ISO 9001, ISO 9002, ISO 9003 - what, if anything, do these international standards tell us about laboratory competency? Very little if the truth be known!

Since the introduction of these international quality management standards in 1987 and the hype that followed, it has become fashionable to seek certification to one of the ISO 9000 standards. Today, unfortunately, many companies are seeking ISO 9000 not primarily to improve their quality practices but as a quality credential to satisfy their customer’s demands. In other words, the primary reason for seeking ISO 9000 certification does not necessarily determine the effectiveness of the process or the value of the outcome.

ISO 9000 certification has been interpreted by many customers as “the quality credential” regardless of the circumstances. However, laboratory customers should really be asking for technical accreditation of the laboratory based on ISO/IEC 17025 (formerly ISO/IEC Guide 25). This is a far more effective demonstration of a laboratory’s technical competence than ISO 9000. Compliance with ISO/IEC 17025 is a requirement of HOKLAS Accreditation.

Both ISO/IEC 17025 and ISO 9000 have similar quality requirements. So what is the advantage of HOKLAS Accreditation over ISO 9000 certification? HOKLAS Accreditation covers not only the generic quality management requirements of ISO 9000 but extends its criteria to cover aspects affecting technical competency (i.e., the accuracy and precision of the analytical data produced). These more laboratory-specific criteria include:-

ISO 9000 Accreditation - What does it all mean!

By Mr. Richard Fung, ALS Technichem (HK) Pty Ltd
The Industry Department, under which HKAS has operated until 30 June 2000, was disestablished on 1 July 2000. As from that date, HKAS operates under the newly established Innovation and Technology Commission (ITC). Apart from the fact that the position of the Head of HKAS has been taken over by the Commissioner for Innovation and Technology, all operations of HKAS remain unchanged.

- the technical qualifications, experience and competence of the staff
- the suitability, calibration and maintenance of analytical equipment
- the adequacy of quality control procedures
- the validity, appropriateness and adherence to sampling and testing procedures
- recording, reporting and review of test data
- suitability of the laboratory environment
- participation in available proficiency testing programs

Upon the establishment of Innovation and Technology Commission under which HKAS now operates, our website address has been changed. The new address is www.info.gov.hk/itcc/hkas/

The contents and arrangement of our website however remain largely unchanged. The email address has correspondingly been changed to hkas@itc.gov.hk

The 1996 publication of the ISO 14000 series of standards for environmental management systems has also resulted in some customers requesting the laboratory be certified to this particular standard. It must be realised that these ISO 14000 standards have nothing whatever to do with the technical performance of analytical laboratories but are intended for use as a voluntary, internal management tool for good environmental compliance, not as a specification standard.

If some confusion still exists regarding the appropriate certification or accreditation you require of the laboratory that you use, then you should discuss this further with HKAS Executive.
ISO/IEC 17025: 1999 “General Requirements for the Competence of Testing and Calibration Laboratories” was published on 15 December last year. This standard replaces and cancels ISO/IEC Guide 25: 1990. ISO/IEC 17025 has been produced as a result of extensive experience in the implementation of ISO/IEC Guide 25. It contains all the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results.

This new international standard will be adopted by HOKLAS as the technical requirements for laboratory accreditation. HOKLAS 003 'Technical Criteria for Laboratory Accreditation' has been revised to make it in line with this new standard. The sixth edition of HOKLAS 003 was published in July. The format of this new edition is the same as the previous one. The requirements and notes of ISO/IEC 17025:1999 are reproduced as the main text and relevant HOKLAS policy is given in shaded boxes following the main text.

To assist laboratories to comply with the requirements, reference to information and guidance published by international and regional laboratory accreditation cooperations such as International Laboratory Accreditation Cooperation (ILAC), Asia-Pacific Laboratory Accreditation Cooperation (APLAC) and European Cooperation for Accreditation (EA) have been included as an appendix.

Copies of this new edition of HOKLAS 003 have been sent to all accredited and applicant laboratories, assessors and other interested persons. Laboratories and HOKLAS assessors have been invited to attend a seminar on this new standard to be held on 15 September 2000. The implementation schedule for this new edition is given below.

| 1 July 2000        | - HOKLAS 003 based on ISO/IEC 17025 published  |
|                   | - Applications for accreditation to ISO/IEC 17025 accepted |
|                   | - Accredited laboratories may elect to be reassessed to ISO/IEC Guide 25 or ISO/IEC 17025 |
| 1 January 2001    | - Applications for accreditation to ISO/IEC Guide 25 cease |
|                   | - Reassessments and assessments for extension of scope based on ISO/IEC 17025 |
| 1 January 2002    | - All accredited laboratories should comply with ISO/IEC 17025 |
The need for a common assessors training course was identified during the APLAC Training Committee meeting held at New Delhi in December last year. It was also agreed that a mock training course would be held based on a syllabus drafted by the Committee. The aim of the mock course is to provide a chance for interested members to have a full and in-depth understanding of the contents of the course. In this way, they could evaluate the course syllabus in detail and provide feedback, particularly on the course’s applicability to their own operational needs and cultures. The mock course also aims at giving trainers from member economies a chance to share experience and to improve their own training courses. All participants agreed that harmonization of their existing training courses amongst member economies is a bonus to this mock course. The draft course syllabus will be revised to include the feedback from the participants.

The Common APLAC Assessor Training course aims to provide the necessary training to laboratory assessors. By successfully completing this course, the trainees will satisfy the training requirement of ILAC for assessor. Having a common assessor course syllabus will greatly enhance the confidence amongst member economies of APLAC, which underpins the APLAC Mutual Recognition Arrangement.

The organizer wishes to thank all participants for their active participation in the discussion. We are particularly grateful to Dr. Max Robertson, Mr. Daren Valentine and Mr. Ivan Waple for their voluntary services in presenting the mock course. Without their kind assistance, we would not see the realization of the mock course.
The acceptance of test and calibration reports by foreign users of laboratory services has been greatly enhanced by Mutual Recognition Arrangement (MRA). MRAs between accreditation bodies are non-governmental arrangements whereby an accreditation body recognises that the accreditations granted by the other signatories are technically equivalent to its own. The acceptance of test and calibration reports of exporting economies by importing economies is a major step toward eliminating technical barrier to trade (TBT) and has thus facilitated the free trading of goods - a major mission of the World Trade Organisation (WTO). Currently, HOKLAS endorsed test reports are recognised by 29 overseas accreditation bodies through the APLAC and EA multilateral MRAs. MRA is established and maintained based on a "peer evaluation" process. Representatives from member accreditation bodies of APLAC or EA are selected to form an evaluation team. Applicants to the MRA are evaluated by the evaluation team against ISO/IEC Guide 58 "Calibration and testing laboratory accreditation systems - General requirements for operation and recognition" and the APLAC MR-001 "Procedures for the Establishing and Maintaining Mutual Recognition Agreements between Laboratory Accreditation Bodies", or other procedures of regional laboratory accreditation cooperations. Existing signatories to the MRA are also required to be re-evaluated once every four years to maintain their signatory status.

In view of the growing number of signatories to the APLAC multilateral MRA, which now stood at 13, APLAC envisaged the need to expand the list of evaluators. As a consequence, a five-day training course for the training of APLAC evaluators was held in Sydney, Australia on 3-7 April 2000. Five experienced lead evaluators presented the course for 26 participants from APEC / APLAC member economies. The course was funded by the APEC Trade Investment Liberalisation and Facilitation (TILF) programme and the Australian Government. HKAS was represented by Dr. L.H. Ng, Executive Administrator, who was one of the presenters and by Mr. C.K. Cheung, Senior Accreditation Officer.

The contents of the course comprised a thorough introduction of ISO/IEC Guide 58, APLAC MR001 and other relevant APLAC and ILAC documents. Role plays on how to conduct peer evaluations of accreditation bodies were conducted and evaluation techniques and cultural and language issues were discussed. This course provided an interactive forum for the participants of APLAC member economies to discuss MRA evaluation issues. The vigorous discussions and exchange of views between the presenters and participants during the five-day session will no doubt result in a more structured and consistent approach for future APLAC evaluations. This in turn will enhance confidence in the process for admitting members to the APLAC multilateral arrangement and hence add value to the agreement. Moreover, the provision of more trained evaluators will help expedite the peer evaluation of new APLAC MRA member economies in the Asia Pacific region. The ultimate aim is to facilitate free trade and prevent technical barriers of trade between economies in APEC and eventually between economies in APEC and other economies globally when APLAC joins the multilateral arrangement of the International Laboratory Accreditation Co-operation.
There has always been a strong demand for foundation testing in the construction industry. Whilst some foundation testing, such as sonic logging, pile integrity, pile dynamic, are conducted by testing laboratories, others are, traditionally, conducted by the contractors themselves, as part of the contractual requirement. With the growing awareness of the importance and benefits of independent testing, it becomes evident that foundation testing be preferably carried out by independent testing laboratories. As a matter of fact, the Housing Authority has already started to require its contractors to employ independent testing laboratories to carry out static loading tests on piles.

Common foundation tests include sonic logging, pile integrity, pile dynamic, static loading on piles, plate loading and ultrasonic echo sounding tests. Laboratories that wish to seek HOKLAS accreditation for foundation tests may refer to HOKLAS Supplementary Criteria No. 16 “Construction Materials Test Category - Accreditation of Foundation Tests” for details of specific requirements. The requirements described in this Supplementary Criteria are in line with international practices. To ensure that test results are accurate and reliable, special emphasis has been placed on the calibration and checking of foundation testing equipment and measuring devices. Testing personnel are also required to fulfill specific requirements before they could be allowed to conduct the tests. HKAS will also arrange proficiency testing programmes to assure the continual technical competence of the accredited laboratories.
The recently issued Technical Criteria for Entry to the Works Bureau List of Approved Suppliers of Materials and Specialist Contractors for Public Works Ground Investigation (GI) Field Work specify that all Group I and Group II ground investigation contractors be accredited for selected processes of ground investigation work. HOKLAS will, in a phased programme, offer accreditation for these ground investigation tests. Initially, standard penetration tests (SPT) and Mazier sampling will be offered. The test standard for SPT is BS1377: Part 9: 1990 with minor modifications to suit local conditions. Subsequently, the scope of accreditation will be extended to other tests, such as vane shear, permeability, packer and pressuremeter tests, and piston sampling.

A proficiency testing programme for SPT is being organised by HKAS. The performance of laboratories as well as the repeatability and reproducibility of SPT will be assessed. A SPT analyser will be used to measure the energy transfer of the SPT hammer system. Participation in this proficiency testing programme is a pre-requisite for accreditation.

Since most GI testing houses are certified to ISO 9000, their quality management systems should be more or less in line with the management requirements of ISO/IEC 17025. However, their level of technical competence may have to be raised in order to comply with the technical requirements of ISO/IEC 17025. In this regard, extra resources may be required and management of GI testing houses should be aware of this.

Approved signatories and drillers registration systems will be introduced. Approved signatories should fulfil the requirements given in 5.2.H of HOKLAS 003 (sixth edition), and drillers need to be examined for their technical competence to perform GI drilling, sampling and testing work. A HOKLAS Supplementary Criteria covering accreditation of ground investigation tests will be published.

**Ground Investigation Tests**

The scope of accreditation has been expanded to cover the following 13 areas:

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<thead>
<tr>
<th>Area No.</th>
<th>Description</th>
<th>NACE Code</th>
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<tbody>
<tr>
<td>6</td>
<td>Wood and wood products</td>
<td>DD</td>
</tr>
<tr>
<td>16</td>
<td>Concrete, cement, lime, plaster etc.</td>
<td>DI 26.5, 6</td>
</tr>
<tr>
<td>17</td>
<td>Basic metals and fabricated metal products</td>
<td>DJ</td>
</tr>
<tr>
<td>19</td>
<td>Electrical and optical equipment</td>
<td>DL</td>
</tr>
<tr>
<td>23</td>
<td>Manufacturing not elsewhere classified</td>
<td>DN 36</td>
</tr>
<tr>
<td>28</td>
<td>Construction</td>
<td>F</td>
</tr>
<tr>
<td>29</td>
<td>Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods</td>
<td>G</td>
</tr>
<tr>
<td>31</td>
<td>Transport, storage and communication</td>
<td>I</td>
</tr>
<tr>
<td>32</td>
<td>Financial intermediation; real estate; renting</td>
<td>J, K 70, K 71</td>
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<td>33</td>
<td>Information technology</td>
<td>K 72</td>
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<tr>
<td>34</td>
<td>Engineering services</td>
<td>K 73, 74.2</td>
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<tr>
<td>35</td>
<td>Other services</td>
<td>K 74 minus K 74.2</td>
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<tr>
<td>36</td>
<td>Public Administration</td>
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The HKAS Executive congratulates Simon Marketing (Hong Kong) Ltd., Quality Control Department on their success in obtaining accreditation for pre-shipment inspection of toys. The accreditation, HKIAS 001, was granted on 28 April 2000 and is the first granted by the Hong Kong Accreditation Service (HKAS) under the Hong Kong Inspection Body Accreditation Scheme (HKIAS).

Accreditation of inspection body is a new service launched by HKAS in December 1999. At present, accreditation is available for inspection of consumer products, such as toys and children's products, textiles, garments, footwear, electrical and electronic products. The types of inspection covered include pre-production inspection, during production inspection, pre-shipment inspection and factory evaluation.

Accredited inspection bodies may issue inspection reports and certificates bearing the HKIAS accreditation mark as shown below. The HKIAS accreditation mark clearly conveys the message that the competence of the inspection body for the reported inspection has been confirmed by an independent third party.

International standards are used by HKIAS. HKAS Executive is operated in accordance with ISO/IEC TR 17010:1998 and accredited inspection bodies are required to comply with the “Criteria for Accreditation of Inspection Bodies” - HKIAS 003, which comprises all ISO/IEC 17020:1998 requirements and HKIAS policies.

When an acceptable application is received, an advisory visit will be conducted to the office of the inspection body to enhance mutual understanding and to evaluate whether the applicant is ready for the formal assessment. The formal assessment will include witnessing the performance of a representative sample of real on-site inspections and rigorous examination of office operation by assessment teams consisting of quality system and inspection experts. Particular attention will be given to inspector competence, integrity and supervision.

Applications from all Hong Kong inspection bodies are welcome. For further information, please contact the HKAS Executive.
Further Discussion on Harmonisation of Certification Practices

- Certification bodies should not issue HKCAS endorsed certificates until their scopes of accreditation have been extended to cover the new standard. Witness audit to the new standard is required for the extension of scope. For organisations already certified to the 1994 edition, certification bodies should issue certificates stating compliance to the 2000 edition only when all aspects in the new edition have been audited. This could be done over several audits, or in an extra audit, if so required by the certified organisation.

During the last meeting on 11 February 2000, it was agreed that discussions on certification practices should be held regularly. The second meeting, which was held on 12 June 2000 at HKAS, started with a detailed explanation by HKAS Executive on the progress and development in the IAF WG.1 meeting held on 17-19 May 2000 in London. Representatives from certification bodies were also informed of the requirements of draft guidance documents published by IAF that might affect their operations. Other salient points discussed were:

Guidance on Scope Statements for Certification

It was generally agreed that the document on scope statements presented by HKQAA in the last meeting could serve as a useful guidance for defining certification scopes.

Organisations Certified by HKCAS Accredited Certification Bodies

It was also agreed that some information of these organisations would be posted on the HKAS website. While the format had yet to be agreed, the information would include the name, address, scope and standard of certification, and contacts of the organisation. The information would be updated at three-month intervals.

Auditor Days Required for Auditing Contractors

The number of employees of an organisation is a major factor for the determination of the number of man-days required for an audit. HKAS Executive is concerned that while the number of employees of a main contractor could be very small the number of workers at the construction sites could be very large. This is due to the common practice of subcontracting in the construction industry. HKAS Executive expects certification bodies to take into account the actual number of workers on site including staff of the subcontractors as well as the number of projects the contractor has in hand when allocating auditor man-day. Certification bodies are required to have procedures to obtain the required information prior to planning such audits, which should include both surveillance and reassessment audits.

Certification to ISO 9001:2000

Certification bodies should not issue HKCAS endorsed certificates until their scopes of accreditation have been extended to cover the new standard. Witness audit to the new standard is required for the extension of scope. For organisations already certified to the 1994 edition, certification bodies should issue certificates stating compliance to the 2000 edition only when all aspects in the new edition have been audited. This could be done over several audits, or in an extra audit, if so required by the certified organisation.

The next meeting is scheduled for 20 November 2000. Mr. Wilson Tsui of DNV has kindly agreed to arrange the next meeting.
New Laboratory Accreditations Granted

Ten laboratories have obtained HOKLAS accreditations since the last issue of HKAS News, bringing the total number of accreditations granted to 117. The newly accredited laboratories are:

- Hong Kong Calibration Service (HOKLAS 108) for Calibrations Services Test Category
- Hong Kong Curtain Wall Testing Centre Ltd. (HOKLAS 109) for Construction Testing Test Category
- JAS (Inspection & Testing) Limited (HOKLAS 110) for Construction Testing Test Category
- Testing Laboratory of Pinefield Chemical Company Ltd. (HOKLAS 111) for Toys and Children Product Test Category
- Physical Laboratory of Jetta (Guangzhou) Co. Ltd. (HOKLAS 112) for Toys and Children Product Test Category
- Quality Approval Laboratory of Wah Heng Toys (Shenzhen) Co. Ltd. (HOKLAS 113) for Toys and Children Product Test Category
- Quality Assurance Laboratory of Chit Tat Industrial (Shenzhen) Co. Ltd. (HOKLAS 114) for Toys and Children Product Test Category
- Quality Assurance Laboratory of The Merton Company Limited (HOKLAS 115) for Toys and Children Product Test Category
- Sun Yick Plastic Products (Shenzhen) Co. Ltd. (HOKLAS 116) for Toys and Children Product Test Category
- Tai Po Laboratory of The Hong Kong & China Gas Co. Ltd. - Tai Po Laboratory (HOKLAS 117) for Environmental Testing Test Category

We offer our congratulations to them on their success in gaining HOKLAS accreditations.

Laboratory Accreditations Suspended and Terminated

- The Marketing Store Worldwide Asia Limited (HOKLAS 081) voluntarily suspended all tests in the Toys and Children's Products Test Category effective 19 May 2000.
- Wasserbel Testing Laboratory Ltd. (HOKLAS 008) voluntarily terminated all tests in the Toys and Children's Products Test Category, Electrical and Electronic Products Test Category effective 17 March 2000, and all tests for food containers in the Food Test Category effective 31 March 2000.
- Eastern Technical Services Ltd. (HOKLAS 079) voluntarily terminated their accreditation effective 28 July 2000.
Staff Changes

We have seen the departure of two of our staff members recently. After working for HKAS for about two years, Mr. K.W. Pong, who was responsible for toys and children's products and electrical testing decided to pursue a new career. Mr. Pong left HKAS in April 2000. His duties are now being undertaken by Ms. Sandra Ho. Mr. Gilbert Ho, who joined HKAS in 1998, resigned from HKAS in February 2000. His duties are temporarily being undertaken by Mr. S.S. Chan. We wish them every success in their new careers.

Proficiency Testing Update

- **Programmes Completed**
  - The APLAC T016 Proficiency Testing Programme on flammability of toys to EN71 Part 2: 1993 has been completed and the final report was published in June. We are encouraged by the better-than-expected response to this programme. We will definitely consider organising similar proficiency testing programmes in future.

- **Programmes Underway**
  - Samples for the APLAC T022 Proficiency Testing Programme on acoustical testing to EN71 Part 1: 1998 are being circulated amongst participating laboratories.
  - The EA Interlaboratory Comparison Programme (EA-F3) on calibrating force transducer is being organized. Laboratories will be notified when the samples are ready for collection.

- **Electrical and Electronic Products**
  - Samples for APLAC T023 Proficiency Testing Programme on electrical safety testing to IEC 60335-2 have been distributed to participating laboratories.

- **Construction Materials**
  - The proficiency testing programme on non-destructive testing (NDT) is complete and final reports have been distributed to participants. Laboratories with outlying results are requested to investigate the causes and report the findings to HKAS.
Upcoming Training Courses

A 5-day QA/RQA
Registered Assessor/
Lead Assessor Training
Course will be held
from 9 to 13 October 2000.

A 3-day Training Course
on ISO Guide to
Expression of Uncertainty
in Measurement
will be held on
13, 14 and 15 October 2000.

The Quality Management
in the Laboratory Workshop
will be held
from 9 to 11 October
and 11 to 13 December 2000.

The Internal Quality System
Audit Workshop
will be held from
12 to 13 October
and 14 to 15 December 2000.

If you wish to contribute to the next newsletter or require further information on any of the items in this newsletter, please contact the HKAS Executive
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