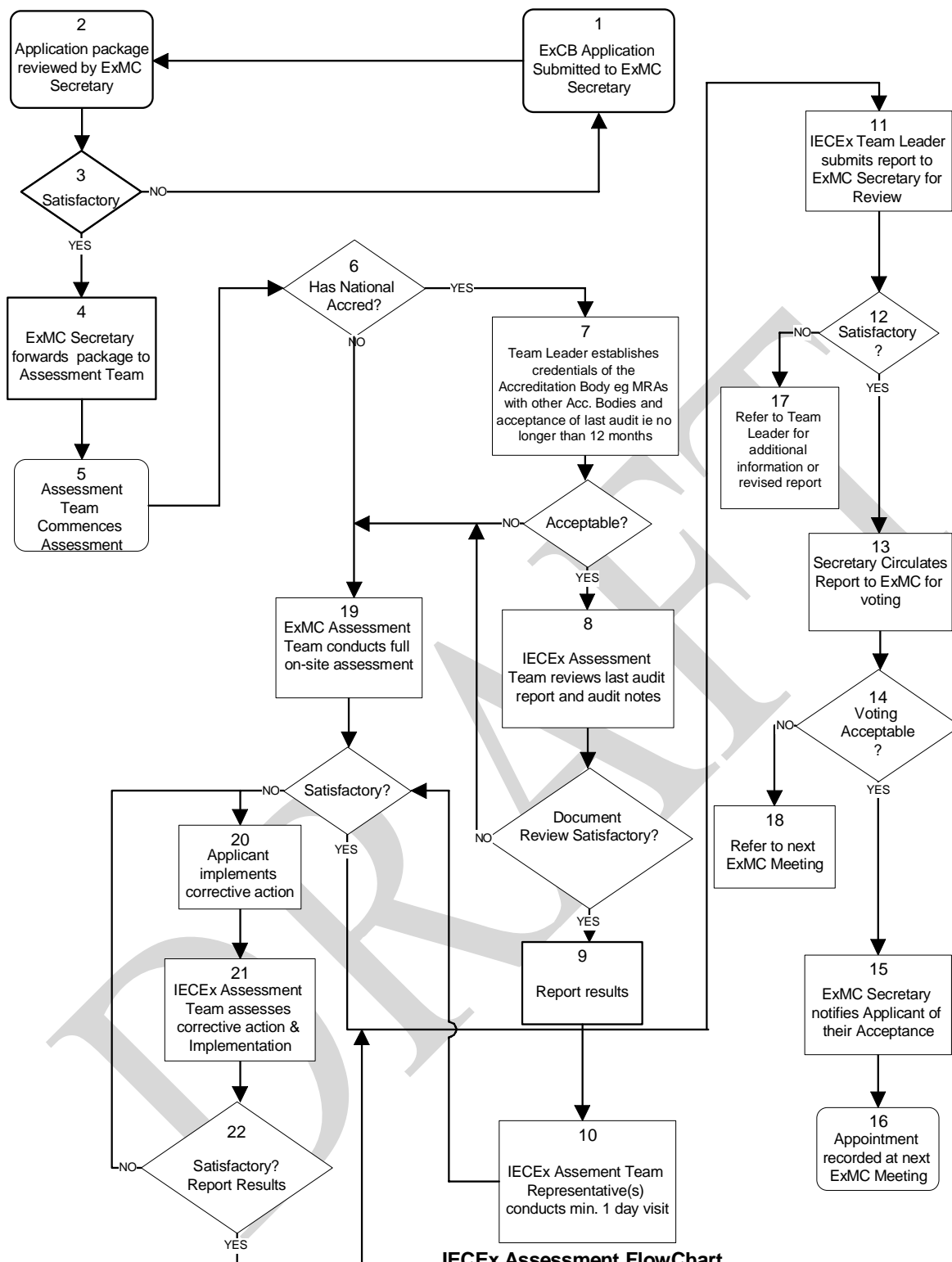
The steps identified in the table correspond to the steps shown in the flowchart.

SECTION 1 INITIAL ASSESSMENT & RE-ASSESSMENT

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 ExMC Secretary and endorsed by ExMC. Steps 1 – 4 are applicable to new applications.

Step	Activity	By Whom	Desired Outcome
Formal Application Submitted to ExMC Secretary			
1	Application received by ExMC Secretary, in accordance with IECEx 05	ExMC Secretary	Candidate ExCB
2	Application assessed for completeness. Appointed Assessment Team accepted by ExMC	ExMC Secretary	Assessment team proposed by IECEx Secretary and accepted by ExMC.
3	ExMC Secretary reviews application documentation for completeness. ExMC Secretary may request further information from the candidate. ExMC Secretary to report findings to candidate ExCB	ExMC Secretary	
4	ExMC Secretary forwards Application package to Members of the appointed Assessment Team.	ExMC Secretary	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. 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 designate	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	*Verification of MRAs *Notification of Government recognition *Use of IECEX 01:1999, <i>Basic Rules of the IECEx Scheme</i> . ISO/IEC Guide 2:1996, <i>Standardization and related activities - General vocabulary</i> . ISO/IEC 17000:2004 <i>Conformity Assessment – Vocabulary and general principles</i> ISO/IEC 17024:2003 <i>Conformity Assessment – General requirements for bodies operating certification of persons</i> IAF GD 24:2004 <i>IAF Guidance on the Application of ISO/IEC 17024:2003</i> *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 ExMC Secretary

Step	Activity	By Whom	Desired Outcome
On-site Visit			
10	A minimum of one representative of the IECEx Assessment Team visits candidate to conduct a minimum 1 day site visit for each ExCB application. This visit is to verify implementation of certification or auditing procedures	At least 1 person from IECEx Ass. 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 ExMC Secretary 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 ExMC Secretary.	ExMC Secretary	Review by ExMC Secretary to ensure completeness of information and ready for circulation to ExMC for voting.
13	ExMC Secretary prepares Report for voting and submits to ExMC Members for formal voting, via correspondence or at the next ExMC meeting	ExMC Secretary	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 ExMC Secretary as soon as possible and by due date	ExMC Members	Majority acceptance vote approves application (re Clause 12.2 of IECEx01)
15	If voting is acceptable then ExMC Secretary notifies applicant of their acceptance	ExMC Secretary	ExMC Letter to accepted ExCB
16	Appointment recorded at next ExMC meeting	ExMC Secretary to arrange	Recorded in Minutes
17	Where review in step 12 is unsatisfactory, ExMC Secretary refers the matter to the IECEx Assessment Team Leader seeking additional information or revised report	ExMC Secretary	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	ExMC Secretary 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 ExMC Secretary 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 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	Notification of results of step 5 to candidate ExCB and IECEx Chairman	Team Leader	Letter, Fax or e-mail to Chairman of Assessing Panel



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

SECTION 2 ON GOING ASSESSMENTS

This Section applies to ExCBs that have been accepted into the IECEx Scheme for the scope of issuing IECEx Certification of Personnel Competencies to provide cross-industry competencies 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 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, the ExMC. 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.

2.1.2 Procedures

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

a) Any changes in the organisation

Description of changes in the organisation of the ExCB, its staff, facilities, quality system, operating procedures, or other similar changes, that relate to the ExCB's operation under IECEx05.

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 Guidance Documents 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 ExMC Secretary shall review the information to ensure:

- Site assessed aligns with the site previously approved by ExMC;
- All Clauses of ISO/IEC Guide 2, ISO/IEC 17000 and ISO/IEC 17024, as applicable, have been covered;
- Ensure that Technical Guidance Documents 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 Officers 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 to the IECEx Board of Appeals, if requested by the ExCB. During the period of referral to the Board of Appeal, the ExMC 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 ExMC is to decide on the final action to be taken.

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

2.1.4 Re-assessment

On the 5th 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 1, shall be performed by an IECEx Assessment Team appointed by ExMC.

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

ExCBs 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.

The appointed assessor shall carry out an assessment for compliance with ISO/IEC Guide 2, ISO/IEC 17000 & ISO/IEC 17024 and IECEx Scheme Rules. The Team Leader will then issue a report.

Where the original assessment team is no longer available a new assessment team shall be appointed by ExMC.

These reports shall be forwarded to the ExMC Secretary who shall review them for completeness and any non conformances. Where non-conformances have not been identified the reports shall be retained, for a minimum of 10 years, for record keeping purposes, by the ExMC Secretary.

2.2.3 Non-conformances

Where Non-Conformances have been identified the reports shall be referred to ExMC Secretary who shall consult with IECEx Officers 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 IECEx Board of Appeal. During the period of referral to ExMC, the ExMC 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 ExMC will then decide on the final action to be taken.

2.2.4 Fifth anniversary

On the 5th anniversary of the original appointed or 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.

Annex A

IECEX ASSESSMENT REPORT FORM For ExCB

(IECEX Certification Body –for Certification of Personnel Competencies Program)

Type of Assessment:

- Initial Assessment for Candidate 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 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:

- i) IECEx 05 First Edition
- ii) IECEx Operational Document OD/xxA
- iii) IECEx Operational Document OD xxB, XXC, xxD
- iv) ISO/IEC 1700 & ISO/IEC 17024
- v) ExCB application documents dated



A.1.6 Scope Of Application

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

Product Category	Standard
General Requirements	ISO/IEC 17024
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(List all Standards within scope of application or acceptance within IECEx)

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 Testing Laboratories

Names of Laboratories	Address
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A.1.10 Associated Certification Functions

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A.1.11 National Marks And Certificates

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A.1.12 Financial Support

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A.1.13 History

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A.1.14 Standards Accepted

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A.1.15 National Differences To IEC Standards

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A.2 ORGANISATION

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 Other Employees in ExCB activity

Name	Title	Responsibility
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A.2.6 Organisational Structure

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A.2.7 Administration

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A.2.7.1 Administrative Structure

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A.2.7.2 Terms of Reference of the Governing Board

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A.3 RESOURCES

(Verification that ExCB has all necessary resources for its operation in-house, including personnel trained and experienced in factory inspection / quality audits).

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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 Personnel Competencies for the Ex Protection under this application during the past 2 years:

Competency	IEC 60079 Part
Repair & Overhaul	19
Area Classification	10
Selection	14
Installation	14
Maintenance	17

A.7 DOCUMENTATION

Document and Change Control

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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 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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