

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

For Consideration by Members of the IECEX Management Committee, ExMC

For Information: Members of ExTAG and Working Group WG 6 – Revision of IECEX Assessment Procedures

DRAFT OPERATIONAL DOCUMENT

OD003

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

Introductory Note

During the 2000 ExMC Braunschweig meeting it was agreed to form Working Group WG 6 to consider comments discussed during the ExMC meeting and prepare a revised draft for consideration by ExMC.

This Committee Draft is based on document ExMC/58/CD and incorporates comments from members of Working Group WG 6. Specific comments from RU and AU are also included.

Changes to document ExMC/58/CD include the following:

- Identifying the individual stages of the assessment process
- Clarification of the term “Lead Assessor”
- Clarification of the role of accreditation Bodies
- Clarification concerning the required 1 day visit by the IECEX Assessment Team to ACBs and ExTLs with acceptable accreditation
- Removal of the requirement that ACBs must hold accreditation for the certification of ISO 9000 Quality Management Systems

This draft is now submitted for consideration by Members of ExMC.

Comments should be submitted to the ExMC Secretariat, details below, by

7 September 2001.

It would be appreciated if comments were submitted in the form of suggested text in MS Word 6 format and via e-mail

Chris Agius
ExMC Secretariat
E-Mail chris.agius@gas.com.au

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.

International confidence is established by evaluating the competence of a certifying body or Ex test laboratory to comply with the IEC Ex scheme and associated rules. The assessment will cover the competence, experience and familiarity of personnel and the organisation with the relevant explosion protected standards, quality management systems, IECEX scheme and associated rules and ISO/IEC guide 65 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 two Sections:

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

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 IECEEx Scheme and re-assessment of existing ACBs and ExTLs. The term Lead Assessor, as used throughout this document, shall mean the IECEEx Assessment Team Leader appointed by ExMC.

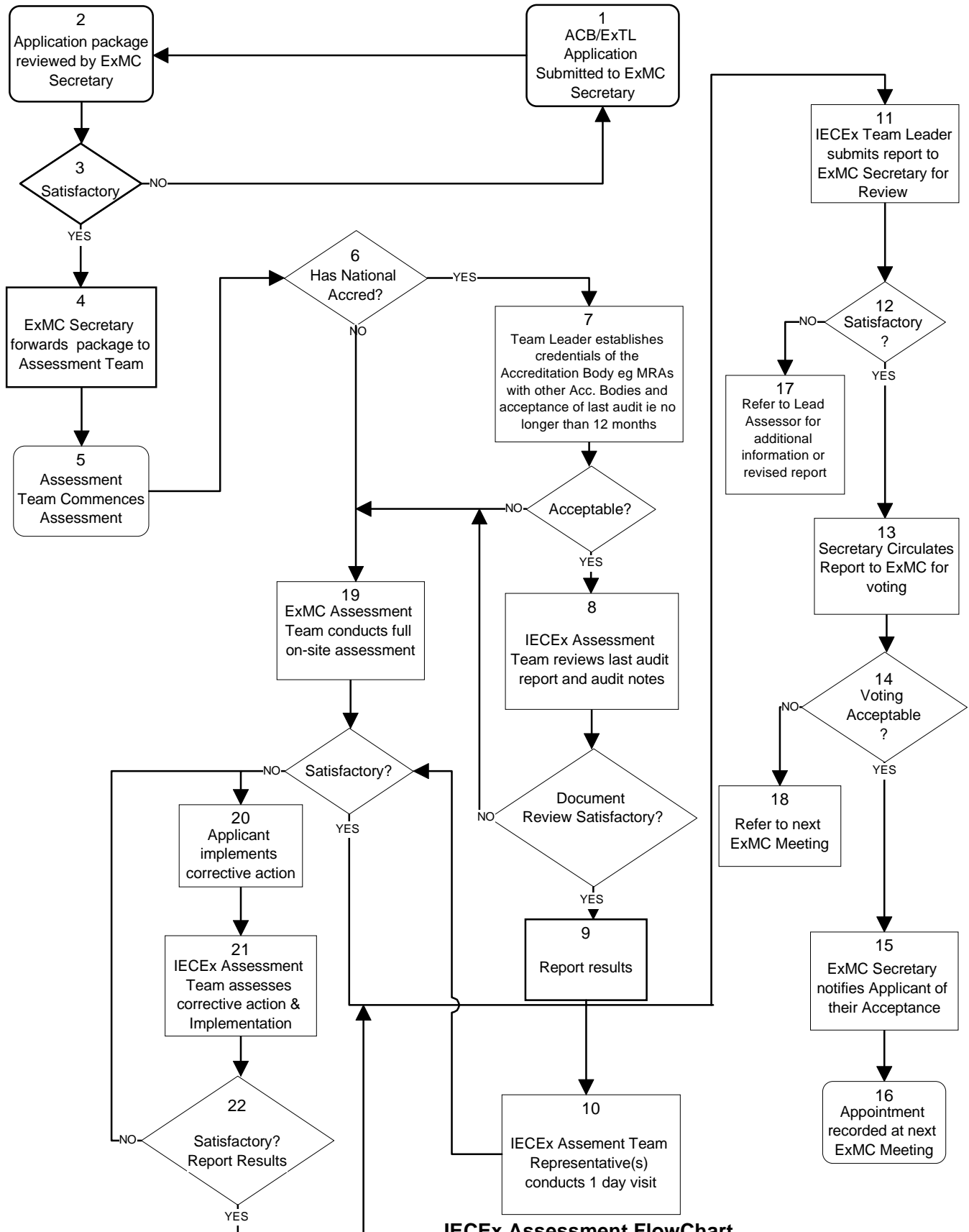
Steps 1 – 4 are applicable to new applications.

IECEEx Assessment Procedure Refer attached IECEEx Assessment Flow Chart

Step	Activity	By Whom	Desired Outcome
Formal Application Submitted to ExMC Secretary			
1	Application received by ExMC Secretary, in accordance with IECEEx 02.	ExMC Secretary	Candidate ACB or ExTL
2	Application assessed for completeness. Appointed Assessment Team accepted by ExMC	ExMC Secretary	Assessment team proposed by IECEEx Assessment Panel Chairman 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 ACB or ExTL	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	IECEEx Assessment Team commences assessment. Lead Assessor, in conjunction with team members reviews application documentation to satisfy steps 6 to 8. Lead Assessor may request additional information from the Candidate ACB or ExTL	Lead Assessor to Manage	Lead Assessor notifies candidate of successful review of documentation and then prepares to arrange site visit
6	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
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	Lead Assessor	*Verification of MRAs *Notification of Government recognition *Use of ISO/IEC Guides 25 or ISO 17025 and 65 *Frequency of surveillance

Step	Activity	By Whom	Desired Outcome
	<p>*What Standards or Guides are used</p> <p>IECEEx Assessment Lead Assessor may obtain information directly from accreditation body or candidate ACB or TL and circulate to other IECEEx Assessment team members for review via correspondence.</p> <p>Note: ACB or TL should obtain all necessary information from accreditation body for presentation to IECEEx Assessment Team Leader.</p>		audits
8	Review of past audit reports, issued by the accreditation body, by Assessment Team to establish compliance with the requirements of IECEEx 02, Technical Guidance Documents, ISO/IEC Guide 25 or ISO/IEC 17025 and ISO/IEC Guide 65.	Assessment Team managed by Lead Assessor	Acceptance by IECEEx Assessment Team of information and audit reports as evidence of compliance to the requirements of IECEEx 02 and the Technical Guidance Documents
9	Notification of results of step 6-8 to candidate ACB or TL and ExMC	Lead Assessor	Letter, Fax or e-mail to Candidate ACB or ExTL. Copy to ExMC Secretary
	On-site Visit		
10	A minimum of one representative of the IECEEx Assessment Team visits candidate to conduct a minimum 1 day site visit for each ACB and ExTL application (where the ACB and ExTL are one organisation 2 mandays is required. This may be 1 Team member for 2 days or 2 team members for 1 day. This visit is to verify implementation of certification or testing procedures	At least 1 person from IECEEx Ass. Team Usually Lead Assessor Lead Assessor to appoint	<p>Visit notes to be included in assessment file.</p> <p>The Lead Assessor in consultation with his Team shall decide if more than 1 manday visit is necessary.</p>
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 and B. Final report to be reviewed by all members of the assessment team	Lead Assessor	Lead Assessor to commence arrange for a final assessment report compiling a Report
12	Final IECEEx 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 ACB or ExTL

Step	Activity	By Whom	Desired Outcome
	Final Approval of ACB or ExTL 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 IECEEx 01)
15	If voting is acceptable then ExMC Secretary notifies applicant of their acceptance	ExMC Secretary	ExMC Letter to accepted ACB and ExTL
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 IECEEx Assessment Team Lead Assessor seeking additional information or revised report	ExMC Secretary	An acceptable report for circulation to ExMC
18	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
19	If at the conclusion of the “Document Review Stage”, the Assessment Team are not satisfied with the information presented, the Lead Assessor shall inform the candidate ACB or ExTL and ExMC Secretary of the Assessment team’s views. In order for the assessment to proceed, the IECEEx Assessment Team shall then conduct 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.
20	Where non-conformances are identified during the assessment process the candidate ACB or TL implements corrective action if they wish to proceed with their application	Candidate ACB or TL	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	Lead Assessor to manage	Report on assessment of corrective actions
22	Notification of results of step 5 to candidate ACB or TL and Chairman of IECEEx 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 applies to all ACBs and ExTLs that have been accepted into the IECEEx 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 IECEEx 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 IECEEx 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 IECEEx 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/IEC Guide 25, ISO/IEC 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 and report at the next ExMC meeting. Where the ACB or ExTL does not agree with the course of action, proposed by WG 4, the matter shall be referred to the ExMC. During the period of referral to ExMC, the ExMC Chairman in consultation with the other IECEX Officers shall decide on the status of the ACB or ExTL 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.

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/IEC 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 and report at the next ExMC meeting. Where the ACB or ExTL does not agree with the course of action, proposed by WG 4, the matter shall be referred to the ExMC. During the period of referral to ExMC, the ExMC Chairman in consultation with the other IECEX Officers shall decide on the status of the ACB or ExTL 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 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.

Assessments of ACBs are aimed at demonstrating compliance with ISO/IEC Guide 65 and IECEx 02. This includes verifying:

- An agreement between the ACB and a recognised ExTL (where separate)
- An organisational chart - note where the ACB is also an ExTL the organisational chart shall demonstrate independence of testing and certification up to at least manager level
- Copies of proposed certificates of conformity in accordance with ExMC requirements. (IECEX 02, section 8.1.2)
- Certification procedure. (IECEX 02, section 9.1, 9.2, 9.3 and 9.4)
- Procedures for assessing manufacturers quality plans, these to include the evaluation of documents that attest to a manufacturers certification/registration to such as ISO9001. (IECEX 02, section 9.5)
- Procedures for completing an independent review of ATR's.
- Procedures for retaining, recording, filing and reporting such things as ATR's, QAR's and IECEx certificates of conformity. (IECEX 02, section 9.6)
- Procedures for carrying out periodic surveillance of the manufacturers quality plans. (IECEX 02, section 9.7)
- Procedures for dealing with changes to certified Ex equipment. (IECEX 02, section 9.9)
- Confidentiality procedures when keeping technical documents etc. (IECEX 02, section 9.11)
- Procedures for suspending or withdrawing a certificate of conformity. (IECEX 02, section 9.13 and 9.14)
- Procedures for dealing with transitional arrangements of the IECEx scheme (IECEX 02, section 10.2, 10.3, 10.4 and 10.5)
- Procedures for national certification and approval, including whether foreign manufacturers are required to make application through a resident agent. (IECEX 02, section 11.1.3)

The ACB assessment shall also review the ACB's ability to perform assessment of Quality Management Systems covering the manufacturer of Ex apparatus. This shall include verifying:

- ISO 9000 qualifications of ACB staff, eg membership of International Quality Associations; or
- National and International ISO 9000 accreditation of the ACB, eg member of IQNET; or
- Acceptance of the ACB as an ISO 9000 certification body in their own country; or
- Experience with operating Product Certification Programs incorporating surveillance of manufacturers

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

- Declaration as per appendix C of IECEx 02
- An organisational chart - note where the ACB is also an ExTL the organisational chart shall demonstrate independence of testing and certification up to at least manager level
- Information as per appendix D of IECEx 02
- A statement respecting the confidentiality of any information they obtain and how this is achieved (IECEx 02, section 6)
- 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 included as Annex A and B.

To assist IECEx Assessment Teams, the IECEx Management Committee have appointed ExMC Working Group 4 with the task acting as a reference body for Assessment Teams. In addition the ExMC Secretary and ExTAG Secretary and other IECEx Officers are always willing to provide assistance. Therefore Lead Assessors should feel free to make use of this assistance throughout the course of their assessments.

Assessor fees are currently set at:

- CHF 1'200 per day or part thereof for Lead Assessors (plus expenses)
- CHF 1'000 per day or part thereof for Assessors (plus expenses)

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

*** END OF DRAFT ***

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
------	-------	------------

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

Name	Title	Experience
------	-------	------------

2.3 *Name And Title of Nominated Principal Contact*

Name	Title	Comments
------	-------	----------

2.4 *Name and Title of Signatories for Certification*

Name	Title	Comments
------	-------	----------

2.5 *Other Employees in ACB activity*

Name	Title	Responsibility
------	-------	----------------

2.6 *Organisational Structure*

2.7 *Administration*

2.7.1 Administrative Structure

2.7.2 Terms of Reference of the Governing Board

3. RESOURCES

Secretariat

(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)

Secretariat

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