

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Ex Management Committee, ExMC
Ex Testing and Assessment Group, ExTAG

Document to be Considered – IEC/CAB ILAC COOPERATION
DEVELOPING A COMMON APPROACH

Introduction

A Task Force comprising representatives from the IEC Schemes and ILAC has prepared a discussion document for consideration as a starting point for possible collaboration between the IEC Schemes and ILAC with respect to the assessment and accreditation of Test Laboratories.

This document, ExMC/76/DC is submitted to ExMC and ExTAG members for consideration during the 2000 series of IECEx Meetings, with a view to endorsing the document or proposing modifications if required. Points raised in this document, eg implementation of ISO 17025, will be discussed during the upcoming Braunschweig meetings.

IEC/CAB ILAC COOPERATION

DEVELOPING A COMMON APPROACH

18 August 2000

Following the CAB/ILAC Workshop "Exploring Calibration" held in Geneva on 20 May 1999, a small Task Force was established to investigate possibilities for cooperation between ILAC and IEC/CAB at a technical level. In particular, the following issues were identified as issues for possible complementary activities, which might reduce duplication or divergence of approach when dealing with laboratories by both parties.

- Implementation of ISO/IEC 17025
- Measurement uncertainty (IECEE-CTL document to be considered)
- Proficiency testing
- Calibration

The Task Force currently consists of Mr Anthony Russell, Chief Executive, of National Association of Testing Authorities, Australia (NATA - representing ILAC), Mr Pierre de Ruvo of the IEC Central Office (representing the IECEE Scheme) and Mr Chris Agius of Quality Assurance Services (QAS - representing the IECEx scheme). Mr Richard Kay, Secretary IECQ has also provided input on behalf of the IECQ scheme.

A meeting was held between Chris Agius and Tony Russell on Monday 10 April 2000 to collate existing information available from both ILAC and IEC, relevant to the topics listed above. The following sections of this paper report on the current situation as known at August 2000, and additional information is now sought to update ILAC's Accreditation Policy Committee and the IEC/CAB.

1. Implementation of ISO/IEC 17025 - The Current Situation

ISO/IEC 17025 was published in December 1999 and its adoption and implementation by both ILAC and IEC/CAB member bodies will affect laboratories coming under both the ILAC and the IEC/CAB schemes.

The following is the known position to date of the respective ILAC and IEC/CAB schemes:

1.1 ILAC

The 1999 General Assembly of ILAC made the following decisions regarding adoption and implementation of ISO/IEC 17025 at its meeting held in Rio de Janeiro on 19-20 October 1999:

The General Assembly endorses the recommendations of the Technical Accreditation Issues Committee (TAIC) that:

3.7.8 ILAC accept, two years from the date of its availability, to implement ISO/IEC 17025 and check for compliance in the laboratories through the normal surveillance schemes.

In addition, the TAIC currently has a work item for preparation of a guidance document to assist accreditation bodies to have a common approach in the transition period over the next two years. In preparing that document the TAIC concluded that, due to translation and other needs, it would be more appropriate to set a deadline for all accredited laboratories to comply with ISO/IEC 17025 by 31 December 2002.

The TAIC document, entitled "Guidance for accreditation to ISO/IEC 17025" is currently under review for technical comment by ILAC members and members of the ILAC Laboratory Liaison Committee. It is expected to be distributed for voting in August 2000 for final approval at the ILAC General Assembly in Washington in November 2000.

The ILAC Laboratory Liaison Committee (LLC) which is a stakeholder group of laboratory representatives in the ILAC system, has also drafted a document entitled "Guidance for accreditation to ISO/IEC 17025 and what evidence to look for." Comment on this document is expected to be submitted to the LLC by 11 August 2000.

1.2 IECEE

Currently the IECEE scheme is working to ISO/IEC Guide 25 plus Operational Documents; the list of Current Decisions from the Committee on Testing Laboratories (CTL); and specifically to IEC Standards which constitute the essence of the technical competence and capability of laboratories operating within the CB Scheme.

IECEE has reviewed the differences between ISO/IEC Guide 25 and ISO/IEC 17025 and concluded that the substance has not changed but more details are given in ISO/IEC 17025 to clarify the relevant requirements. For its 1999 reassessment program, IECEE has been using ISO/IEC Guide 25 with ISO/IEC 17025 used as a reference guide to clarify any doubt.

The adoption of ISO/IEC 17025 is to be further considered by the IECEE's EVA-G (Evaluation Group) and CMC (Certification Management Committee) to determine when ISO/IEC 17025 should be implemented.

1.3 IECEx

Currently the IECEx scheme is working to ISO/IEC Guide 25 plus three specific Technical Guidance Documents for the IEC 60079 series (namely Ex'd', IEC 60079-0 and 60079-1; Ex'e', IEC 60079-7; Ex'i', IEC 60079-11).

There is not yet an IECEx stated policy on adoption and implementation of ISO/IEC 17025. This policy is to be considered at the next IECEx Management Committee meeting (4-8 September 2000).

1.4 IECQ

The current IECQ criteria for approval of an independent testing laboratory are detailed in clause 2.4 of IECQ QC001002-3, Third Edition (1998), *“Rules of Procedure of the IEC Quality Assessment System for Electronic Components (IECQ), Part 3: Approval Procedures”*.

The criteria for approval include:

- compliance with ISO/IEC Guide 25 or equivalent regional or national standards;
- additional interpretive requirements of ISO/IEC Guide 25 as defined in clause 2.4.2, *Technical Competence*, of the *Approvals Procedures*; and
- special requirements for subcontracting of calibration or testing by an approved laboratory.

For use of subcontracted laboratories clause 2.4.2 states that “... *Where possible the nominated testing laboratory shall be approved to ISO/IEC Guide 25 by a nationally recognised accreditation body.*”

Clause 2.4.3 deals with appraisal of independent testing laboratories and states that “... *In performing the appraisal, account shall be taken of any comparable approvals granted by a recognised international, regional or national accreditation (certification) body.*”

The IECQ's policy on future implementation of ISO/IEC 17025 was considered at the IECQ-ICC meeting on 22 May 2000 which endorsed the proposition that, in the first instance, it should be implemented by IECQ accredited Supervising Inspectorates by 2001-12. The decision on adoption and referencing in the relevant IECQ governing documents is likely to be taken in 2001.

IECQ publishes a *“List of Approved Testing Laboratories”* as QC 001005, *“IECQ Register of Approvals, Part 1, Section 3.”* It is available on the IECQ website, www.iecq.org and currently lists approved laboratories in France, Germany, India, Japan, the Russian Federation, Singapore, United Kingdom and USA.

Commentary

- a) In terms of consistency between ILAC and IEC/CAB, it would be desirable if IEC/CAB considered adoption of a common policy on implementation time-frames for ISO/IEC 17025.
- b) It would be desirable if ILAC member bodies had available copies of the IECEx Technical Guidance Documents for those laboratories that are covered by both the IECEx scheme and ILAC members' accreditations for the same scope. This could ensure that the ILAC assessments cover the specific needs of the IECEx scheme.
- c) The IEC schemes would benefit from supply of the ILAC accreditation bodies' assessment reports on IEC/CAB scheme-related scopes. These would need to be provided directly by the accredited bodies, due to the confidentiality responsibilities of the ILAC member bodies to their accredited facilities.
- d) The IECEx scheme would want on-site assessments by ILAC accreditation bodies to include evaluation of the laboratory's ability to deal with the interpretation elements of relevant standards for compliance purposes, including use of the IECEx Technical Guidance Documents.

2. Measurement Uncertainty

Below is summarised the currently known situations within ILAC and the IEC/CAB schemes, relevant to measurement uncertainty issues.

2.1 ILAC

The current ILAC position on measurement uncertainty is summarised in Decisions of the ILAC 1999 General Assembly.

The ILAC decisions essentially relate to two groups of laboratories. The first group is testing laboratories and the expectation for them is that they will comply with the measurement uncertainty requirements in Clause 5.4.6.2 of ISO/IEC 17025 within the two year transition period for adoption of this new Standard.

The second group of laboratories is those involved in calibration and measurement (and includes those testing laboratories that perform their own calibrations). For this group the ILAC 1999 General Assembly Decision number 3.7.6 applies to ILAC members that will be part of the imminent ILAC Multilateral Mutual Recognition Arrangement (expected to come into effect later in 2000). Decision 3.7.6 states:

ILAC Arrangement Signatories shall have and implement criteria for the determination of uncertainty of measurements in calibration by June 2000.

The signatories shall demonstrate that such documents are equivalent to the GUM Guide (ISO Guide to Uncertainty of Measurement). The document EAL-

R2 (now EA-4/02) "Expression of the Uncertainty of Measurements in Calibration" will be used as the measuring stick for such documents as a temporary measure pending the development of an ILAC document.

Many ILAC accreditation bodies have developed their own guidance documents for application of the GUM, and most have a series of worked examples to assist laboratories to estimate their own uncertainties.

2.2 IECEE

The IECEE CTL in 1994 published its "Guidance Document on Measurement Uncertainty". That Guide is a condensation of some of the ISO GUM and is consistent with it. The IECEE's Committee on Testing Laboratories (CTL) is currently reviewing its measurement uncertainty requirements and expects to propose a revised document by the end of 2000.

It is understood that CTL might also use another document which lists "accuracy" requirements for the various instruments used in various tests covered by the CB scheme.

The CTL Guidance document also includes a Clause 5 dealing with 'pass/fail' decisions on measurements whose uncertainties straddle a specification limit. This clause sets a general rule for such decisions when not covered specifically in a standard. In ILAC's case, it has published a separate document on this topic, ILAC-G8:1996 "Guidelines on Assessment and Reporting Compliance with Specification". That ILAC Guide gives a range of difference decision mechanisms that could be specified for compliance. It is currently under review within the ILAC Technical Accreditation Issues Accreditation Committee (TAIC).

2.3 IECEx

IECEx established a working group to deal with measurement uncertainty and it is due to report to the Ex Testing and Assessment Group (Ex TAG) by September 2000. It is considering the IECEE CTL document in that process.

2.4 IECQ

IECQ's requirements for measurement uncertainty are referred to in clause 2.4.2 and Annex C (normative) to clause 2 of QC 001002-3. It includes guidance from ISO 10012-1 and the Annex deals with IECQ policy on uncertainty of measurement and inset limits.

Commentary

- a) Both the IECEE and ILAC policies and procedures are consistent with the ISO GUM Guide, and both bodies have found it necessary to provide simplified guidance to their laboratories.

- b) IECCE (CTL), ILAC (TAIC) and IECEx (EXMC) have processes available to develop technical advice on measurement uncertainty for affected laboratories. It would be useful to distribute such advice between these respective groups on issues such as measurement uncertainty.
- c) There may be laboratory reporting requirements in the IEC/CAB schemes which may be different to some of the requirements of ISO/IEC 17025. It would be useful for the IEC schemes to compare their existing requirements for reporting with those specified in ISO/IEC 17025, Clauses 5.10.2 and 5.10.3. (Measurement uncertainty is one such issue).
- d) It would be desirable for ILAC member bodies to be aware of the specific reporting requirements and formats of the IEC/CAB schemes so that these could be taken into account in their on-site assessments of laboratories. This is consistent with the extra reporting requirements specified from special client groups as detailed in Clause 5.10.3.1(e) of ISO/IEC 17025.
- e) It would be desirable for ILAC member bodies to be aware of the requirements for compliance decisions, specified in Clause 5 of the IECCE/CTL (Sec) 956/94 guidance document.

3. Proficiency Testing

3.1 ILAC

The ILAC Mutual Recognition Arrangement has established policies on proficiency testing and its use in the accreditation process. ILAC has also published ILAC-G13:2000 "Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes".

Many ILAC members undertake their own proficiency testing programs, including measurement audits of calibration laboratories. Others outsource most of the proficiency testing to specialist bodies. Some use a combination of their own and external schemes.

To date, due to the nature of the testing and the limited numbers of electrical safety testing laboratories in individual economies, there has been very few proficiency testing activities undertaken in the areas of relevance to laboratories covered by the IEC/CAB schemes. Some international programs have been conducted, however.

3.2 IECCE

The CTL has been running "proficiency testing" for the past ten years but these were called "Round Robin Tests". Formal "proficiency testing" was initiated in 1999 and in the 1999-2000 periods covered temperature rise in

switches, ball pressure test and electric strength test. Additional programs were being considered at the CTL meeting held in May 2000.

Individual laboratories participating in the CB Scheme are required also to participate in national proficiency testing programs.

3.3 IECEEx

The IECEEx scheme has only been operational since 1999 and to date no proficiency testing has been undertaken. This issue is to be considered by the IECEEx TAG (Testing and Assessment Group).

3.4 IECQ

IECQ's Approval Procedures (QC 001002-3) do not currently refer to participation in proficiency testing by approved laboratories.

Commentary

- a) Due to the resources involved and limited opportunities for operation of proficiency testing schemes in this area, it would be desirable to have cooperative involvement between IEC/CAB and ILAC on proficiency testing.
- b) The outcomes from such PT's could be usefully shared, also, with the agreement of the affected laboratories, to resolve issues such as poor performance by individual laboratories and effectiveness of their corrective actions and difficulties in interpretations of specific standards, which are often identified as a result of a proficiency testing program.
- c) It could be useful to establish a formal liaison between IECEE (and other CAB schemes), and ILAC on the topic of proficiency testing to explore in more depth opportunities to collaborate in this area.

4. Calibration

The current situation regarding calibration issues, as known to date, is as follows:

4.1 ILAC

ILAC has published two documents on calibration and the related topic of traceability of measurements. These documents are ILAC-G5:1994, "Calibration and Maintenance of Test and Measuring Equipment" and ILAC-G2:1994, "Traceability of Measurements". Both documents are currently under revision within the ILAC Technical Accreditation Issues Committee, and it is likely that ILAC will adopt as its policy on traceability of measurement, a joint policy that has previously been developed by two regional Multilateral Mutual Recognition Arrangements (EA and APLAC).

Individual accreditation bodies within ILAC have established specified calibration procedures and recalibration intervals. Others have adopted a case-by-case approach to calibration periods and procedures applicable to individual laboratories.

4.2 IEC EE

The IEC EE has advised that existing reference standards on the topics of calibration and measurement traceability are sufficient and no further documents need development.

4.3 IEC Ex

The IEC Ex scheme has not to date specified any policy on the topic of calibration and traceability. This issue is to be addressed by IEC Ex Testing and Assessment Group (TAG).

4.4 IEC Q

IEC Q's policy on measurement traceability and calibration requires mandatory compliance with ISO 10012; Part 1. This policy is defined in clause 2.4.2 of IEC Q's Approval Procedures (QC 001002-3).

Commentary

- a) It would be desirable to publish the availability of networks of ILAC members' accredited calibration laboratories, to support the testing activities of laboratories involved in the IEC/CAB schemes. As it is a fundamental requirement for such accredited calibration laboratories to demonstrate traceability to national and international standards of measurement, this should add confidence to the calibration status and traceability of testing equipment used in the IEC/CAB scheme's laboratories.
- b) It would be desirable also for ILAC and the IEC/CAB schemes to have a common policy on acceptable sources of measurement traceability. The EA/APLAC policy could be considered by CAB to achieve such a common approach.