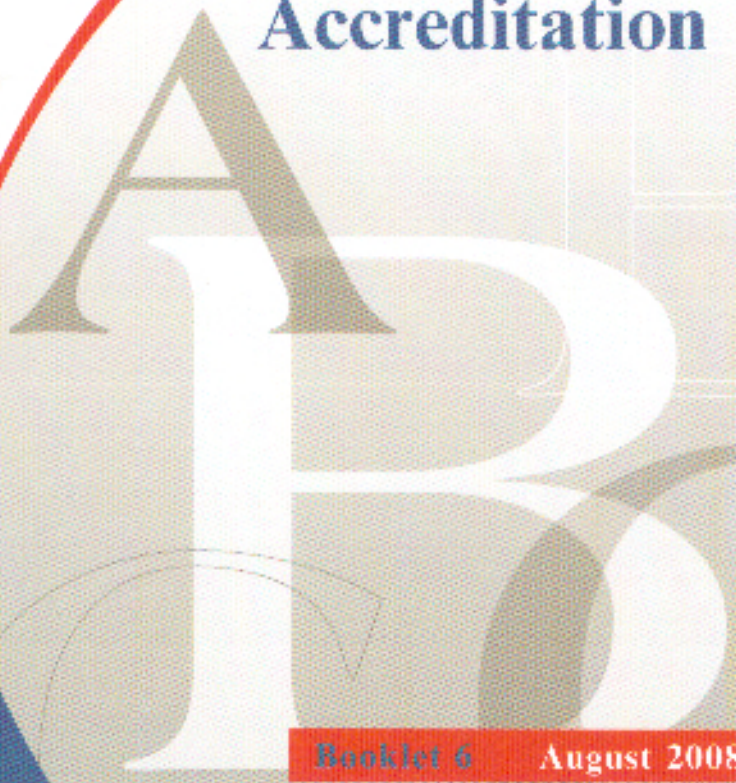
QUALEB
QUALITY PROGRAMME

QUALITY Guide

An ABC Guide on

Accreditation



Booklet 6 August 2008

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QUALITYGuide

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An ABC Guide on ACCREDITATION

This is the sixth in a series of booklets produced by the Quality Programme, as a guide to understanding the role and importance of relevant issues, on Accreditation

Produced in the framework of the MEDA Project:
Strengthening Quality Management, Capabilities and Infrastructure in Lebanon - QUALEB, the Quality Programme, hosted at the **Ministry of Economy & Trade** - Europe Aid/17725/D/SV/LB

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Dear Reader,

This guide is one of a series published by the Quality Programme, funded by the European Union, which supports Lebanese Companies to increase the exports of their goods and services to foreign markets. It also aims at increasing the level of quality and safety of products distributed in the Lebanese market, in order to better protect the health of Lebanese consumers.

The Quality Programme is in the process of supporting the creation and development of institutions that will assist the business sector to comply with international standards and requirements for product manufacturing and distribution. Therefore, building a Quality Infrastructure in Lebanon is imperative.

Such infrastructure consists of testing and calibration laboratories, inspection and certification bodies, standardisation and accreditation institutes along with governmental organisations that are responsible for product verification, certification and other activities.

It is a fact that some issues related to the Quality Infrastructure might be confusing. Therefore, these guides are intended to explain the different aspects. They are not reference books, but simply introductory information channels for different quality related topics.

Nevertheless, the guides provide solid references to documents and websites that contain more elaborate, detailed and specific information.

The major objective is to provide useful and accessible updates to everyone. Suggestions are highly appreciated and accepted through the contact details of the Quality Programme.

We hope that you will benefit from this ABC Guide which is produced to assist you in better understanding related quality issues.

Ali Berro, PhD
Director, Quality Programme

TABLE OF CONTENTS

AN ABC GUIDE ON ACCREDITATION

1 - LIST OF ABBREVIATIONS

1.1 LIST OF ABBREVIATIONS USED IN THE TEXT OF THIS GUIDE

AB/ABs	Accreditation Body/Accreditation Bodies
CAB/CABs	Conformity Assessment Body/Conformity Assessment Bodies
EMAS	Eco-Management and Audit Scheme
EMS	Environmental Management System
MRA/MRAs	Mutual Recognition Arrangement (s)
MLA/MLAs	Multilateral Recognition Agreement (s)
MOU	Memorandum of Understanding
MRA	Mutual Recognition Arrangement(s)
PT	Profeciency Testing
RCB/RCBs	Regional Co-operation Body in the field of accreditation

1.2 List of the abbreviations of relevant organisations and bodies engaged in Accreditation

AALA	American Association for Laboratory Accreditation
APLAC	Asia Pacific Laboratory Accreditation Co-operation
BIPM	Bureau International des Poids et Mesures (International Bureau For Weights and Measures)
CAC-MAS-Q	Central Asian Co-operation on Metrology, Accreditation, Standardisation
CASCO	Committee on Conformity Assessment
CIPM	Comité International des Poids et Mesures (International Committee for Weights and Measures)
CITAC	Co-operation on International Traceability in Analytical Chemistry
DAR	Deutscher Akkreditierungsrat (German Accreditation Council)
EA	European co-operation for Accreditation

EURACHEM	European co-operation in the field of chemical analyses and reference materials
EURAMET e.V.	European Collaboration in Measurement Standards
IAAC	Interamerican Accreditation Co-operation
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Co-operation
IRMM	Institute for Reference Materials and Measurements of the European Commission Directorate
ISO	International Organisation for Standardisation
NVLAP	National Voluntary Laboratory Accreditation Programme
OIML	Organisation Internationale de Metrologie Legace (International Organisation for Legal Metrology)
PAC	Pacific Accreditation Co-operation
SADCA	Southern African Development Community in Accreditation
SIM	Inter-american Metrology System
UILI	Union Internationale des Laboratoires Independants (International Union of Independent Laboratories)
UNIDO	United Nations Industrial Development Organisation
WTO	World Trade Organisation

2 - REFERENCES TO TERMINOLOGY

References to the relevant terminology standards and standard documents

- ISO/IEC 17000:2004, Conformity assessment - Vocabulary and general principles
- ISO 9000:2005, Quality management systems - Fundamentals and vocabulary
- ISO/IEC Guide 2:2004, Standardisation and related activities - General vocabulary
- ISO 10012:1993, Measurement management systems - Requirements for measurement processes and measuring equipment
- International vocabulary of basic and general terms in metrology (VIM), Issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML, Third edition
- ISO Guide 30:1992, Terms and definitions used in connection with reference materials
- Guide to the Expression of Uncertainty in Measurement (GUM), issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML, 1995
- ISO 5725-1:1994, Accuracy (trueness and precision) of measurement methods and results - Part 1: General principles and definitions plus ISO 5725-1:1994/Cor 1:1998
- ISO/TS 21748:2004, Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation

- VIML:2000 – International Vocabulary of Terms in Legal Metrology, issued by OIML
- ISO 3534-1:2006, Statistics - Vocabulary and symbols - Part 1: General statistical terms and terms used in probability
- ISO 3534-2:2006, Statistics - Vocabulary and symbols - Part 2: Applied statistics
- ISO 3534-3:1999, Statistics - Vocabulary and symbols - Part 3: Design of experiments (NB a new standard is under development)
- ISO 15189:2007, Medical laboratories - Particular requirements for quality and competence
- ISO/IEC Guide 43-1:1997, Proficiency testing by interlaboratory comparisons - Part 1: Development and operation of proficiency testing schemes (two new ISO/IEC standard documents are under development)
- ISO 13528:2005, Statistical methods for use in proficiency testing by interlaboratory comparisons

3 - PART 1: WHAT IS ACCREDITATION ?

Definition of Accreditation

Accreditation is a third-party attestation, related to a conformity assessment body (CAB) conveying a formal demonstration of its competence, to carry out specific conformity assessment tasks (definition 5.6 from ISO/IEC 17000).

Accreditation involves regular management system assessment and technical competence assessment of a body or a person, including a relevant number of performed witness audits. Accreditation is designed to be a transparent process in which all interested parties should be aware of precisely described rules, underlying the accreditation system.

3.1 Short history of Accreditation

More then thirty years ago, different technical issues caused significant problems for importers and exporters. This situation together with other technical barriers concerning free movement of goods led to the extension of repeated testing, certification and inspection of the same types of products in different countries. An idea evolved for having only one testing and/or one certification or inspection of products (so called one-way testing and/or certification or inspection) based on mutually recognised testing and/or certification or inspection procedures performed by mutually recognised and technically competent bodies. This led to the creation of the first pre-accreditation bodies, ensuring assessment of the above mentioned technical competence of the relevant testing laboratories, certification and inspection bodies.

Formation of the first pre-accreditation bodies started in the field of calibration and testing laboratories and culminated in the creation of ILAC

(at that time, this abbreviation meant International Laboratory Conference) - the first worldwide organisation for co-operation in the field of accreditation. Creation of the first national accreditation bodies, ILAC formation and formation of the first regional co-operation bodies in the field of accreditation (RCBs), moved significantly towards changing the whole situation.

Example: In Europe, the co-operation of pre-accreditation bodies started in WEMC (Western European Metrology Club) in 1973 and continued in WECC (Western European Calibration Co-operation) founded in 1975. WELAC (Western European Laboratory Accreditation) was founded in 1987 and organised in co-operation with European accreditation bodies, engaged in the field of testing laboratory accreditation. EAC (European Accreditation of Certification) was founded in 1991 and was engaged in co-operation with European accreditation bodies, performing accreditation of certification and inspection bodies. In 1994, WECC merged with WELAC in EAL (European Accreditation of Laboratories). EAL organised co-operation of European accreditation bodies in the field of calibration and testing laboratories accreditation. Finally in 1997, EAL merged with EAC to become known as EA (European co-operation for Accreditation).

The evolution of ILAC was prompted by the Tokyo Round of international trade negotiations under the General Agreement on Tariffs and Trade (GATT), the outcome of which was the GATT Standards Code. This agreement between the Member States, encouraged the recognition of the equivalence of different standards and the variety of testing and accreditation regimes.

Later, ABs (Accreditation Bodies) provided their services not only in the field of accreditation of laboratories but also in the field of inspection and

certification bodies. During the 1980s, the first ISO/IEC Guides concerning requirements on operation of ABs, CABs and laboratories were issued. CASCO, which could not originally develop standards, was responsible for development of these first guides in the field of conformity assessment and accreditation. Nowadays, there are 26 valid ISO/IEC standards and guides in the field of conformity assessment and accreditation (most are part of ISO/IES 17000 series).

IAF (International Accreditation Forum), founded in 1993, has engaged in the field of worldwide co-operation of different types of certification bodies and relevant CABs. Finally in 1996, ILAC became a legal entity, changed its name (ILAC - International Laboratory Accreditation Co-operation) and its structure with the aim of supporting mutual recognition of ABs and harmonisation in the field of accreditation. In the near future, ILAC and IAF will probably merge and create one general worldwide international organisation in the field of accreditation co-operation.

3.2 Accreditation in the national and international context

Throughout the world, many countries rely on 'Accreditation', to determine the technical competence of their laboratories, certification bodies, inspection bodies, PTs (proficiency testing) scheme providers and so on. The accreditation process is generally provided by one AB within a country. Accreditation reduces the risk for government, business and customers by ensuring, through regular surveillance, that CABs are both independent and competent. Some developing economies, without established ABs, can seek to have their CABs accredited by an established accreditation system in another country.

How does accreditation differ from ISO 9001 certification? ISO 9001 certification demonstrates that a relevant body has an established quality management system, but it does not address technical competence.

Accreditation takes the next step, using criteria and procedures specifically developed to determine technical competence of the relevant body. Accreditation is concerned only with the assessment of CABs (laboratories, certification bodies, inspection bodies) and some other clearly specified bodies linked with conformity assessment (e.g. PT scheme providers, producers of certified materials and so on).

All members of society (consumers, manufacturers, governmental bodies etc.) are faced with a more complex and dynamic marketplace. Consumers especially demand confidence in the quality of the products and services they use. There are serious environmental and health care issues as well. The relevance of services which guarantee this confidence must be checked and ensured, by an independent and impartial institution. Accreditation is the relevant tool which is able to ensure public confidence in the reliability of activities and have a real impact on health, welfare, security and environment. It is very often used by governmental bodies for the identification of relevant competent conformity assessment bodies.

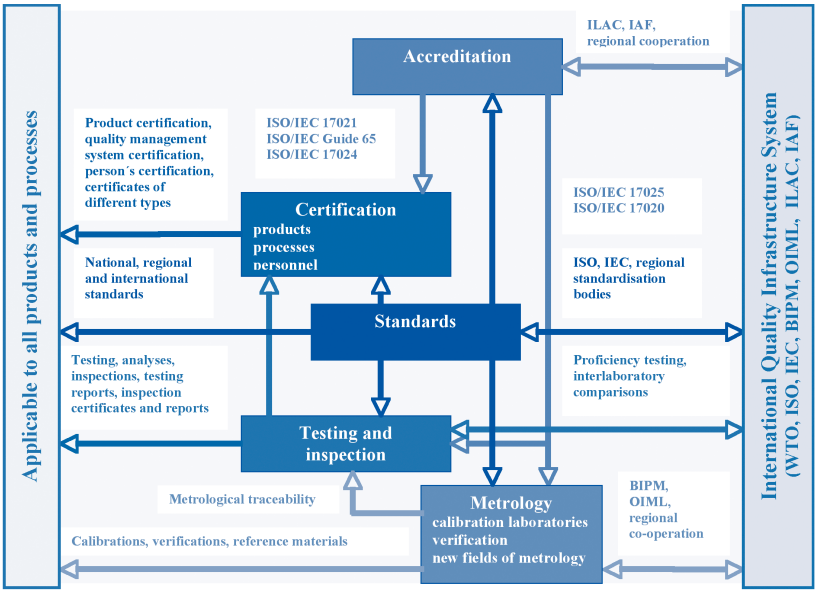
Accreditation is for manufacturers - or better said for industry - the basic tool in the field of decision making and risk management. The selection of an accredited supplier (eg laboratory), can save time and money and provide an assurance that such a supplier is technically competent. Furthermore, accreditation can provide a relevant competitive advantage as a result of its system of mutual recognition arrangements (MRAs) and/or multilateral agreements (MLAs). Accreditation guarantees that the relevant calibrations, tests and conformity assessment procedures are performed in compliance with best practice, limiting all serious non-conformities and control of manufacturing costs.

3.3 Accreditation and the Quality Infrastructure

Quality infrastructure relates to all fields of metrology, standardisation and testing, of quality management and conformity assessment, including certification and accreditation. In the past, the abbreviation MSTQ (Metrology, Standardisation, Testing and Quality Assurance) was used for this combination of single elements. Quality infrastructure must ensure the:

- elaboration and implementation of technical regulations for products, moving from compulsory standards to voluntary ones
- application of good practice codes regarding standardisation
- elimination of all measures that cause trade barriers - not only customs, taxes and quantitative restrictions, but all measures with equivalent (protectionist) effects

The overall description of the quality infrastructure is defined in the following diagram:



The national quality infrastructure is based on a number of components. These components are closely related and form a network, whose logical links are based on a technical hierarchy. This national network must be linked to the relevant international requirements. Only if these requirements are met, international commodity trading and an exchange of services are possible. The national quality infrastructure is closely linked with the International Quality Infrastructure System, which is based on the existence of the relevant international organisations in the fields of:

- standardisation (ISO, IEC, regional standardisation bodies)
- metrology (Metric Convention, CIPM, BIPM, OIML, regional co-operation in the field of metrology and legal metrology)
- testing
- certification
- quality management systems and conformity assessment (WTO, regional co-operation in the field of testing and certification)
- accreditation (ILAC, IAF, RCBs)

3.4 Accredition Bodies and areas of Accreditation

The subject areas of accreditation are CABs (Conformity Assessment Bodies) and some other related bodies, that play a central role in conformity assessment.

Conformity assessment offers a demonstration and certified proof that specified requirements (e.g. requirements of ISO/IEC standards relating to a product/service), process, system, person or body, are adequately and professionally fulfilled. The processes that need to be followed, to clearly demonstrate that they meet the requirements, are also contained in ISO/IEC standards and guides.The subject field of conformity assessment includes activities defined as testing, inspection and certification. The term conformity assessment also includes the accreditation of conformity assessment bodies.

A CAB is defined as a body that performs conformity assessment services (e.g. testing, inspection, certification) and the subjects of accreditation are:

- calibration laboratories
- testing laboratories (including medical laboratories)
- inspection bodies
- certification bodies certifying products
- certification bodies certifying management systems (including EMS)
- certification bodies certifying persons

However, there is an exception - ABs are not conformity assessment bodies, although they perform conformity assessment activities (accreditation of CABs).

Additionally, there are the following bodies which are also accredited in many countries:

- proficiency testing scheme providers
- reference material producers
- EMAS verifiers (only in EU or EEA countries)

Accreditation bodies in some countries provide services in the field of GLP (Good Laboratory Practice) or in the field of accreditation of attestors in the field of public procurement (only in EU or EEA countries – accreditation based on EN 45503). An overview of the relevant standards, standard documents and recommended guidance documents containing accreditation criteria and requirements concerning Accreditation, are set out in Annex 1.

3.5 Advantages of using accredited Conformity Assessment Bodies

When selecting a CAB to fulfil the appropriate calibration, testing, inspection, certification etc., it is vital to ensure that they can provide accurate and reliable results. The technical competence of the CAB depends on a number of factors including:

- qualifications, training and experience of its staff
- correct equipment
- adequate quality assurance procedures
- proper sampling practices
- appropriate conformity assessment procedures
- accurate recording and reporting etc.

Customers of CABs need to minimise risk and to avoid conformity reassessment, which can be expensive and time consuming. Also, one time testing through a technically competent (i.e. accredited) CAB enhances the confidence of customers, reduces costs and improves acceptance of goods abroad.

Accredited CABs receive a form of international recognition, through a system of international agreements, which allows their certificates to be more readily accepted in overseas markets. This recognition helps to reduce costs for manufacturers and exporters using services of accredited CABs.

Throughout the world, many countries rely on a process called CAB Accreditation, as a means of CAB determining technical competence. CAB accreditation also covers the quality systems elements addressed in ISO 9001 certification. To ensure continued compliance, accredited CABs are regularly re-examined to check that they are maintaining their standards of technical expertise. Some types of CABs may also be required to participate in regular PT programmes (laboratories and inspection bodies) as an on-going demonstration of their competence. CAB accreditation thus provides a means of evaluating the competence of CABs to perform specific types of conformity assessment tasks.

Accredited CABs usually issue certificates or reports bearing some type of symbol or endorsement indicating their accreditation. It is also possible to check with the relevant CAB as to what specific conformity assessment procedures (calibrations, tests, measurements, inspections, certifications etc.) it is accredited for and the range / scope. This is normally specified in the Scope of Accreditation, which may be supplied by the CAB, upon request.

ABs shall publish lists or directories of the CABs they have accredited, together with the CABs contact details and information on their conformity assessment capabilities. If necessary, it is possible to contact the AB and find out whether there are any accredited CABs which can perform the appropriate conformity assessment tasks.

The uniform approach of ILAC and/or IAF allows countries to establish agreements among themselves, based on mutual evaluation and acceptance of each others CAB systems. These agreements, called MRAs and/or MLAs, are crucial in enabling conformity assessment outputs to be accepted between countries. In effect, each partner in such an MRA and/or MLA, recognises the other partners accredited CABs, as if they themselves had undertaken the accreditation of the other partners CABs. This system of international MRAs and/or MLAs between accreditation bodies has enabled accredited CABs to achieve a form of international recognition and allowed data accompanying exported goods and services to be more readily accepted in overseas markets. This effectively reduces costs for both the manufacturer and the importers, as it reduces or eliminates the need for products to be retested in another country.

Many official bodies, like government agencies, have come to appreciate the importance of credible accreditation programmes that are based on internationally recognised standards. With restricted budgets, many

government agencies can no longer do it all themselves and increasingly, rely on third-party CABs to support their regulatory efforts. When they do so, they need a fair and meaningful basis for identifying qualified providers. Accreditation provides such a service and the MRAs and/or MLAs provide a means for recognition of acceptable accreditation bodies.

Industry users of CABs output documents can take similar advantage of MRAs and/or MLAs. Users have greater confidence in the correctness of different certificate reports as they have been generated by competent CABs. Manufacturers also gain efficiency because of accreditation through use of assessments of competent accreditation authorities that are relevant MRAs and/or MLAs signatories.

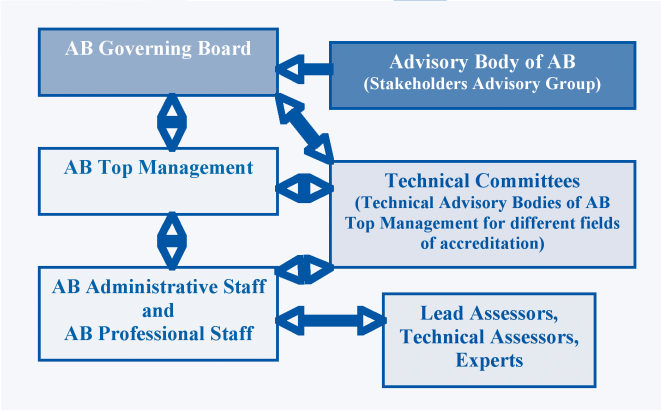
3.6 Common structures of Accreditation Bodies

The common structure of an AB is given by ISO/IEC 17011 and the principle structural issues that must be addressed relate to ensuring:

- impartiality
- objectivity
- non-discriminatory policies
- avoidance of conflicts of interests

In many small countries, there is the intention to centralise many relating activities (metrology, standardisation, testing, certification and accreditation) within the same body. This can be a source of conflict of interest, which can threaten the impartiality, objectivity and non-discriminatory policies. Even standards writing, can be in conflict with performing of accreditation services.

AB should be either governmental or non-profit organisations. Private non-profit organisations can be more flexible and can have some freedom from more rigid government budget rules. In the following diagram, a common recommended structure of an AB can be found, which is a general basic format.



Commonly recommanded structure of an AB

The AB governing board represents the highest level of decision making. It should be responsible for the appointment of the AB top management, supervision of overall AB activities, approval and supervision of AB budgets, approval of the AB scope of accreditation activities and so on. The advisory body of AB should have well balanced structure and should consist of representatives of all relevant stakeholders in the country. The AB top management is responsible for:

- day to day operations of the AB
- ensuring the appropriate staffing of the AB
- having the relevant advisory bodies organised in a form of technical committees in all relevant fields of AB accreditation activities (calibration, testing, inspection, certification etc.)

The AB staff should manage accreditation processes in a proper professional manner and in close co-operation with top management. Technical Committees should ensure that a relevant number of experienced assessors and experts are available for the required scope of AB accreditation activities. All activities of ABs shall be in line with the requirements and criteria of ISO/IEC 17011.

3.7 International and Regional Accreditation co-operation

Consumers demand confidence in the safety and quality of the products they use, the environment they live in, the reliability of health care services etc., which has led in part to widely based co-operation in the field of accreditation and conformity assessment. It is also important for businesses and regulators to have confidence in the integrity and quality of the services supplied by laboratories, inspection and certification bodies. It is the independence, competence and impartiality of AB members of LAC, IAF and/or RCBs (e.g. EA, APLAC, PAC etc) that guarantee this confidence.

These international organisations and RCBs are usually non-profit bodies which do not provide accreditation services themselves. Other important features of this international and regional co-operation include:

- harmonisation of accreditation procedures and processes performed by ABs
- a common approach to the development of accreditation worldwide
- intensive co-operation with other relevant bodies and organisations engaged in the field of conformity assessment (e.g. WTO, UNIDO, CIPM, OIML, CITAC, UILI etc.)
- fruitful exchange of information and experience, involving a wide spectrum of stakeholders
- a fostering of international and regional co-operation, by means of establishing relevant technical working committees and groups

The missions of ILAC, IAF and/or RCBs include the following responsibilities:

- to ensure transparency of the operations (including assessments) and results of its members

- to ensure a common interpretation of the standards they use
- to manage a peer evaluation system, consistent with international practice – RCBs are special members of ILAC and IAF
- to support and promote mutual recognition and acceptance of accredited conformity assessment services and results

The common objective is to develop co-operation and build up confidence in the services offered by member ABs in response to well identified market needs. Basically, the aim of signed MoUs is to provide recognition of accredited results, with a view to avoiding duplication of assessments.

Some of the advantages of involvement in the international and regional co-operation of Accreditation Bodies

ABs and other bodies involved in this co-operation can exchange their experience and compare their situation to other countries. They may participate in the meetings of different GAs of ILAC, IAF and relevant RCBs, but also at meetings on development of the relevant accreditation procedures and tasks in many working technical committees, working groups and relevant task forces. They can harmonise their working procedures, thus contributing to developing good practice in the field of accreditation. One of the most important results of co-operation of ABs on the international and regional level, is a possibility to sign on the bases of their successful evaluation (peer to peer audit) the relevant MRAs and/or MLAs of ILAC, IAF and/or RCBs. The relevant MRAs and/or MLAs provide a means for goods and services to cross boundaries in different regions and throughout the world.

A test or inspection report or a certificate issued by an accredited body in one country is recognised as equivalent to a report or a certificate issued by an accredited body in any of the countries signatories to the relevant

MRA and/or MLA. Accreditation bodies recognise that they operate in an equivalent way and that they deliver equivalent accreditations, providing the same level of competence and confidence.The MRAs and/or MLAs enable the provision of an accreditation 'passport', which facilitates access to regional and international markets through co-operation with ILAC and IAF.

Individual members that are signatories to the relevant MRAs and/or MLAs are subject to regular and stringent multi-national peer evaluations. The purpose of these routine on-site evaluations is to verify the signatories continuing conformity with the internationally accepted criteria (ISO/IEC 17011 and applicable guidance documents).These peer evaluations ensure consistent, harmonised accreditation practices and also facilitate the exchange of information and experience between the signatories.

3.8 Relevant International Accreditation Bodies

The two international worldwide organisations in the field of accreditation are ILAC and IAF.

3.8.1 ILAC

ILAC (International Laboratory Accreditation Co-operation) is an international co-operation of laboratory and inspection accreditation bodies, which provides a focus for:

- developing and harmonising laboratory and inspection accreditation practices
- promoting laboratory and inspection accreditation to industry, governments, regulators and consumers
- assisting and supporting developing accreditation systems
- global recognition of laboratories via the ILAC MRA, thus facilitating acceptance of test and calibration data accompanying goods across national borders

There are several kinds of membership in ILAC as follows:

Full Members are ABs that have been accepted as signatories to the ILAC MRA and meet the requirements for Associates. Each AB that is a signatory to ILAC MRA, agrees to abide by its terms and conditions and by the ILAC evaluation procedures. To do this, the signatory must maintain:

- conformance with ISO/IEC 17011
- related ILAC guidance documents
- important, supplementary requirements
- ensure that all its accredited laboratories comply with ISO/IEC 17025 and related ILAC guidance documents

Associates are ABs that, while not yet signatories to the ILAC MRA, operate accreditation schemes for testing laboratories, calibration laboratories, inspection bodies and/or other services, as decided from time to time by the ILAC GA. These ABs can provide evidence that they are operational and committed to comply with the requirements set out in relevant standards established by appropriate international standards. They are in compliance with the obligations of the ILAC MRA and they are recognised in their economy as offering an accreditation service.

Affiliates are ABs that are currently operating, being developed or intended to be developed for testing laboratories, calibration laboratories, inspection bodies, and/or other services as decided from time to time by the ILAC GA. They must declare their intention to operate their accreditation programmes in compliance with the requirements set out in relevant standards, established by appropriate international standards and ILAC application documents.

National Co-ordination Bodies have responsibility for the co-ordination of laboratory and/or inspection body accreditation activity in particular economies (e.g. DAR in Germany).

Regional Co-operation Bodies are formally established regional accreditation co-operations, having objectives similar to and compatible with ILAC, committed to the ILAC Mutual Recognition Arrangement and consisting of formally nominated representatives of the accreditation interests from at least four economies. Recognised RCBs are those, whose regional MRA/MLA have been successfully peer-evaluated by ILAC.

Stakeholders represent international, regional and national organisations, having an interest in the work of ILAC (ie associations of laboratories, associations of laboratory practitioners, inspection body associations, purchasing organisations, regulatory authorities, consumer associations and trade organisations.

ILAC MRA (Mutual Recognition Arrangement) is based on the results of an intensive evaluation of each body carried out in accordance with the relevant rules and procedures contained in several ILAC publications (see Annex 3 and condition for ILAC full members). The ILAC MRA builds upon existing or developing regional arrangements established around the world. The bodies participating in these regional arrangements are responsible for maintaining the necessary confidence in accreditation bodies from their region that are signatories to the ILAC MRA.

Each recognised RCB must abide by the procedures defined in ILAC requirements documents. The European co-operation for Accreditation (EA), the Asia Pacific Laboratory Accreditation Co-operation (APLAC) and the Inter-American Accreditation Co-operation (IAAC) are the current ILAC-recognised regions, with acceptable mutual recognition arrangements (MRAs) and evaluation procedures.

3.8.2 IAF

IAF (International Accreditation Forum, Inc.) is the world association of ABs, CABs and other bodies interested in conformity assessment in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment. IAF provides a focus for the following:

- developing a single worldwide programme of conformity assessment which reduces the risks for business and its customers, by assuring them that accredited certificates may be relied upon
- ensuring that its AB members only accredit bodies that are competent to do the work they undertake and are not subject to conflicts of interest
- establishing mutual recognition arrangements, known as IAF MLA, between its AB members which reduces the risk to business and its customers by ensuring that an accredited certificate may be relied upon anywhere in the world

There are several kinds of membership in IAF:

AB Members are ABs, conducting and administering programmes, by which they accredit bodies for certification/registration of quality systems, products, services, personnel, environmental management systems of similar programmes of conformity assessment, which declare their common intention to join the IAF MLA, recognising the equivalence of other members accreditations to their own.

IAF MLA Members are ABs that have been accepted as signatories to the IAF MLA.

Associate Members are other organisations involved in the use or implementation of certification/registration systems.

Special Recognition Organisations - Regional Accreditation Groups are regional groupings of ABs whose aims include the maintenance of Regional MRAs/MLAS recognising the equivalence of their members accreditations.

Partner Members and Special Recognition Organisations - Observer Members IAF are organisations which are related to IAF or are invited to be Observers.

IAF MLA (MLA refers to Multilateral Recognition Arrangement) - ABs (AB members of IAF) are admitted to the MLA only after a most stringent evaluation of their operations by a peer evaluation team which is charged to ensure that the applicant member complies fully with both the international standards and IAF requirements. Once an accreditation body is a member of the MLA, it is required to recognise the certificates issued by certification/registration bodies accredited by all other members of the MLA.

IAF has granted Special Recognition to two Regional Accreditation Groups, the European co-operation for Accreditation (EA) and the Pacific Accreditation Co-operation (PAC), on the basis of the acceptance of the mutual recognition arrangements established within these organisations. Membership of the IAF MLA is recognised as being satisfied by membership of either the EA MLA or the PAC MLA and IAF members who are also signatories of these regional MLAs are automatically accepted into the IAF MLA. Special Recognition was granted to the Inter-american Accreditation Co-operation (IAAC) for the Quality Management Systems (QMS) MLA, at the IAF Annual Meetings held in Cancun, Mexico in November 2006.

3.9 Relevant RCBs and their MRAs and MLAs

The relevant RCBs are the following:

- European co-operation for Accreditation (EA)
- Asia Pacific Laboratory Accreditation Co-operation (APLAC)
- Pacific Accreditation Co-operation (PAC)
- Inter American Accreditation Co-operation (IAAC)
- Southern African Development Community in Accreditation (SADCA)
- Central Asian Co-operation on Metrology Accreditation and Quality (CAC-MAS-Q)

A) EA

EA (European Co-operation for Accreditation) is a non profit association which was set up in November 1997 and registered as an association in the Netherlands in June 2000 (after the merger of EAC, European Accreditation of Certification and EAL, European co-operation for Accreditation of Laboratories). EA is the European network of nationally recognised ABs based in the EEA. EA develops and maintains a high level of service for the benefit of the European economy: the European Commission and EFTA, European industries, European governments and citizens. All interested parties and stakeholders are involved in EA activities; they can and do contribute to the EA work through membership in the committees and working groups. EA covers accreditation of laboratories (testing and calibration), inspection bodies, certification bodies (QMS, EMS, products and services, persons and EMAS verifiers). The EA mission includes the following factors:

- to ensure transparency in the operations (including assessments) and results of its members
- to ensure common interpretation of the standards they use

- to manage a peer evaluation system, consistent with international practice - EA as a region is a member of ILAC and IAF
- to support and promote mutual recognition and acceptance of accredited conformity assessment services

EA has 34 full members representing 32 European countries. 17 non-European ABs have signed a contract of co-operation with EA out of which 9 have entered into a bilateral agreement with EA which, as far as recognition and mutual acceptance are concerned, conveys the same rights and duties and benefits as the EA multilateral agreements.

The EA MLA (MLA means in this case Multilateral Agreement) provides a means for goods and services to cross boundaries in Europe and throughout the world. The MLA makes accreditation a 'passport', which facilitates access to the EU and international markets through co-operation with ILAC (International Laboratory Accreditation Co-operation) and IAF (International Accreditation Forum).

B) APLAC

APLAC (Asia Pacific Laboratory Accreditation Co-operation) is a co-operation of ABs in the Asia Pacific region that accredits laboratories, inspection bodies and reference material producers. It is recognised by APEC. Its primary objectives are:

- to provide a forum for exchange of information and to promote discussion among laboratory and inspection body ABs and among organisations that are interested in laboratory and inspection body accreditation and related activities
- to improve the standard of accreditation services provided by members
- to organise proficiency testing and related activities in the region

- to build up and maintain mutual confidence in the technical competence among Full Members and to work towards further development of the APLAC MRA
- to promote international acceptance of test, calibration and inspection reports and other documents issued by laboratories and inspection bodies accredited by signatories to the APLAC MRA
- to co-operate with other national, regional and international bodies with similar or complementary objectives

Currently 26 of the 36 full APLAC members are signatories to the APLAC MRA.

The APLAC MRA (MRA means in this case Mutual Recognition Arrangement) is based on the results of an intensive evaluation of each accreditation body carried out in accordance with procedures, detailed in the relevant APLAC publications. Each APLAC MRA signatory has demonstrated compliance with the international standard ISO/IEC 17011 and that its accredited facilities are in compliance with ISO/IEC 17025 (labs), ISO 15189 (medical labs) and/or ISO/IEC 17020 (inspection bodies). A re-evaluation is done at a maximum of 4-yearly intervals by a team of trained APLAC peer-evaluators.

C) PAC

PAC (Pacific Accreditation Co-operation) is an association of ABs and other interested parties whose objective is to facilitate trade and commerce among economies in the Asia Pacific region. Its ultimate objective is the creation of a global system that grants international recognition of certification or registration, of management systems, products, services, personnel and other programmes of conformity assessment. The PAC promotes the international acceptance of accreditations granted by its accreditation body members, based on the

equivalence of their accreditation programmes. The PAC operates within the framework of the International Accreditation Forum (IAF) and in co-operation with other regional groups of accreditation bodies around the world. PAC has 18 full members and 5 associate members. PAC MLA (MLA means in this case Multilateral Recognition Arrangement) covers certification in the field of QMS, EMS and products.

D) IAAC

IAAC (InterAmerican Accreditation Co-operation) is an association of accreditation bodies in the Americas and other organisations interested in conformity assessment. IAAC members are classified as Full members, Associate members and Stakeholder members. Full members are signatories to the IAAC MLA. IAAC has 23 full members, 8 associate members and 10 stakeholder members.

The IAAC MLA (Multilateral Recognition Arrangement) is an agreement among accreditation bodies by which they recognise the accreditations issued by each other. Such a system of mutual recognition of accreditation is based on the proper operation of the accreditation system of the bodies that join the arrangement. A programme to establish and maintain mutual confidence among the bodies that are signatories to the IAAC MLA, is required in order to establish and maintain an MLA. The principal elements of that programme are:

- participation in programmes of peer evaluation and re-evaluation
- exchange of information in the development and operation of accreditation systems
- participation of personnel from IAAC MLA members in assessment, re-assessment or surveillance visits to conformity assessment bodies performed by other IAAC MLA member bodies
- participation in IAAC meetings

E) SADCA

SADCA (Southern African Development Community in Accreditation) is the regional accreditation structure of SQAM (Standardisation, Quality Assurance, Accreditation and Metrology), tasked with defining a suitable accreditation infrastructure. This task focused on enabling organisations in the SADC Member States to access accreditation services from internationally recognised national ABs within their countries, or to form a regional accreditation service.

F) CAC-MAS-Q

CAC-MAS-Q (Central Asian Co-operation on Metrology, Accreditation, Standardisation) is a new RCB which has been established by Kazakhstan, Kyrgyzstan, Tajikistan and Uzbekistan.

3.10 Process of evaluation of Accreditation Bodies

The evaluation of an AB involves a team of peers (generally senior staff of experienced ABs). Evaluations include time spent at the headquarters office of the applicant body to determine compliance with ISO/IEC 17011. Additionally, the evaluators witness the performance of the applicants assessors during actual assessments/reassessments to determine if the CABs are in compliance with the relevant standards and if there is sufficient depth of examination to determine competence. There are applied standard documented procedures for appointment of experiences and especially trained international or regional evaluators who shall, on the bases of a site visit to premises of the AB, elaborate an evaluation report which is considered in the appropriate committee of ILAC, IAF or RCB (committee is called Multilateral Agreement or Mutual Arrangement Committee (MAC)). All signatories of the appropriate MRA and/or MLA are represented in such MAC and all have the right to make comments to the

evaluation report and require further explanation. MAC is a decision making body in the matters linked with signing of the relevant MRA and/or MLA.

In order to maintain the value and meaning of the appropriate MRA and/or MLA, the signatories agree to notify each other about any significant changes in the status or operation of the body. Issues of significance include:

- changes in name or legal/corporate status
- new agreements negotiated with other ABs
- the revision, suspension or termination of any agreements
- changes in key senior staff or the organisational structure
- significant changes in the operations of the AB

Each signatory to the MRA and/or MLA must also designate a liaison officer to afford a consistent channel of communication between the ABs. Detailed information on the appropriate evaluation procedures and needed preconditions, which shall be fulfilled before their performance are in the relevant documents of ILAC, IAF and relevant fully developed RCBs (see Annex 3).

ILAC and IAF have developed marks which can be used by the member accreditation bodies and their accredited bodies under specific conditions set out in a licence agreement. The ILAC and IAF marks demonstrate:

- the signatory status to the ILAC / IAF arrangement
- that the test report or certificate has been issued by a body accredited by a member of the ILAC/IAF arrangement - as such, it can be recognised and accepted by any of the signatories of these arrangements

4 - PART 2: SUMMARY OF ISO/IEC 17011:2004, CONFORMITY ASSESSMENT

4.1 Short overview of criteria and requirements

ISO/IEC 17011:2004 specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies (CABs). It is also appropriate as a requirements document for the peer evaluation process for mutual recognition arrangements between accreditation bodies. Accreditation bodies operating in accordance with ISO/IEC 17011:2004 do not have to offer accreditation to all types of CABs. For the purposes of ISO/IEC 17011:2004, CABs are organisations providing the following conformity assessment services: testing, inspection, management system certification, personnel certification, product certification and in the context of this standard, calibration.

ISO/IEC 17011 requires and specifies the following:

- **Accreditation body and legal responsibility** - AB shall be a registered legal entity - the detailed description of the legal status of AB is required
- **Structure** - AB shall have clear and well defined structure (entire structure shall be documented) and scope of its activities to give confidence in its accreditations - AB shall have appropriate advisory bodies having rules for appointment, terms of reference and operation
- **Impartiality** - AB shall be non-discriminatory and impartial - it shall have policies and procedures for safeguarding its objectivity and impartiality - AB shall be free from any undue commercial, financial and other pressures that could compromise impartiality

- **Confidentiality** - AB shall be confidential concerning the information obtained in the process of its accreditation
- **Liability and Financing** - AB shall have arrangements to cover liabilities arising from its activities and have the financial sources for performing its activities
- **Accreditation Activity** - AB shall clearly describe its accreditation activities and establish policies and procedures for extending its activities and to react to demands of interested parties

- **Management**
  - AB shall establish, implement and maintain a management system and continually improve its effectiveness in accordance with the requirements of ISO/IEC 17011
  - AB top management shall define and document policies and measurable objectives, including a quality policy for its activities and it shall provide evidence of commitment to quality and to compliance with the requirements of ISO/IEC 17011
  - All applicable requirements of ISO/IEC 17011 shall be addressed either in an accessible manual or in accessible associated documents
  - The top management shall appoint an AB quality manger (member of AB management)
  - AB shall establish policies and procedures to control all documents (internal and external) that relate to its accreditation activities
  - AB shall establish policies and procedures for identification, collection, indexing, accessing, filing, storage, maintenance and disposal of its records

- AB shall establish policies and procedures for retaining records for a period consistent with its contractual and legal obligations
- AB shall establish policies and procedures for the identification and management of nonconformities in its own operations (AB is responsible for maximum elimination of non-conformities causes)
- AB shall establish policies and procedures to identify opportunities for improvement and to take preventive actions to eliminate the causes of potential non-conformities
- AB shall establish policies and procedures for internal audits (performed normally at least once a year) to verify that they conform to the requirements of ISO/IEC 17001- there shall be a planned audit programme
- AB top management shall establish policies and procedures to review its management system at planned intervals (normally once a year)
- AB shall establish policies and procedures for dealing with complaints

- **Human Recourses**
  - AB shall have a sufficient number of competent personnel (internal, external, temporary, or permanent, full time or part time staff members, lead assessors, technical assessors, experts) educated, trained and experienced for performing the accreditation services
  - Duties, responsibilities, rights and obligations of personnel shall be clearly stated

- Description of individual positions in AB, qualification requirements, training plans and detailed personal records shall exist
- Personal records shall be maintained and their scope shall be in line with requirements of ISO/IEC 17011
- AB shall ensure the satisfactory performance of the assessment and the accreditation decision-making process by establishing procedures for monitoring the performance and competence of the personnel involved

- **Accreditation Process - AB shall make publicly available:**
  - detailed information about its assessment and accreditation processes
  - its requirements for accreditation, general information about the fees relating to the accreditation
  - a description of the rights and obligations of customers
  - its own rights and obligations
  - a list of accredited entities together with relevant required information
  - procedures concerning objections and complaints solving
  - information on its financial sources
  - information on the scope of its activities
  - information about its related bodies

- **In addition:**
  - ABs shall require a duly completed formal application concerning its services – it shall review each application
  - AB shall review its ability to carry out the assessment of the applicant

- If the AB subcontracts assessments, it shall have a policy describing the conditions under which subcontracting may take place - subcontracting of decision making is forbidden and there shall be a contract in place in relation to subcontracting
- AB shall have full responsibility for subcontractors
- AB shall maintain a list of its subcontractors, monitor and assess their competences, as required
- AB shall formally appoint an assessment team consisting of a lead assessor and a suitable number of technical assessors and/or experts for each specific scope –the customer shall be informed sufficiently in advance about names and occupation of the assessment team members to be able to make any objections, if any
- AB shall have a policy for dealing with such objections
- AB shall clearly define the assignment given to the assessment team
- AB shall establish policies and procedures for sampling (if applicable) where the scope of the customer covers a variety of specific conformity assessment services
- AB shall agree, together with the customer and the assigned assessment team, the date and schedule for the assessment
- AB shall ensure the appropriate criteria documents, previous assessment records and the relevant documents and records of the customer for the assessment team
- AB shall ensure that the assessment is performed in line with its stated and fully documented accreditation procedure (see 4.2 page 41) for a short description of the accreditation process)

- AB shall remain responsible for the content of the assessment report, including nonconformities, even if the lead assessor is not a permanent staff member of the accreditation body
- AB shall ensure that the responses of the customer to resolve non-conformities are reviewed, to see if the actions appear to be sufficient and effective
- AB shall, without undue delay, make the decision on whether to grant or extend accreditation on the basis of an evaluation of all information received and any other relevant information
- AB shall provide an accreditation certificate to the accredited customer - this accreditation certificate shall identify all relevant information stated in ISO/IEC 17011
- AB shall establish policies and procedures to address appeals by customers
- AB shall establish policies and procdures and plans for carrying out periodic surveillance onsite assessments, other surveillance activities and reassessments
- AB shall design its plan for reassessment and surveillance of each accredited customer so that representative samples of the scope of accreditation are assessed on a regular basis
- AB shall confirm the continuation of accreditation, or decide on the renewal of accreditation, based on the results of surveillance and reassessments described above
- AB shall undertake the necessary activities to determine whether or not the extension may be granted
- AB shall establish policies and procedures for the suspension, withdrawal or reduction of the scope of accreditation

- AB shall make decisions to reduce the scope of accreditation of the customer to exclude those parts where the customer has persistently failed to meet the requirements for accreditation, including competence
- AB shall maintain records on customers to demonstrate that requirements for accreditation, including competence, have been effectively fulfilled
- AB shall establish policies and procedures for the participation of the laboratory and performance in proficiency testing
- AB shall maintain a list of appropriate proficiency testing and other comparison programmes

Responsibilities of AB and its customers

- AB shall require information from accredited bodies, without delay, of significant changes relevant to its accreditation
- AB shall make publicly available information about the current status of the accreditations, granted to its customers
- AB shall provide the customer with information about suitable ways to obtain traceability of measurement results, in relation to the scope for which accreditation is provided
- AB shall, where applicable, provide information about international arrangements, in which it is involved
- AB shall give due notice of any changes to its requirements for accreditation
- AB, as proprietor of the accreditation symbol that is intended for use by its accredited customers, shall have a policy governing its protection and use
- AB shall take suitable action to deal with incorrect references to accreditation status, or misleading use of accreditation symbols found in advertisements, catalogues, etc.

Basic requirements of ABs and other possible relevant requirements and obligations of international organisations, in the field of accreditation and/or RCBs

There is a note in ISO/IEC 17011 which states that: those accreditation bodies that are signatories to MRA and/or MLA may refer to the obligations of this MRA and/or MLA in their policies (and in their procedures also).

The general requirements of ILAC, IAF or the relevant RCB is that an AB which is, or would like to be a signatory to the relevant MRA and/or MLA shall respect ILAC, IAF or relevant RCB evaluation procedures (see Annex 3)

To do this, the signatory must:

- maintain conformance with ISO/IEC 17011, related ILAC, IAF or the relevant RBC guidance documents and a few, but important, supplementary requirements
- ensure that all its accredited customers comply with the relevant standard of ISO/IEC 17000 series and related ILAC, IAF or the relevant RCB guidance documents

These signatories have, in turn, been peer-reviewed and shown to meet the relevant criteria for competence. Furthermore ABs, while not yet signatories to the appropriate MRA and/or MLA, shall:

- operate the relevant accreditation schemes as decided from time to time by the ILAC GA, IAF GA on the relevant RCB GA
- provide evidence that they are operational and committed to comply with (a) the requirements set out in relevant standards established by appropriate international standards writing bodies, such as the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC) and

ILAC, IAF or the relevant RCB application documents; and (b) the obligations of the appropriate MRA and/or MLA

- be recognised in their economy as offering an accreditation service

4.2 Short description of the Accreditation process

The AB shall require an authorised representative of the applicant to make a formal application that includes all relevant information stated in ISO/IEC 17011. This is the start of the accreditation process. The most technically important part of this application is the scope of accreditation. On the bases of this scope and on the bases of other relevant information, the AB can review its ability to perform the assessment of the applicant, in terms of its own policy, its competence and the availability of suitable assessors and experts. The AB shall ensure itself that the required assessment is possible. This review can include a preliminary visit with the agreement of the applicant. When the application is acceptable, the AB shall register it and shall start with finalising the assessment contract. The AB shall start with establishment of the assessment team.

As a rule, the lead assessor is responsible for the first part of assessment which is the initial assessment review of all relevant documents and records supplied by the applicant to evaluate its system for conformity with the relevant standard(s) and other requirements for accreditation. The AB may decide not to proceed with an on-site assessment based on the non-conformities found, during document and record review. In such cases, the nonconformities shall be reported in writing to the applicant.

The on-site assessment shall start with an opening meeting at which the purpose of the assessment and accreditation criteria are clearly defined and the assessment schedule, as well as the scope for the assessment are

confirmed. For initial assessments, in addition to visiting the main or head office, visits shall be made to all other premises of the applicant from which one or more key activities are performed and which are covered by the scope of accreditation. For surveillance and reassessment, where the applicant works from various premises, the accreditation body shall establish procedures for sampling, to ensure proper assessment. All premises from which one or more key activities are performed should be assessed within a defined timeframe.

The assessment team shall conduct the on-site assessment at the premises of the applicant from which one or more key activities are performed and where relevant, shall perform site inspections at other selected locations, to gather objective evidence that the applicable scope is competent and conforms to the relevant standard(s) and other requirements for accreditation. The assessment team shall perform a relevant number of witness audits and shall analyse all relevant information and evidence gathered during the on-site assessment. This analysis shall be sufficient to allow the team to determine the extent of competence and conformity of the applicant with the requirements for accreditation. All this work shall be summarised in the appropriate assessment reports and records on non-conformities. It must ensure that the responses of the applicant to resolve nonconformities are reviewed to see if the actions appear to be sufficient and effective. If the CAB responses are found not to be sufficient, further information shall be requested. Additionally, evidence of effective implementation of actions taken may be requested, or a follow-up assessment may be carried out to verify effective implementation of corrective actions. Finally, the team shall elaborate final reports of all assessors and the lead assessor summarises all findings in its final summary report. These reports together with all other supporting

documentation and evidence are then provided to the accreditation decision-maker.

AB shall, without undue delay, make the decision on whether to grant or extend accreditation on the basis of an evaluation of all information received and any other relevant information. The AB shall then provide an accreditation certificate to the accredited CAB or information as to why the new accreditation certificate has not been issued. The applicant has the right to make an appeal against this decision.

Reassessment is similar to an initial assessment as described above, except that experience gained during previous assessments shall be taken into account. Surveillance on-site assessments are less comprehensive than reassessments. Reassessments and periodic surveillances are based on plans for performing these services. AB shall design plans for reassessments and surveillances for each accredited body, so that representative samples of the scope of accreditation are assessed on a regular basis. AB may conduct extraordinary assessments as a result of complaints or changes, etc. AB shall advise accredited bodies of this possibility. AB shall, in response to an application for an extension of scope of an accreditation already granted, undertake the necessary activities to determine whether or not the extension may be granted.

AB shall have procedures for the suspension, withdrawal or reduction of the scope of accreditation which means that AB shall be able to make decisions to reduce the scope of accreditation of the accredited body to exclude those parts where the accredited body failed to meet the requirements and criteria for accreditation. Furthermore AB may organise proficiency testing or other comparisons itself, or may involve another body, judged to be competent. AB shall maintain a list of appropriate

proficiency testing and other comparison programmes. The participation of laboratories and nowadays even inspection bodies in these proficiency testing schemes is required by ABs and checking this participation of laboratories and inspection bodies in PT schemes, is a part of the standard surveillance activities of ABs.

Finally, the AB shall take suitable action to deal with incorrect references to accreditation status, or misleading use of accreditation symbols found in advertisements, catalogues, etc.

4.3 How to find the relevant Accreditation body?

To find out if there is a relevant AB in a country, it is helpful to contact the National Standardisation Body or the Ministry for Industry or Technology or Trade. Alternatively, it is possible to visit the website of ILAC (calibration, testing and/or inspection), IAF (certification) and use the directory of the relevant accreditation bodies available on these websites.

5 - PART 3: ACCREDITATION IN LEBANON

5.1 Current status of Lebanese Accreditation

The current status of Law No. 572 dated 11 December 2004, on the establishment of the National Lebanese Accreditation Body, is as follows:
- Lebanese Accreditation Council (henceforth COLIBAC) has been approved. Inspite of the formal appointment of the board of directors, COLIBAC in reality does not exist. There is, on the other hand, an intention to change this situation and to start step by step with a proper procedure for establishing COLIBAC. There will be some relevant amendments to the Law which will be in line with recommendations and findings involved in the document 'Strengthening Quality Management, Capabilities and Infrastructure in Lebanon, EuropeAid/117725/D/SV/LB, Legal Assessment of the Law on the Establishment of the Lebanese Accreditation Council'.

5.2 The next steps proposed for the development of recognised accreditation services in Lebanon

It is recommended to start step by step work on realising the following important actions:

- Establishment of COLIBAC Financial and Administration Rules and Funding
- Appointment of the COLIBAC Director General
- Hiring the COLIBAC staff
- Establishing the COLIBAC Accreditation committee (advisory body to the Board and COLIBAC)
- Establishing the Technical Committees (advisory committees body to the COLIBAC Director General)
- Ensuring COLIBAC premises and basic equipment
- Starting the process of developing the COLIBAC management system documentation
- Starting with the appropriate training of COLIBAC staff immediately after appointment of the COLIBAC Director General and hiring COLIBAC staff members
- Implement the COLIBAC management system
- Starting with the selection of the COLIBAC assessors (lead assessors and technical assessors), who shall later be part of the Technical Committees and approved by COLIBAC Top Management, immediately after the appointment of the Director General
- Starting the initial training of the first COLIBAC assessors
- Start-up the COLIBAC accreditation activities and perform two or three joint assessments with an experienced European accreditation body

6 - RELATED WEBSITES

International organisations engaged in the field of Accrreditation

IAF	http://www.iaf.nu/
ILAC	http://www.ilac.org

Regional Cooperation Bodies in the field of accreditation

APLAC	http://www.aplac.org/
EA	http://www.european-accreditation.org/
IAAC	http://www.iaac.org.mx/
PAC	http://www.apec-pac.org/
SADCA	http://www.sadca.org/

Some relevant Accreditation Bodies signatories of ILAC MRA or IAF MLA or both arrangements which have their web sites completely in English, French or Arabic

A2LA (USA)	http://www.a2la.org
ANAB (USA)	http://www.anab.org/
COFRAC (France)	http://www.cofrac.fr
NATA (Australia)	http://www.nata.asn.au
NLAB (Egypt)	http://www.egac.gov.eg
NVLAP (USA)	http://www.nist.gov/nvlap
SANAS (South Africa)	http://www.sanas.co.za
UKAS (UK)	http://www.ukas.com

Other relevant organisations and bodies

APEC	http://www.apecsec.org.sg/
APLMF	http://www.aplmf.org/
APMP	http://www.apecsec.org.sg/
ASEAN	http://www.aseansec.org
BIPM	http://www.bipm.org

CEN	http://www.cenorm.be/cenorm/
CENELEC	http://www.cenelec.org/
CIPM	http://www.bipm.org/en/committees/cipm/
CITAC	http://www.citac.cc/
COOMET	http://www.coomet.org/
CORDIS	http://cordis.europa.eu/
EASC	http://www.easc.org.by
EEE-PT	http://www.lgc.co.uk
EFTA	http://www.efta.int/
EGOLF	http://www.egolf.org.uk/
EMLMF	http://www.industrie.gouv.fr/metro/f3m_med.htm
ENFSI	http://www.enfsi.eu/
EOQ	http://www.eoq.org/start.asp
EPTIS	http://www.eptis.bam.de
EU	http://europa.eu/
EURACHEM	http://www.eurachem.org
EUROLAB	http://www.eurolab.org/
EUROMET	http://www.euromet.org/
EURAMET e.V.	http://www.euromet.org/euramet/euramet.html
European Parliament	http://www.europarl.europa.eu/
European Union Law	http://eur-lex.europa.eu/
ICSCA	http://www.icsca.org.au
IEC	http://www.iec.ch/
IMEKO	http://www.imeko.org/
INFO ON ACCESSING THE EU MARKET	http://ec.europa.eu/trade/issues/global/development/
ISO	http://www.iso.org/
JCDCMAS	http://www.jcdcmas.org
JCTLM	http://www.bipm.org/en/committees/jc/jctlm/

OECD	http://www.oecd.org
OIML	http://www.oiml.org
SIM	http://www.sim-metrologia.org.br/
THE COUNCIL OF THE EUROPEAN UNION	http://www.consilium.europa.eu/
UNIDO	http://www.unido.org
VIRM	http://www.virm.net/
WADA	http://www.wada-ama.org
WELMEC	http://www.welmec.org/
WTO	http://www.wto.org/

ANNEX 1 - OVERVIEW OF STANDARDS, STANDARD DOCUMENTS AND RECOMMENDED GUIDANCE DOCUMENTS USED IN DIFFERENT FIELDS OF ACCREDITATION

Testing and calibration laboratories (with the exception of medical laboratories)

- **Standards**

ISO/IEC 17025:2005	General Requirements for the Competence of Testing and Calibration Laboratories

- **Recommended guidance documents**

ILAC-G7:1996	Accreditation Requirements and Operating Criteria for Horseracing Laboratories
ILAC-G8:1996	Guidelines on assessment and reporting of compliance with specification
ILAC-G9:2005	Guidelines for the Selection and use of Reference Materials
ILAC-G17:2002	Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025

ILAC-G19:2002	Guidelines for Forensic Science Laboratories
ILAC-G22:2004	Use of Proficiency Testing as a tool for Accreditation in Testing
ILAC-G24:2007	Guidelines for the Determination of Calibration Intervals of Measuring Instruments
APLAC TC 002	Internal Audits for Laboratories and Inspection Bodies
APLAC TC 003	Management Review for Laboratories and Inspection Bodies
APLAC TC 004	Method of Stating Test and Calibration Results and Compliance with Specification
APLAC TC 005	Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing
APLAC TC 007	APLAC Guidelines for Food Testing Laboratories
EA-2/10	EA Policy for Participation in National and International Proficiency Testing Activities
EA-3/04	Use of Proficiency Testing as a Tool for Accreditation in Testing
EA-4/02	Expression of the Uncertainty of Measurement in Calibration
EA-4/07	Traceability of Measuring and Test Equipment to National Standards
EA-4/09	Accreditation for Sensory Testing Laboratories
EA-4/10 with EURACHEM	Accreditation for Microbiological Laboratories
EA-4/14	Selection and Use of Reference Materials
EA-4/15	Accreditation for Bodies Performing non-Destructive Testing

EA-4/16	EA Guidelines on the Expression of Uncertainty in Quantitative Testing
AOAC INTERNATIONAL	Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals - an aid to Interpretation of ISO/IEC 17025
EURACHEM/CITAC	Traceability in Chemical Measurement (2003) – A Guide to Achieving Comparable Measurement Results
EURACHEM/CITAC	Guide to Quality in analytical Chemistry(2002) – An Aid to Accreditation
EURACHEM/CITAC	Quantifying Uncertainty in Analytical Measurement 2nd Edition (2000)
EURACHEM/CITAC	Quality Assurance for Research and Development and Non-routine Analysis (1998)
EURACHEM	The Fitness for Purpose of Analytical Methotds (1998) – A Laboratory Guide to Method Validation and Related Topics
EUROLAB No. 2/2006	Guidance for the Management of Computers and Software in Laboratories with Reference to ISO/IEC 17025:2005
JAB NOTE 4	Estimation of MU (Electrical Testing/High PowerTesting)
VAM	Meeting the Traceability Requirements of ISO 17025 - an Analysts Guide, 2nd Edition, November 2003
CEC	ISO/IEC 17025 interpretation document for CEC test methods (2006)

OMCL	Validation of analytical procedures (2005)
OMCL	Scope of accreditation of official medicines laboratories
OMCL	Uncertainty of measurement
EWDTS	European Laboratory Guidelines for Legally Defensible Workplace Drug Testing

- **Medical laboratories - Standards**

ISO 15189:2007	Medical laboratories - Particular requirements for quality and competence

Other relevant standards and standard documents

ISO 15190:2003	Medical laboratories -- Requirements for safety

- **Recommended guidance documents**

ILAC-G8:1996	Guidelines on assessment and reporting of compliance with specification
ILAC-G17:2002	Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025
ILAC-G19:2002	Guidelines for Forensic Science Laboratories
APLAC TC 002	Internal Audits for Laboratories and Inspection Bodies
APLAC TC 003	Management Review for Laboratories and Inspection Bodies
APLAC TC 004	Method of Stating Test and Calibration Results and Compliance with Specification
APLAC TC 005	Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing
EA-4/02	Expression of the Uncertainty of Measurement in Calibration
EA-4/07	Traceability of Measuring and Test Equipment to National Standards

EA-4/10	Accreditation for Microbiological Laboratories with EURACHEM
EA-4/14	Selection and Use of Reference Materials
EA-4/16	EA Guidelines on the Expression of Uncertainty in Quantitative Testing

- **Certification bodies certifying products - Standard documents**

ISO/IEC Guide 65:1996	General requirements for bodies operating product certification systems

- **Other relevant standards and standard documents**

ISO/IEC Guide 23:1982	Methods of indicating conformity with standards for third-party certification systems
ISO Guide 27:1983	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
ISO/IEC Guide 28:2004	Conformity assessment - Guidance on a third-party certification system for products
ISO/IEC Guide 53:2005	Conformity assessment - Guidance on the use of an organisations quality management system in product certification
ISO/IEC Guide 67:2004	Conformity assessment - Fundamentals of product certification
ISO/IEC 17030:2003	Conformity assessment - General requirements for third-party marks of conformity

- **Recommended guidance documents**

IAF GD 5:2006	Guidance on ISO/IEC Guide 65:1996 (Issue 2, issued on 8 December 2006; application from 8 December 2007)
EA-6/02	EA Guidelines on the Use of EN 45011 and ISO/IEC 17021 for Certification to EN ISO 3834
EA-6/03	EA Guidance For Recognition of Verification Bodies under EU ETS Directive

EUREPGAP - (now GLOBALGAP)	General regulations – Integrated Farm Assurance

- **Certification bodies certifying management systems - Standards**

ISO/IEC 17021:2006	Conformity assessment - Requirements for bodies providing audit and certification of management systems

- **Other relevant standards and standard documents**

ISO/IEC Guide 23:1982	Methods of indicating conformity with standards for third-party certification systems
ISO Guide 27:1983	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
ISO/IEC 17030:2003	Conformity assessment - General requirements for third-party marks of conformity

- **Recommended guidance documents**

IAF GD 2:2005	Guidance on the Application of Guide 62:1996 (Issue 4, issued on 15 December 2005; application from 15 December 2006)
IAF GD 8:2007	Informative Guidance on the Transition to ISO/IEC 17021 - Accreditation from ISO/IEC
Guide	62 and ISO/IEC Guide 66
EA-7/03	Guidelines for Accreditation of bodies operating certification/registration of Information Security Management Systems
EA-7/04	Legal compliance as a part of Accredited ISO14001:2004 certification
ISO/TS 22003	Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems

- **Certification bodies certifying personnel - Standards**

ISO/IEC 17024:2003	Conformity assessment -- General requirements for bodies operating certification of persons

- **Other relevant standards and standard documents**

ISO/IEC Guide 23:1982	Methods of indicating conformity with standards for third-party certification systems
ISO Guide 27:1983	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
ISO/IEC 17030:2003	Conformity assessment - General requirements for third-party marks of conformity

- **Recommended guidance documents**

IAF GD 24:2004	Guidance on the Application of ISO/IEC 17024:2003

- **Inspection bodies - Standards**

ISO/IEC 17020:1998	General criteria for the operation of various types of bodies performing inspection

- **Recommended guidance documents**

IAF/ILAC-A4:2004	Guidance on the Application of ISO/IEC 17020
ILAC-G8:1996	Guidelines on assessment and reporting of compliance with specification
ILAC-G22:2004	Use of Proficiency Testing as a Tool for Accreditation in Testing
APLAC TC 002	Internal Audits for Laboratories and Inspection Bodies
APLAC TC 003	Management Review for Laboratories and Inspection Bodies
APLAC TC 004	Method of Stating Test and Calibration Results and Compliance with Specification

APLAC TC 006	Guidance Notes on ISO/IEC 17020
EA-2/10	EA Policy for Participation in National and International Proficiency Testing Activities

- **Proficiency testing scheme providers - Standard documents**

ISO/IEC Guide 43-1	Proficiency testing by interlaboratory comparisons – Part 1: Development and operation of proficiency testing schemes

- **Other relevant standards and standard documents**

ISO/IEC Guide 43-2	Proficiency testing by interlaboratory comparisons - Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies
ISO 13528:2005	Statistical methods for use in proficiency testing by interlaboratory comparisons

- **Recommended guidance documents**

ILAC-G13:08/2007	ILAC Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes
EA-2/09	EA Policy on the Accreditation of Providers of Proficiency Testing Schemes
EA-3/04	Use of Proficiency Testing as a Tool for Accreditation in Testing
EA-4/07	Traceability of Measuring and Test Equipment to National Standards
EA-4/16	EA Guidelines on the Expression of Uncertainty in Quantitative Testing
EURACHEM	Selection, use and interpretation of proficiency testing (PT) schemes by laboratories

IUPAC Technical Report — The International Harmonised Protocol for the proficiency testing of analytical chemistry laboratories

- **Reference materials producers - Standard documents**

ISO Guide 34:2000 — General requirements for the competence of reference material producers

ISO Guide 34:2000/Cor 1:2003 - correction issued

- **Other relevant standards and standard documents**

ISO Guide 31:2000 — Reference materials - Contents of certificates and labels

ISO Guide 35:2006 — Reference materials - General and statistical principles for certification

- **Recommended guidance documents**

ILAC-G12:2000 — Guidelines for the Requirements for the Competence of Reference Materials Producers

APLAC TC 008 — APLAC Guidelines on the Approach to the Assessment of Reference Material Producers and the Resulting Scope of Accreditation

Annex 2 - Overview of standards, standard documents and recommended guidance documents concerning activities of Accreditation Bodies

- **Standards**

ISO/IEC 17011:2004	General requirements for accreditation bodies accrediting conformity assessment bodies

- **Other relevant standards and standard documents**

ISO 9000:2005	Quality management systems - Fundamentals and vocabulary
ISO/IEC 17000:2004	Conformity assessment - General vocabulary
VIM:1993	International vocabulary of basic and general terms in metrology, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML
ISO 9001:2000	Quality management systems - Requirements
ISO 19011:2002	Guidelines for quality and/or environmental management systems auditing
ISO/TR 10013:2001	Guidelines for quality management system documentation
ISO/TR 10017:2003	Guidance on statistical techniques for ISO 9001:2000

- **Recommended guidance documents**

ILAC-G3:1994	Guidelines for Training Courses for Assessors used by Laboratory Accreditation Schemes
ILAC-G10:1996	Harmonised Procedures for Surveillance and Reassessment of Accredited Laboratories
ILAC-G11:07/2006	ILAC Guidelines on Qualifications and Competence of Assessors and Technical Experts
ILAC-G18:2002	The Scope of Accreditation & Consideration of Methods & Criteria for the Assessment of the Scope in Testing

ILAC-G20:2002	Guidelines on Grading of Non-conformities
ILAC- G21:2002	Cross Frontier Accreditation – Principles for Avoiding Duplication
IAF PL 1:2003	Code of Conduct for Accreditation Body members of the IAF
IAF GD 3:2003	Guidance on Cross Frontier Accreditation
APLAC SEC 042	Code of Ethics for Laboratory and Inspection Body Accreditation Organisations
APLAC TR001	Guidelines on Training Course for Assessors
EA-2/05	The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in testing (with EUROLAB AND EURACHEM)
EA-3/01	EA Conditions for the use of Accreditation Marks previously EAL-R4, 1996 Conditions for Use of the National Accreditation Logo by Accredited Laboratories
EA-3/05	Guidelines for Training Courses for assessors used by Laboratory Accreditation Schemes
EA-3/06	Guidelines for selection of participants to Courses for the Training of assessors involved in Assessments of laboratories applying for Accreditation
EA-3/07	Programme for Course for Tutors for Assessor Training
EA-3/09	Surveillance and Reassessment of accredited organisations

Annex 3 - Overview of documents concerning MRAs and/or MLAs of relevant international organisations of ABs and RCBs

- **ILAC**

ILAC-P1:07/2007	ILAC Mutual Recognition Arrangement (Arrangement): Requirements for Evaluation of Accreditation Bodies by ILAC-recognised Regional Cooperations
ILAC-P2:2003	ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Evaluation of Regional Cooperation Bodies for the Purpose of Recognition
ILAC-P3:07/2007	ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Evaluation of Unaffiliated Bodies for the Purpose of Recognition
ILAC-P4:2003	ILAC Mutual Recognition Arrangement: Policy Statement
ILAC- P5:04/2007	ILAC Mutual Recognition Arrangement
ILAC-P6:2003	Application for Full Member Status
ILAC-P8:07/2006	ILAC Mutual Recognition Arrangement: Supplementary Requirements and Guidelines for the use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories
ILAC-P9:2005	ILAC Policy for Participation in National and International Proficiency Testing Activities
ILAC-P10:2002	ILAC Policy on Traceability of Measurement Results

ILAC-P11:2004	Monitoring Performance of ILAC Evaluators
ILAC-P12:2005	Harmonisation of ILAC Work with the Regions
ILAC: 2004	ILAC Mutual Recognition Arrangement (Arrangement):Terms of Reference and Composition of the Arrangement Management Committee

• **IAF**

IAF ML 1:2003	Procedure for Exchange of Documentation among IAF MLA Accreditation Bodies
IAF ML 2:2004	General Principles on Use of the IAF MLA Mark
IAF ML 3:2004	IAF Procedure on Responding to Inquiries on Multilateral Recognition Arrangement (MLA) Signatory Equivalence
IAF ML 4:2005	MLA Policies and Procedures
IAF ML-99-001	IAF Multilateral Recognition Arrangement
IAF–BD–00-038	IAF MLA - Procedure for Identification of Equivalence of Accreditations
IAF-GM-02-001	IAF Guidance on Completing Peer Evaluation Reports for the IAF Multilateral Recognition Arrangement

• **Joint ILAC/IAF Publications**

IAF/ILAC-A1:05/2007	IAF/ILAC Multi-Lateral Mutual Recognition Arrangements: Requirements for Evaluation of a Regional Group
IAF/ILAC-A2:05/2007	IAF/ILAC Multi-Lateral Mutual Recognition Arrangements: Requirements for Evaluation of a Single Accreditation Body

IAF/ILAC-A3:05/2007	IAF/ILAC Multi-Lateral Mutual Recognition Arrangements: Key Performance Indicators - a Tool for the Evaluation Process

• **EA**

EA-1/06	EA Multilateral Agreement
EA-1/08	EA Multi and Bilateral Agreement Signatories
EA-2/02	EA Policy and Procedures for the Multilateral Agreement

• **APLAC**

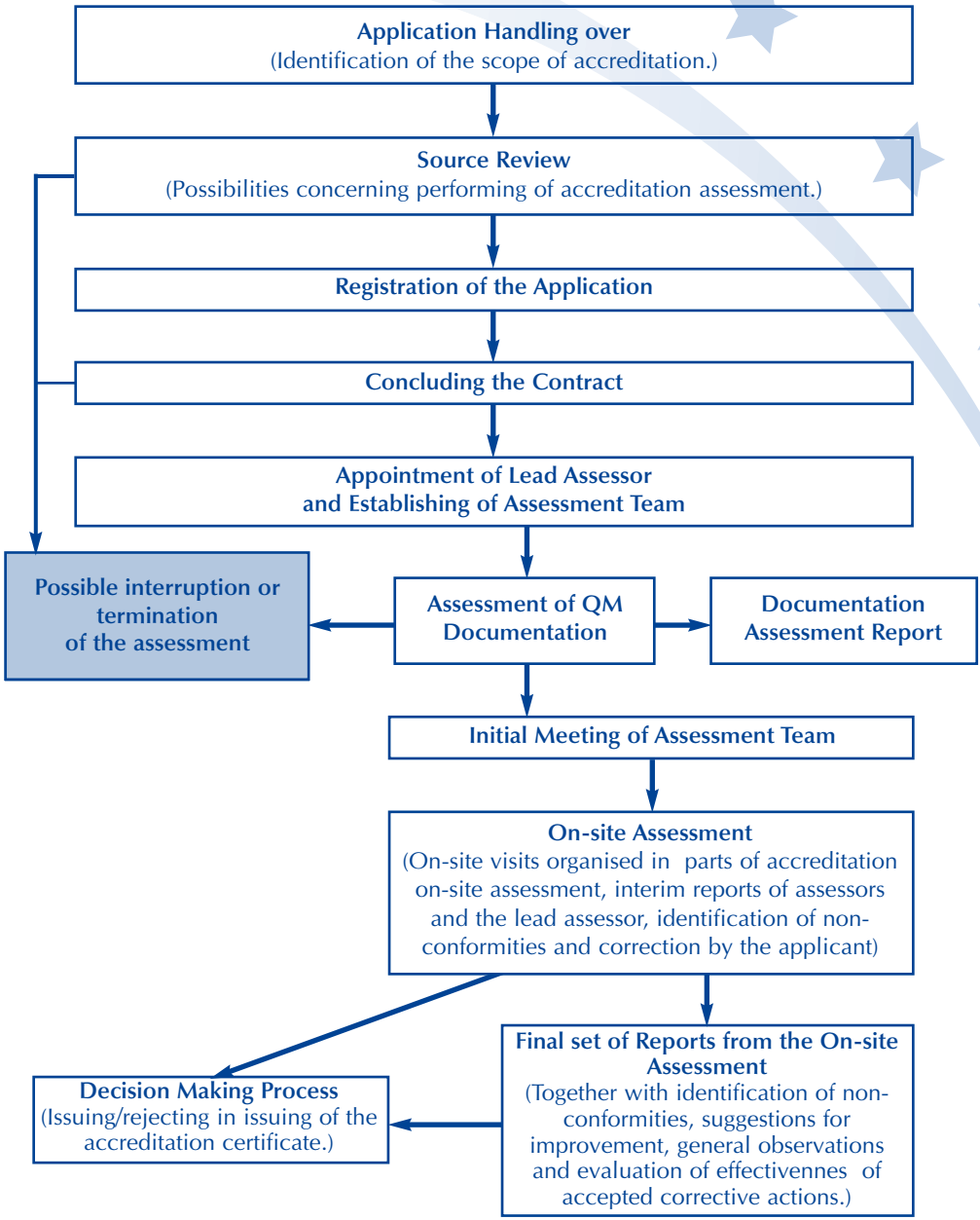
APLAC MR 001	Procedures for Establishing and Maintaining the APLAC Mutual Recognition Arrangement amongst Accreditation Bodies
APLAC MR 002	Asia Pacific Laboratory Accreditation Cooperation Mutual Recognition Arrangement (MRA)
APLAC MR 003	Application for Signatory Status in the APLAC Multilateral Mutual Recognition Arrangement (APLAC MRA)
APLAC MR 004	APLAC Evaluators – Qualifications, Training and Monitoring Performance
APLAC MR 006	APLAC Procedure for the Conduct of Joint Evaluation with Another Regional Cooperation
APLAC MR 007	APLAC Evaluation checklist
APLAC MR 008	APLAC MRA Council – Rules for Operation
APLAC MR 009	APLAC Evaluation Report Template

• **PAC**

PAC-DOC-002	PAC Multilateral Recognition Arrangement
PAC-DOC-003	Certificates of Mutual Recognition - MLA

PAC-DOC-008	MLA Appeals Procedure
PAC-DOC-009	Application to Join PAC MLA
PAC-DOC-010	MLA Policies and Procedures
PAC-DOC-018	MLA Nomination of Potential Team Members
PAC-DOC-020	PAC Procedure for Confidentiality
PAC-DOC-021	Procedure for Providing Basis for Decision of Membership of MLA Group
PAC-DOC-022	Procedure for Evaluation of Peer Evaluators Performances by the Team Leader
PAC-DOC-023	PAC Mutual Recognition Agreement - Peer Evaluation Guidance on Completing Peer Evaluation Reports
PAC-DOC-024	PAC Procedure for Internal Audit of the MLA Management Process
PAC-DOC-030	PAC MLA - Evaluation Summary Proforma
PAC-DOC-032	General Letter containing MLA Member Details
PAC-DOC-41	Evaluation by Participants of the PAC PE Workshop
PAC-DOC-42	Assessment of Trainee PAC Peer Evaluators during PAC PE Workshops
PAC-DOC-43	Peer Evaluation Feedback
PAC-DOC-047	PAC MLA Ad-Hoc Review Group Report
PAC-DOC-048	CHECKLIST - Conformity Assessment - General Requirements for Accreditation Bodies accrediting Conformity Assessment Bodies ISO/IEC 17011
PAC-DOC-049	Auditor / Reviewer Evaluation Report

ANNEX 4 – BASIC STEPS OF THE ACCREDITATION PROCEDURE



ANNEX 5 – BASIC STEPS OF THE SURVEILLANCE PROCEDURE