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

**TITLE: Outcome of IECEx ExMC Working Group 1 Meeting – Background Document**

**Circulation to: Members of the IECEx Management Committee, ExMC**

**INTRODUCTION**

This document has been prepared by Dr Munro and is provided as background to the proposed changes to IECEx 02 and IECEx OD 009 (refer ExMC/158/DV and ExMC/1859/DV).

The proposed changes to IECEx 02 and OD 009 related to roles associated with ExTRs and seek to clarify how to apply them in relation to ISO/IEC 17065 and 17025, and to ensure consistent use of terminology to avoid confusion.

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ExCB and ExTL roles for ExTRs

1. Scope

This paper examines roles associated with ExTRs with a view to clarifying how to apply them in relation to ISO/IEC 17065 and 17025, and to ensure consistent use of terminology to avoid confusion.

It is provided as background to the many of the proposed changes to IECEx 02 and OD 009 to be agreed by WG1 and voted on by ExMC.

NOTE Section 6 in the previous version of this paper showed feedback from ExMCWG18 on the first version of this paper. That has been removed from this version of the paper, so it only reflects that agreed positions from the WG1 meeting.

1. Background

During the ExMCWG18 meeting on 24 March 2022 aimed at clarifying for IECEx the application of “Independent verifier” from IEC 60079-33, it was realised that there was potential for different interpretations for the other roles for those signing ExTRs with particular reference regarding how those roles relate to ISO/IEC 17065 and 17025.

The terms “review” or “reviewer” appear in both ISO/IEC 17065 and 17025, and that can lead to potential confusion as they have different roles in an ExCB and ExTL. It is also important to clarify where how the requirement for independence between ExCB and ExTL roles is achieved during a project and how that relates to those signing the ExTR, including the cover sheet.

When the concept of an ExTR was developed in IECEx, it was decided that a “test report” which may incorporate assessment, would be the prime responsibility of the ExTL and hence the people signing for the compiler and reviewer are clearly shown as from the ExTL. Note the following definition of ExTL in IECEx02:

**3.14**

**Ex Testing Laboratory (ExTL)**

a testing laboratory which is accepted according to these Rules and which performs tests and assessments and compiles IECEx Test Reports for endorsement by the associated ExCB.

In OD 009 we have the following definition (which also includes requirements):

**ExTR Package**

An ExTR Package comprises an ExTR Cover Sheet and one or more associated ExTR documents (which may include ExTRs, ExTR Addendums and ExTR of National Differences).

All ExTR Package documents are compiled and reviewed by the ExTL and are then endorsed by an issuing ExCB on an ExTR Cover Sheet to indicate final approval of the overall ExTR Package

It should be noted that some accreditation bodies within ILAC take a similar view, but others regard only physical testing as covered their accreditation. This can lead to confusion but does not change how IECEx views the roles when the ExTR is developed. Bodies within the scheme are also often structured different. Some bodies have separate staff doing the testing and the assessment. Others have staff doing both roles. This decision on the structure may be taken by the body or it may be dictated by the local accreditation body.

Further during the above development of the ExTR concept it was agreed that the IECEx Equipment Certification Scheme is a mutual cooperation between certifying bodies and so although the technical content of an ExTR is developed and signed off by the ExTL, a cover page is added which includes an endorsement by the ExCB. The ExTR cannot be issued until the cover page is signed by all parties. When that is done, IECEx allows the ExTR to be issued by either the ExCB or the ExTL.

The ExTR cover shows the following roles and signatures:

Compiled by + signature (ExTL)

Reviewed by + signature (ExTL)

Endorsed by + signature (ExCB)

The above roles are not formally defined in IECEx documentation and the respective review roles of the ExCB and ExTL are not clearly addressed. Discussion in the ExMCWG18 meeting indicated that this could lead to different interpretation for the roles by different bodies. This paper includes recommendation to address this.

**From ISO/IEC 17065:**

7.5 **Review**

7.5.1 The certification body shall assign at least one person to **review** all information and results related to the evaluation. The **review** shall be carried out by person(s) who have not been involved in the evaluation process.

It should be noted that for IECEx, the above review does not just apply to the ExTR review (which is part of the endorsement process), but also applies to review of the QAR. Both must be done before a decision can be taken to issue a CoC. In IECEx, where the ExCB does not have totally separate staff from the ExTL, IECEx requires that there are procedures in place to ensure that the person providing the ExCB review and endorsing the ExTR has not acted in an ExTL role for that project.

**From ISO/IEC 17025:**

**6 Resource requirements**

**6.2 Personnel**

**6.2.6** The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following: …..

c) report, **review** and authorization of results.

**7.7 Ensuring the validity of results**

**7.7.1** The laboratory shall have a procedure for monitoring the validity of results…. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to: ………

i) **review** of reported results;

**7.8 Reporting of results**

**7.8.1 General**

**7.8.1.1** The results shall be **reviewed** and authorized prior to release.

The above clearly indicates that report must be reviewed as part of the actives covered by ISO/IEC 17025. This is also a requirement of IECEx. So, it is important to differentiate between the review as part of the ExTL ExTR process and the review required by the ExCB as part of their endorsement process.

1. Inconsistences in Rules and OD 009

* 1. General

The following are extracts from IECEx 02 and OD 009. It can be seen that there is inconsistency within and between the documents in the use of the terms “prepare” and “compile”. There are also inconsistences in the use of the term “issue”, in particular who issues the ExTR. The use of the term “review” is also inconsistent.

* 1. IECEx 02

In 8.2.1 **Preparation**, states “An ExTR is **prepared** and **issued** by an ExTL but must be endorsed by an ExCB, associated with the ExTL,”.

11.3.1 “The supervising ExTL **issues** the ExTR”. In ATF procedure.

Table in Introduction in ExTR Application and CoC Application: “ExTL prepares and **issues** ExTR to ExCB”, “ExCB reviews and endorses ExTR”, and “ExCB issues ExTR to the applicant”. There is not mention in ExTR Application about publishing the ExTR summary report on the IECEx On-Line System,

9.4 “The ExTL shall …and **compile** an ExTR”.

3.14 “a testing laboratory which is accepted according to these Rules and which performs tests and assessments and **compiles** IECEx Test Reports

* 1. IECEx OD 009

Clause 2.1 definition: on ExTR Package: “All ExTR Package documents are **compiled** and **reviewed** by the ExTL and are then **endorsed** by an issuing ExCB on an ExTR Cover Sheet to indicate final **approval** of the overall ExTR Package

Clause 2.1 definition: on ExTR Blank Report Forms: “Official templates prepared and maintained by IECEx Working Groups that shall be used by accepted IECEx Certification Bodies and Ex Test Laboratories to **prepare** ExTRs.”

Section 2 Step 8 for ExTRs: “The relevant IECEx Test Report (ExTR) Blank Report Forms for the relevant Standard(s) and Edition(s) thereof shall be used to **prepare and compile** an ExTR.” Plus “An ExTR shall also be **compiled** by the ExTL”

Section 2 Step 9 for ExTRs: “the **ExCB shall prepare the ExTR** cover sheet and **compile** the ExTR package encompassing all ExTRs”

Section 5 Step 7: “On satisfactory completion of testing an ExTR shall be **prepared** and issued”

1. Proposal

It is recommended that consistent terminology be adopted across the IECEx 02, OD 009, and the ExTRs and associated cover sheets in relation to the preparation, reviews, endorsement and issuing of ExTRs.

The following is proposed:

Ex TL role – **preparation** is used is for the complete work of the ExTL, including:

* **Compiling**; and
* **Reviewing** (in accordance with ISO/IEC 17025)
* Where IEC 60079-33 is involved, there also roles for the **independent verifiers**. This is addressed in OD 233

ExCB role – encompasses

* **Reviewing** of the ExTR (in accordance with ISO/IEC 17065)
* **Endorsing** of the ExTR where there is a successful review

There is inconsistency as to who can issue the ExTR, being ExCB, ExTL or either. At the ExMC WG1 on 2 May 2022 it was agreed that only the ExCB may issue the endorsed ExTR.

1. Recommended changes

Recommended changes to IECEx 02 and OD 009 are included in ExMC/1858/DV and ExMC/1859/DV respectively.

Possible future changes to the ExTR cover include:

* Including information that the ExTL review is in accordance with ISO/IEC 17025
* Including “Reviewed and” in front of “endorsed”
* Including information that the ExCB review is in accordance with ISO/IEC 17065