



IECEX OPERATIONAL DOCUMENT

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

**Assessment Procedures for IECEx acceptance of Candidate Accepted
Certification Bodies (ExCBs) and Ex Testing Laboratories (ExTLs) –
Part 2: Assessment, surveillance assessment and re-assessment of
ExCBs and ExTLs operating in the IECEx 02, IECEx Certified Equipment
Scheme**





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(ExTLs) –**

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Equipment Scheme**

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Foreword

This OD 003 Part 2 sets out the *Assessment Procedures for IECEx acceptance of Candidate Accepted Certification Bodies (ExCBs) and Ex Testing Laboratories (ExTLs)* operating in the IECEx Certified Equipment Scheme.

The new OD 003 is being published in the following two parts:

OD 003-1 Edition 1.0 Published 2009-04

Assessment Procedures for IECEx acceptance of Candidate Accepted Certification Bodies (ExCBs) and Ex Testing Laboratories (ExTLs) – Part 1: Appointment and Surveillance of IECEx appointed Assessors

OD 003-2 IECEx Assessment Procedures

Part 2: Assessment, surveillance assessment and re-assessment of ExCBs and ExTLs (this document)

The following major changes are included:

- Reference to the use of pre-assessments has been introduced but on a voluntary basis. This has been found to be a very effective tool in recent years.
- Reference has been included to OD 032 *Assessor's Guide* and this has enabled less information to be included in this document.
- Revised daily rates for lead assessors and assessors to take account inflation over that has occurred during the 12 year period since rates were first set.
- Reference to the Team Leader liaising with the National Member Body has been removed from Section 4.
- The assessment report forms in Annexes A and B have been revised and take account of suggestions for them to be filled in prior to an assessment.

Introduction

This part 2 of OD 003 details the assessment procedures established by the IECEx System's Management Committee, ExMC, for the purpose of ensuring a thorough assessment of candidate and existing ExCBs and ExTLs operating in the IECEx Certified Equipment Scheme. The principal aim of these procedures is to instil international confidence of manufacturers, users and regulators in the bodies' competence and capabilities for performing testing and certification of Ex equipment.

NOTE: Operational Documents exist covering the assessment and surveillance of ExCBs operating in the IECEx Certified Service Facility and IECEx Certificate of Personal Competency Schemes as OD 016 and OD 501 respectively.

International confidence is established by evaluating the competence of a certifying body or Ex test laboratory to comply with the IEC Ex System and associated Scheme rules. The assessment will cover the competence, capability, experience and familiarity of personnel and the organisation with the relevant explosion protection standards, quality management systems, IECEx scheme and associated rules, ISO/IEC Guide 65 and 17025, 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 four Sections:

- Section 1 – Initial Assessment, Re-Assessment and Scope Changes
- Section 2 – On-going Assessments
- Section 3 - Surveillance Audits of Issued ExTRs And QARs
- Section 4 – Notes to Assessors

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. More guidance for assessors can be found in OD 032 Assessor's Guide.

Throughout the application and assessment process communication shall be a combination of written and oral communication, where written communication shall include paper or electronic means, eg E-mail communication shall be deemed an acceptable form of formal communication and record keeping.

1 Initial Assessment, Re-Assessment and Scope Changes

1.1 Scope

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

Note: Applications from candidate ExCBs and ExTLs are made using forms ExMC/47H/Q for ExCBs and ExMC/48H/Q for ExTLs, as amended.

The term “applicant body” used throughout this document shall mean the Applicant ExCB and also the Applicant ExTL either together or individually.

This Section is also applicable for re-assessments with the following variations:

- Steps 1 to 5 and 16 to 18 are not applicable
- Where the term ‘Candidate ExCB or ExTL’ is used this should be replaced with ‘Accepted ExCB or ExTL’.
- Where an ExCB is also an IECEx Mark License issuing ExCB, compliance with IECEx 04, OD 022 and OD 023 shall be included.

This Section is also applicable for scope extensions (applied for using ExMC/251A/Q) where the IECEx Secretary identifies the need for a site visit with the following variations:

- Step 3 is not applicable.
- Step 15, The assessment reports produced shall be submitted to IECEx Officers to consider approval of the scope extension and reported at the next ExMC meeting.

1.2 IECEx Assessment Procedure

The IECEx Assessment Flow Chart should be read in conjunction with the table below.

Step	Activity	By Whom	Desired Outcome
Formal Application Submitted to ExMC Secretary			
1	Application received by ExMC Secretary, in accordance with IECEx 02	ExMC Secretary	An application from a new applicant ExCB or ExTL, shall only be processed by the Secretariat when it has been endorsed by the IECEx Member Body. The Member Body shall provide written confirmation of their endorsement.
2	Review of application documentation for completeness.	ExMC Secretary	ExMC Secretary reviews the application and for new application issues an Application Review Report to applicant. This may require further information from the applicant ExCB or ExTL
3	Invoice prepared for the application fee.	ExMC Secretary	Invoice to applicant ExCB and/or ExTL

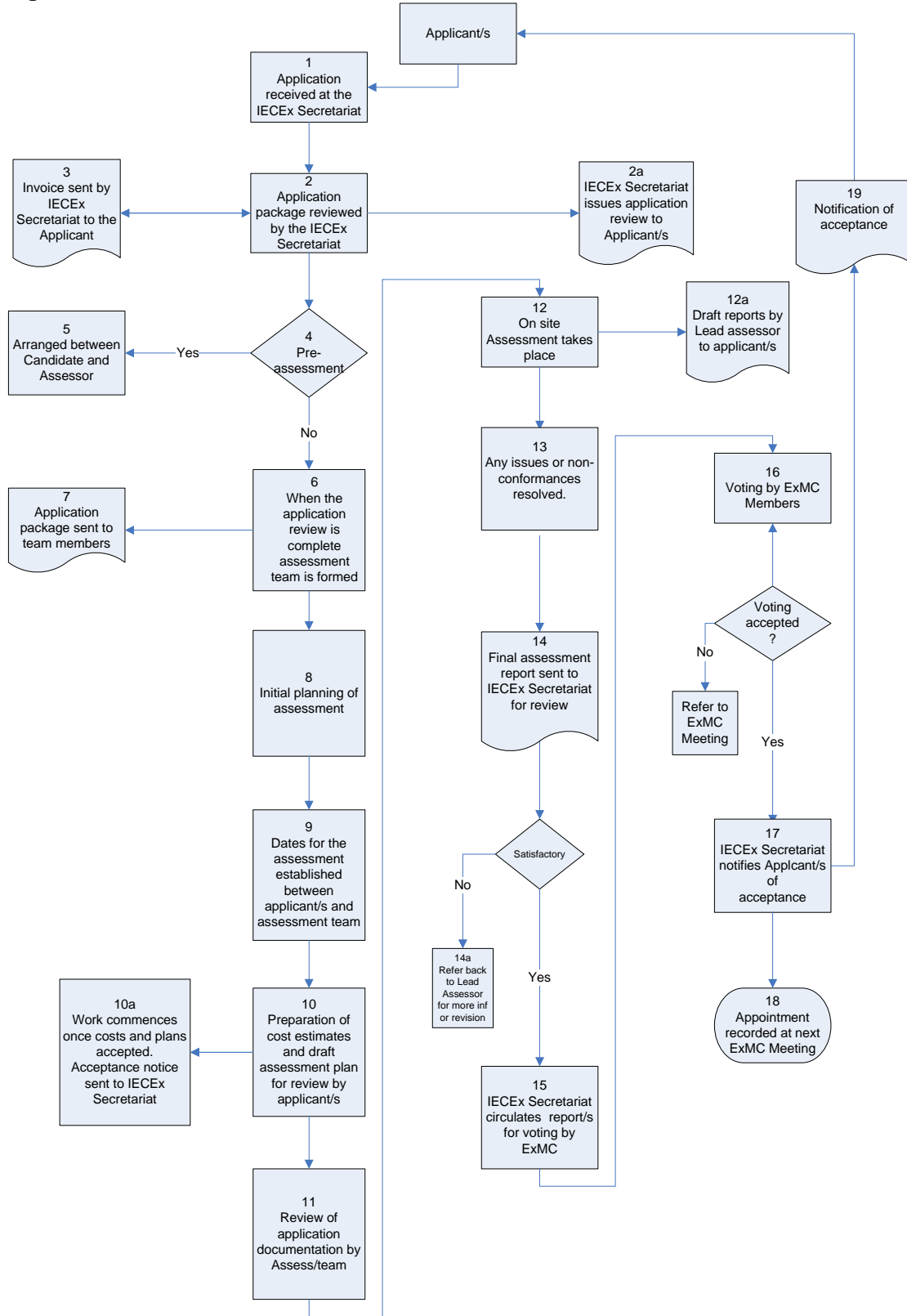
Step	Activity	By Whom	Desired Outcome
Possible Pre-Assessment			
4	<p>In conjunction with above review, ExMC Secretary informs the applicant of the potential benefit that a pre-assessment may bring.</p> <p>Note: It is intended that the pre-assessment use a similar approach to a normal assessment but focussing on areas requested by the applicant. It may also include the provision of information about the Scheme and typical areas that need attention. If the pre-assessment is done in this way the assessor may be included in the initial assessment team. However, if the assessor takes on a consulting or assisting role he/she shall not be part of the IECEX assessment team.</p>	ExMC Secretary	Recommendation to applicant regarding pre-assessment.
5	<p>If applicant agrees to a pre-assessment, IECEX Secretary informs the applicant body of suitable experienced assessors. The applicant body engages the assessor directly and no formal reporting of findings is required to be retained by the IECEX Secretariat.</p> <p>Assessors engaged for pre-assessments are to notify the IECEX Secretariat as this may impact the composition of the assessment team</p>	ExMC Secretary	A pre-assessment visit with confidential gap analysis report provided to the applicant body.
Formation of Assessment Team			
6	When the application is considered to be complete and any pre-assessment is finalised (or for re-assessments when the date for re-assessment is about to fall due) an assessment team is formed from the IECEX pool of Assessors as approved by ExMC.	ExMC Secretary	<p>Acceptance received from proposed members of the IECEX Assessment Team</p> <p>Acceptance of proposed members of the Team received from applicant.</p>
7	Application package forwarded to members of the appointed Assessment Team.	ExMC Secretary	All relevant information available for team to commence their assessment.
Planning the Assessment			
8	Initial planning for the assessment is carried out taking into account whether there is an ExCB, ExTL or both. The number of on-site assessors and number of days for the assessment will then be determined. Account will be taken of relevant national accreditation. As an indication, for an assessment of a new combined ExCB and ExTL with a reasonably large scope it is expected that it will be	Assessment Team Leader in conjunction with ExMC Secretary	Initial plan for the number of days on site and the number of assessors on site.

Step	Activity	By Whom	Desired Outcome
	necessary to have three assessors on site for three days.		
9	Dates for the assessment as established in consultation with the applicant body and the assessors.	Assessment Team Leader	Dates established
10	<p>Preparation of a consolidated cost estimate and draft assessment program for review by the applicant ExCB or ExTL.</p> <p>Work should only commence after the applicant has accepted the cost estimate. A copy of this acceptance should be provided to the ExMC Secretary.</p>	Assessment Team Leader in conjunction with team members	<p>A copy of the cost estimate and draft assessment plan to the applicant and ExMC Secretary.</p> <p>Acceptance of the cost estimate and plan by the applicant.</p>
11	Review of application documentation. Assessment Team Leader may request additional information from the Candidate ExCB or ExTL	Assessment Team Leader in conjunction with team members	Request for additional information if needed.
On-site Visit			
12	<p>The assessment visit takes place. Refer to OD 032 Assessor's Guide for more information on this process. At the closing meeting the findings will be discussed with the management of the applicant body.</p> <p>The documentation produced from the assessment will fall into two categories:</p> <ol style="list-style-type: none"> 1. Reports that will be circulated for voting by the member bodies 2. Documentation that supports the findings of the assessment and how any issues have been resolved. This documentation is treated as confidential but copies will be held by the IECEX Secretariat. 	Assessment Team	<p>Following reports shall be completed:</p> <ul style="list-style-type: none"> -OD 006 Site Assessment Report -OD 007 Guide 65 report for ExCB, -OD 018 17025 Report for ExTL - TGDs Technical Guidance Documents - Draft reports for the ExCB and ExTL for voting as applicable in accordance with Annexes A and B

Step	Activity	By Whom	Desired Outcome
Post Assessment Visit Actions			
13	<p>Any issues or non-compliances identified during the assessment process must be resolved by the applicant body to the satisfaction of the assessment team.</p> <p>In some cases it may be necessary for a follow-up visit by one or more members of the Assessment Team.</p> <p>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</p> <p>Where results of site visit require rectification or corrective action by the candidate ExCB or ExTL, the assessment Team Leader shall review the corrective actions and determine whether the item(s) raised have been sufficiently addressed in order to close the issue.</p> <p>Where non-compliances, identified during the site visit, remain unresolved more than 12 months beyond the site visit, the ExMC Secretary in consultation with the IECEX Officers shall determine whether a further site visit shall be required.</p>	<p>Body under assessment & Assessment team</p> <p>Assessment Team Leader</p>	<p>Final reports for submission to the ExMC Secretary, reviewed by all members of the assessment team</p> <p>Assessment Team Leader to arrange for compilation of final assessment reports for voting by ExMC.</p>
14	<p>Final IECEX Assessment Team reports reviewed by ExMC Secretary.</p> <p>Once the review is completed, the following is added at the bottom of the report: 'Independently reviewed by the IECEX Secretariat'</p>	ExMC Secretary	Review by ExMC Secretary to ensure completeness of information and ready for circulation to ExMC for voting.
14A	<p>Where review in step 14 raises questions, ExMC Secretary refers the matter to the IECEX Assessment Team Leader seeking additional information or revised report.</p> <p>The ExMC Secretary may consult with the IECEX Officers as part of this review.</p>	ExMC Secretary	An acceptable report for Circulation to ExMC
15	<p>ExMC Secretary prepares a Voting Document containing the Assessment Report for voting and submits to ExMC Members for formal voting, via correspondence or at the next ExMC meeting. There are separate Voting Documents and associated reports for ExCB</p>	ExMC Secretary	ExMC Document issued for voting, with a copy submitted to candidate ExCB or ExTL

Step	Activity	By Whom	Desired Outcome
	and ExTL.		
Final Approval of ExCB or ExTL by ExMC			
16	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 IECEX 01 voting procedures)
16A	Where voting is unsuccessful the application is then referred to IECEX Secretary for further action which will normally involve discussion at the next ExMC meeting	ExMC Secretary to arrange	Findings recorded in the minutes ExMC Secretary consults with the IECEX Chairman
17	If voting is acceptable then ExMC Secretary notifies the applicant body of its acceptance	ExMC Secretary	ExMC Letter to accepted ExCB and ExTL Certificate of Acceptance issued to the Body Secretariat updates the IECEX records, eg OD 001 and arranges access for ExCB to use IECEX On-Line Certificate system
18	Appointment recorded at next ExMC meeting	ExMC Secretary to arrange	Recorded in Minutes

Fig 1 Flow chart



2 ON-GOING ASSESSMENTS

2.1 Scope

This Section applies to all ExCBs and ExTLs that have been accepted into the IECEx Certified Equipment Scheme. The purpose of ongoing assessments is to satisfy the International Ex community that ExCBs and ExTLs maintain their facilities and capabilities that enabled their entry into the Scheme. The following two different situations are addressed:

- 1) ExCBs and ExTLs that maintain relevant national accreditation that is found to be acceptable by the original IECEx Assessment Team, and through the ExMC vote
- 2) ExCBs and ExTLs that do not have relevant national accreditation or whose accreditation is not acceptable to the ExMC.

2.2 Surveillance of ExCBs and ExTLs with Acceptable National Accreditation

2.2.1 Procedure

The IECEx Secretariat shall, on at least an annual basis confirm the accreditation status and scope of all ExCBs holding national accreditation that are not subject to annual IECEx surveillance assessments.

This may require the IECEx Secretariat seeking confirmation from accreditation bodies and ExCBs and ExTLs along with a call for audit reports issued by accreditation bodies and internal audit reports of the ExCB and ExTLs in order to gain evidence of compliance with ISO/IEC 17025 and Guide 65 along with IECEx Scheme requirements.

In addition to the above, ExCBs and ExTLs shall advise the IECEx Secretary of any changes in their organisation affecting the ExCBs or ExTLs operation in the IECEx Certified equipment Scheme such as the organisation of the ExCB or ExTL, its staff, facilities, quality system, operating procedures, and accreditation status.

2.2.2 Review

The ExMC Secretary shall review the information to ensure:

- ExCB and ExTL Sites covered by accreditation aligns with the site previously approved by ExMC;
- All Clauses of ISO/IEC 17025 for ExTLs and ISO/IEC Guide 65 for ExCBs, as applicable, have been covered;
- Ensure that IECEx requirements are met
- Any Non-Conformances are identified;

Where major Non-Conformances have been identified the ExMC Secretary may consult with the IECEx Chairman and Officers to decide on such action to be taken 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 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.

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

2.2.3 Re-assessment

On the fifth anniversary of the original assessment visit or re-assessment visit of an ExCB or ExTL a re-assessment, in accordance with the assessment procedure detailed in Section 1, shall be performed, by an assessment team appointed by the ExMC Secretary.

2.3 Surveillance of ExCBs and ExTLs without Acceptable National Accreditation

2.3.1 Preparation

The ExMC Secretary shall arrange for an annual on-site surveillance assessment of the ExCB and ExTL. This should normally be carried out by one member of the original IECEx assessment team. The assessor shall be appointed by the ExMC Secretary. The ExCB and ExTL shall agree to cover the costs associated with this on-site assessment and may object to the selection of the appointed Assessor, giving reasons for such objection. In such cases the ExMC Secretary shall consult with the IECEx Chairman and Officers.

The appointed assessor shall carry out an assessment for compliance with ISO/IEC 17025 for ExTLs and IECEx Technical Guidance Documents (TGDs). For ExCBs the assessment shall be conducted according to ISO/IEC Guide 65 and their ability to comply with IECEx Rules and Operational Documents. The assessor shall then report back to the ExMC Secretary whom may consult with the original IECEx Assessment Team Leader.

The Assessor shall prepare a site assessment report using OD 006, to the ExMC Secretary, with copy to the ExCB or ExTL.

2.3.2 Procedure

The report shall be reviewed by the ExMC Secretary for completeness and how any issues or non-conformances have been addressed. The report shall be retained, for a minimum of 10 years, for record keeping purposes, by the ExMC Secretary.

If any issues or non-compliances are identified during the assessment they shall be resolved to the satisfaction of the assessor and Assessment Team Leader

Where major Non-Conformances have been identified the ExMC Secretary may consult with the IECEx Chairman and Officers to decide on such action to be taken 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 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.

2.3.3 Re-assessment

On the fifth anniversary of the original assessment visit or re-assessment visit of an ExCB or ExTL a re-assessment, in accordance with the assessment procedure detailed in Section 1, shall be performed, by an assessment team appointed by the ExMC Secretary.

3 SURVEILLANCE AUDITS OF ISSUED ExTRS AND QARS

3.1 Scope

This section addresses the on-going surveillance of ExCBs and ExTLs in the IECEx Scheme via random surveillance assessments of ExTRs and QARs that are issued to support an IECEx Certificate of Conformity (CoC).

3.2 Purpose

The purpose of conducting surveillance assessments of issued ExTRs and QARs is for the international Ex industry, regulators and all IECEx Member ExCBs and ExTLs to gain confidence that IECEx Certificates of Conformity are supported by credible tests and assessments, and that the IECEx rules and procedures are followed by all IECEx Bodies.

3.3 Approach

The surveillance shall be conducted in accordance with the procedures outlined in below or may be conducted as part of the annual surveillance visit.

3.4 Procedures

During each calendar year the ExMC Secretary shall arrange for ExTR and QAR documents, relating to an issued IECEx Certificate of Conformity (CoC), from each ExCB to be subjected to a technical review.

3.5 Appointment of Reviewer

The Secretary shall be responsible for appointment of reviewers. Any person appointed should be able to demonstrate current knowledge of IECEx certification process and the explosion-protection concepts involved. It would normally be expected that a reviewer would be drawn from the pool of assessors approved by the ExMC. Where a reviewer is drawn from elsewhere it will be necessary to take into account his/her compliance with the relevant criteria applied to assessors.

3.6 Sampling

The method of sampling ExTRs and QARs shall take into account the following:

- The level of activity of an ExCB and ExTL in the Certified Equipment Scheme
- The sampling of ExTRs and QARs shall cover a cross section of the ExCBs and ExTLs range of scope at least annually.
- The various sites and locations of the ExTLs and ExCBs

3.7 Review Criteria

The criteria for such review shall include the following:

- a) That the ExTR and QAR show clear relationship to the product(s) covered by the IECEx CoC.
- b) The ExTR and QAR are complete and address all clauses and requirements of both the IEC Standard shown on the CoC and the Quality System requirements of OD 005.
- c) ExTR provides sufficient information on the evidence of compliance with the requirements of Standards, eg inclusion of details of tests such as identification of samples used for testing, equipment used, measured results etc.
- d) Where tests are omitted the ExTR contains sufficient engineering rationale to justify the omission.
- e) That ExTRs use the IECEx approved format.
- f) A general appreciation for technical compliance is available, eg that an item intended as submersible or exposed to weather has an appropriate IP rating.
- g) QARs clearly show the locations of the manufacturing sites audited.
- h) QARs contain sufficient information to give the reader confidence that the auditor has conducted a thorough audit, eg recording of individual procedures reviewed during the audit, recording of persons interviewed during the audit, etc.
- i) That the ExTRs and QARs give sufficient information to demonstrate to the reviews satisfaction feel that the IECEx Rules, Operational Documents and ExTAG Decisions have been met.
- j) The CoC shall also be reviewed as part of the ExTR and QAR review for consistency between ExTR, QAR and CoC.
- k) The CoC shall also clearly identify what product(s) are covered by the certificate with any conditions listed to be clear and appropriate.

3.8 Outcome of the Review

The outcome of the Review may fall under the following categories:

a) *Review is Satisfactory, No Major Issues Raised*

Where the review has been found to be satisfactory even with some minor issues raised, eg that the ExTR or QAR should have contained a little more information to be complete, then the report shall indicate the result and any areas where improvements could be made. This report shall be retained by the ExMC Secretary with a copy to the ExCB and ExTL responsible for the ExTR and QAR.

The ExMC Secretary shall retain copies of the report on file at the Secretariat Office for a minimum of 5 years.

General findings shall be included in an annual report to the ExMC.

b) *Review is Un-satisfactory, with Major Issues Raised*

Where major issues have been identified that may suggest that Ex products MAY NOT comply with the IEC Standards listed in the CoC, and the products have been, or there is a potential that they will, be released to the market, the ExMC Secretary shall notify the IECEx Chairman whom shall examine the details surrounding the issues raised and arrive at a course of action to be taken, either by the ExCB responsible or the ExMC Secretariat.

Such action may include a request for the ExCB and ExTL to re-assess the application or a special site assessment of the ExCB and ExTL responsible, or other actions deemed appropriate. The IECEx Chairman may consult with other Officers or experts as the Chairman deems necessary.

Such action shall be recorded by the ExMC Secretary and included in the annual report to the ExMC

3.9 Funding

The initial review of ExTRs and QARs shall be funded as part of the costs of the IECEx System. Where follow up action of a substantial nature is required, eg reviews of additional ExTRs and QARs or site visits, such costs shall be paid by the ExCB or ExTL responsible for the CoC, ExTR and QAR that are in question, subject to their prior agreement. Any such follow up actions shall be managed by the ExMC Secretariat in consultation with the IECEx Chairman and Officers.

4 Notes to Assessors

4.1 Scope

This section provides instructions to assessment teams and assessment team leaders. It also establishes the daily rates to be charged for assessments.

Further guidance for assessors can be found in OD 032 Assessor Guide.

4.2 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.

4.3 Instructions for IECEx Assessment Team Leaders

Assessment Team Leaders have the additional task of coordinating the assessment process of the ExCB or ExTL under assessment by their team.

Once an assessment team has been appointed, the Team Leader should make contact with his/her team members and the candidate ExCB and ExTL Body as soon as possible. It is the Team Leader's responsibility to ensure that all team members have the following:

- Copies of the ExCB and ExTL applications and supporting documentation
- Technical Guidance Documents, where available.
- Working copy of IECEx 02
- IECEx Assessment Procedure, OD 003-2, this document
- OD 032 Assessor Guide.

An assessors' package of relevant documents is available from the IECEx Website at http://www.iecex.com/assessors_package.htm.

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

The Team Leader generally acts as the contact between the assessment team members and candidate ExCB or ExTL and is responsible for all correspondence.

The Team Leader should liaise with the ExMC Secretary and candidate ExCB or ExTL regarding the assessment program and estimated costs (assessment fees and travel costs). The ExCB or ExTL should reach agreement with the Lead Assessor on costs before assessment work commences.

The Team Leader shall ensure that the assessment procedures, detailed in this document are followed and that the approach of assessments is one of seeking evidence of compliance with requirements. This includes reporting how 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 ExCBs are aimed at demonstrating compliance with ISO/IEC Guide 65 and IECEx 02. This includes verifying:

- An agreement between the ExCB and a recognised ExTL (where separate)
- An organisational chart - note where the ExCB is also an ExTL the organisational chart shall demonstrate independence of testing and certification up to at least manager level.
- Complementing the above, procedures addressing the issue that persons involved in the decision to certify should not have had any involvement in past testing and assessment for the particular product.
- Certification procedure. (IECEX 02, OD 009)
- Procedures for assessing manufacturers quality plans, these to include the evaluation of documents that attest to a manufacturers certification/registration to such as ISO9001. (OD 005, OD 025)
- Procedures for completing an independent review of ExTRs.
- Procedures for retaining, recording, filing and reporting such things as ExTRs, QARs and IECEx certificates of conformity.
- Procedures for carrying out periodic surveillance of the manufacturers quality plans (OD 009, OD 005, OD025).
- Procedures for dealing with changes to certified Ex equipment.
- Confidentiality procedures when keeping technical documents etc.
- Procedures for suspending or cancelling a certificate of conformity.
- Procedures for dealing with ExTRs and QARs for the purpose of issuing their own National Certification
- Procedures for national certification and approval, including whether foreign manufacturers are required to make application through a resident agent.

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

- Understanding of the differences between auditing of Quality management Systems to ISO 9001 and Quality Plans associated with product certification systems;
- Assessing the ExCB's system for the appointment of auditors to audit manufacturers under the IECEx Scheme (noting that IECEx require that all ExCB auditors appointed to audit manufacturers are required to have up-to- date Ex technical expertise for the types of protection in the scope, see OD 025);
- A thorough understanding by the ExCB's auditors of the requirements of OD 005, OD 025 and OD 009;
- Experience with operating Product Certification Programs incorporating surveillance of manufacturers
- The Assessment should also conduct a Technical interview of some or all ExCB auditors to determine their level of both Ex knowledge and requirements of OD 005 and OD 025.

Assessments of ExTLs are aimed at demonstrating compliance with 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 ExCB 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
- Suitable facilities are available and the necessary test and measuring equipment for the scope are available
- That the laboratory has appropriately qualified and experienced staff with intimate knowledge of testing and assessing Ex equipment
- Implementation of IECEx Operational Documents and ExTAG Decisions into their own documentation structure.
- Implementation of testing procedures and acceptance of test facilities at national level

As part of the assessment procedure, it is the responsibility of the Team Leader to provide the IECEx Secretariat with an IECEx Assessment Report for each ExCB and ExTL their team have assessed. A separate report is required for each. Proforma Reports for both ExCBs and ExTLs are included as Annex A and B.

To assist IECEx Assessment Teams, the IECEx Management Committee has appointed an IECEx Assessor Panel Chairman 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 Team Leader should feel free to make use of this assistance throughout the course of their assessments.

4.4 Assessor Fees

Assessor fees, payable by the ExCB and ExTL are currently set at:

- CHF 1,500 per day or part thereof for Lead Assessors (plus expenses)
- CHF 1,250 per day or part thereof for Assessors (plus expenses)

4.5 Closing Comment

The above instructions for Team Leaders, 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 candidate ExCB, ExTL. Points of non-compliance raised by any team member must be immediately brought to the Team Leader's attention who will then raise the non-conformity with the candidate ExCB 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 Team Leaders. Should any assessor have difficulty in meeting their obligations they are requested to contact their Lead Assessor immediately and advise the ExMC Secretary.

Assessing of ExCB and ExTL 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.

ANNEX A

IECEX ASSESSMENT REPORT FOR.....

ExCB (IECEX Certification Body)

Type of Assessment: (please mark)

Initial Assessment for Candidate ExCB	X
Re-Assessment of ExCB	X
Scope Extension of ExCB	X

1. OBJECT AND FIELD OF APPLICATION

1.1. Country:

To be initially completed by applicant or body being re-assessed

1.2. Name of Candidate ExCB

To be initially completed by applicant or body being re-assessed

1.3. Members of the Assessment Team

1.4. Place and Date of Assessment

Address(es) to be initially completed by applicant or body being re-assessed

1.5. Assessment References (IECEX Certified Equipment Scheme)

- i) IECEx 02 Fourth Edition 2010-08 IECEx Certified Equipment Scheme covering equipment for use in explosive atmospheres – Rules of Procedure
- ii) OD 003-2 Procedures for the assessment, surveillance assessment and reassessment of ExCBs and ExTLs
- iii) OD 005-1 IECEx Quality System Requirements for Manufacturers – Part 1: Guidance on the establishment and maintenance of a quality system
- iv) OD 005-2 IECEx Quality System Requirements for Manufacturers – Part 2: Audit Checklist. (This is available in a Word format for use by ExCBs).
- v) OD 009 Issuing of CoCs, ExTRs and QARs
- vi) OD 025 Guidelines on the Management of Assessment and Surveillance programs for the assessment of Manufacturer's Quality Systems in accordance with the IECEx Scheme
- vii) OD 026 IECEx Certified Equipment Scheme – Guidelines for the qualification of Lead Auditor and Auditors, in accordance with the IECEx System.

- viii) ISO/IEC Guide 65:1996
- ix) OD 017 Drawing and documentation guidance
- x) ExCB application documents dated To be initially completed by applicant or body being re-assessed
- xi) IECEx 04, OD 022 and OD 023 - For re-assessments where the ExCB is an IECEx Mark License issuing ExCB
- xii) OD 033 IECEx Certified Equipment Scheme - IECEx Operations Manual – IECEx Unit Verification Certificates

1.6. Scope of Application (to be selected)

To be initially completed by applicant or body being re-assessed

Number	Title
60079-0 Edition 5	Explosive atmospheres - Part 0: Equipment - General requirements
60079-1 Edition 6	Explosive atmospheres - Part 1: Equipment protection by flameproof enclosures "d"
60079-2 Edition 5	Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure «p»
60079-5 Edition 3	Explosive atmospheres - Part 5: Equipment protection by powder filling «q»
60079-6 Edition 3	Explosive atmospheres - Part 6: Equipment protection by oil immersion «o»
60079-7 Edition 4	Explosive atmospheres - Part 7: Equipment protection by increased safety "e"
60079-11 Edition 5	Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i"
60079-13 Edition 1	Explosive atmospheres – Part 13: Equipment protection by pressurized room "p"
60079-15 Edition 4	Electrical apparatus for explosive gas atmospheres - Part 15: Construction, test and marking of type of protection "n" electrical apparatus
TR 60079-16 Edition 1	Electrical apparatus for explosive gas atmospheres. Part 16: Artificial ventilation for the protection of analyser(s) houses
60079-18 Edition 3	Electrical apparatus for explosive gas atmospheres - Part 18: Construction, test and marking of type of protection encapsulation "m" electrical apparatus
60079-25 Edition 2	Electrical apparatus for explosive gas atmospheres - Part 25: Intrinsically safe systems
60079-26 Edition 2	Explosive atmospheres - Part 26: Equipment with equipment protection level (EPL) Ga
60079-27 Edition 2	Electrical apparatus for explosive gas atmospheres - Part 27: Fieldbus intrinsically safe concept (FISCO) and Fieldbus non-incendive concept (FNICO)
60079-28 Edition 1	Explosive atmospheres - Part 28: Protection of equipment and transmission systems using optical radiation

Number	Title
60079-29-1 Edition 1	Explosive atmospheres - Part 29-1: Gas detectors – Performance requirements of detectors for flammable gases
60079-29-4 Edition 1	Explosive Atmospheres – Part 29-4: Gas detectors - Performance requirements of open path detectors for flammable gases
60079-30-1 Edition 1	Explosive atmospheres – Part 30-1: Electrical resistance trace heating – General and testing requirements
60079-31 Edition 1	Explosive atmospheres – Part 31: Equipment dust ignition protection by enclosure "t"
61241-0 Edition 1	Electrical apparatus for use in the presence of combustible dust - Part 0: General requirements
61241-4 Edition 1	Electrical apparatus for use in the presence of combustible dust Part 4: Type of protection "pD"
61241-11 Edition 1	Electrical apparatus for use in the presence of combustible dust – Part 11: Protection by intrinsic safety 'iD'
62013-1 Edition 2	Caplights for use in mines susceptible to firedamp Part 1: General requirements - Construction and testing in relation to the risk of explosion
62013-2 Edition 2	Caplights for use in mines susceptible to firedamp Part 2: Performance and other safety-related matters

1.7. Candidate ExCB Persons Interviewed

Name	Position

1.8. Legal Entity of the Candidate ExCB

To be initially completed by applicant or body being re-assessed

1.9. Associated Testing Laboratories

To be initially completed by applicant or body being re-assessed

1.10. Associated Certification Functions

To be initially completed by applicant or body being re-assessed

1.11. National Marks and Certificates

To be initially completed by applicant or body being re-assessed

1.12. Financial Support

To be initially completed by applicant or body being re-assessed

1.13. History

To be initially completed by applicant or body being re-assessed

1.14. Standards Accepted

See clause 1.6 of this report

1.15. National Differences to IEC Standards

National differences to IEC standards are those for the <country/Group> Differences listed in the latest version of the IECEx System Bulletin.

2. ORGANISATION

Tables below to be initially completed by applicant or body being re-assessed

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 ExCB activity

Name	Title	Responsibility and Experience in Ex

2.6. Organizational Structure

2.7. Administration (including Indemnity Insurance)

To be initially completed by applicant or body being re-assessed

3. RESOURCES

4. COMMITTEES / Governing Board / Appeals / Advisory Board

To be initially completed by applicant or body being re-assessed

5. CERTIFICATION OPERATIONS

5.1. *National Approval/Certification Methods*

To be initially completed by applicant or body being re-assessed

5.2. *Certification Policy*

To be initially completed by applicant or body being re-assessed

5.3. *Application for Certification*

To be initially completed by applicant or body being re-assessed

5.4. *Certification Decision*

To be initially completed by applicant or body being re-assessed

5.5. *Suspension and Cancellation of Certificates*

To be initially completed by applicant or body being re-assessed

6. STATISTICS

To be initially completed by applicant or body being re-assessed

6.1. *Certificates Issued*

Number of certificates issued under the IECEx, national or regional schemes in the preceding four years for each type of protection:

Standards	Title	Number of issued certificates				Total Part 0 included in numbers below
		2007	2008	2009	2010	

7. DOCUMENTATION

7.1. *Quality Manual*

To be initially completed by applicant or body being re-assessed

7.2. *Procedures*

To be initially completed by applicant or body being re-assessed

7.3. Records

To be initially completed by applicant or body being re-assessed

7.4. Document Change Control

To be initially completed by applicant or body being re-assessed

8. CONFIDENTIALITY

To be initially completed by applicant or body being re-assessed

9. PUBLICATIONS

To be initially completed by applicant or body being re-assessed

10. NATIONAL ACCREDITATION

To be initially completed by applicant or body being re-assessed

11. RECOGNITION AND AGREEMENTS

To be initially completed by applicant or body being re-assessed

12. INTERNAL AUDIT AND PERIODIC MANAGEMENT REVIEW

To be initially completed by applicant or body being re-assessed

13. SUBCONTRACTING, USE OF OTHER LABS AND USE OF OTHER LOCATIONS

To be initially completed by applicant or body being re-assessed

14. TRAINING

To be initially completed by applicant or body being re-assessed

15. ASSESSMENT OF MANUFACTURERS AND ISSUE OF QARS

To be initially completed by applicant or body being re-assessed

16. COMPLAINTS AND APPEALS (Including appeals to IECEx)

To be initially completed by applicant or body being re-assessed

17. SPECIAL FACTS TO BE NOTED

17.1. Supporting Documentation

Copies of additional supporting information for this assessment have been provided to the applicant and the IECEx Secretariat. These are included in a site assessment report and include:

- Details of issues raised and how these have been resolved
- Checklist for ISO/IEC Guide 65
- Other?

17.2. Other?

18. COMMENTS (Including issues found during assessment)

19. RECOMMENDATION

Based on the assessment performed on <dates>, <body > is/is not recommended for (continued) acceptance in the IECEx scheme as an IECEx Certification Body (ExCB) according to the scope of the standards listed in this document (including the extension of scope), (subject to resolution of the issues found during the assessment).

Lead Assessor

Expert Assessor

Expert Assessor

Date:

List of Annexes:

1. Overall Organization Chart of To be provided by applicant or body being re-assessed
2. Organization Chart of To be provided by applicant or body being re-assessed
3. Accreditation Certificate for Product Certification to be provided by applicant or body being re-assessed

ANNEX B

IECEX ASSESSMENT REPORT FOR ...

ExTL (IECEX TEST LABORATORY)

Type of Assessment: (please mark)

Initial assessment for Candidate ExTL	X
Re-Assessment of ExTL	X
Scope Extension of ExTL	X

1. OBJECT AND FIELD OF APPLICATION

1.1. *Country:*

To be initially completed by applicant or body being re-assessed

1.2. *Name of Candidate TL*

To be initially completed by applicant or body being re-assessed

1.3. *Members of the Assessment Team*

1.4. *Place and Date of Assessment*

Address(es) to be initially completed by applicant or body being re-assessed

1.5. *Assessment References (IECEX Certified Equipment Scheme)*

- i) IECEx 02 Fourth Edition 2010-08 IECEx Certified Equipment Scheme covering equipment for use in explosive atmospheres – Rules of Procedure
- ii) 003-2 Procedures for the assessment, surveillance assessment and reassessment of ExCBs and ExTLs
- iii) OD 009 Issuing of CoCs, ExTRs and QARs
- iv) ISO/IEC 17025:2005
- v) IECEx Technical Guidance Documents (TGDs)
- vi) ExTAG decision sheets (DSs)
- vii) ExTL application documents dated..... To be initially completed by applicant or body being re-assessed
- viii) OD 024 IECEx Rules of Procedure covering testing, or witnessing testing at a manufacturer's or user's facility

1.6. *Scope of Application (to be selected)*

To be initially completed by applicant or body being re-assessed

Number	Title
60079-0 Edition 5	Explosive atmospheres - Part 0: Equipment - General requirements
60079-1 Edition 6	Explosive atmospheres - Part 1: Equipment protection by flameproof enclosures "d"
60079-2 Edition 5	Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure «p»
60079-5 Edition 3	Explosive atmospheres - Part 5: Equipment protection by powder filling «q»
60079-6 Edition 3	Explosive atmospheres - Part 6: Equipment protection by oil immersion «o»
60079-7 Edition 4	Explosive atmospheres - Part 7: Equipment protection by increased safety "e"
60079-11 Edition 5	Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i"
60079-13 Edition 1	Explosive atmospheres – Part 13: Equipment protection by pressurized room "p"
60079-15 Edition 4	Electrical apparatus for explosive gas atmospheres - Part 15: Construction, test and marking of type of protection "n" electrical apparatus
TR 60079-16 Edition 1	Electrical apparatus for explosive gas atmospheres. Part 16: Artificial ventilation for the protection of analyser(s) houses
60079-18 Edition 3	Electrical apparatus for explosive gas atmospheres - Part 18: Construction, test and marking of type of protection encapsulation "m" electrical apparatus
60079-25 Edition 2	Electrical apparatus for explosive gas atmospheres - Part 25: Intrinsically safe systems
60079-26 Edition 2	Explosive atmospheres - Part 26: Equipment with equipment protection level (EPL) Ga
60079-27 Edition 2	Electrical apparatus for explosive gas atmospheres - Part 27: Fieldbus intrinsically safe concept (FISCO) and Fieldbus non-incendive concept (FNICO)
60079-28 Edition 1	Explosive atmospheres - Part 28: Protection of equipment and transmission systems using optical radiation
60079-29-1 Edition 1	Explosive atmospheres - Part 29-1: Gas detectors – Performance requirements of detectors for flammable gases
60079-29-4 Edition 1	Explosive Atmospheres – Part 29-4: Gas detectors - Performance requirements of open path detectors for flammable gases
60079-30-1 Edition 1	Explosive atmospheres – Part 30-1: Electrical resistance trace heating – General and testing requirements
60079-31 Edition 1	Explosive atmospheres – Part 31: Equipment dust ignition protection by enclosure "t"
61241-0 Edition 1	Electrical apparatus for use in the presence of combustible dust - Part 0: General requirements
61241-4	Electrical apparatus for use in the presence of combustible dust

Number	Title
Edition 1	Part 4: Type of protection "pD"
61241-11 Edition 1	Electrical apparatus for use in the presence of combustible dust – Part 11: Protection by intrinsic safety 'iD'
62013-1 Edition 2	Caplights for use in mines susceptible to firedamp Part 1: General requirements - Construction and testing in relation to the risk of explosion
62013-2 Edition 2	Caplights for use in mines susceptible to firedamp Part 2: Performance and other safety-related matters

1.7. Candidate TL Persons Interviewed

Name	Position

1.8. Legal Entity of The Candidate TL

To be initially completed by applicant or body being re-assessed

1.9. Associated ExCB

To be initially completed by applicant or body being re-assessed

1.10. Financial Support

To be initially completed by applicant or body being re-assessed

1.11. History

To be initially completed by applicant or body being re-assessed

2. ORGANISATION

Tables below to be initially completed by applicant or body being re-assessed

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. Employees

Name	Title	Experience

2.5. Organizational Structure

3. RESOURCES

4. DOCUMENTATION

4.1. *Quality Manual*

To be initially completed by applicant or body being re-assessed

4.2. *Procedures*

To be initially completed by applicant or body being re-assessed

4.3. *Work Instructions*

To be initially completed by applicant or body being re-assessed

4.4. *Records*

To be initially completed by applicant or body being re-assessed

4.5. *Document Change Control*

To be initially completed by applicant or body being re-assessed

4.6. *Test Records*

To be initially completed by applicant or body being re-assessed

5. TEST REPORTS

To be initially completed by applicant or body being re-assessed

5.1. *Test Reports Issued*

Number of test reports issued under the IECEx, national or regional schemes in the preceding four years for each type of protection:

Standards	Title	Number of issued test reports				Total
		2007	2008	2009	2010	

6. CALIBRATION

To be initially completed by applicant or body being re-assessed

7. CONFIDENTIALITY

To be initially completed by applicant or body being re-assessed

8. NATIONAL ACCREDITATION

To be initially completed by applicant or body being re-assessed

9. RECOGNITION AND AGREEMENTS

To be initially completed by applicant or body being re-assessed

10. INTERNAL AUDIT AND PERIODIC REVIEW

To be initially completed by applicant or body being re-assessed

11. COMPLAINTS AND APPEALS (Including appeals to IECEx)

To be initially completed by applicant or body being re-assessed

12. SPECIAL FACTS TO BE NOTED

12.1. *Supporting Documentation*

Copies of additional supporting information for this assessment have been provided to the applicant and the IECEx Secretariat. These are included in a site assessment report and include:

- Details of issues raised and how these have been resolved
- Checklist for ISO/IEC 17025
- Completed technical guidance notes (TGDs) for ...
- Photos of the facilities
- Other?

12.2. Other?

13. COMMENTS (Including issues found during assessment)

14. RECOMMENDATION

Based on the re-assessment performed on <dates>, <body> is/is not recommended for (continued) acceptance in the IECEx scheme as a IECEx Testing Laboratory (EXTL) according to the scope of the standards listed in this document (including the extension of scope), (subject to resolution of the issues found during the assessment).

Lead Assessor

Expert Assessor

Expert Assessor

Date:

List of Annexes:

1. Overall Organization Chart of..... To be provided by applicant or body being re-assessed
2. Organization Chart of..... To be provided by applicant or body being re-assessed
3. Accreditation Certificate for ISO/IEC 17025 To be provided by applicant or body being re-assessed

*** END OF DOCUMENT ***