

INTERNATIONAL ELECTROTECHNICAL COMMISSION

IEC SCHEME FOR CERTIFICATION TO STANDARDS FOR SAFETY OF ELECTRICAL EQUIPMENT FOR EXPLOSIVE ATMOSPHERES (IECEX SCHEME)

For Consideration by Members of IECEX Management Committee, ExMC

COMMITTEE DRAFT

Operational document No Ex/OD003

TITLE: Assessment Procedures for IECEX acceptance of Candidate Accepted Certification Bodies (ACBs) and Ex Testing Laboratories (ExTLs)

Introductory Note

This Draft Operational Procedure has been prepared by the ExMC Secretariat and incorporates the following documents:

- ExMC/05/Inf Assessment procedures for applicant ACBs and ExTLs
- ExMC/15/CD Draft surveillance procedures for ACBs and ExTLs
- ExMC(Sydney/Sec)19 Amendment to ExMC/15/CD

This draft also incorporates the decisions of the ExMC Sydney 1999 meeting and is submitted for consideration at the ExMC Braunschweig 2000 meeting. ExMC members are requested to consider the draft and either submit comments to the ExMC Secretariat or have them prepared for discussion during the ExMC Braunschweig meeting.

To assist in collating comments, ExMC members are requested to submit any comments via e-mail, to the ExMC Secretariat by Monday 7 August 2000:

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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 ACBs and ExTLs. The principle aim of these procedures is to instil international confidence of manufacturers, users and regulators, in the body's competence and capabilities for performing testing and certification of Ex equipment.

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

This document provides the following two Sections:

- Section 1 – Initial Assessment and Re-Assessment of ACBs and ExTLs
- Section 2 – On going Surveillance of ACBs and ExTLs

This document is based on the previous documents, ExMC/05/Inf, ExMC/15/CD and decisions taken during the September 1999 Sydney meeting of ExMC.

The procedures are set out in table form identifying:

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

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

Further instructions are included to assist Assessment Team Members in performing their duties.

SECTION 1 – INITIAL ASSESSMENT & RE-ASSESSMENT

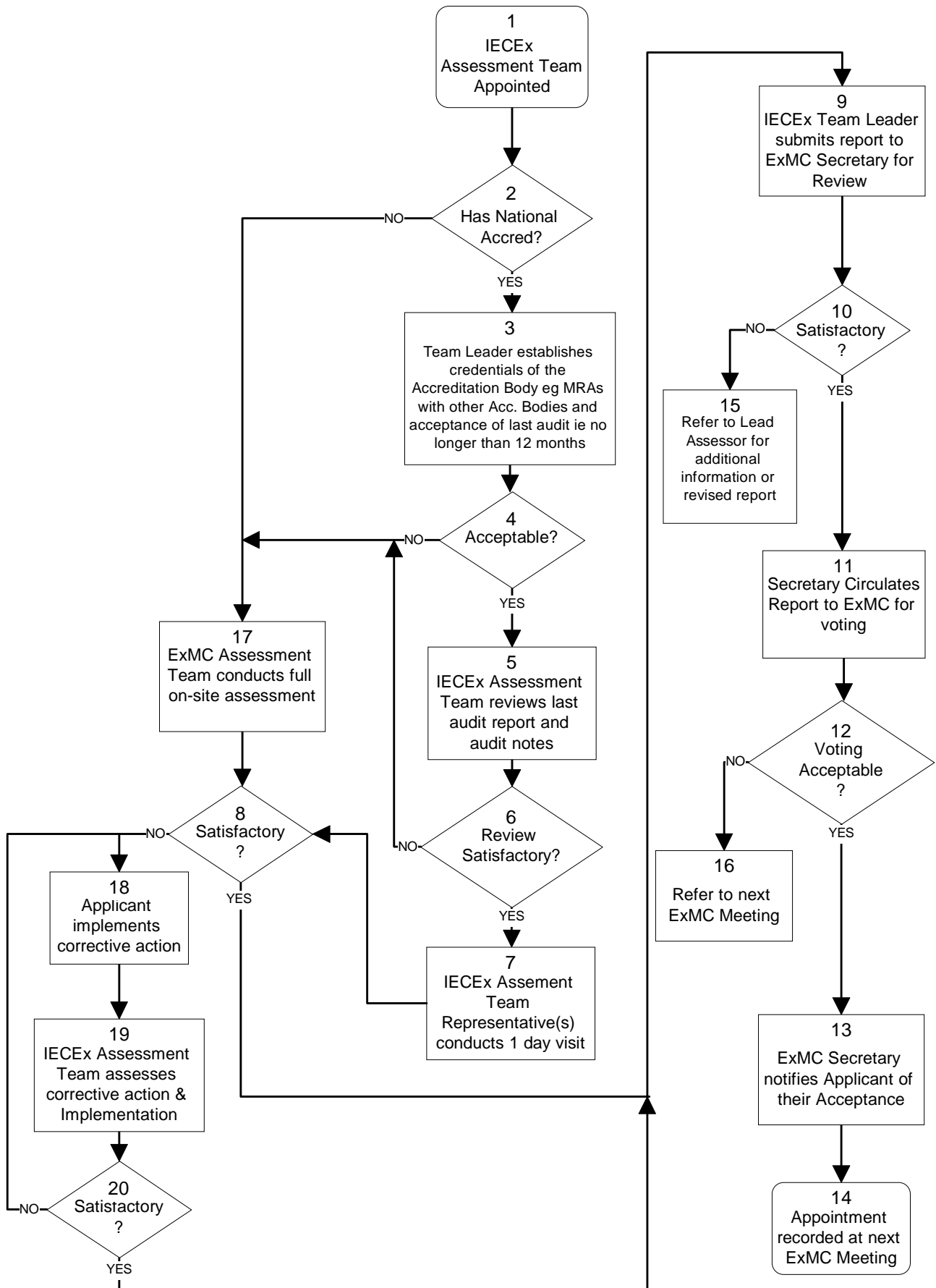
This Section is to be applied for the initial assessment of ACBs and ExTLs prior to their acceptance in the IECEX Scheme and re-assessment of existing ACBs and ExTLs.

IECEX Assessment Procedure Refer attached IECEX Assessment Flow Chart

Step	Activity	By Whom	Desired Outcome
1	Assessment Team Appointed	Assessment Panel Chairman	Details of Assessment Team forwarded to ExMC Secretary. Team approved via correspondence by ExMC
2	Lead Assessor, in conjunction with team members determines whether the applicant ACB or ExTL has Independent Accreditation	Lead Assessor or his designate	Formal notification of accreditation, with a copy being submitted by the applicant
3	<p>Assessment of the accreditation and credentials of the accreditation body. For example determining:</p> <ul style="list-style-type: none"> *Whether the body has Mutual Recognition Agreements with other bodies *Whether the body has National Government recognition *What Standards or Guides are used <p>IECEX Assessment Team Lead Assessor may obtain information directly from accreditation body or candidate ACB or TL and circulate to other IECEX Assessment team members for review via correspondence.</p> <p>Note: ACB or TL should obtain all necessary information from accreditation body for presentation to IECEX Assessment Team Leader.</p>	Lead Assessor	<ul style="list-style-type: none"> *Verification of MRAs *Notification of Government recognition *Use of ISO/IEC Guides 25 or ISO 17025 and 65 *Frequency of surveillance audits
4	Assessment of details and documentation acquired for step 3 above.	Lead Assessor to manage	Acceptance of accreditation body by IECEX Assessment Team.
5	<p>Review of past audit reports, issued by the accreditation body, by Assessment Team to establish compliance with the requirements of IECEX 02, Technical Guidance Documents, ISO/IEC Guide 25 or ISO 17025 and IEC/ISO Guide 65.</p> <p>The candidate ACB or TL must have been audited within the last 12 months</p>	Assessment Team managed by Lead Assessor	Acceptance by IECEX Assessment Team of information and audit reports as evidence of compliance to the requirements of IECEX 02 and the Technical Guidance Documents
6	Notification of results of step 5 to candidate ACB or	Lead	Letter, Fax or e-mail to

Step	Activity	By Whom	Desired Outcome
	TL and Chairman of IECEEx Assessment Panel	Assessor	Chairman of Assessing Panel
7	A minimum of one representative of the IECEEx Assessment Team visits candidate to conduct a minimum 1 day site visit to verify implementation of certification or testing procedures	1 person from IECEEx Ass. Team Usually Lead Assessor	Visit notes to be included in assessment file
8	Assessment of visit determined	Lead Assessor	Team Leader to commence compiling a Report
9	Final IECEEx Assessment Team Report submitted to ExMC Secretary for Review by ExMC Secretary.	Lead Assessor and ExMC Secretary	Completed report identifying evidence of compliance with requirements of IECEEx 02 and Technical Guidance Documents
10	Review of Assessment Report	ExMC Secretary	Maintain a level of quality and consistency throughout the reports
11	Assessment Report circulated for voting by ExMC Members	ExMC Secretary	Report and Voting form submitted to ExMC
12	Assessment of report 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 IECEEx 01)
13	If voting is acceptable then ExMC Secretary notifies applicant of their acceptance	ExMC Secretary	ExMC Letter to accepted ACB and ExTL
14	Appointment recorded at next ExMC meeting	ExMC Secretary to arrange	Recorded in Minutes
15	Where review in step 10 is unsatisfactory, ExMC Secretary refers the matter to the IECEEx Assessment Team Lead Assessor seeking additional information or revised report	ExMC Secretary	An acceptable report for circulation to ExMC
16	Where voting is unsuccessful the application is then referred to the next ExMC meeting for discussion	ExMC Secretary to arrange	Findings recorded in the minutes
17	Where either steps 2, 3, 4, 5 or 6 are unsuccessful then ExMC Assessment team conducts a full on site assessment in accordance with IECEEx 02 and Technical Guidance Documents, ISO/IEC Guide 25 or ISO 17025 and ISO/IEC Guide 65 as applicable	Lead Assessor to manage	Assessment report by Lead Assessor
18	Where non-conformances are identified during the assessment process the candidate ACB or TL implements corrective action if they wish to proceed	Candidate ACB or TL	implementation of corrective actions

Step	Activity	By Whom	Desired Outcome
	with their application		
19	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	Lead Assessor to manage	Report on assessment of corrective actions
20	Notification of results of step 5 to candidate ACB or TL and Chairman of IECEx Assessment Panel	Lead Assessor	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 is applied to all ACBs and ExTLs that have been accepted into the IECEX Scheme. The purpose of on going assessments is to satisfy the International Ex community that ACBs and ExTLs maintain their facilities and capabilities that enabled their entry into the Scheme.

2.1 Surveillance of ACBs and ExTLs with National Accreditation acceptable by ExMC

2.1.1 Scope This section covers ACBs and ExTLs 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.

2.1.2 Procedures Each year, prior to the anniversary date of acceptance into the IECEX Scheme, ACBs and ExTLs 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 ACB or ExTL, its staff, facilities, quality system, operating procedures, or other similar changes.

AND

- b) Activity Report

Report on the number of ATRs issued and/or accepted for each standard or type of protection during the preceding 12 months.
Supplementary information on related technical activities may be provided at the discretion of the ACB or ExTL.

AND

- c) Annual audit report
Copy of the 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

- d) Report by the ACB or ExTL based on its own internal audit(s) carried out during the preceding 12 months. A standardised report format should be used for this purpose. Annex A and B include sample audit report. Once every two years, the report, prepared by the ACB or ExTL shall be endorsed by the National Accreditation Body.

Items a) and b) are mandatory and either c) or d)

1.4 The ExMC Secretary shall review the information to ensure:

- *Site assessed aligns with the site previously approved by ExMC;
- *All Clauses of ISO/Guide 25, ISO 17025 and ISO/IEC Guide 65, as applicable, have been covered;
- *Ensure that Technical Guidance Documents have been used;
- *Any Non-Conformances are identified;

Where Non-Conformances have been identified the reports shall be referred to ExMC Working Group WG 4 - *Technical Reference Group for Assessment of ACBs and ExTLs*. WG 4 shall propose appropriate action to be taken. The ExMC will then 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.

1.5 On the 5th anniversary of the original assessment or re-assessment of an ACB or ExTL a re-assessment, in accordance with the assessment procedure detailed in Section 1, shall be performed by the original assessment team. Where the original assessment is no longer available the re-assessment shall be performed by an IECEX Assessment Team appointed by ExMC.

2.2 Surveillance of ACBs and ExTLs without National Accreditation acceptable by ExMC

2.2.1 Scope This section covers ACBs and ExTLs 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 ACBs and ExTLs 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 ACB and ExTL 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 25 or ISO 17025 for ExTLs and ISO/IEC Guide 65 for ACBs. This being in accordance with the requirements of the IECEX Technical Guidance Documents. The assessor shall then report back to the original IECEX Assessment Team Leader. The Team Leader will then issue a report using the format given in Annex A and B.

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 Where Non-Conformances have been identified the reports shall be referred to ExMC Working Group WG 4 – *Technical Reference Group for Assessment of ACBs and ExTLs*. WG 4 shall propose appropriate action to be taken. The ExMC will then decide on the final action to be taken.

2.2.4 On the 5th anniversary of the original assessment or re-assessment of an ACB or ExTL a reassessment, in accordance with the assessment procedure detailed in Section 1, shall be performed by the original assessment team. Where the original assessment team is no longer available a new assessment team shall be appointed by ExMC.

SECTION 3 – NOTES TO ASSESSORS

Instructions for Assessment Teams

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

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

Instructions for Lead Assessors

Lead assessors are also known as Assessment Team Leaders and as such have the additional task of coordinating the assessment process of the ACB or ExTL under assessment by their team.

Once an assessment team has been appointed, Lead Assessors should make contact with their team members and the candidate ACB and ExTL and their ExMC National Member Body as soon as possible. It is the Lead Assessor's responsibility to ensure that all team members have the following:

- *Copies of the ACB and ExTL applications and supporting documentation
- *Technical Guidance Documents, where available.
- *Working copy of IECEX 02
- *IECEX Assessment Procedure, Doc. ExMC/OD003, this document

In addition, all team members must have their own working copies of the relevant ISO/IEC Guides, eg 25 and 65 and ISO 17025.

The Lead Assessor generally acts as the contact between the assessment team members, National Member Body and their candidate ACB or ExTL and is responsible for all correspondence.

The Lead Assessor should liaise with the National Member Body and their candidate ACB or ExTL regarding the assessment program and estimated costs (assessment fees and travel costs). The National Member Body in conjunction with their candidate ACB or ExTL should reach agreement with the Lead Assessor on costs before assessment work commences.

The Lead Assessor should ensure that the assessment procedures, detailed in this document are followed and that the spirit of assessments is one of seeking evidence of compliance with requirements. This includes reporting of examples where the requirements of ISO/IEC Guides, the Technical Guidance Documents and IECEX 02 are met and implemented

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

Assessment teams are reminded that assessment of the ACB's ability to perform ISO 9002 assessments are part of an ACB's assessment. This includes verifying:

- ISO 9000 qualifications of ACB staff, eg membership of International Quality Associations
- National and International ISO 9000 accreditation of the ACB, eg member of IQNET
- Acceptance of the ACB as an ISO 9000 certification body in their own country

Assessment of ExTLs are aimed at demonstrating compliance with ISO/IEC Guide 25 or ISO 17025, the Technical Guidance Documents and verification of the requirements of IECEx 02. This includes verifying:

- Suitable facilities are available and the necessary test and measuring equipment are available
- That the laboratory has appropriately qualified and experienced staff with intimate knowledge of testing and assessing Ex equipment
- Implementation of testing procedures and acceptance of test facilities at national level

As part of the assessment procedure, it is the responsibility of the Lead Assessor to provide the ExMC Secretary with an IECEx Assessment Report for each ACB and ExTL their team have assessed. A separate report is required for each. Pro forma Reports for both ACBs and ExTLs are to be used and available from the ExMC Secretary.

Closing Comment

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

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

ACB and ExTL assessments is an extremely important process and will greatly assist in establishing and maintaining the IECEx Scheme's credibility. The Assessment Panel Chairman, ExMC Chairman and Officers are all available should assessors require

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assistance. Assessors may contact the ExMC Secretary if they need assistance at any stage of the assessment process.

ANNEX A - IECEx ASSESSMENT REPORT FORM For ACB (Accepted Certification Body)

Type of Assessment:

Initial Assessment for Candidate ACB ☐
Surveillance Assessment for existing ACB ☐

1. OBJECT AND FIELD OF APPLICATION

1.1 *Country:*

1.2 *Name of Candidate ACB*

1.3 *Members Of The Assessment Team*

1.4 *Place And Date Of Assessment*

1.5 *Assessment References*

Document:

- i) IECEx 02 First Edition
- ii) IECEx Operational Document OD/003
- iii) ISO/IEC Guide 65 1996
- iv) ACB application documents dated.....

1.6 *Scope Of Application*

Product Category

General Requirements

Standard

IEC 60079-0

(List all Standards within scope of application or acceptance within IECEx)

1.7 *Candidate ACB Persons Interviewed*

Name

Position

1.8 *Legal Entity Of The Candidate ACB*

1.9 *Associated Testing Laboratories*

Names of Laboratories

Address

1.10 *Associated Certification Functions*

1.11 *National Marks And Certificates*

1.12 *Financial Support*

1.13 *History*

1.14 *Standards Accepted*

1.15 *National Differences To IEC Standards*

2. ORGANISATION

2.1 *Names, Titles And Experience Of The Senior Executives*

Name	Title	Experience
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2.2 *Name, Title And Experience of The Quality Management Representative*

Name	Title	Experience
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2.3 *Name And Title of Nominated Principal Contact*

Name	Title	Comments
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2.4 *Name and Title of Signatories for Certification*

Name	Title	Comments
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2.5 *Other Employees in ACB activity*

Name	Title	Responsibility
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2.6 *Organisational Structure*

2.7 *Administration*

2.7.1 Administrative Structure

2.7.2 Terms of Reference of the Governing Board

3. RESOURCES

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

4. COMMITTEES

5. CERTIFICATION OPERATIONS

5.1 *National Approval/Certification Methods*

5.2 *Certification Policy*

5.3 *Staff Work Instructions*

5.4 *Application for Certification*

6. STATISTICS

Certificates issued during the past 2 years:

flameproof	d
intrinsic safety	i
increased safety	e
special	s
powder filled	q
encapsulated	m
type	n
pressurised	p
Gas Detectors	
Apparatus for Dusts	

7. DOCUMENTATION

7.1 *Document and Change Control*

8. RECORDS

9. CONFIDENTIALITY

10. PUBLICATIONS

11. APPEALS

12. NATIONAL ACCREDITATION

13. RECOGNITION AND AGREEMENTS

14. QUALITY MANUAL

15. INTERNAL AUDIT AND PERIODIC REVIEW

16. COMPLAINTS

17. WITHDRAWAL AND CANCELLATION OF CERTIFICATES

18. SPECIAL FACTS TO BE NOTED

19. RECOMMENDATION

LIST OF ANNEXES

ANNEX B - IECEx ASSESSMENT REPORT FORM (TEST LABORATORY – ExTL)

Type of Assessment:

Initial Assessment for Candidate ACB ☐
Surveillance Assessment for existing ACB ☐

1. OBJECT AND FIELD OF APPLICATION

1.1 *Country:*

1.2 *Name of Candidate TL*

1.3 *Members Of The Assessment Team*

1.4 *Place And Date Of Assessment*

1.5 *Assessment References*

Document:

- i) IECEx 02 First Edition 1995-03
- ii) IECEx Operational Document OD/003
- iii) ISO/IEC Guide 25: 1990 or ISO 17025
- iv) IECEx Technical Guidance Documents
- iv) ExTL application documents

1.6 *Scope Of Application*

Product Category
General Requirements

Standard
IEC 60079-0

(List all Standards within scope of application or acceptance within IECEx)

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1.7 *Candidate TL Persons Interviewed*

Name

Position

1.8 *Legal Entity Of The Candidate TL*

1.9 *Associated ACB*

Names of Laboratories

Address

1.12 *Financial Support*

1.13 *History*

1.14 *Relevant Standards*

2. ORGANISATION

2.1 **Names, Titles And Experience Of The Senior Executives**

2.2 **Name, Title And Experience Of The Quality Management Representative**

2.3 **Name And Title Of Nominated Principal Contact**

2.4 **Employees**

2.5 **Organisational Structure**

3. RESOURCES

4. TEST METHODS

4.1 Procedures

4.2 Staff Work Instructions

5. TEST REPORTS AND RECORDS

5.1 Test Reports Issued

The following table is an example

Type of protection	Number of test reports
d	
e	
i	
o	

5.2 Test Records

6. CALIBRATION

7. DOCUMENTATION

7.1 *Quality Manual*

7.2 *Document Change Control*

8. CONFIDENTIALLY

9. NATIONAL ACCREDITATION

10. RECOGNITION AND AGREEMENTS

11. INTERNAL AUDIT AND PERIODIC REVIEW

12. COMPLAINTS MECHANISM

13. SPECIAL FACTS TO BE NOTED

14. COMMENTS

15. RECOMMENDATION

LIST OF ANNEXES