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

**Title: Discussion Document – Subcontracting of Tests within the IECEx Certified Equipment Scheme**

**Circulated to: ExTAG – IECEx Testing and Assessment Group**

**INTRODUCTION**

At various times the subject of IECEx requirements surrounding “Subcontracting” of tests arise throughout discussions.

In addition, noting changes included in Edition 3 of ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, have also resulted in questions being raised concerning the IECEx 02 Certified Equipment Scheme requirements governing “Subcontracting” of Tests.

This document, prepared by the IECEx Secretariat, in consultation with ExTAG (IECEx Testing and Assessment Group) and ExAG (IECEx Assessment Group) Officers is to be discussed during the technical session of the 2021 ExTAG Remote Meeting.

ExTAG Members are requested to note this document and be prepared for a brief discussion during the 2021 ExTAG meeting.

**IECEx Secretariat**

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1. **Background**

The subject of “Subcontracting” of tests is certainly not new to IECEx discussions. ExTAG members may recall past ExTAG discussions such as the 2014 ExTAG meeting where document ExTAG/325/CD “use of subcontractors” was discussed with the 2014 ExTAG meeting agreeing to the following resolution {Mins ExTAG/346/R}

“*The discussion was then extended to include the definition of minimum test equipment required for a Test Laboratory. The IECEx Secretary suggested that ExMC WG02 includes in the TCD the list of minimum test equipment for each standard. It was also agreed by the members, that even for the tests concerned by these equipment, subcontracting may be possible, for example because of temporary capacity issues*.”

One of the results from the 2014 ExTAG discussions was the inclusion of “Minimum Testing Capability” in the IECEx Technical Capability Documents (TCDs) used for the IECEx peer assessment of IECEx Testing Laboratories, ExTLs and candidate ExTLs.

Various levels of use of subcontracting by an ExTL is a necessary part of daily business due to either or both:

1. Limitation of resources (equipment/expertise) to undertake specialised tests that may only be conducted very infrequently, for example, CTI (Comparative Tracking Index) testing; or
2. As a result of capacity issues relating to workload or sample size limitation etc.

During early development of the IECEx Certified Equipment Scheme, a key principle established required ExTLs to have and maintain a certain level of testing capability, as determined by the collective IECEx Membership. This principle has been maintained through the years of IECEx’s development and continues today. In support of this principle IECEx through its specialist Working Group, ExMC WG2 developed and maintain the IECEx TCD to address each standard used within the IECEx 02 Certified Equipment Scheme. Current editions of TCDs are available from <https://www.iecex.com/members-area/documents/tcds/>

The TCDs have evolved to be an integral instrument and tool for conducting IECEx assessments of Laboratories seeking to join IECEx and for the 5 year re-assessment of ExTLs.

To be clear subcontracting of tests is still a provision used within the IECEx 02 Certified equipment Scheme, under set guidelines and provisions.

1. **“Subcontracting” versus “Contracting”**

When discussing the topic of Subcontracting it is important that a distinct separation is made between subcontracting with an organisation versus contracting of persons to support the human resources of an ExTL.

For the purposes of IECEx peer assessments of ExTLs and IECEx Certification Bodies (ExCBs) the clear distinction made has long been that contracted resources, for example, contracted Quality Management System (QMS) auditors, are regarded as a contracting arrangement, similar to an employment contract with staff, as both employees and contracted persons, such as QMS auditors have their training and competence evaluated by the ExTL or ExCB engaging them AND both employees and contracted staff MUST conduct their work in accordance with the procedures and work instructions of the ExTL or ExCB they work for.

When ExTLs and ExCBs are assessed by the IECEx Assessment Teams, both employees and contracted persons are regarded as one in the same with the ExTL and ExCB under assessment needing to demonstrate systems and procedures addressing training and evaluation of ALL persons that perform key tasks within the ExTL or ExCB.

When it comes to “Subcontracting” this is a term used to identify the “Outsourcing” of tasks/work to another organisation, relying on that other organisation’s own internal Quality Management System’s procedures and systems for having the task/work performed to the satisfaction of the ExTL or ExCB that has engaged the “other organisation”.

A quick look at International Standard, ISO/IEC 17021-1 *Conformity assessment —*

*Requirements for bodies providing audit and certification of management systems —*

*Part 1: Requirements,* Clause 7.5.1 of “the Outsourcing Clause”, extracted below, includes a very useful statement that aligns with the above description.

**7.5 Outsourcing {Extract from ISO/IEC 17021-1 Ed 1.0}**

**7.5.1 The certification body shall have a process in which it describes the conditions under which outsourcing (which is subcontracting to another organization to provide part of the certification activities on behalf of the certification body) may take place**

While the scope of ISO/IEC 17021-1 applies to Certification Bodies, this principle associated with outsourcing of tasks applies equally to Testing Laboratories, which we will see later in this document.

Regardless of whether subcontracting or contracting is being used by an ExTL or ExCB, IECEx expects that ExTLs or ExCBs have a responsibility towards:

1. The Tasks/work performed; and
2. Evaluation of the subcontractor or contractor and monitoring of their performance

While in both subcontracting and contracting situations, the ExTL and ExCB takes responsibility for the task/work done by both, control over task/work performed by contracted persons is much simpler as it is the ExTL or ExCB’s own procedures and systems that are used hence the level of monitoring and control may be more straightforward.

When using another organisation to perform tasks, such as tests, under a subcontracting arrangement the ExTL or ExCB may need to rely on a number of means to evaluate the competence and overall quality of the Organisation to whom they are subcontracting to. Other means includes use of ISO/IEC 17025 accreditation according to structured approach such as that under the ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum).

1. **ISO/IEC 17065 Requirements of ExCBs concerning Subcontracting (Outsourcing)**

Apart from specific requirements contained within IECEx rules of procedures and Operational Documents (ODs), the fundamental requirements of ISO/IEC 17065 *Conformity assessment — Requirements for bodies certifying products, processes and services* apply, in particular those of Clause 6.2.2 “External resources (outsourcing)” and its subclauses 6.2.2.1 to 6.2.2.4.

A key requirement of Clause 6.2.2 and its subclauses is that contained under item a) of 6.2.2.4 requiring that the Certification Body to

* *“take responsibility for all activities outsourced to another body”*
* *have documented policies, procedures and records for the qualification, assessing and monitoring of all bodies that provide outsourced services used for certification activities*
* Others (refer to the text of ISO/IEC 17065)

We are also reminded of the requirements of IECEx 02 regarding the need for the IECEx Management Committee, ExMC to approve the cooperation between ExCBs and ExTLs where they are not part of the same organisation, noting in particular the following extracted bullets from Clause 11.1.1 of IECEx 02:

* The certification body shall have within its organization, or have an agreement to employ, an ExTL accepted by the ExMC according to these Rules for the relevant types of protection
* Where the certification body wishes to cooperate with more than one ExTL, the certification body shall have a separate agreement with each ExTL and such cooperation shall be agreed by ExMC either at a meeting or voting via correspondence.

1. **ISO/IEC 17025 Requirements concerning Subcontracting of Tests**

In focusing our attention on the subcontracting of tests, we see that previous editions of ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* included a dedicated Clause on the topic of “Subcontracting of Tests”, such as Clause 4.5 of Edition 2.0, extracted below

**4.5 Subcontracting of tests and calibrations {Extract from ISO/IEC 17025 Edition 2}**

**4.5.1** When a laboratory subcontracts work, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard for the work in question.

**4.5.2** The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.

**4.5.3** The laboratory is responsible to the customer for the subcontractor’s work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

**4.5.4** The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.

A separate Clause, Clause 4.6 *“Purchasing services and supplies*”, to address the control of service providers and suppliers beyond those providing subcontracted testing services was also included in previous editions of ISO/IEC 17025.

During the revision of ISO/IEC 17025 Ed 2.0 both items of Clause 4.5 and 4.6 were somewhat combined and now presented under Clause 6.6 “**Externally provided products and services**”, extract below:

**6.6 Externally provided products and services {Extract from ISO/IEC 17025 Edition 3}**

**6.6.1** The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

a) are intended for incorporation into the laboratory’s own activities;

b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;

c) are used to support the operation of the laboratory.

NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services

**6.6.2** The laboratory shall have a procedure and retain records for:

a) defining, reviewing and approving the laboratory’s requirements for externally provided products and services;

b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;

c) ensuring that externally provided products and services conform to the laboratory’s established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;

d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

**6.6.3** The laboratory shall communicate its requirements to external providers for:

a) the products and services to be provided;

b) the acceptance criteria;

c) competence, including any required qualification of personnel;

d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.

A common theme that has existed throughout the various editions of ISO/IEC 17025 has been the need for Testing laboratories to have available the necessary personnel, facilities, equipment and systems to perform its testing services. This has now been made very clear via Clause 6.1 Under **Resource Requirements** of the current edition 3 of ISO/IEC 17025, extract below.

**6.1 General {Extract from ISO/IEC 17025 Edition 3}**

The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

A very important message to convey at this point is that in subcontracting to another organisation to provide a service, does not enable one to subcontract its responsibility.

Bottom line, is that Testing Laboratories are responsible for the Test reports they issue and must have processes and procedures for:

* Evaluating;
* Appointing; and
* Monitoring

Of External Service Providers (subcontractors – including subcontracting of tests, where the IECEx TCD permits this) when using such.

1. **IECEx requirements concerning IECEx Testing Laboratories (ExTLs)**

IECEx 02 *IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres (IECEx System) Rules of Procedure* Clause 11.2 and subclauses details the requirements of Organisations seeking acceptance as an ExTL. In particular, the 4th Bullet of subclause 11.2.1 includes the following requirement

**IECEx 02 Ed 7.1 Clause 11.2.1 4th Bullet extract**

..........The general competence, efficiency, experience, familiarity with the relevant standards and the types of protection included in those standards as well as compliance with ISO/IEC 17025 and the IECEx Technical Guidance Documents shall be assessed......

In addition, subclause 11.2.2 of IECEx 02 “Application” requires candidate ExTLs to submit information contained in Annex B and C to be provided to the IECEx Secretariat when making application to join the IECEx 02 Certified equipment scheme. Included in the information to be provided by candidate ExTLs is information concerning Subcontracting of tests, re item C.6.2 of IECEx 02, extracted below:

**C.6.3 Subcontract work**

What type of testing is to be subcontracted in respect of the recognition being sought?

This information assists the IECEx peer Assessment Teams to prepare for the IECEx assessment of candidate ExTLs, whom, as part of the IECEx peer assessment will check and confirm that the candidate ExTL have procedures and systems to address a number of matters such as:

1. Whether the subcontracting of tests is in line with the provisions of the IECEx TCDs;
2. The systems and procedures used by the ExTL for evaluating subcontracted laboratories align with requirements for IECEx requirements associated with
   1. The subcontracted test labs capability for performing the tests;
   2. Whether or not the subcontracted test lab holds accreditation by an ILAC member accreditation body, or is an Accepted ExTL within IECEx;
   3. If accredited, are the tests covered by the scope of accreditation and is accreditation current;
   4. If the test lab is not accredited or the tests are not covered by accreditation, the ExTL must have a procedure for assessing the test lab itself;
   5. Others
3. The systems and procedures used by the ExTL for monitoring subcontracted laboratories align with requirements for IECEx requirements associated with
   1. On-going checking of status of accreditation or IECEx acceptance when using another ExTL;
   2. On-going assessment by the ExTL itself where the subcontracted test lab does not hold accreditation by an ILAC member accreditation body;
   3. Others
4. **Conclusion**

This document does not contain any recommendations, nor propose any changes to the current IECEx rules but rather is presented as a timely reminder for the IECEx community which includes ExTLs and ExCBs, of the IECEx requirements regarding the use of external resources, whether referred to as Subcontracting / Outsourcing etc for which the starting point of such are the general requirements contained within the ISO/IEC 17000 suite of Standards.

This document is being presented at the 2021 Annual meeting of the ExTAG.

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