APLAC
Asia Pacific Laboratory Accreditation Cooperation

June 2005 APLAC NEWS NOTES Issue No. 80

APLAC is an organization 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
- Harmonization of requirements
- Mutual recognition of systems meeting harmonized requirements

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www.aplac.org

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The next issue will be published in August 2005 by Thailand (DSS, DMSc, TLAS)

APLAC/ILAC Meetings in Narita, Japan

International Accreditation Japan (IAJapan)

A series of APLAC meetings and the APLAC Lead Evaluator & ISO/IEC17011 Workshop was held on 21-27 April 2005 at Hotel Nikko Winds Narita, Narita, Japan. Japan Laboratory Accreditation Cooperation (JLAC), which is formed by four Japanese accreditation bodies, namely IAJapan, JAB, JCLA, and VLAC hosted these meetings. IAJapan also hosted ILAC Accreditation Committee (AIC) meeting at the same hotel on 28-29 April 2005.

APLAC meetings: The Board of Management was convened on 21 and 27 April, and the MRA Council met on 25-26 April. Forty-two delegates from 20 economies gathered for the MRA Council.

APLAC Lead Evaluator & ISO/IEC 17011 Workshop: The APLAC Lead Evaluator & ISO/IEC17011 Workshop took place on 22-24 April. There were 42 participants from 20 economies in this workshop.

ILAC AIC meeting: ILAC Accreditation Committee (AIC), which was chaired by Ms. Merih Malmqvist from SWEDAC, was held on 25-26 April. A number of accreditation issues were on the agenda, such as implementation of ISO/IEC 17011 and new ISO/IEC 17025. Twenty-two committee members and two observers from 18 economies around the world discussed such issues.




Photos APLAC/ILAC meetings in April, NARITA

Report from Secretariat

Helen Liddy, Janet Clark, Jane King
APLAC Secretariat

Many thanks to Japan for their excellent arrangements for the APLAC ISO/IEC 17011 training course and meetings held in Narita on 21–27 April. Special thanks to Dr. Katuo Seta, Oh Shin, Takako Suzuki and Yoshinobu Uematsu.

The training course on ISO/IEC 17011 for APLAC lead evaluators and representatives of APLAC full members that do not have lead evaluators went very well. The presentations by the facilitators, Peter Unger, Barry Ashcroft and Panadda Silva were entertaining and thought provoking. Many thanks to them for all their hard work. The PowerPoint presentations for the course and the group reports on the course exercises will be posted on the 'members only' section of the APLAC website in the next few weeks. Once they have been posted the secretariat will e-mail all members advising them of this.

The APLAC Board of Management met on 21 and 27 April. Topics covered included:

- the appointment of Chang Kwei Fern of SAC as the APLAC Treasurer until 31 December 2006;
- a management review of APLAC's operations;
- incorporation of APLAC in New Zealand;
- a review of ISO/IEC17011 training course reports from the Chairs of APLAC committees;
- a proposal to restructure the APLAC Nominations Committee;
- progress with the ILAC evaluation of APLAC
- APLAC's response to the ILAC Business and Strategic Plan;
- the date for APLAC 2006.

We are progressing with the incorporation of APLAC in New Zealand under the Incorporated Societies Act. In the next few weeks a second draft of the new APLAC Constitution will be sent out to members for a 60 day comment period. You are encouraged to review the draft and send in your comments.

The APLAC MRA Council met on 25 and 26 April. Congratulations to IAS (USA) whose APLAC MRA recognition was extended to include calibration. We have recently sent out to two 30-day postal ballots;

- application for full membership by L-A-B (USA) (one vote per full member)
- issue 3 of APLAC MR 004, Evaluator Performance (one vote per economy)

Please take time to read the ballots and return your completed ballot paper. As agreed at the General Assembly in Hanoi, the secretariat is now keeping a record of members' responses to postal ballots and the results will be tabled at each General Assembly meeting. When the new APLAC application forms were re-signed by members last year, the representatives of each member accepted, as an obligation of membership, the need to return postal ballots within the prescribed timeframe.

Members have recently been advised of the updates to the following APLAC documents that are now available on the APLAC website:

- APLAC MR 002, MRA text
- APLAC MR 003, application for MRA signatory status
- APLAC PT 003, PT directory
- APLAC PT 004, measurement audits
- APLAC PR 007, APLAC PowerPoint presentation
- APLAC SEC 017, application for APLAC membership

TISI, Thailand has recent sent out to members invitations for APLAC 2005. Please book your hotel room early as Chiang Mai is a busy place in mid-November. Please also register early and remember that the registration fee can only be paid in USD in cash on arrival for the APLAC meetings.

We have recently emailed members advising that APLAC 2006 will be held in Taipei, Chinese Taipei in the week 10 – 15 September 2006. We have had to select an earlier date than usual as, although a specific date has not yet been set, we understand that ILAC 2006 will be in mid-November 2006.

Photo APLAC Lead Evaluator Training

Report from MRA Council – Working Group

APLAC Workshop on Reference Material Producer Accreditation

W. W. Wong
Hong Kong Accreditation Service (HKAS)

At the 14th APLAC MRA Council meeting, it was resolved that a workshop be held in Hong Kong to discuss issues related to a possible extension of the APLAC Mutual Recognition Arrangement (MRA) to cover accreditation of reference material producers (RMPs). The MRA Council also resolved that the timeline for the work of RMP MRA Working Group only be finalized after the outcome of the workshop is reviewed at the April 2005 MRA Council meeting. The following are the expected deliverables from the workshop:

- Technical issues relevant to accreditation of RM producers;
- Exploration of the extent of interest in an extended APLAC MRA to cover accreditation of RM producers;
- Possible mechanics for implementing a potential extension of the APLAC MRA to include accreditation of RM producers;
- Draft advice on practices in the accreditation of RM producers.

The workshop was held on 11 and 12 March 2005 and was attended by 20 representatives from 14 APLAC accreditation bodies from 12 economies. A representative from InterAmerican Accreditation Cooperation (IAAC) also attended the workshop.

The workshop was divided into four sessions, each dedicated to a specific topic and led by a facilitator. Three facilitators were invited. They were:

- Dr. Ed de Leer, Chair. of International Advisory Group on Reference Materials (IAGRM) and Director of Science of NMi Van Swinden Laboratorium, Dutch National Measurement Standards Institute;
- Dr. Robert Watters, Chief, Analytical Measurement Division, National Institute of Standards and Technology, and
- Mr. Alan Squirrell, ILAC Secretary.

Mr. Tony Russell, Chair of APLAC also attended the workshop. Mr. W. W. Wong of HKAS is the convener of the APLAC Working Group on Reference Material Producers. He explained the purpose and expected deliverables of the workshop. The workshop identified a number of issues and action items. The workshop also recommended that the APLAC MRA should be extended to cover accreditation of RMPs. A report on the workshop was presented to the APLAC MRA Council in April.

The following are some key conclusions of the workshop.

1. APLAC should proceed with the extension of the current APLAC MRA to cover accreditation of RMPs. A timeframe of now to two years from now has been suggested.
2. Some amendments have been identified at the workshop. ISO/REMCO should be informed of the suggested amendments to ISO Guides 31, 34 and 35 and requested to consider them in the next revision of the Guides.
3. Five modes of operation of RMPs were envisaged – ranging from performing all testing activities by the RMP to outsourcing all testing activities. A matrix showing the application of ISO/IEC 17025 and ISO Guide 34 to these modes of operation should be developed.
4. Variations in the description of scopes of accreditation were identified. Harmonization of the description of scopes of accreditation is suggested.
5. A global workshop is suggested to discuss the interpretation and implementation of ISO/IEC 17025, ISO Guide 34 (and other relevant ISO Guides and Standards) and the accreditation body requirements for accreditation of RMPs.

Photo APLAC Reference Material Workshop in Hong Kong

Reports from Members

Accreditation Programme for Gemstone Testing Laboratory in Hong Kong

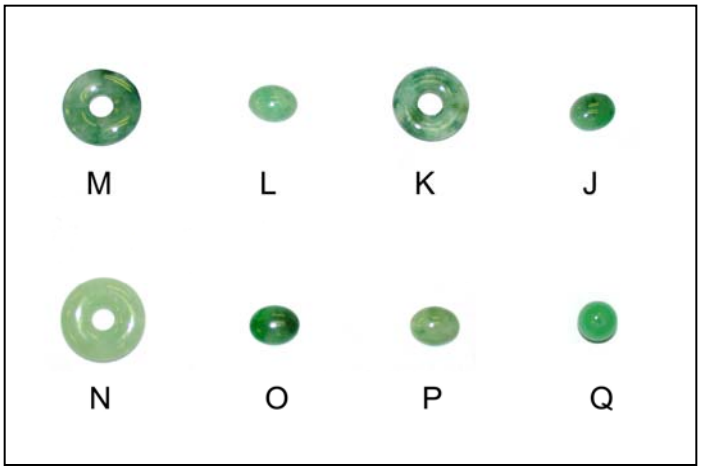
Honk Kong Accreditation Service

A new accreditation programme for gemstone testing laboratories was launched by the Hong Kong Accreditation Service earlier this year. Four laboratories have already been accredited for performing physical tests for identification of jadeite jade and some other applications are being processed.

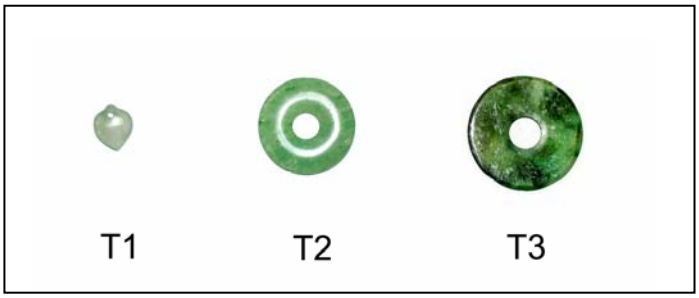
This programme is an example of successful collaboration between HKAS and the industry. Knowing that a credible laboratory accreditation programme will help to enhance the image and credibility of Hong Kong's gemstone industry and facilitate cross border trade, the industry invited HKAS to set up the programme in early 2004. The first problem encountered was the difficulty in finding suitable standard testing methods. After an intensive literature search, review and discussion, the industry determined that it was most suitable to set up local standards for the tests. Thus a group of local gemmologists, academia and representatives from gemstone and jewellery associations was established to draft the "Standard Methods for Testing Jadeite Jade for Hong Kong". After a lot of hard work, the standard was finally published by the Gemological Association of Hong Kong in early 2005. On the other hand, a Task Force under the Accreditation Advisory Board of HKAS was formed to establish the accreditation criteria. This Task Force has strong representation form the industry.

As part of the gemstone accreditation programme, HKAS has collected a set of reference jadeite jades exhibiting various degrees of important characteristics, including transparency, ultraviolet fluorescence, chelsea color filtering, polariscopic identification and refractive index, etc. (Pictures 2 and 3 show two examples of reference jadeite jades). Using these reference jadeite jades as artifacts, a proficiency test covering all the 13 standard jadeite jade tests included in the Hong Kong standard was carried out. The findings indicated that results from most participant laboratories were in agreement. (Picture 1 shows the eight pieces of jadeite jade for the proficiency test.)

The accreditation of laboratories for jadeite jade physical tests is the first stage of the gemstone testing accreditation programme. HKAS is studying to extend the programme to cover jadeite authentic verification and diamond identification and grading. Accreditation for identification of other colored gemstones, i.e. ruby, emerald & sapphire, may also be provided.



Picture 1 Eight different variety of jades (numbered from J, K, L, M, N, O, P, and Q) including natural, dyed, resin impregnated, enhanced and treated jadeite jades were used as artifacts in a proficiency test.



Picture 2 Reference jadeite jades for various degrees of transparency (Transparent T1, Translucent T2 and opaque T3)

Picture 3 Reference jadeite jades for various degrees of ultraviolet fluorescence (Strong UV1, Medium UV2, Faint UV3and Inert UV4)

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The First Accreditation to ISO 15189 Issued in Hong Kong

Bella Ho, Senior Accreditation Officer (Medical Testing)
Hong Kong Accreditation Service

A medical virology laboratory of the Department of Health of the Hong Kong Special Administrative Region (HKSAR) Government has become the first laboratory in Hong Kong accredited under the medical testing programme of the Hong Kong Laboratory Accreditation Scheme (HOKLAS). HOKLAS is operated by the Hong Kong Accreditation Service (HKAS). The accreditation was granted to the laboratory in early March 2005. HKAS is a section within the Innovation and Technology Commission of the HKSAR Government.

HOKLAS is a voluntary scheme open to testing and calibration laboratories in Hong Kong. The accreditation standard used for non-medical test areas is ISO/IEC 17025:1999. Medical testing was first added to the service of HOKLAS in February 2004. The accreditation criteria used is the new international standard for medical laboratories, i.e. ISO 15189:2003 *Medical laboratories – Particular requirements for quality and competence*. Hong Kong is among the first accreditation bodies in adopting ISO 15189 to accredit medical laboratories. To prepare for launching of the new programme, HKAS has in the past two years provided assessor training to over 70 professionals and experts in the medical field. After observing an assessment, these trained potential assessors would be officially appointed. Up till now, over 20 medical assessors in different pathology disciplines had been appointed.

Although there is no regulatory requirement in Hong Kong for medical laboratories to be accredited, this new programme aroused attention in the local medical field, because many laboratories have decided to demonstrate their competence through accreditation. Public and private medical laboratories providing diagnostic testing services in five pathology disciplines - anatomical pathology (including autopsy, histopathology and cytology), chemical pathology, clinical microbiology and infection, haematology (including general haematology and blood banking), and immunology - can seek accreditation under HOKLAS. Medical laboratories accredited by HKAS under HOKLAS will be categorized into either "P" or "S" to denote laboratories directed by "Pathologist" or "Scientist" respectively. To introduce the HOKLAS accreditation criteria, HKAS has organized a series of training courses for laboratories. A number of medical laboratories have started preparation for accreditation.

Experience gained in establishing and implementing the programme

Both the launching of the medical testing programme and the successful accreditation of the first medical laboratory to ISO 15189 provided HKAS valuable experience in applying the new standard. The medical testing programme of HOKLAS has been established through cooperation and thorough discussion among stakeholders. Though there were differences in the interpretation of some requirements of ISO 15189 e.g. requirements of Laboratory Director, different parties worked together and came up with the current programme that is accepted and supported by all stakeholders. Our experience showed that it is essential to have good cooperation and relationship with various stakeholders such as the professional bodies representing the pathologists, scientists and medical laboratory technologists, the private laboratories, and associations and unions representing different interests.

Preparation for obtaining accreditation

As any new accreditation programmes, it was expected that medical laboratories would encounter difficulties when they started to implement the accreditation criteria. HKAS had put in a lot of effort to explain the accreditation criteria and requirements to staff of medical laboratories. Feedback showed that team spirit and staff morale of laboratories pursuing for accreditation had been heightened through the preparation for accreditation and the accreditation process itself. Laboratory staff began to appreciate the value of setting up a quality system and changes that could be achieved through accreditation.

Technical issues

On the whole, HKAS did not experience much difficulty in applying the requirements of ISO 15189. However, the following observation is worth noting.

Measurement uncertainty

Measurement uncertainty is certainly a concern of many medical laboratories. The current international consensus is that it is only applicable to quantitative measurements. Therefore, qualitative or semi-quantitative test results such as those of clinical microbiological tests, calculation of MU is currently not necessary. Experience in applying MU to other pathology disciplines, in particular chemical pathology, is still very limited.

In order to meet the accreditation requirement, many laboratories preparing for accreditation are exploring ways

to deal with the calculation of measurement uncertainty and its routine application; and they have arranged training seminars to introduce the concept of MU to their staff. Similar seminars are also arranged by medical professional associations for their members. More international guidance documents on MU in medical testing would certainly be welcome by the medical laboratories. In fact, much work is ongoing internationally.

The establishment of the Joint Committee on Traceability in Laboratory Medicine (JCTLM) by the Bureau International des Poids et Mesures (BIPM), International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), and International Laboratory Accreditation Cooperation (ILAC) is an important step to help laboratories in measurement traceability and uncertainty. The listing of the reference materials and reference measurement procedures by JCTLM is of great help to laboratories. Manufacturers of diagnostic testing kits could also contribute to building up knowledge on MU through provision of relevant information on traceability of the reference materials used in their diagnostic kits. With the current pace of development and the concerted effort put in by various parties, the medical professionals will soon pick up.

Quality Assurance Programmes

Participation in external quality assurance programme presents no great difficulties to most laboratories in Hong Kong. However, some reputable external quality assurance programmes are not accredited to any standard. This raised the question of whether their operation is "in substantial agreement with ISO/IEC Guide 43" as required in ISO 15189. While a number of external quality assurance programmes already claimed to be accredited to ISO/IEC Guide 43 or ILAC G13 or both, there is still no international consensus on whether ISO/IEC Guide 43 could be used as the sole accreditation criteria for proficiency testing providers. Lacking of a clear indicator on the quality and standard of external quality assurance programmes presents some difficulties to accreditation bodies.

MRA Acceptance by the Taiwanese Regulator: a Success Story

CNLA/Taiwan Accreditation Foundation

The Taiwanese regulator, the National Treasury Agency at the Ministry of Finance, will implement new regulations on 1st July 2005 pertaining to the permissible content of alcoholic beverages. These new regulations, established pursuant to the existing Tobacco and Alcohol Administration Law, specify clearly the maximum tolerable amounts of impurities such as methanol, lead, and sulphur dioxide.

Since early 2004, CNLA/TAF has been entering into negotiations with the regulator with the goal of lessening the impact that these new regulations might have on the Taiwanese alcohol market (e.g., technical barriers to trade). Initial face-to-face contact and over-the-phone conversations facilitated the progress of including CNLA/TAF accreditation into the regulatory process. Then, in March 2004, CNLA/TAF conducted a domestic Proficiency Testing Program to demonstrate to the regulator the competence of its alcohol-testing laboratories. We later had the pleasure of announcing, at an event to inform our alcohol-testing laboratories of the new regulations, that the regulator would indeed be accepting CNLA/TAF accreditation, and would be making use of their accredited alcohol-testing laboratories.

CNLA/TAF had been actively working to promote the use of the accredited alcohol-testing laboratories of their MRA member ABs. To smooth the process of acceptance by the regulator, CNLA/TAF had striven to demonstrate the equivalent technical competence of these alcohol-testing laboratories by applying the international APLAC Proficiency Testing Program T021. Thanks to these efforts, the National Treasury Agency eventually agreed to accept testing reports issued by accredited alcohol-testing laboratories, according to lists provided by the ILAC MRA member ABs.

The ultimate goal would be for the regulator to recognise the common ILAC MRA-Mark without need to refer to such lists. CNLA/TAF will continue to do everything it can to achieve this goal.

JAB Starts Inspection Body Accreditation Programme

Yuichiro Isu, Executive director,
Japan Accreditation Board for Conformity Assessment (JAB)

JAB is pleased to announce the launch of its Inspection Body (IB) accreditation programme, based on ISO/IEC 17020: 1998 *General criteria for the operation of various types of bodies performing inspection.* The first assessment will be conducted in August.
The IB accreditation programme was presented to the public on 5 October 2004 at a JAB seminar in Tokyo. About

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forty people, mainly from the inspection industry, participated in the seminar, at which the following topics were explained:

- conformity assessment;
- ISO/IEC 17020;
- IAF/ILAC Guidance on the application of ISO/IEC 17020
- inspection body;
- accreditation body;
- difference between "inspection", "testing" and "product certification".

IAJapan is developing the Accreditation Programme for Remote Calibration "e-trace"

International Accreditation Japan (IAJapan)

IAjapan has recently started joint activity with the National Metrology Institutes, Japan (NMIJ) to establish an accreditation programme for the remote calibration.

Since economy has been more globalized, the demand for the calibration services with higher accuracy and less cost is increasing in various fields.

In this circumstance, the NMIJ has developed a remote calibration technology so-called "e-trace" by utilizing information and telecommunications networks, e.g. internet, fiber optic networks and the Global Positioning System (GPS). This technology enable calibrations to be quicker and with more reasonable price. At present, it is applicable to the fields of time & frequency, length, electric current and radioactivity, etc. The trial of the frequency calibration by using GPS signal between NMIJ and a laboratory in China has been successfully demonstrated in early 2005.

The feature of the "e-trace" is different from traditional calibrations. For instance, the instrument to be calibrated is controlled remotely without sending any laboratory staff to the client site. There are two key issues for this type of calibration, the one is creditability of remote control and the other is data security. Hence, some interpretations of ISO/IEC 17025 requirements are necessary for implementing accreditation of the laboratories that perform this type of calibration.

IAJapan is now finalizing the application guideline for the remote calibration within its technical committee and will start accreditation in some fields in the near future. It has asked ILAC AIC to discuss this issue in the forthcoming meeting in Auckland.

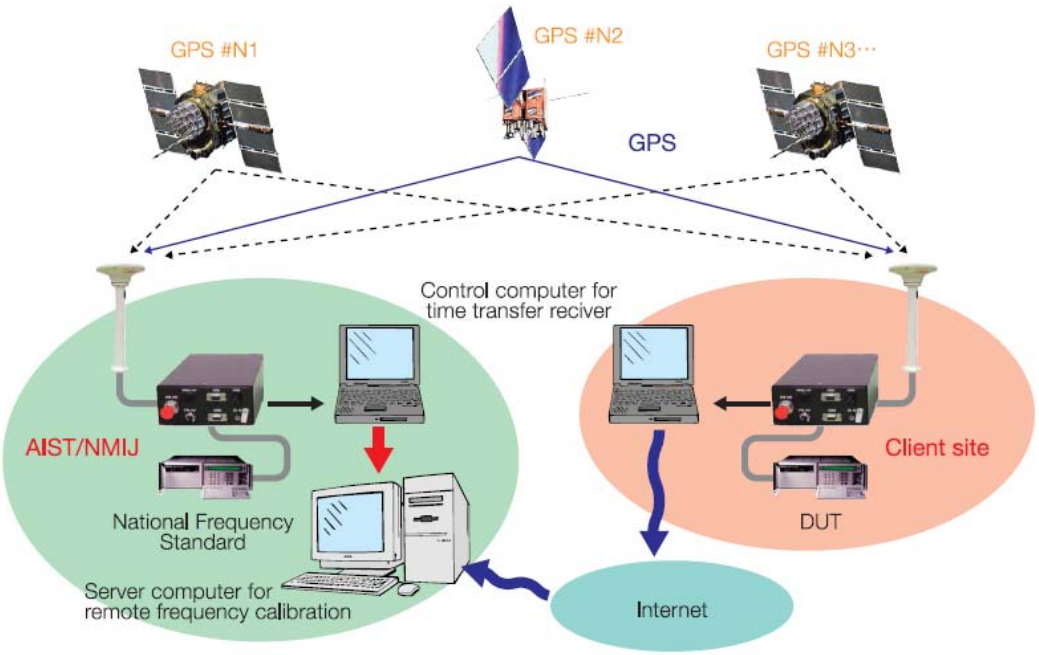

Figure1 Frequency remote calibration using GPS common view method

Utilizing the information and telecommunication technology (e.g. Internet, optic fiber networks, GPS, etc.), the "e-trace" aims to promptly; reasonably and accurately provide Measurement standards, which are the foundations of quality assurance.

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Revision of JNLA Programme

International Accreditation Japan (IAJapan)

The newly amended Japanese Industrial Standardization (JIS) Law, promulgated on 9 June 2004, has been enforced since 1 October 2004. With this enforcement of the amended law, Japan National Laboratory Accreditation Program (JNLA) has also been modified.

The new JNLA accreditation programme supports "self-declaration" of conformity of products with JIS standards. In addition, JNLA accreditation is utilized for the new JIS marking system, product certification.

The Scope of the accreditation has been extended

To support new self-declaration and JIS marking system, the scope of the accreditation of the JNLA programme has been extended from limited number of test methods to all test methods specified by JIS standards. The new programme is expected to be more widely used in various industries.

According to the extension of the scope of the accreditation field has been changed. The accreditation fields as of 1 October 2004 are as follows:

- Civil Engineering and Architecture
- Mechanical Engineering
- Electronic and Electrical Engineering
- Automotive Engineering
- Railway Engineering
- Ferrous Materials and Metallurgy
- Non-ferrous Materials and Metallurgy
- Chemical Engineering
- Textile Engineering
- Mining
- Pulp and Paper
- Ceramics
- Domestic Wares
- Medical Equipment and Safety Appliances
- Miscellaneous (Packaging, Welding, Radioactivity) Radioactivity.

New Accreditation Symbols for IAJapan's Accredited Laboratories

International Accreditation Japan (IAJapan)

Based on the "ILAC MRA Mark License Agreement" between ILAC and IAJapan in 2004, IAJapan has started contracting "ILAC MRA Mark Sublicense Agreement" with its accredited laboratories for the use of the "Combined Accreditation Symbol" since 1 April 2005. IAJapan is planning to sign the contract of the Sublicense Agreement with all accredited laboratories by the end of 2005.

The laboratories that have drawn up the sublicense agreement are asked to replace with the "Combined Accreditation Symbol" from the date of the Contract. Laboratories are also asked to cease using the old accreditation symbol from 1 January 2006.

The new IAJapan "Combined Accreditation Symbols" are shown as below:

For JCSS

For JNLA

For ASNITE

Finis