



ExMC/1261/CD
July 2017

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

To: Members of the IECEx ExMC

**Title: Draft Requirements for Additional Testing Facilities – for discussion
within ExMC WG1 prior to issuing to ExMC**

INTRODUCTION

During the 2016 meeting of WG1 a special AdHoc Group was formed to consider requires for Additional Testing Locations/Facilities that are neither an ExTL nor fall under the IECEx OD 024 “Testing at Other Locations” situations. A verbal report was given during the 2016 ExMC Umhlanga meeting.

Further work was undertaken by both ExMCWG1 and the AdHoc Group during May 2017 to prepare this Document.

This Document also contains an Annex A that suggests change to IECEx 02 Rules to accommodate “Additional Testing Facilities” (ATF) for ExMC to consider.

ExMC Members will be asked to consider this Draft Document and the Annex during the ExMC 2017 Washington meeting.

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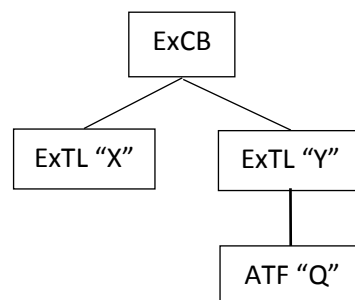
Additional Testing Facilities – DRAFT 1 (as reviewed by ExMC WG1)

Background

Following on a brief meeting of the AdHoc WG during the 2016 IECEx Meeting, this document is a revised version of the Principles document considered by the AdHoc WG and is now presented for consideration at the ExMC WG1 Meeting Hawarden UK, May 2017

Definition and description an Additional Testing Facility (ATF)

A testing laboratory located remotely from an accepted ExTL which is accepted according to the IECEx Rules and which is under the complete control of, or belongs to or works under a written agreement with a single Ex Testing Laboratory (ExTL). An ATF is in effect a part-ExTL because it lacks the complete equipment, personnel, experience and/or expertise to be a full ExTL. An ATF can thus be a facility with very limited scope (e.g. thermal conditioning) or one with nearly full scope that has potential to become an ExTL in its own right. The principle of an ATF is to support the supervising ExTL with test results under a transparent process that is fully recognised by the IECEx Rules.



How an ATF differs from an ExTL

- An ExTL has to meet rigorous criteria for expertise across the full range of testing and assessment against a given standard. An ATF by comparison is defined by the tests that it can conduct.
- An ATF (i.e. ATF "Q" in the diagram) may work only for a single, supervising ExTL (i.e. ExTL "Y" in the diagram). This ensures proper control of laboratories which do not have the level of expertise or equipment of a full ExTL.
- An ATF produces test and assessment results but does not issue the ExTR. The supervising ExTL always issues the ExTR.
- The frequency of the IECEx re-assessment of the ATF is determined as the same as for the supervising ExTL.
- An ATF may not subcontract any of its work. An ATF is in effect a special subcontractor for the ExTL and is not considered competent to further subcontract the work.
- Another ExTL (e.g. ExTL "X" in the diagram) may only use an ATF linked to another ExTL via subcontract to that supervising ExTL (ExTL "Y" in the diagram). Direct use is not permitted.



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Obligations of the supervising ExTL (ExTL “Y” in the diagram)

- This ExTL is responsible for supervising the work of the ATF.
- The ExTL approves and issues the ExTR containing any test results obtained at the ATF.
- The ExTL must apply the rules of the ExTL’s own quality system to the ATF and conduct an on-site, internal audit of the ATF at least annually.
- Contribution to Annual fees being same annual fee that applies to ExTLs for each ATF

Action points

- Update IECEx 02 to reflect the role of the Additional Testing Location. See the appendix to this paper for a first go at proposed wording.
- We need to decide how the testing/assessment scope of ATFs is recorded and made available to receiving ExCB since the ATF will not always be working to full standards.
- The “IECEx Test Report Cover” should contain a statement informing (to the level of detail needed) about the use of ATF assessment and/or testing so that testing outside of “IECEx approved scope” doesn’t occur.

Annex A – Suggested Changes to IECEx 02 to accommodate ATFs

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APPENDIX

Changes required to IECEx 02 to accommodate “IECEx Additional Testing Facilities”

Changes as proposed to IECEx 02 are shown via the tracking tool below.

Addition of new definition 3.15 after those currently used for ExCB and ExTL. All other definitions to be renumbered.

3.15

Additional Testing Facility (ATF)

a testing laboratory located remotely from an accepted ExTL which is accepted according to these Rules and which is under the complete control of, or belongs to or works under a written agreement with a single Ex Testing Laboratory (ExTL). This ExTL is responsible for the work of the ATF, and applying the rules of the ExTL quality system to the ATF.

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Addition of new section 11.3 for acceptance of ATF:

11.3 Acceptance of Additional Testing Facilities

11.3.1 Conditions for acceptance

Acceptance of a testing laboratory as an ATF is subject to the following conditions and to the procedures stipulated in 11.3.2 to 11.3.10:

- The Additional Testing Facility shall be located in a participating country.
- The Additional Testing Facility can operate as an ATF if it is under the complete technical and legal control of a single ExTL or has a written agreement with a single ExTL to undertake work with it according to these Rules.
- The supervising ExTL shall demonstrate how it takes full responsibility for the work of the ATF including the conduct of internal audits of the ATF.
- The competence of the Additional Testing Facility shall be demonstrated by assessment. The general competence, efficiency, experience, familiarity with the relevant standards and the types of protection included in those standards as well as compliance with

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Annex A – Suggested Changes to IECEx 02 to accommodate ATFs

ISO/IEC 17025 and the IECEx Technical Guidance Documents shall be assessed. Acceptance in another IEC Conformity Assessment System or IECEx Scheme or accreditation by a recognized national accreditation body shall be taken into account. The ExMC shall decide upon the extent of the assessment that is necessary.

- The Additional Testing Facility shall not be part of, or under the influence of, manufacturing interests associated with Ex products or services
- The Additional Testing Location shall not subcontract any of its work.
- The Additional Testing Location shall not issue the ExTR. The ExTL issues the ExTR containing any test results obtained at the ATF.

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11.3.2 Application

An application for the acceptance of a laboratory as an ATF for assessment and testing according to one or more standards accepted for use in the IECEx Certified Equipment Scheme shall be made by the supervising ExTL and via the Member Body of the ExMC. The application shall be submitted to the Secretary of the ExMC and shall be accompanied by a declaration as detailed in Annex D.

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11.3.3 Assessment

The candidate ATF shall be assessed to determine that the conditions according to 11.3.1 are fulfilled. Assessors approved by the ExMC shall carry out the assessment. The assessment team shall be led by a Lead Assessor appointed by the ExMC and shall include one member from an ExCB or an ExTL.

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Assessors with prior experience working in an ExCB or ExTL and whose knowledge of standards and certification matters is current may be used. When the laboratory is integral with a candidate ExTL, or is to be assessed on the same occasion as a candidate ExTL, a combined assessment team may be appointed.

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The candidate ATF and its supervising ExTL shall be given the names and current appointments of the assessors proposed to be appointed by the ExMC. Candidates may object "for cause" (reasons to be stated) to the appointment of the assessors.

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The laboratory to be assessed shall express its willingness to pay the professional fees of the assessors, the amount to be decided by the ExMC, and the reasonable travelling and living expenses arising from

Annex A – Suggested Changes to IECEx 02 to accommodate ATFs

the assessment. An estimate of these expenses shall be provided to the candidate ATF in advance and agreed by the candidate.

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The Secretary of the ExMC shall manage the assessment process, including the appointment of assessment teams from a list of assessors approved by the ExMC.

11.3.4 Resolution of differences

During the assessment, the assessors shall prepare a draft report that shall be discussed with the management of the candidate ATF and its supervising ExTL. Efforts should be made to resolve any differences of opinion between the assessors and the candidate during this discussion.

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11.3.5 Report to ExMC

The assessors shall submit to the ExMC Secretary, with a copy to the representatives of the candidate ATF and its supervising ExTL, a confidential report containing their findings and recommendations, taking into account the declaration submitted together with the application. The supervising ExTL may attend an ExMC meeting or submit written comments to respond to enquiries regarding its application.

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11.3.6 Acceptance

The ExMC shall decide upon the acceptance of the candidate ATF at a meeting or by correspondence. In the latter case, the decision shall be reported to the next meeting of the ExMC and recorded in the minutes.

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11.3.7 Notification

If the decision of the ExMC is positive, the Secretary of the ExMC shall inform the candidate ATF and the supervising ExTL in writing. If the decision of the ExMC is negative, the Chairman of the ExMC may, depending on the findings, suggest to the candidate ExTL

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- to withdraw the application, or
- to accept a new assessment.

11.3.8 Extension of scope

When an ATL wishes to extend its acceptance to further standards or tests accepted for use in the IECEx Certified Equipment Scheme, an application shall be made to the Secretary of the ExMC. When the ATE

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Annex A – Suggested Changes to IECEX 02 to accommodate ATFs

has been assessed within the last five years, the members of the Assessment Team that assessed the ATL should give their comments on the application.

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The ExMC Secretary in consultation with the IECEX Executive shall decide whether the extension may require a full or limited assessment, on the basis of the information thus available. Decisions shall be reported to the next ExMC meeting.

11.3.9 Re-assessment

By means of re-assessment and comparative assessment and testing to the extent and frequency deemed necessary, the ExMC shall verify whether the ATFs and supervising ExTLs are still fulfilling the conditions of 11.3.1. The re-assessment schedule for the ATF shall be the same as for the supervising ExTL.

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11.3.10 Suspension

The acceptance of an ATF may be suspended or withdrawn by the ExMC if that ATL no longer fulfils the conditions of 11.3.1 or if it violates these Rules. Before such a recommendation is made, the ATL shall have the opportunity to take corrective action over a period of six months and state its own opinion on the matter.

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In case of a suspension or a withdrawal, the ATF in question shall not be allowed to claim any relationship with the IECEX Certified Equipment Scheme.

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Revision of title for Annex C:

Annex C Additional information to be provided by a testing laboratory in applying for acceptance as an ExTL or ATF

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Addition of new Annex D for ATF:

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As a means of ensuring confidence among Scheme Members, newly accepted ExTLs shall submit a copy of the first completed ExTR to the ExMC Secretary who will arrange for it to be reviewed. The outcome of this review may require corrective actions to be undertaken by the ExTL and review of further ExTRs.¶

Annex D

Declaration by a testing laboratory applying

Annex A – Suggested Changes to IECEx 02 to accommodate ATFs

to become an IECEx Additional Testing Facility

The declaration by a testing laboratory applying for acceptance as an Additional Testing Location shall be a self-contained document including the following information:

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- a) A description of the laboratory which gives, in addition to an organization chart, information about
- relationship between the laboratory and the relevant supervising ExTL;
 - the legal status of the laboratory;
 - the address(es) at which it carries out its operations;
 - the responsibilities concerning assessment and testing;
 - the means by which the laboratory will demonstrate compliance with ISO/IEC 17025;
 - the documents available for providing supporting information, for example with regard to existing accreditation.

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b) A list of the tests and standards accepted for use in the IECEx Certified Equipment Scheme according to which the laboratory intends to conduct tests

c) The information required in annex C.

d) A statement of the number of test reports issued in the preceding two years for each type of test covered by the standards listed in b).

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e) A statement that the laboratory will abide by the Rules.