



# APLAC

Asia Pacific Laboratory Accreditation Cooperation

October 2003

## APLAC News Notes

Issue No. 069

**APLAC** is an organisation of laboratory accreditation bodies in the Asia Pacific area that have expressed a desire to cooperate in fostering the development of competent laboratories in member economies.

### Cooperation is to include:

- Exchange of information
- Joint training programs
- Proficiency testing
- Harmonisation of requirements
- Mutual recognition of systems meeting harmonised requirements

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**APLAC** also maintains an Internet site at:  
<http://www.aplac.org/>

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### Focus:

## The Establishment and Development of the Taiwan Accreditation Foundation

Written by Neng-Jong Lin, chairman of board, Taiwan Accreditation Foundation

Global trade liberalization in recent years has prompted many countries, regional alliances and international organizations (such as the WTO) to focus their efforts on how to efficiently verify that products and services meet environmental, health, safety and quality requirements prior to being sold or accepted. The establishment of an effective conformity assessment scheme has also become a critical trade development measure in most countries.

Since 1990, Ministry of Economic Affairs (MOEA) has promoted and implemented the Chinese National Laboratory Accreditation (CNLA) Scheme. Presently, the CNLA is a formally recognized member of the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and International Laboratory Accreditation Cooperation (ILAC). The CNLA is also a signatory to the Asia Pacific Laboratory Accreditation Cooperation, Mutual Recognition Arrangement

(APLAC MRA) as well as the International Laboratory Accreditation Cooperation, Mutual Recognition Arrangement (ILAC MRA).

In 1997, the MOEA set up the Chinese National Accreditation Board (CNAB) to carry out the accreditation of management systems and products as well as auditor certification organizations and training organizations. The CNAB is a member of such international organizations as the Pacific Accreditation Cooperation (PAC), International Accreditation Forum (IAF) and International Auditor and Training Certification Association (IATCA). It is also a signatory to the Pacific Accreditation Cooperation Multilateral Recognition Arrangement (PAC MLA) and International Accreditation Forum Multilateral Recognition Arrangement (IAF MLA).

Although the CNLA and CNAB have laid a solid foundation for the development of an accreditation scheme, further development is limited by current operations. Various competent authorities within the government have encountered problems of overlapping resources, rendering the efficient use of such resources difficult. At the same time, Taiwan must now meet the requirements of the WTO conformity assessment framework since its official admission to the international body on January 1, 2002. Conformity Assessment systems in most countries are also now moving towards the integration of accreditation resources to boost industry exports and competitiveness by creating a single window providing comprehensive

services. It is thus that the idea for developing and establishing an independent accreditation foundation was conceived.

The Taiwan Accreditation Foundation, in accordance with international standards and the principles of independence and fairness upheld by international accreditation organizations, will not intervene in current CNLA and CNAB operations. In the area of accreditation both in nationally and internationally, it will continue to use the current names of CNLA and CNAB. The Taiwan Accreditation Foundation will primarily assume the role of supervisor or manager, requiring that the CNLA and CNAB conduct accreditation work in accordance with international standards and the requirements of international organizations.



Mr. Neng-Jong Lin  
Chairman of board, Taiwan Accreditation Foundation

The Taiwan Accreditation Foundation is integrating the operations of the CNLA and CNAB with the purpose of providing independent, third party

accreditation services that meet the economic and social development needs of fairness, objectivity and independence while also meeting international regulations. The scope of its services will include the accreditation of management system certification organizations; the accreditation of product certification organizations; the accreditation of auditor certification organizations; the accreditation of auditor training organizations; the accreditation of inspection organizations; the accreditation of laboratories; proficiency testing; future advanced accreditation development; international affairs; personnel training and promotion; and other accreditation related services.

To ensure that the Foundation operates independently and objectively and accepts constructive recommendations for prospective development from all concerned, the Foundation's board shall comprise conformity assessment experts and institutions, manufacturers and providers, users, and representatives of government and non-government organizations. The Foundation will operate in accordance with international norms, taking advantage of the accumulated successes of the CNLA and CNAB during their many years of operation. It will help government agencies and the industrial sector to make use of the Foundation's accreditation services as well as the international MRA scheme to reduce redundant financial and human resource investments.

The CNLA and CNAB are already signatories to and have participated in a number of MRA schemes. Since the establishment of the Taiwan Accreditation Foundation, several short-term objectives in this regard have been established:

The first is to strengthen coordination with the various authorities in Taiwan to facilitate closer cooperation between conformity assessment mechanisms for meeting international standards, such as accreditation cooperation between designated commodity inspection laboratories, Hazard Analysis Critical Control Point (HACCP), and Occupational Health and Safety Assessment Series (OHSAS).

The second is to create a national conformity assessment database to help users from various sectors quickly obtain the information they require, i.e. the service capabilities of testing or verification organizations, look up services for conformity assessment related laws and regulations, etc.

The third is to increase participation in international conformity assessment activities such as international conferences and technology events, of which the CNLA's imminent signing of the APLAC's Bluetooth MOU is an excellent example.

The fourth is to develop conformity assessment programs for the accreditation of inspection organizations, the accreditation of information and communications security, and the accreditation of medical equipment certification. In line with the shift of Taiwan's businesses toward high value-added

industries, programs will also be developed for the accreditation of product certification organizations for nanotechnology products, functional textiles and biochemical products.

Aside from continuing to provide conformity assessment accreditation services in accordance with international standards, the Taiwan Accreditation Foundation's long-term objectives in Taiwan also include intensifying communications and coordination between conformity assessment groups, helping to set up conformity assessment organizations, and creating an overall healthy environment for conformity assessment. Internationally, the Taiwan Accreditation Foundation will continue to participate and contribute to the international community. It will gradually transform from being a beneficiary to being a contributor by actively working to become an important member of the international conformity assessment community.

## **Inspection Body MRA**

News from International Accreditation New Zealand, New Zealand

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International Accreditation Service Inc. (previously ICBO ES) of the USA, and International Accreditation New Zealand (IANZ) signed a MRA recognising accreditation of inspection bodies from respective jurisdictions.

On 9<sup>th</sup> September, the CEOs of IAS and IANZ signed an MRA for inspection body recognition. This is the first MRA for inspection signed by an American accreditation authority and is the second MRA recognising inspection body accreditation in the world. (The first MRA for inspection body recognition was signed in 1999 between IANZ and NATA.)

## **APMP General Assembly, Singapore, 1<sup>st</sup>-5<sup>th</sup> December 2003**

News from Singapore Accreditation Council, Singapore

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The 19<sup>th</sup> General Assembly of Asia-Pacific Metrology Programme (APMP) will take place in Singapore during the week of 1<sup>st</sup>-5<sup>th</sup> December 2003 at the Hotel Conard Centennial Singapore. During the week, meetings of the Executive Committee, Developing Economies Committee, and 11 technical committees will be held. A Symposium with the theme "Metrology for the 21<sup>st</sup> Century" will also be held on 3<sup>rd</sup> December 2003, in which Dr. Llew Richards from IANZ will presenting a paper "Measurement underpinning for mutual recognition arrangements of accreditation systems" on behalf of APLAC.

Details of the APMP General Assembly can be found in the following website:

<http://www.apmp2003.org/>

## **Topic: The Working Model of CNLA for Mandatory Accreditation**

Written by Nigel Jou, CNLA Secretariat

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Since its establishment in 1990, the Chinese National Laboratory Accreditation (CNLA) has been working on promoting and carrying out the accreditation services of calibration and testing fields for the industry in Taiwan.

CNLA has signed the APLAC MRA as a member in November 1997, and also signed the ILAC MRA as a member in November 2000.

The strategy for development for CNLA is based on the International Mutual Recognition Arrangement. According to this arrangement CNLA accredited laboratories are accepted by local market and government authorities.

At present, there are three working models of CNLA in the mandatory accreditation. The models are shown as follows:

1. The government authorities use the calibration/testing reports of CNLA accredited laboratories in accordance with relevant laws, such as Public Construction Commission enacted under the Government Procurement Law and Central Weather Bureau enacted under the Meteorological Law, etc. (Figure 1)
2. CNLA is designated by the regulator to operate the assessment in accordance with ISO/IEC 17025 and technical regulations for accredited laboratories, such as the Directorate General of Telecommunications enacted under the Telecommunications Act and Bureau of Standards Metrology and Inspection, MOEA enacted under the Commodity Inspection Act. (Figure 2)
3. Government approval of the laboratories and the assessments are operated by CNLA Secretariat based on the regulations of authority, such as the National Institute of Environment Analysis, EPA. (Figure 3)

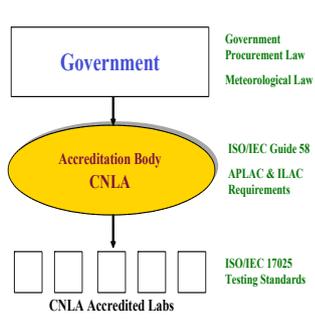


Figure 1

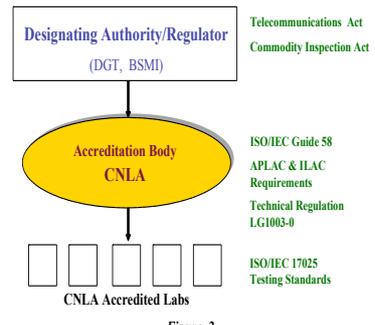


Figure 2

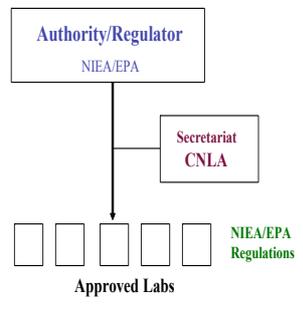


Figure 3

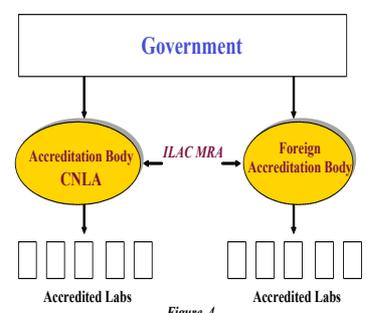


Figure 4

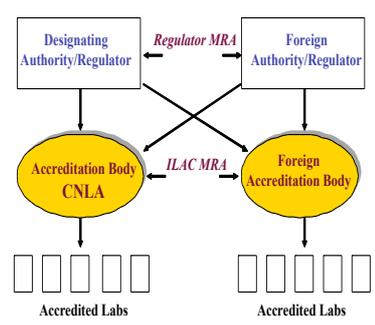


Figure 5

Figure 4 is more ideal for the use of ILAC MRA directly and Figure 5 needs to base the MRA between the regulators of MRA members. Then the ILAC MRA would be useful. The 3<sup>rd</sup> model is the most difficult to use the ILAC MRA, because the assessment standard is not based on ISO/IEC 17025. CNLA needs to persuade the authorities to operate the assessment with the equivalent standards or ISO/IEC 17025.

## Article: Medical Accreditation In CNLA

Written by Chihheng Liao, CNLA Secretariat

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A perfect healthcare system is not only determined by the quality of medical doctor but also depended on the quality of medical laboratory services. Medical laboratory services are essential to patient care and therefore have to be available to meet the needs of all patients and the clinical personnel responsible for caring of those patients. Such services include arrangements for requisition, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent validation, interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work.

Because the international accreditation tendency is toward medical testing laboratory and to improve the quality of medical laboratory in Taiwan, CNLA invited the pathologists, clinician, medical technologists, and representatives from the authorities of Department of Health, Taiwan Joint Commission on Hospital Accreditation and related organizations. These organizations are the Association of Laboratory medicine, Society of Clinical Pathologist and Taiwanese Committee for Clinical Laboratory Standards to establish the medical testing laboratory accreditation system. Since the end of 2000, there

have been 14 accredited laboratories and 7 laboratories under application. Besides, CNLA also establish the medical laboratory training courses such as quality management system, the medical laboratory director performance, and assessor training courses. There are more than 700 participants joining the quality management system training, 35 directors taking the director training courses and at least 100 specialists getting the qualification of assessor. The laboratory criteria and assessment procedure are based on ISO/IEC 17025 and ISO/DIS 15189 for specific requirement. Following the ISO 15189, 2003 published, CNLA has been organized a working group to alter the laboratory criteria. After the working group translated the ISO 15189 and discussed with all related bodies, the new criteria will be approved by the medical technical committee in Oct. Besides, CNLA will take place a training program of ISO 15189 for assessors and accredited laboratory staffs in the end of 2003. CNLA will also accept the medical laboratory application for ISO 15189 the next year.

Furthermore, CNLA will intensify mutual communications with the authorities and related bodies to build up the close relationship. After consultations with the Center of Disease Control, CNLA will be approved to assess the foreign labourers of assigned hospital in Taiwan. Meanwhile, CNLA is willing to contribute the experience of developing the medical accreditation to the international society.

**Activities:  
2004 CNLA's Proficiency Testing Programs**

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Program	Test	Field
CN03	AC Yoke Wet Fluorescent Magnetic Particle Testing	Non-destructive testing
CL01	Test for Water-Soluble Chloride Ion Content in Fine Aggregate	Construction
CL02	Test for Compressive Strength of Cylindrical Concrete Specimens	Construction
CE03	Systems and apparatus of the telecommunication and information technology	Electrical testing
CC13	Diesel Vehicle Smoke Emission for Full Load at Steady Revolution Inspection	Chemical testing
CC13	Diesel Vehicle Smoke Emission for Free Load at Acceleration Inspection	Chemical testing
CK14	Weight	Calibration
CK15	Frequency	Calibration