

David H Stanger Business Development

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RING-IISD PROJECT : STANDARDS FOR SUSTAINABLE TRADE

Background Paper: Emerging International Framework for Accreditation By David H Stanger, OBE.,I.Eng.,FIQA. – Partner – Al Hoty-Stanger Limited.

“ The underlying philosophy of any national conformity assessment infrastructure to attain international acceptance must unify not fragment, be efficient and cost effective, discourage multi-assessments, be all-inclusive not myopic and be demanding yet reasonable.” said the late Earl Hess.

Introduction

Laboratory accreditation was first practiced in 1947 to support the export markets from Australia. It was, however, an initiative of the Under Secretary of State from the US Department of Commerce and his counterpart in Denmark that launched the development of accreditation at the international level. They decided to hold a meeting in Copenhagen in 1977 to discuss concerns over documentation supporting food products being exported from Denmark to the US. As luck would have it they extended an informal invitation to other Governments and international bodies to attend the first International Laboratory Accreditation Conference (ILAC). To their surprise some 20 countries sent trade representatives along with organizations including the Commission of the European Union (EU), the International Standards Organization (ISO) and the International Union of Independent Laboratories (UILI). ILAC has met in plenary session on 20 occasions over the past 25 years. Accreditation of quality management systems (QMS) started in the early 1990's and the launch of the ISO 9000 series plus national quality awareness campaigns have dramatically increased the profile of the International Accreditation Forum, Inc (IAF). During this period, at both national and regional level, the majority of economies developing accreditation services have merged their accreditation of testing and certification activities into one organization. Within the 15 Member States of the EU thirteen have merged their accreditation of testing, calibration and certification services in to one organization. Germany and Belgium have a fragmented national accreditation infrastructure as Has Japan the United States.

At the regional level in recent years the European co-operation for Accreditation (EA), the Asia Pacific Laboratory Accreditation Cooperation (APLAC), Pacific Accreditation Cooperation (PAC) and InterAmerican Accreditation Cooperation (IAAC) have been formed as regional cooperation's with a place on the ILAC and/or IAF Executive Committee. A merger between ILAC and IAF is under consideration assisted by the creation in 1999 of a ILAC/IAF Joint Closer Cooperation Committee (JCCC) that meets twice a year.

In September 2002 a joint two-day ILAC/IAF conference held in Berlin, Germany attracted 508 delegates including 77 speakers from 75 countries. (*Refer to Note 1 for details*) This represents nearly 50 percent of countries, which had (in 1999) or have recently had a population of at least 1m or a GDP of at least \$1bn.

This background paper offers an overview of the emerging international accreditation architecture of mutual recognition of conformity assessment services; assessment of those services offered by national accreditation bodies; identify institutional and technical capabilities countries will need to participate in and take advantage from national, regional and international accreditation frameworks and consider examples of successful bi- and multi-lateral cooperation in the establishment of these accreditation arrangements.

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Summary

The author's experience provides additional information on accreditation developments given in Tom Rotherham's paper, "The Quality Institutions – an enabling framework for international trade", in which he concluded that perhaps the ILAC and IAF multi lateral arrangements have been the most important development in quality assurance harmonization in the last decade. Evidence supports his view and this paper leads to the conclusion that there needs to be a better correlation and understanding between parties responsible for elements of their national strategies for quality. In turn Governments, Accreditation Bodies, Standards Institutions, Certifiers, Laboratories, Consumers and other institutions that create mutual recognition agreements (MRA's) or multi lateral arrangements (MLA's) need to identify their interdependence to accelerate the architecture for conformity assessment services at the international level. These agreements, whether they are government to government MRAs or private sector MLA need to be harnessed within an international system which will result in the cross border testing and certification evidence included in a Suppliers Declaration of Conformity being provided in a more efficient, timely and cost effective manner.

From the conformity assessment and accreditation developments described in this paper, the following issues deserve serious consideration: -

- The precondition for a flourishing international conformity assessment service is mutual recognition between policy makers and the key players including Manufacturers, Standardisers and Consumers of their interdependence.
- To increase confidence in testing, certification and accreditation, an anchor of stability is required that can only be attained by close policy correlation.
- The new international accreditation infrastructures developed by ILAC and IAF have the potential to provide the Customer with elements of their Mutual Recognition Arrangement(s) delivered with international acceptance in mind,
- A new conformity assessment architecture should be developed to match more accurately the Regulator and Customer's needs, increase confidence in mutual recognition agreements and reduce redundant conformity assessments and associated costs, and
- The establishment of a union of international laboratory interests that promotes the views and concerns of any individual practice or association that provides a science based service to the public at large.

Institutions involved in Accreditation

Since the advent of laboratory accreditation in Australia forty years ago, the International Laboratory Accreditation Conference (ILAC) was created in 1977 as a conference, reorganised in 1996 as a co-operation and in September, 2002 the General Assembly endorsed a resolution to be incorporated under The Netherlands Law before the end of this year. ILAC has published a comprehensive set of policy and guidance documents compiled with international acceptance in mind. ILAC has adopted the international standard ISO/IEC 17025:1999 "General requirements for the competence of testing and calibration laboratories" against which their Members accredit all testing and calibration laboratories. ISO Guide 58, 61 and ISO/IEC TR 17010 are to be replaced with ISO/IEC 17011 being the criteria for accreditors operations. ILAC launched its Multi Lateral Agreement (MLA) in Washington, DC USA in September 2000 signed by 37 ILAC Signatories from 28 economies. There are now 42 ILAC Members from 30 economies around the world (*Refer to Note 2 for details*). Acceptance into the MLAs is by peer review against the current ISO Guides until the publication of ISO/IEC 17011 "General requirements for bodies providing assessment

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and accreditation of conformity assessment bodies”. Details on ILAC Members, documents and the MLA can be found on the website www.ilac.org.

The scope of individual accreditation bodies has expanded significantly over recent years to meet national market needs. However in developed countries as well as in developing countries there are still many occasions that accreditation bodies are unable to meet demands for many reasons. In these circumstances an accreditation body in a foreign country provides accreditation services. To identify the principles for avoiding duplication the APC published a Code of good practice for Cross Frontier Accreditation (*attached to this paper as Annex 'B'*). This code of good practice also provides opportunities for accreditation services in economies or regions without a mature accreditation system, an adequate national measurement infrastructure or a lack of certified reference materials to gain experience and avoid accreditation becoming a technical barrier to trade.

The International Accreditation Forum (IAF) was formed in the early 1990's. Its current structure, Members and MLA are similar to the policies practiced by ILAC (*Refer to Note 3 for details*). IAF accredits quality systems, product and personnel certification against the ISO 9000: 2000 series of standards. The IAF MLA was launched in Guangzhou, China in January 1998 and currently has 41 Signatories in 33 economies. Full details on IAF can be found on website www.iaf.nu

The ILAC Arrangement and the IAF Mutual Recognition Arrangement provides significant technical underpinning to international trade. The key to the arrangements is the developing global network of accredited conformity assessment organisations that are assessed and recognised as being competent by the signatories' accreditation bodies. The signatories have, in turn, been peer reviewed and shown to meet ILAC or IAF criteria for competence. Now that the arrangements are in place, governments can take advantage of them to further develop and enhance trade agreements. The ultimate aim is increased use and acceptance by industry as well as government of the results from accredited bodies, including test reports and or certificates from accredited bodies in other countries. In this way, the free trade goal of “Once Tested, Once Certified and Accepted Everywhere” can be realised.

There is an increasing level of collaboration between ILAC and IAF, which is facilitated by the ILAC/IAF Joint Committee for Closer Collaboration (JCCC) that was created in Rio de Janeiro, Brazil in October 1999. The IAF/ILAC JWG on Inspection is one example of the JCCC acting as the steward on work items of common interest. Of equal importance and urgency has been the publication of a document to explain to the market place the differences between accreditation and certification. The JCCC developed a comprehensive paper *Refer to Note 4 for details*). The JCCC paper was used to formulate a two-page information document issued by the IAF-ILAC-ISO/CASCO JWG. The full text of this version that is attached as Annex 'A' as it represents the ILAC/IAF consensus reached after some eighteen months work.

In addition to the ILAC and IAF MLAs there have been established numerous bi-lateral and multi-lateral MOUs between individual national accreditation bodies and emerging accreditation bodies in least developed and developing countries. The EA, with EU Commission support through the Technical assistance for Central & Eastern European countries (PHARE) and the Regional Programme for Quality Assurance (PRAQ) programmes, provides experts for inward missions to those 10 countries engaged in the EU enlargement. At the bi-lateral level Comite Francais d'Accreditation COFRAC, American Association for Laboratory Accreditation (A2LA), National Association of Testing Authorities (NATA) are but examples of the many accreditation bodies that have bi-lateral auditor training and technology transfer agreements with emerging accreditation bodies in developing countries. ILAC, on a case-by-case basis, has funded travel costs for representatives from developing countries to attend ILAC General Assembly and Conferences over recent years.

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To illustrate the increase in ILAC and IAF Membership the following status reports on new members over the past 12 months by economy were elected in September, 2002: ILAC Full Members - Austria, Chile, Croatia, Portugal & Slovenia – Associate Members - Canada, Ecuador, Kyrgyz Republic, Morocco, USA x 2 and Uzbekistan. IAF – Full Members – Chinese Taipei – India and Philippines. These announcements strengthen the membership in both organisations; through associate membership that provides encouragement to the emerging national accreditation bodies and as signatories to one or both MLA's increase acceptance of conformity assessment services that supports national and cross border trade. (*Refer to Notes 2 & 3 for more details*)

The ILAC Members located in all corners of the world are encouraged to form regional groups that comply with and are signatories to the international ILAC MLA. Such regional groups exist in Europe (EA) the Far East (APLAC and PAC), Southern Africa (SADCA) and The Americas (IAAC). With United Nations Industrial Development Organisation (UNIDO) funding, assistance is being given to develop other groups and a number of national accreditation bodies. ILAC's Accreditation Policy Committee (APC) WG 3 coordinates liaisons with UNIDO, Industry Cooperation on Standards & Conformity Assessment (ICSICA), International Bureau of Weights & Measures (BIPM), EA, European Federation of National Associations of Measurement, Testing and Analytical Laboratories (EUROLAB), Focus for European Analytical Laboratories (EURACHEM) and the Agreement for collaboration between European metrological institutes (EUROMET) and a Task Force to harmonise accreditation project at the regional level.

In addition to the many organisations mentioned above that have on-going collaborative arrangements with ILAC and or IAF, the World Trade Organisation (WTO) Agreement on Technical Barriers to Trade (TBT) and other key players that need to be mentioned.

Article 6, para 6.3 of the WTO/TBT Agreement encourages Members “to enter into negotiations of results of each other's conformity assessment procedures” and para 6.1.1. requires the parties to a Mutual Recognition Agreement (MRA) to be mutually satisfied regarding technical competence and verified compliance, “for instance through accreditation with relevant guides or recommendations issued by international standardizing bodies.” One such Agreement on Mutual Recognition between the European Community and the United States of America was signed at the EU-US Summit on 18th May 1998. The EU has signed other MRA's with other economies including Canada, Japan, Australia and New Zealand. The acronym MRA has over recent years become the preserve of government to government agreements and their added value to cross border trade in regulated products and services has yet to be seen. This negative situation is not the case with such arrangements as the ILAC and IAF MLA's that are more flexible, market driven and relevant for products and services offered equally to products and services destined for the regulated and non-regulated sectors of national and international commerce.

The work of the International Standards Organisation (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU) are three of some 50 international standards bodies recognised by the WTO. Through protocols signed between ISO and IEC, many, some might say too many, of the existing standards and programmes for new or revised standards being processed by ISO demand significant resources from all accreditation bodies and their stakeholders.

ISO Council Committee on Conformity Assessment (CASCO) is ISO's policy development committee on conformity assessment. In addition to their mandate to process their mission CASCO also coordinates their work programmes with the IEC Conformity Assessment Board (IEC/CAB). The current conformity assessment standards and Guides used extensively throughout the world are listed in Box 1 of Tom Rotherham's paper and in accordance with the ISO Directives are subject to consideration for review every five years. ILAC/APC WG 7 is dedicated to the liaison with standards activities that impact on the

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conformity assessment and accreditation services. In September 2002 thirteen specific work items from the CASCO Work Programme were assigned Category 1 status requiring a representative to attend all meetings. A further six work items were assigned Category B status requiring a representative to monitor all documentation and keep ILAC membership informed. [Note: The author of this background paper is the Secretary General of the International Union of Independent Laboratories (UIIL). UIIL was awarded 'A' Liaison Status with CASCO in 2000 and the author is rapporteur to CASCO. ILAC and IAF also have Liaison 'A' status with ISO/CASCO.

The ISO publication ISO/TR 14062 "Environmental management – integrating environmental aspects into product design and development" consists of six stages: planning, conceptual design, detailed design, testing/prototype, and market launch and product review. This important technical report is not intended as a specification for certification purposes but reflects increasing discussions among business, consumers, governments, NGO's concerning sustainable development. IEC/CAB (Conformity Assessment Board). Since 1999 the APC and the ILAC Laboratory Committee (LC) have maintained a formal liaison status with this international electro technical standards body.

The WTO TBT Committee has established a dialogue with ILAC and IAF since 1996. ILAC and IAF have both provided speakers for all TBT Workshops on Conformity Assessment and Accreditation. This liaison is further strengthened by those heads of national accreditation bodies that are also members of their national committees to the WTO/TBT Committee.

Accreditation remains a voluntary service. It is to be noted that an increasing number of regulators responsible for trade policy at national, regional and international level, invoke the use of accreditation as a means for parties to demonstrate in whole or in part their compliance with trade or safety regulations.

Attachments

- Notes**
- (1) National delegates to ILAC/IAF Conference. Sept, 2002. Berlin. Germany
 - (2) ILAC Membership Lists (including signatories to the ILAC MLA.
 - (3) IAF Membership Lists (including signatories to the IAF MLA
 - (4) Draft 2 IAF/ILAC Information Paper – Accreditation and Certification of Laboratories – The roles of ISO/IEC 17025 and ISO 9001 (13 pages).
- Annex 'A'** Objectives and Roles of "Accreditation" and "Certification" of Laboratories.
Annex "B" Cross-Frontier Accreditation – Principles for avoiding duplication.

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SCHEDULE OF NOTES

NO:

(1) COUNTRIES REPRESENTED AT ILAC/IAF CONFERENCE, BERLIN, GERMANY – SEPTEMBER, 2002

Argentina, Armenia, Australia, Austria, Belgium, Botswana, Brazil, Canada, Chile, China, Columbia, Costa Rica, Croatia, Czech Republic, Denmark, Ecuador, Egypt, El Salvador, Finland, France, Georgia, Germany, Greece, Honduras, Hong Kong, Hungary, India, Indonesia, Iran, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mexico, Moldova, The Netherlands, New Zealand, Norway, Panama, Paraguay, Peru, Philippines, Poland, Portugal, Romania, Russia, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Tanzania, Thailand, Tunisia, Turkey, United Kingdom, United States, Uruguay, Venezuela and Vietnam.

(2) ILAC – FULL MEMBERS [Note (*) denotes signatory of ILAC MLA]

North, Central and South America – Argentina: Organismo Argentino de Acreditacion (OAA); Brazil CGCRE (*); Canada Standards Council of Canada (SCC)(*); Mexico – Mexican Accreditation Entity (EMA); USA- American Association for Laboratory Accreditation (A2LA)(*); Assured Calibration & Laboratory Accreditation Select Services ACLASS (*); ICBO Evaluation Services (ICBO)(*); National Voluntary Laboratory Accreditation Program (NVLAP)(*); **Europe, Middle East** – Belgium - Beltest OBE/BKO (*); Czech Republic – Czech Accreditation Institute (CAI)(*); Denmark – Danish Accreditation (DANAK)(*); Egypt – National Laboratories Accreditation Bureau (NLAB); Finland – Finnish Accreditation Service (FINAS)(*); France – Comite Francais d’Accreditation COFRAC(*); Germany - Deutsche Akkreditierungsstelle Chemie GmbH (DACH)(*); Deutsches Akkreditierungssystem Prufwesen (DAP)(*); Deutscher Akkreditierungsrat (DAR); DASET; Duursche Akkreditierungsstelle Mineralol (DASMIN)(*); Deutsche Akkreditierungsstelle Technik (DATech)(*); Deutscher Kalibrierdienst (DKD)(*); Greece – Hellenic Accreditation Council (ESYD); Hungary – Hungarian Accreditation Board (NAT); Ireland – National Accreditation Board (NAB)(*); Israel – Israel Laboratory Accreditation Authority (ISRAC)(*); Italy – Sistema Nazionale Per L’Accreditamento Di Laboratori (SINAL)(*); (SIT); - The Netherlands – Raad vor Accreditatie (RvA)(*); Norway - Norwegian Accreditation (NA)(*); - Poland – Polish Centre for Accreditation (PCA); Portugal – Instituto Portugues da Qualidade (IPQ)(*); Romania (RENAR); Slovakia – Slovak National Accreditation Service (SNAS)(*); Spain – Entidad Nacional de Acreditacion (ENAC)(*); Sweden – Swedish Board for Accreditation & Conformity Assessment (SWEDAC)(*); Switzerland – Schweizerische Akkreditierungsstelle (SAS)(*); United Kingdom – United Kingdom Accreditation Service (UKAS)(*); **Asia, Pacific, India, Africa** - Australia – National Association of Testing Authorities (NATA)(*); China Hong Kong – Hong Kong Accreditation Service (HKAS)(*); People’s Republic of China – (CCIBLAC)(*); (CNAACL)(*); Chinese National Laboratory Accreditation (CNLA)(*); India – National Accreditation Board for Testing and Calibration Laboratories (NABL)(*); Indonesia – Badan Standardisasi Nasional (BSN)(*); Japan – Japan Accreditation Board for Conformity & Assessment (JAB)(*); Japanese Calibration Service & Systems (JCSS)(*); Japan National Laboratory Accreditation (JNLA)(*); Republic of Korea – Korean Laboratory Accreditation Scheme (KOLAS)(*); Malaysia – Department of Standards Malaysia (DSM); New Zealand – International Accreditation New Zealand (IANZ)(*); Philippines – Bureau of Products Standards Laboratory Accreditation Scheme (BPSLAS); Singapore – Singapore Accreditation Council (SAC)(*); South Africa - South African National Accreditation System (SANAS)(*); Thailand – Thai Industrial Standards Institute (TISI)(*); Tunisia (CAN); Vietnam – Vietnam Laboratory Accreditation Scheme (VILAS)(*);

ILAC – ASSOCIATE MEMBERS

North, Central and South America – Canada – Quality Management Program Laboratory Services (QMP-LS) Cuba (ONARC); Ecuador - Ecuadorian Accreditation Body (EAB); El Salvador – National Council of Science and Technology (NCST); Trinidad & Tobago (TTBS); United States of America – International Accreditation Registry (IAR); (NFSTC); **Europe & Middle East** - Albania – General Directorate of Standardization (DPS); Armenia – (SARM); Cyprus – (CYS); Jordan (JISM); Kazakhstan – National Centre for Accreditation of Kazakhstan ((NCAK); Kyrgyzstan – State Inspection for Standardization and Metrology of the Government of Kazakhstan (NCAK); Republic of Moldova – Department of Technical Supervision, Standardization and Metrology of the Republic of Moldova; Morocco – Ministry of Industry, Trade, Energy & Mines (MCI); Uzbekistan – State Centre for Metrology and Certification (Uzgosstandard). **Asia, Pacific, India & Africa** - Mauritius – Mauritius Accreditation Service;

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STAKEHOLDER MEMBERS

Association of Official Agricultural Chemists (AOAC); American Council of Independent Laboratories (ACIL); Canadian Association for Environmental and Analytical Laboratories (CAEAL); National Cooperation for Laboratory Accreditation (NACLA); National Conference of Standards Laboratories (NCSL International); Union internationale des Laboratoires Independents (UILI); Croatian Metrology Society (HMD); Nordtest Tekniikantie (NORDTEST); European Federation of National Associations of Measurement, Testing & Analytical Laboratories (EUROLAB); EURACHEM; Association of European Assay Offices (AEAO); International Seed Testing Association (ISTA); Hong Kong Association of Certification Laboratories (HKACL); Cooperation on International Traceability in Analytical Chemistry (CITAC); Japan Laboratory Association (JLA); NATA Laboratory Association (NATA); National Laboratory Association of South Africa (NLA);

IAF ACCREDITATION BODY MEMBERS [Note (*) denotes signatory for IAF MLA for quality management systems]

Argentina – Organismo Argentino de Acreditacion (OAA) – Australia – Joint Accreditation System of Australia and New Zealand (JAS-ANZ)(*) – Austria - Federal Ministry for Economic Affairs & Labor (BMWA); Belgium – (BELCERT)(*); Brazil – National Institute of Metrology, Standardization and Industry Quality (INMETRO)(*); Canada – Standards Council of Canada (SCC)(*); China – China National Accreditation Board for Certifiers (CNAB)(*); Czech Republic – Czech Accreditation Institute (CIA)(*); Denmark – Danish Accreditation (DANAK)(*); Korean Republic – National Accreditation Association (NAA); Finland – Finnish Accreditation Service (FINIS)(*); France – Comite Francais d’Accreditation (COFRAC)(*); Germany – German Accreditation Council (DAR)(*); Hong Kong China – Hong Kong Accreditation Service (HKAS); India – National Accreditation Board for Certification Bodies (NABCB); Indonesia – Komite Akreditasi Nasional (KAN)(*); Ireland – Irish National Accreditation Board (NAB)(*); Italy – Sistema Nazionale per l’Accreditamento degli Organismi Certificazione (SINCERT)(*); Japan – Japan Accreditation Board for Conformity Assessment (JAB)(*); Japan Accreditation System for Product Certification Board (JASC); Malaysia – Department of Standards Malaysia (DSM)(*); Mauritius – Mauritius Accreditation Service (MAURITIS); Mexico – Mexican Accreditation Entity (EMA)(*); The Netherlands – Dutch Accreditation Council (RvA)(*); Norway – Norwegian Accreditation (NA)(*); Philippines – Bureau of Product Standards (BPS); Poland – Polish Centre for Accreditation (PCA); Korean Republic – Korean Accreditation System (KAS); Korean Accreditation Board (KAB)(*); Singapore – Singapore Accreditation Council (SAC)(*); Slovenia – Slovak National Accreditation Service (SNAS); Slovenia – Slovenska Akreditacija (SA); South Africa – South African National Accreditation System (SANAS); Spain – Entidad Nacional de Acreditacion (ENAC)(*); Sweden – Swedish Board for Accreditation and Conformity Assessment (SWEDAC)(*); Switzerland – Swiss Federal Office of Metrology and Accreditation Service (SAS)(*); Chinese Taipei – China National Accreditation Board (CNAB); Thailand – National Accreditation Board (NAC)(*); Tunisia – Tunisian Accreditation Council (TUNAC); United Kingdom – United Kingdom Accreditation Service (UKAS)(*); United States of America – American National Standards Institute/ Registrar Accreditation Board/National Accreditation Program (ANSI-RAB-NAP)(*);

IAF ASSOCIATION MEMBERS

European Federation of Associations of Certification Bodies (EFACB); Canadian Electricity Association (CEA); Bundesverband der Deutschen Industrie e.V (BDI); Agricultural and Processed Food Products Export Development Authority (APEDA); Association of the Italian Independent Certification and Inspection (AIOICI); Italian Association of Independent Test Laboratories and Certification Organisations (ALPI); Japan Association of Certification Bodies (JACB); Association of British Certification Bodies Ltd (ABCB); Independent Association of Accredited Registrars (IAAR); American Electronics Association (AEA); Information Technology Industry Council (ITIC); International Certification Network Association (IQNet); The Food Business Forum (CIES); Independent International Organization for Certification (IIOC);

IAF SPECIAL RECOGNITION REGIONAL GROUPS

Interamerican Accreditation Cooperation (IAAC); Southern African Development Community in Accreditation (SADCA); European Cooperation for Accreditation (EA)(*); Pacific Accreditation Cooperation (PAC)(*);

IAF SPECIAL RECOGNITION INTEREST LIAISON GROUP

International Organisation for Standardization (ISO); The QuEST Forum, Inc.

(4) ILAC/IAF INFORMATION PAPER :

Accreditation and Certification of Laboratories – The Roles of ISO 17025 and ISO 9001. This draft paper has been developed as a task for the ILAC/IAF Joint Committee for Closer Cooperation (JCCC). This paper describes in detail the issues raised in the paper IAF-ILAC-ISO/CASCO Joint Working Group on Image and Integrity of Conformity Assessment included as Annex ‘A’ to this background paper. Application for copies should be made to the ILAC or IAF Secretariats using their contact details provided on their respective websites.

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ANNEX 'A'

IAF-ILAC-ISO/CASCO JOINT WORKING GROUP ON IMAGE AND INTEGRITY OF CONFORMITY ASSESSMENT

OBJECTIVES AND ROLES OF “ACCREDITATION” AND “CERTIFICATION” OF LABORATORIES

1 Background

For laboratories and users of laboratory services, occasionally there is misunderstanding and confusion about the objectives and functions of “accreditation” based on ISO/IEC 17025:1999 *General requirements for competence of testing and calibration laboratories*, and “certification” of laboratories based on ISO 9001:2000, *Quality management systems – Requirements*.

This communiqué was prepared by the IAF-ILAC-ISO/CASCO Joint Working Group on Image and Integrity of Conformity Assessment to clarify the key distinctions between the two different types of recognition of laboratories by either accreditation bodies or certification bodies.

It is important to note that there are differences in both the emphasis of the standards (ISO/IEC 17025 and ISO 9001) and in the processes used to determine compliance with them.

2 What do the Standards Specify?

ISO/IEC 17025 was developed as a special purpose standard for laboratories to specify the general requirements for their *technical competence*. While the Standard is generic it also recognises that for accreditation purposes (i.e. for independent recognition of a laboratory’s competence to perform specific tests, or calibrations) the Standard may require development of guidelines to explain its use in specific areas of testing or measurement.

ISO/IEC 17025:1999 has two major components, namely *management requirements* and *technical requirements*. The *management requirements* are written in 1 language relevant to laboratory operations but were developed to meet the systems requirements of ISO 9001:1994 and ISO 9002:1994¹.

¹ ISO/CASCO is currently reviewing ISO/IEC 17025 *management requirements* for possible alignment with ISO 9001:2000.

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For accreditation against ISO/IEC 17025 the *emphasis* is to establish the *technical competence* of a laboratory for a *defined set of tests, measurements or calibrations*. In doing so, however, compliance with the Standard's management requirements is also assessed. However, accreditation against ISO/IEC 17025 should not be interpreted to be the same as certification against ISO 9001.

ISO 9001:2000 is a generic standard for quality management systems applicable to all organizations irrespective of type, size or product or service provided. Therefore, it is also applicable to laboratories, even though its language is generic. Its purpose is to specify a quality management system that will allow an organisation to demonstrate its ability to provide product that meets customer and applicable regulatory requirements. It also aims to enhance customer satisfaction, including processes for continual improvements and assurance of conformity.

In applying ISO 9001:2000 to a laboratory's operations, the emphasis for certification bodies is to establish compliance with *quality management systems* requirements. Unlike ISO/IEC 17025, it does not contain technical requirements for laboratory personnel and operations and, as such, certification against ISO 9001:2000 should not be interpreted to mean that it demonstrates the technical competence of a laboratory to produce valid data and results.

3 What are the Differences between the Processes used for Laboratory Accreditation and Certification?

Apart from the different emphasis of the two Standards, there are some fundamental differences in the processes used by accreditation bodies and certification bodies to establish compliance with ISO/IEC 17025:1999 and ISO 9001:2000 respectively.

Because laboratory accreditation aims to recognise *specific technical competence*, the assessments of laboratories are conducted by teams comprising relevant technical experts and assessors able to evaluate compliance with the management systems requirements of ISO/IEC 17025. While the management system requirements are an important component of a laboratory's assessment for accreditation, the major *emphasis* is on determining the *specific technical competence* of personnel and the availability of all the technical resources needed to produce reliable data and results for specific test methods. Often the accreditation process will also use objective data from proficiency testing programs to assist accreditation decisions. (Proficiency testing programs are described in detail in ISO/IEC Guide 43: Parts 1 and 2:1997).

For certification of a laboratory against ISO 9001:2000, the assessment team will consist of auditors with detailed experience in assessment of quality management systems. They may have the technical expertise (or be supported by technical experts) to enable them to apply the generic requirements of the Standard to the operations of laboratory services, but the *emphasis* is on determining compliance with the *quality management system requirements*.

4 Accreditation or Certification of a Laboratory or Both?

Some laboratories are not stand-alone facilities. They may form part of a larger organisation, which may have a need to be certified against ISO 9001:2000, while the laboratory's testing or calibration functions may also need to be accredited against ISO/IEC 17025

The decision to seek accreditation or certification of a laboratory (or both) will depend on the overall needs of each laboratory and the expectations of its customers, regulators or other interested parties for their reassurance about the

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specific technical competence of a laboratory or about its compliance with quality management systems only.

ANNEX 'B'

CROSS-FRONTIER ACCREDITATION

PRINCIPLES FOR AVOIDING DUPLICATION

ILAC is the international forum for laboratory accreditation bodies. The ILAC Mutual Recognition Arrangement is designed to ensure that test reports and calibration certificates issued by accredited laboratories under their defined scopes of accreditation will be accepted worldwide.

For this to be achieved, the accreditation bodies operate as a network, each providing an equivalent accreditation service. This is assured by the ILAC peer evaluation.

The signatories to the ILAC Arrangement normally operate from a national base, providing laboratory accreditation for their home market. The effect of the Arrangement, based on the ILAC peer evaluation, is that the accredited laboratories should receive recognition from the whole global market for the test reports and calibration certificates that they issue under their scopes of accreditation.

Accreditation bodies may have published policies limiting the scope of the accreditation service they offer, which may include geographic limitations. In which case, so long as they are consistent in the application of these policies and have not been successfully challenged, they may decline to accept applications from outside their defined customer base.

There are however situations where laboratories will seek more than one accreditation, or a “foreign” accreditation, and it is their right to do so. Only when all countries or economies have accreditation bodies that are members of the ILAC Arrangement and when the user market has fully recognised and accepted the mutual recognition behind the Arrangement will this cease to be required. ILAC’s objective is to offer this to the market so that duplicate accreditations will no longer be necessary.

Reasons why a laboratory may seek accreditation from bodies outside its own country include:

- The local accreditation body/bodies do(es) not offer the required scope
- The local accreditation body/bodies is/are not a signatory/signatories to the Arrangement
- There is no local accreditation body

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- Its clients demand a specific accreditation and will not be persuaded to accept an equivalent
- It is part of a chain of laboratories with a single owner who wants all the laboratories to have the same accreditation and who is not willing to work with the ILAC Arrangement partners.

In these and similar circumstances, an ILAC Arrangement signatory, if asked to provide accreditation to a laboratory outside its country or economy, may respond positively (but see 4th paragraph above). However it should take the following steps before accepting the contract:

If there is an ILAC Arrangement signatory/signatories covering the scope of the required accreditation in the country or economy of the applicant, it should

- enquire whether the applicant is aware of the local accreditation body/bodies,
- suggest that the accreditation could be more economically performed by a local body,
- point out the equivalence of the local accreditation demonstrated through the ILAC Arrangement.

Only if the applicant still persists in requiring its accreditation should it proceed, in which case it should request the applicant to be allowed to inform the local accreditation body/bodies that it will be undertaking the work, to explain the circumstances, and to invite any relevant local accreditation body to be an observer at the assessment. It may also suggest that a joint accreditation be offered by it and a local accreditation body.

If there is an ILAC member accreditation body/bodies in the country or economy of the applicant that is not an ILAC signatory for the scope, it should enquire whether the applicant would be prepared to have any relevant local accreditation body informed of the application with the option of

- observing the assessment for experience
- providing a team member or members to the accreditation body's assessment team, or
- performing a joint assessment with the objective of dual accreditation.

In all these cases, the objective of eventual handover of the accreditation to the relevant local accreditation body should be borne in mind, either when that body joins the ILAC Arrangement for the scope, or when the applicant laboratory may choose. This approach will serve to strengthen the international network of laboratory accreditation bodies provided through ILAC.

This in turn will assist the WTO/TBT objective of facilitating international trade by removing technical barriers to trade through mutual recognition between the nationally based conformity assessment systems

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Amended 29 October 2001 - ILAC 11th APC meeting

ILAC Decision GA 5.19 General Assembly, Kyoto, Japan – 2nd November, 2001