

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: www.aplac.org

Secretariat for APLAC:

National Association of Testing Authorities (NATA)

71-73 Flemington Road
North Melbourne VIC 3051
Australia

Telephone: +61 3 9329 1633
Fax: +61 3 9326 5148
Email: aplac@nata.asn.au

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National Accreditation Body of Indonesia (KAN)

Manggala Wanabakti Building, 4th floor
Block IV.

Jend. Gatot Subroto Street, Senayan
Jakarta 10270
Indonesia

Telephone: +62 21 574 7043
Fax: +62 21 579 029 48
Email: laboratorium@bsn.or.id

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CURRENT STATUS OF KAN ACCREDITATION



Mr. Iman Sudarwo
Chairman of KAN

In line with the increase needs on the independent services of accreditation and conformity assessment in Indonesia to better services in facilitating trade, the works of National Accreditation Body of Indonesia (KAN) is mainly focused on how our activities will benefit to all stakeholders.

At our third year after re-organization of KAN, we do believe that being credible, independent and transparent is the track to reach global recognition and acceptance. Therefore, KAN commits to provide professional and non discriminatory accreditation services. Larger trust and expectation from our clients as well as higher acceptance from Indonesian regulators encourage us to always pay attention to what they are demanding.

In term of global recognition, we keep on investing our efforts to gain recognition from our partner either accreditation bodies in the Asia Pacific region or those in global forum. By November 2003, KAN has been the mutual recognition signatories for Testing and Calibration Laboratory within Asia Pacific Laboratory Accreditation Cooperation (APLAC) and International Laboratory Accreditation Cooperation (ILAC). These are part of the milestones in our roadmap to be able to facilitate free trade, especially for the interest of Indonesia in facing globalization era.

Mr. Iman Sudarwo
Chairman of KAN

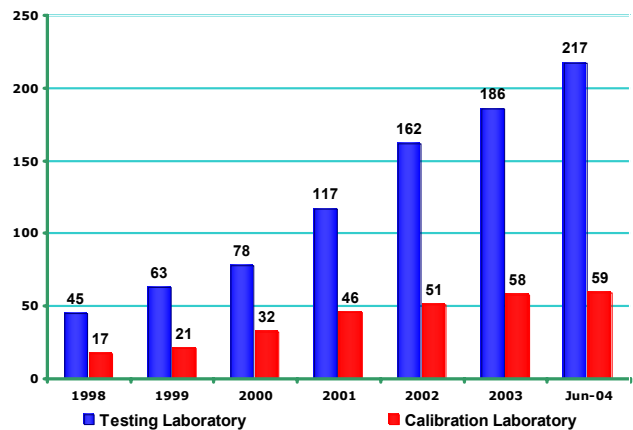
KAN Update

Current Status of Activities

As an accreditation body, acceptance of KAN accreditation system in either regional as well as international forum is a necessity in order to play its role to facilitate free trade, particularly the area of which becomes interest of Indonesia. KAN has been actively involved in regional and international organization on accreditation body cooperation. KAN is a full member of Asia Pacific Laboratory Accreditation Cooperation (APLAC), and International Laboratory Accreditation Cooperation (ILAC).

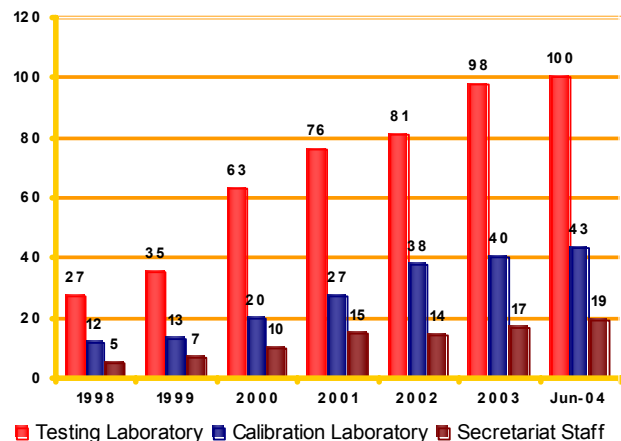
For the ultimate goal of being mutually recognized by foreign accreditation bodies as well as by foreign regulator, KAN is operated based on the existing International Standard and Guides as well as other agreed additional requirements for recognition.

The trend of the growth on the number of KAN accredited laboratories, assessors and staffs are shown in graphic.



KAN Accredited Laboratories

As of June 2004, the numbers of KAN accredited laboratories are increased in significant number.



Laboratory Assessors and KAN Secretariat Staffs

KAN recruits assessors, as well as secretariat staff, as number of laboratories and scope of accreditation steadily increase.

The Acceptance of KAN Accredited Laboratories by Indonesian Regulatory Authorities

Stipulation of Indonesian National Standard (SNI) as mandatory standard brings into a consequence that the Indonesian Government has to provide respective competence technical infrastructures like testing laboratories and product certification bodies. As of March 2004, 82 SNI have been stipulated as mandatory at

which 74 SNI are from Ministry of Trade and Industry (MTI), 7 SNI are from Ministry of Energy and Mineral Resources (MEMR) and, currently, Ministry of Agriculture (MA) constitutes 1 mandatory SNI.

During the last 2 years, MTI has stipulated almost 10 Ministerial Decrees which related to

products under mandatory SNI. In general, the decree regulates the requirements to comply with SNI for certain strategic product such as fertilizer and wheat flour. Consequently, competence testing laboratories is required to execute a part of the technical regulation. In this regard, MTI employs KAN accredited testing laboratories as far as they are available. When those accredited testing laboratories have not been available yet, the Ministry appoints certain laboratories to carry out the respective required certification. However, those appointed laboratories must seek KAN accreditation and have to be achieved within a certain time frame, generally 1 year after its appointment.

The similar scheme has been implemented by MEMR due to the mandate stated in Electrical Energy Law at which they are responsible for

safety of the electrotechnical products. The recognition by the Ministry as the regulatory authority is relied mainly on the SNI which are basically adopted from IEC standard. Similar to MTI, MEMR also has stipulated some Ministerial Decree related to the safety of electrotechnical products at which the Ministry also employs KAN accredited testing laboratories whenever available.

Very recently, Ministry of Agriculture has stipulated a technical regulation relating to 1 mandatory SNI of raw sugar. In the regulation, although the Ministry has appointed 20 testing laboratories to support the raw sugar quality control, it is also stated that those 20 testing laboratories must seek KAN accreditation no later than 2 years after being appointed.

Transfer of Testing/Calibration Laboratories Accreditation Status from Signatory of APLAC/ILAC MRA to National Accreditation Body of Indonesia (KAN)

National Accreditation Body of Indonesia (KAN) will automatically accept accreditation status transferred from accreditation bodies who are signatory of APLAC/ILAC MRA after receiving both application letter from the laboratories and recommendation letter from the accreditation bodies as far as the scopes being transferred is within KAN's scope.

KAN accredited testing/calibration laboratories at which they also hold the accreditation status from the accreditation bodies who are signatory of APLAC/ILAC MRA, their accreditation status will automatically be included into the

accreditation scopes which have been granted by KAN.

Testing/calibration laboratories which have been accredited by accreditation body who are signatory of APLAC/ILAC MRA, whereas they have not been accredited by KAN, KAN will grant new accreditation number in accordance with KAN term and regulation.

KAN will conduct confirmation on accreditation status to synchronize with KAN system.

Accreditation of NMI

In relation with the requirement for the NMI towards Global Recognition (CIPM MRA) and the requirement for traceability of measurement in accordance with the APLAC MRA Document, the Indonesian NMI (KIM LIPI) choose pathway (a) - accreditation by a signatory of APLAC/ILAC MRA for the Accreditation of Calibration Laboratory in demonstrating the implementation of its quality system based on ISO/IEC 17025 as a part of requirements of CIPM MRA.

It is planned that KIM LIPI will be assessed each measurement field separately. The assessment for the length measurement will be

conducted for three days (27 to 29 July 2004), the quality system assessor is Mr. Sunyoto, he is the senior lead assessor of KAN and previously he used to be KAN Senior Executive for the Accreditation of Laboratory and Inspection Body. While the technical assessor for length measurement is Mr. Ichiro FUJIMA from NMIJ - Japan.

It is expected that 4 (four) KIM LIPI's measurement fields, which are important in giving traceability for the standard and conformity assessment activities in Indonesia will have been assessed by December 2004, and the other measurement fields will be assessed until the middle of 2005.

KAN Workshop on Revised System of Grading Non Conformities

After its publication of ILAC Guide 20 on Grading Non Conformities, KAN has decided to adopt the Guide as the basis on revising existing KAN guide on Grading Non Conformities since January 2004. Significant changes have been made to KAN Guide, for example the impact of non conformity categorized as Category 1 ("very serious indeed"), particularly when this non conformity is reported during surveillance visit.

In order to prepare the implementation of such Guide, KAN has conducted a Workshop on 18-

19 April 2004 in Jakarta with special topic to discuss the new Guide. The workshop was attended by approximately 40 participants consisting of laboratory lead assessor, technical committee members as well as KAN Secretariat Staff. It has also been announced to all KAN accredited laboratories that the revised KAN Guide on Grading Non Conformities will be effective starting on 1 August 2004.

KAN is Preparing Accreditation Program for Medical Laboratories Based on ISO 15189

In response to the need of many applicant laboratories to be accredited based on new standard ISO 15189, KAN is now in the process of preparing criteria and other guides for such accreditation. ISO 15189 (Medical laboratories – Particular requirements for quality and competence) has been adopted and will become the main requirement. Certain supplementary requirements to ISO 15189 for specific area such as haematology, immunology etc have been being drafted to complement ISO 15189.

A technical working group responsible for preparing the accreditation criteria has been working since January 2004. The membership of the working group comes from related

association and professional in the field of medical laboratories such as Indonesian Association of Medical Laboratory Technical Expert, Association of Clinical Pathology etc, including representative from Ministry of Health as regulatory authority in Indonesia.

In addition, KAN will also participate in the APLAC ISO 15189 Workshop which will be held in Taiwan on 5 to 9 July 2004 by sending two lead assessors for testing laboratory. It is planned that the accreditation program for medical laboratories based on ISO 15189 will commence October this year.

APLAC Re-Evaluation for Testing and Calibration and Initial Evaluation for Inspection to KAN

APLAC Re-evaluation of KAN for Testing and Calibration will be conducted on 21 –26 June 2004 after having been the APLAC MRA Signatory since May 2001 for Testing and November 2003 for Calibration. At the same time, extension of MRA scope for Inspection will also be carried out by having initial evaluation for Inspection.

The APLAC Evaluator team will be led by Dr. Panadda Silva from Department of Medical Science (DMSc) Thailand, whereas team members consist of Mr. CK Cheung from HKIAS Hongkong, Ms. Sylvia Lin from CNAL Taiwan

and Ms. Kyoko Yamasaki from IA Japan. One observer from TLAS Thailand will also be in attendance. During evaluation, 5 testing laboratory onsite assessment (mechanical, veterinary, environment, agriculture products and food), 2 calibration laboratory onsite assessment and 2 inspection body onsite assessment will be witnessed. Evaluator team will also visit KIM LIPI as Indonesian National Metrology Institute.

It is expected that the outcome of this evaluation will be reported to APLAC MRA Council Meeting which will be held in Hanoi Vietnam in December this year.

News from the Secretariat

Helen, Janet, Jane
APLAC Secretariat

Congratulations and many thanks to A2LA, especially to Berta Hakes, for the excellent arrangements made for the APLAC meetings held in Columbia, MD, USA on 18-22 April. They even provided us with lovely spring weather!

The APLAC Board of Management met on 18 and 19 April and considered a number of issues, including the following:

- applications for membership from MASM, Mongolia and PNAC, Pakistan
- progress on investigation of incorporation of APLAC
- revisions to application forms (SEC 017, MR 003) to align them more with the corresponding ILAC forms
- draft guidelines document on cross-frontier accreditation
- approval of SEC 049, Maintenance and Archiving of APLAC Files

It also reviewed the corrective actions taken following the last internal audit and undertook a management review.

Members are asked to return their ballot papers on the applications from MASM and PNAC to the secretariat as soon as possible so that we can ensure a valid ballot.

The Board decided to continue investigating incorporation of APLAC in Australia and the next step is to seek legal advice on what changes are needed to the MOU and Rules of Procedure to meet incorporation legislation.

During its meeting the APLAC Chair, Peter Unger, on behalf of APLAC, signed a Deed of Agreement with NATA for the provision of the APLAC secretariat until at least the end of 2008.

On 20 April APLAC hosted an ILAC forum on accreditation for US regulators. Several US regulators attended and heard a variety of presentations including from APLAC members, US regulators and BIPM.

All agreed that the forum had assisted regulators and accreditors to better understand each other's area of activity.

The APLAC MRA Council met on 21 and 22 April. On the evening of 21 April there was the official signing ceremony for the inaugural signatories to the APLAC MRA for inspection. This part of the MRA came into force on 13 November 2003 and the signing ceremony merely formalised the process. The inaugural signatories are NATA, HKAS, IANZ, and SAC. At the same time KAN, JAB and DSM signed for the extension of their signatory status to include calibration. These extensions also had come into force on 13 November 2003.

As a result of the review of evaluation reports by the MRA Council, IAS was accepted as a signatory to the APLAC MRA for inspection. Its recognition for inspection came into force on 21 April 2004.

Other matters considered by the APLAC MRA Council at its meeting were:

- appointment of new lead evaluators
- assignment of team leaders for evaluations scheduled for 2005
- revisions to MR 001, previously approved at the November 2003 General Assembly
- proposed revision to the MRA text (MR 002) to align it more closely with the text of the ILAC Arrangement
- proposal to describe scopes of recognition in more detail
- progress with procedures for the implementation of the extension of the APLAC MRA to include RM procedures

Congratulations to Regina Robertson (NATA) and Ned Gravel (CAEAL, SCC partner) on their appointments as lead evaluators.

Either at the MRA Council meeting or by mail all APLAC MRA signatories should by now have received their APLAC recognition plaque that was organised by the APLAC Public Information Committee. You are encouraged to

display the plaque in a prominent position in your office.

All members, including Associate members, have also been sent a parcel of APLAC pens to be used as promotional material as you see fit. The pens will also be used as promotional material on the APLAC booth at the annual NCSLI meeting to be held in Salt Lake City, Utah, USA in July 2004.

Members have been invited to send a maximum of 2 representatives to a workshop on ISO 15189 to be held in Chinese Taipei in early July. The presenters of the workshop will be Regina Robertson (NATA), Phil Barnes (IANZ) and Dr Panadda Silva (DMSc). EA, IAAC and SADCA have also been invited to send participants.

The following documents have recently been or are about to be added or updated on the APLAC web site:

- **APLAC MR 002:** APLAC MRA, April 2004;
- **APLAC PT 004:** APLAC Measurement Audits;
- **APLAC PR 008:** International Recognition of Accredited Test and Inspection Reports (now includes a summary of the APLAC MRA text);
- **APLAC SEC 049:** Maintenance and Archiving of APLAC Files;
- **APLAC TC 004:** APLAC Method of Stating Test and Calibration Results and Compliance with Specification;
- **APLAC TC 005:** APLAC Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing.

Information about the APLAC 2004 General Assembly and associated meetings, to be held in Hanoi in December, will be sent out to members in the next few weeks.

Lastly, the APLAC secretariat is pleased to announce that Jane King has officially started working part-time in the secretariat. Helen and Janet welcome her most warmly.

News from APLAC Members

IANZ – New Zealand

Medical Laboratory (ISO 15189) Training

Phil Barnes, the Medical Laboratory Accreditation Programme Manager at International Accreditation New Zealand (IANZ) travelled to Hong Kong to provide a variety of short courses on the specialist topic of medical laboratory accreditation to ISO 15189. The courses were well attended and well received.

The courses were:

1. "Laboratory Quality Management to ISO 15189", a three day course attracting 24 participants;
2. "Internal Auditing for Medical Laboratories to ISO 15189", a two day course also attracting 24 participants;
3. "Preparing for Accreditation of Medical Laboratories", a two day course attracting 18 participants;
4. "Technical Assessor Training for ISO 15189", a two day course attracting 35 participants.

DMSc - Thailand

The first ISO 15189 accredited clinical laboratory in Thailand

On 30 April 2004, clinical laboratory of the Department of Laboratory Medicine, Chulalongkorn University Hospital has been accredited according to ISO 15189 by the BLQS, DMSc, Thailand.

*Prof. Dr. Navapun Charuruks, MD
Head of the first ISO 15189 accredited
laboratory was standing in front of her
laboratory.*





APLAC PUBLICATIONS LIST

Most of the following APLAC documents are available from the APLAC web site. They can also be emailed out by the APLAC Secretariat as PDF files.

Asia Pacific Laboratory Accreditation Cooperation Secretariat, 71 – 73 Flemington Road, North Melbourne, VIC 3051, Australia.
Tel: +61 3 9329 1633; fax: +61 3 9326 5148; email: aplac@nata.asn.au

APLAC Mutual Recognition Arrangement Advisory Committee

APLAC MR001	Issue No. 5 12/03	Procedures for Establishing and Maintaining Mutual Recognition Agreements Between Accreditation Bodies
APLAC MR002	04/04	Asia Pacific Laboratory Accreditation Cooperation Mutual Recognition Arrangement
APLAC MR003	Issue No. 8 06/04	Application for Signatory Status in the APLAC Multilateral Mutual Recognition Arrangement (APLAC MRA)
APLAC MR004	Issue No. 2 08/03	APLAC MRA Council Working Group on Evaluation Performance – Policy and Procedures
APLAC MR005	Issue No. 1 09/03	Procedure for Training MRA Evaluators

APLAC Nominations Committee

APLAC NC001	Issue No. 3 12/03	APLAC Nominations Committee and the APLAC Nomination Process
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APLAC Proficiency Testing Committee

APLAC PT001	Issue No. 3 03/03	APLAC Calibration Inter laboratory Comparisons
APLAC PT002	Issue No. 4 12/03	APLAC Testing Interlaboratory Comparisons
APLAC PT003	Issue No. 4 04/03	APLAC Proficiency Testing Directory
APLAC PT004	Issue No. 3 12/03	APLAC Measurement Audits
APLAC PT005	Issue No. 1 06/04	Artefacts for Measurement Audits

APLAC Public Information Committee

APLAC PR001	Issue No. 1 01/01	APLAC Publications Numbering Policy
APLAC PR003	Issue No. 2 02/01	Procedure for Adoption of APLAC Documents
APLAC PR007	Issue No. 10 06/04	Power Point Presentation - APLAC Its Role And Structure
APLAC PR008	Issue No. 13 06/04	International Recognition of Accredited Test and Inspection Reports
APLAC PR009	Issue No. 4 03/04	APLAC Procedures for Editors of APLAC News Notes

APLAC Secretariat

APLAC SEC001	Issue No. 3 12/02	APLAC Memorandum of Understanding, second edition
APLAC SEC004	Issue No. 4 12/02	APLAC Rules of Procedure
APLAC SEC009	Issue No. 41 06/04	APLAC Publications List
APLAC SEC017	Issue No. 9 06/04	APLAC Application for Membership
APLAC SEC020	Issue No. 36 06/04	APLAC General Assembly Delegates List

APLAC Secretariat

APLAC SEC021	Issue No. 15 06/04	APLAC Board of Management Membership List
APLAC SEC022	Issue No. 11 06/04	APLAC Committee Chairs and Secretaries List
APLAC SEC023	Issue No. 37 06/04	APLAC MRA Council Membership List
APLAC SEC026	Issue No. 9 11/03	APLAC Nominations Committee Membership List
APLAC SEC027	Issue No. 13 06/04	APLAC Public Information Committee Membership List
APLAC SEC028	Issue No. 16 03/04	APLAC Proficiency Testing Committee Membership List
RAPLAC SEC029	Issue No. 22 05/04	APLAC Technical Committee Membership List
APLAC SEC030	Issue No. 19 05/04	APLAC Training Committee Membership List
APLAC SEC035	Issue No. 26 06/04	APLAC MRA Signatories List
APLAC SEC036	Issue No. 2 08/03	APLAC Complaints Handling Procedures
APLAC SEC037	Issue No. 1 02/01	APLAC Document Control and Document Format
APLAC SEC038	Issue No. 14 06/04	APLAC Membership Summary List
APLAC SEC039	Issue No. 10 05/04	APLAC MRA Signatories Summary List
APLAC SEC040	Issue No. 2 06/03	APLAC Procedure for Issuing Invoices for Annual Fees
APLAC SEC041	Issue No. 1 06/03	APLAC Guidelines for Hosts of the APLAC General Assembly and Associated Meetings (only available from the Secretariat)
APLAC SEC042	Issue No. 2 07/03	Code of Ethics
APLAC SEC043	Issue No. 1 10/02	Requirements for APLAC Funding Requests
APLAC SEC044	Issue No. 2 08/03	Procedure for Appeals and Alternative Dispute Resolution Process.
APLAC SEC045	Issue No. 1 09/03	APLAC Procedure for Management Review and Internal Audits
APLAC SEC046	Issue No. 2 01/03	Guidelines for use of the APLAC Logo
APLAC SEC047	Issue No. 1 12/03	Processing Notification of Changes within an APLAC MRA Signatory Organisation
APLAC SEC048	Issue No. 1 12/03	APLAC Register of Delegated Responsibilities
APLAC SEC049	Issue No. 2 06/04	Maintenance and Archiving of APLAC files

APLAC Technical Committee

APLAC TC002	Issue No. 2 02/04	APLAC Internal Audits for Laboratories and Inspection Bodies
APLAC TC003	Issue No. 2 02/04	APLAC Management Review for Laboratories and Inspection Bodies
APLAC TC004	Issue No. 2 03/04	APLAC Method of Stating Test and Calibration Results and Compliance with Specification
APLAC TC005	Issue No. 2 03/04	Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing

APLAC Training Committee

APLAC TR001	Issue No. 1 12/01	Guidelines on Training course for Assessors
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