

# HKAS

News Issue No. 62

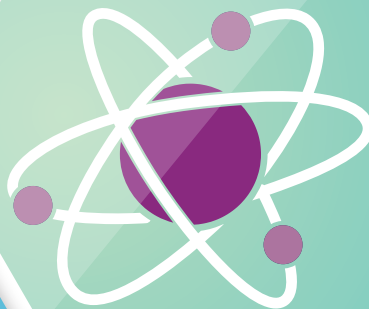
Hong Kong Accreditation Service



November 2017

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Seminar on Revision of  
ISO/IEC 17025

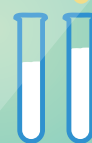


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## Seminar on Revision of ISO/IEC 17025

The international standard ISO/IEC 17025 reached its final stage of revision. Final Draft International Standard (FDIS) ISO/IEC 17025 was balloted and the new standard will likely be published at the end of the year. In order to let accredited non-medical testing and calibration laboratories under Hong Kong Laboratory Accreditation Scheme (HOKLAS) have a better understanding of the background and main changes in the latest draft of the standard, HKAS organised a half-day seminar on 18 September 2017. Ms Anne Hofstra, Operations Manager of the International Accreditation New Zealand (IANZ), a member of the ISO CASCO Working Group 44 for the revision of ISO/IEC 17025, was invited to deliver the seminar. Ms Hofstra has been working in IANZ for over 18 years and is currently responsible for accrediting laboratories of various technical disciplines and also for proficiency testing providers (PTP) and reference material producers (RMP). At international level, Ms Hofstra is an APLAC Lead Evaluator for testing, PTP and RMP.

The seminar highlighted key changes to ISO/IEC 17025 which include new structure of the standard, new requirements on impartiality, reporting of results for compliance with specifications, control of data and information management, risk-based thinking, Options A and B for management system, etc. Ms Hofstra also shared with participants the possible challenges ahead when implementing the revised standard. The seminar attracted over 250 participants, including technical assessors and representatives from accredited laboratories. Most participants considered this seminar as a good starting point for them to get prepared for the transition to the new version of ISO/IEC 17025.



*Ms Anne Hofstra introducing FDIS ISO/IEC 17025:2017 to the participants*



*Participants asking questions about implementation of the revised standard*

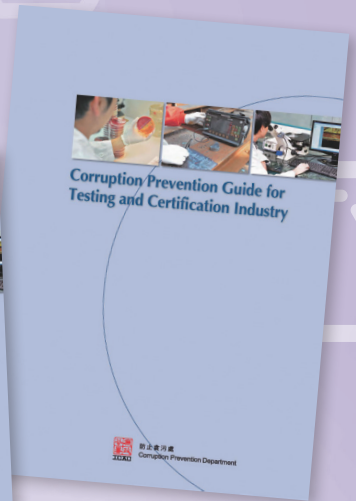
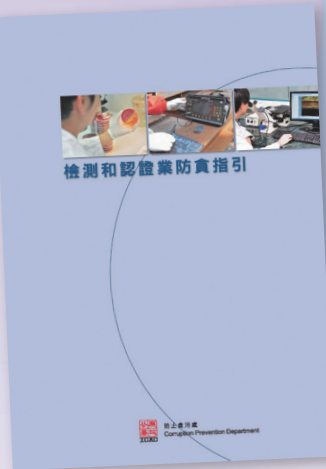


# HKAS and ICAC Join Hands to Promote Corruption Prevention

Testing and certification industry cannot be so successful without high level of integrity and credibility of the practitioners. In the past few years, Hong Kong Accreditation Service (HKAS) and Independent Commission Against Corruption (ICAC) have been working closely to provide training courses and seminars to frontline staff and managerial staff of conformity assessment bodies (CABs), lead assessors and technical assessors/experts to raise their awareness in corruption prevention.

HKAS and ICAC have also produced The Corruption Prevention Guide for Testing and Certification Industry to promote good corporate governance and provide some good practices to all practitioners. The Guide also contains sample Code of Conduct (CoC) document and forms which can be modified and adapted to suit individual organisation's operational needs. All applicant and accredited organisations are strongly advised to download it from Corruption Prevention Advisory Service, ICAC (<https://cpas.icac.hk>) for reference when developing or refining the organisation's own CoC document.

CABs are also encouraged to review if the contents of their CoC contain all important elements as described in the Guide. If there is any doubt, CABs should consult ICAC for

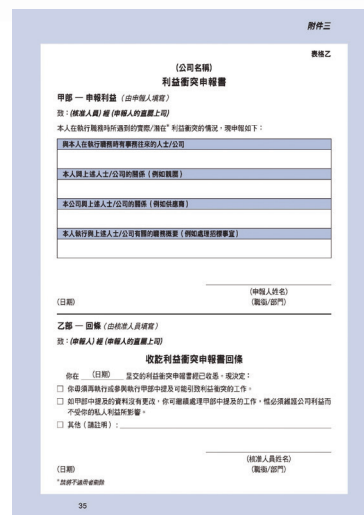
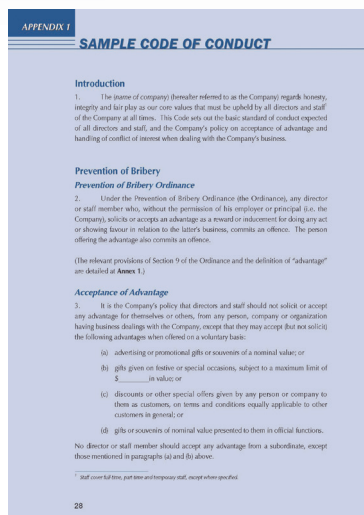


The Corruption Prevention Guide for Testing and Certification Industry

professional advice. Corruption Prevention Advisory Service of the Corruption Prevention Department of ICAC is a specialised unit dedicated to providing free, confidential and tailor-made corruption prevention advice to private companies, organisations and individuals. For further information, please contact the unit at 2526 6363.

When conducting assessments, HKAS assessment teams will pay careful attention to the contents of CoC and training given to staff to make sure CABs conform to relevant requirements in HKAS SC-06. In early 2018, HKAS and ICAC will organise more training courses to accredited organisations. CABs are expected to send staff at different levels, including directors, to these training courses.

Sample Code of Conduct



Sample form for declaration of conflict of interest

## 2017 Tripartite Seminar on Accreditation for Medical Testing

The Tripartite Meeting has been an annual meeting among the three accreditation bodies, viz. Hong Kong Accreditation Service (HKAS), China National Accreditation Service for Conformity Assessment (CNAS) and Taiwan Accreditation Foundation (TAF) since the accreditation to ISO 15189 for medical testing laboratories was in place. Accreditation officers and assessors from the three economies gathered on this occasion to discuss hot topics of accreditation, harmonise accreditation requirements and share experience on the implementation of the medical accreditation programme. This year, the event was co-organised by HKAS and the Hong Kong College of Pathologists on 6 and 7 September in Hong Kong.

This year's programme was divided into three sessions: technical issues related to accreditation, accreditation experience sharing, and management of the accreditation programme. Risk assessment is a new requirement in ISO 15189:2012 and it is going to be a key element in the new editions of other ISO standards for accreditations. Medical laboratories are still in a stage of exploring how to effectively conduct

risk assessment in order to fully comply with the concept of risk management. Mr Watson Wong, an experienced assessor of HKAS was invited to give a talk on this hot topic. Verification of sigma performance is a relatively new tool undertaken by a number of chemical pathology laboratories in the three economies for quality assurance and Dr Richard Pang, also an assessor of HKAS was invited to enlighten the participants on the application. Ms You Ya Yan, an experienced



*Participants actively discussed common problems encountered in assessments*



*Participants of the 2017 Tripartite Meeting in Hong Kong*

assessor of TAF shared with the participants her experience in accrediting molecular testing and the expected parameters for method validation of a molecular test. Dr Wong Kit-fai, Chairman of HKAS' Task Force on Medical Genetics, shared his concern on the accreditation of laboratories using next-generation sequencing for non-diagnostic purposes.

Following Dr Wong's presentation on the dilemma of accrediting such new technologies, representatives of the three accreditation bodies also shared their views on the appropriate standard to be used for accrediting advanced technologies, and other related services such as physiological testing for health check. The three accreditation bodies had a consensus that if advanced technologies such as next-generation sequencing and microarrays were to be used for diagnosis in clinical setting, ISO 15189 is of no doubt the most appropriate standard for accreditation. If the technology is to be used for non-diagnostic purposes, ISO/IEC 17025 will be a more appropriate standard. This also includes laboratory facilities under the umbrella of a medical centre to carry out research studies using these technologies.

ISO 15189:2012 states in its introduction that this standard is also appropriate for accrediting other disciplines such as clinical, physiological, medical imaging, and medical physics. Both TAF and CNAS are implementing or developing new programmes for health check purposes. Apart from laboratory testing, such programmes also consider the accreditation of other examinations such as X-ray, hearing ability, lung capacity, eyesight, and other occupational health related characteristics. TAF has introduced the accreditation of health check service for importing labours. CNAS is exploring the combined use of ISO 15189 and ISO/IEC 17020 which is a standard for inspection to accredit health check services. For both CNAS and HKAS, developing an accreditation programme for imaging facilities is in progress.

Interesting scenarios were raised in the experience



*Visit to the Hong Kong Museum of Medical Sciences*

sharing session. Dr Que Tak-lun, Chairman of HKAS' Working Party on Medical Testing, shared his experience on why nonconformities are repeated in accredited laboratories. He revealed that laboratories might have difficulties in understanding the reported findings, and might not be able to identify the root causes as well as to implement effective actions to eliminate such root causes. The first day ended with Ms Bella Ho's presentation on some scenarios related to ISO 15189:2012 and the interpretation of its requirements.

The second day of the programme focused on improving the management of the accreditation programmes. Different practices among the three accreditation bodies in training assessors, managing assessment teams, allocating assessment time, reporting findings, interviewing signatories were discussed and problems encountered were shared. Through this discussion, HKAS realised that some challenges encountered in assessments were common among the three accreditation bodies and participants shared valuable experience to manage these challenges.

The Tripartite Meeting ended with a visit to the Hong Kong Museum of Medical Sciences located at Caine Lane, Mid-Levels. This museum is housed in a beautiful Edwardian style heritage building, which was originally the Bacteriological Institute, Hong Kong's first purpose-built public health and medical laboratory. The exhibits also brought us through our path in combating the mysterious SARS epidemic.

## HKAS Organises APLAC ISO/IEC 17011 Training



ISO/IEC 17011 is a very important international standard for accreditation bodies as it stipulates requirements on their operation, impartiality and personnel competence. Accreditation bodies, including HKAS, have to comply with this standard in order to be a signatory to the mutual recognition arrangements (MRA) established in regional and international accreditation co-operations. This standard has recently been revised by ISO CASCO Working Group 42 (WG42) and the new version was published in November 2017.

Asia Pacific Laboratory Accreditation Cooperation (APLAC) organised training courses on the revision to ISO/IEC 17011 to help its peer evaluators and member accreditation bodies to prepare for the transition to the revised standard. Two training courses, one for lead evaluators and one for accreditation body staff, were conducted back to back in Hong Kong from 19 to 22 September 2017. HKAS was the host of the courses.

The training was delivered by three experienced APLAC lead evaluators: Mr Ned Gravel, Convener of the APLAC Evaluator Training Working Group; Ms Roxanne Robinson, former Chair of the APLAC MRA Council and member of ISO CASCO WG42; and Ms Anne

Hofstra, member of the New Zealand mirror committee for WG42. At the training, key changes in the revised standard, including criteria for the accreditation process, resources of the accreditation body, its management system, risk-based assessment principles, impartiality and confidentiality were introduced. The trainers also explained the intention behind the revisions made, and share on what a peer evaluator could look for to determine if an accreditation body had fulfilled certain requirements. A total of 20 APLAC lead evaluators and 29 delegates from 22 accreditation bodies attended the courses. There were fruitful discussions among the trainers and participants on how some of the new requirements could be interpreted and implemented.

ILAC and IAF have jointly decided on a three-year transition period for the new version of ISO/IEC 17011 after its publication. HKAS will review current accreditation procedures and management system to identify any deviations from the revised requirements, and implement necessary changes in a timely manner. HKAS will ensure that all accreditation schemes are fully complying with the revised standard before the end of the transition period so that the MRA signatory status will be maintained.

# ILAC IAF General Assembly and Associated Meetings 2017

The International Laboratory Accreditation Cooperation / International Accreditation Forum (ILAC/IAF) General Assembly and Associated Meetings 2017 were held in Vancouver, Canada from 21 to 30 October 2017. The following are highlights of the meeting.

## ILAC

1. The ILAC General Assembly endorsed the recommendation of the Accreditation Committee (AIC) to withdraw ILAC P13:10/2010 Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers when the new version of ISO/IEC 17011:2017 is fully implemented. According to ISO/IEC 17011:2017, accreditation bodies are no longer allowed to organise proficiency testing.
2. A new version of ISO/IEC 17025 has nearly finalised and will likely be issued by the end of 2017. The ILAC AIC is identifying relevant ILAC technical documents to be amended as a result of the revision of this key standard. AIC is now working on the ILAC documents P9, P10, P14, G8, G17 and G18.
3. ISO 15189 (the accreditation standard for medical testing laboratories) is due for a systematic review by ISO with a closing date of 5 March 2018. ILAC liaison to ISO Technical Committee (TC) 212 (the ISO TC responsible for developing standards of clinical laboratory testing and in vitro diagnostic test systems) informed that ISO is preparing a survey to collect views from accreditation bodies and related stakeholders about the revision.
4. Arab Accreditation Cooperation (ARAC) has become a recognised region of ILAC. Recognition of ARAC MLA for the accreditation of calibration (ISO/IEC 17025), testing (ISO/IEC 17025), medical testing (ISO 15189) and inspection (ISO/IEC 17020) has been accepted by ILAC.
5. The following accreditation bodies were admitted to the ILAC mutual recognition arrangement (MRA) at the 2017 ILAC General Assembly:
  - a. Algerian Accreditation Body (ALGERAC), Algeria: calibration (ISO/IEC 17025), testing (ISO/IEC 17025) and inspection (ISO/IEC 17020)
  - b. Southern African Development Community Accreditation Service (SADCAS), Botswana: extension for medical testing (ISO 15189) and inspection (ISO/IEC 17020)
  - c. Ente Costarricense de Acreditación (ECA), Costa Rica: extension for medical testing (ISO 15189)
  - d. National Accreditation Body of Republica de Cuba (ONARC), Cuba: extension for inspection (ISO/IEC 17020)
  - e. Organismo Salvadoreño de Acreditación (OSA), El Salvador: extension for calibration (ISO/IEC 17025)
  - f. Ethiopian National Accreditation Office (ENAO), Ethiopia: testing (ISO/IEC 17025) and medical testing (ISO 15189)
  - g. National Accreditation Authority (NAH), Hungary: calibration (ISO/IEC 17025), testing (ISO/IEC 17025), medical testing (ISO 15189) and inspection (ISO/IEC 17020)
  - h. Jordan Accreditation & Standardization Systems - Accreditation Unit (JAS-AU), Jordan: calibration (ISO/IEC 17025), testing (ISO/IEC 17025) and medical testing (ISO 15189)
  - i. Kenya Accreditation Services (KENAS), Kenya: calibration (ISO/IEC 17025), testing (ISO/IEC 17025), medical testing (ISO 15189) and inspection (ISO/IEC 17020)



- j. Korea Laboratory Accreditation Scheme (KOLAS), Korea: extension for medical testing (ISO 15189)
  - k. National Centre of Accreditation of the Republic of Moldova (MOLDAC), Moldova: calibration (ISO/IEC 17025), testing (ISO/IEC 17025), medical testing (ISO 15189) and inspection (ISO/IEC 17020)
  - l. Federal Service for Accreditation (RusAccreditation), Russia: calibration (ISO/IEC 17025), testing (ISO/IEC 17025)
6. Accreditation Education Research & Scientific Services Center Pvt. Ltd. (AERSSC), Nepal was accepted as ILAC Associate at the 2017 ILAC General Assembly.

## IAF

1. At the end of the transition period, 15 September 2018, all ISO 9001:2008 and ISO 14001:2004 certifications shall expire or be withdrawn. As of 15 March 2018, certification bodies shall conduct all ISO 9001 and ISO 14001 initial, surveillance, and recertification audits to the new versions (ISO 9001:2015 and ISO 14001:2015). The outcomes of such audits shall be considered by the certification bodies for further decision on accredited certifications to ISO 9001:2008 and ISO 14001: 2004 as deemed appropriate.
2. The transitional arrangement for the revision of ISO 50001:2011 Energy Management Systems – Requirements with guidance for use will be three years from the date of publication of the revised standard. All ISO 50001:2011 certifications shall expire or be withdrawn at the end of the transition period.

Within this transition timeline:

- Accreditation bodies shall be ready to carry out transition assessments for

ISO 50001:2018 within six months from the date of publication of the revised standard.

- Certification bodies shall complete the transition with ABs for ISO 50001:2018 within 18 months from the date of publication of the revised standard.
- Certification bodies shall cease conducting audits, including initial, surveillance and recertification to the ISO 50001:2011 within 18 months from the date of publication of the revised standard. The outcomes of such audits to the revision of ISO 50001:2011 shall be considered by the CAB for further decision on accredited certifications to ISO 50001:2011 as deemed appropriate.

3. The transitional arrangement for the revision of ISO 14064-1:2006 Greenhouse gases - Part 1: Specification with guidance at the organization level for quantification and reporting of greenhouse gas emissions and removals, and ISO 14064-2:2006 Greenhouse gases - Part 2: Specification with guidance at the project level for quantification, monitoring and reporting of greenhouse gas emission reductions or removal enhancements will be three years from the date of publication of the revised standard.

Within this transition timeline:

- Accreditation bodies shall be ready to carry out transition assessment for ISO 14064-1:2018 and ISO 14064-2:2018 within six months from the date of publication of the revised standards. If there is an exception to the above, the accreditation body shall justify the exception based on valid reasons.
- Conformity assessment bodies shall complete the transition with accreditation bodies for ISO 14064-1:2018 and ISO 14064-2:2018 within three years from the date of publication of the revised standards.

4. The period for transitioning of accredited certifications to the next revision of ISO 22000:2005 Food safety management systems - Requirements for any organization in the food chain will be three years from the date of publication.
5. There will not be any accredited certification to ISO 31000:2009, Risk management – Principles and guidelines (publication date 13 November 2009) since ISO 31000 explicitly states that it is not intended or appropriate for certification, and any certification would be a misuse of the standard. Therefore, certification bodies are strongly urged not to promote or provide certification to ISO 31000. Accreditation bodies and certification bodies are requested to report any misuse or need for certification to the ISO Secretariat.
6. The regional accreditation group member Arab Accreditation Cooperation (ARAC) was admitted to the IAF MLA – Main Scope: Management Systems Certification – ISO/IEC 17021-1, Level 4: ISO/TS 22003; Sub-scope: Level 5: ISO 22000, ISO 9001 and ISO 14001 since the 2016 General Assembly.
7. The following accreditation bodies were admitted to the IAF MLA since the 2016 General Assembly:
  - a. IOAS United States of America — Main Scope: Product Certification — ISO/IEC 17065 (PAC)
  - b. NAAU Ukraine — Main Scope: Product Certification – ISO/IEC 17065; Main Scope: Certification of Persons - ISO/IEC 17024; Main Scope: Management Systems Certification – ISO/IEC 17021-1; Sub-Scopes: Level 5: ISO 9001 and ISO 14001 (EA)
  - c. NAH Hungary — Main Scope: Product Certification – ISO/IEC 17065; Main Scope: Certification of Persons - ISO/IEC 17024; Main Scope: Management Systems Certification — ISO/IEC 17021-1; Sub-Scopes: Level 5: ISO 9001 and ISO 14001 (EA)
  - d. KENAS Kenya — Main Scope: Management Systems Certification — ISO/IEC 17021-1; Sub-Scope Level 4: ISO/TS 22003; Sub-Scopes Level 5: ISO 22000, ISO 9001 and ISO 14001
8. The following accreditation bodies have extended their MLA scopes since the 2016 General Assembly:
  - a. NCA Kazakhstan – Main Scope: Management Systems Certification – ISO/IEC 17021-1; Sub-Scope Level 5: ISO 9001 (PAC)
  - b. NACI Iran, SAC Singapore – Sub-Scope Level 5: ISO 14001 (PAC)
  - c. EA-BAS Bulgaria – Main Scope: Management Systems Certification – ISO/IEC 17021-1; Sub-Scopes: Level 5: ISO 9001, ISO 14001 (EA)
  - d. EA-BAS Bulgaria – Main Scope: Product Certification – ISO/IEC 17065 (EA)
  - e. PNAC Pakistan – Main Scope: Product Certification – ISO/IEC 17065 (PAC)
  - f. DAC United Arab Emirates, HKAS Hong Kong, China, NACI Iran, NSC Thailand, Standards Malaysia Malaysia – Sub-Scope Level 4: ISO/TS 22003; Sub-Scope Level 5: ISO 22000 (PAC)
  - g. EGAC Egypt – Sub-Scope Level 4: ISO/TS 22003; Sub-Scope Level 5: ISO 22000
  - h. TUNAC Tunisia – Sub-Scope Level 4: ISO/TS 22003; Sub-Scope Level 5: ISO 22000 (ARAC)
  - i. CNAS China, EMA Mexico, Standards Malaysia Malaysia – Sub-Scope Level 4: ISO/IEC 27006; Sub-Scope Level 5: ISO 27001 (PAC)

## New Staff Member

Ir Lee joined HKAS as Senior Accreditation Officer in August 2017. Ir Lee obtained his Bachelor of Engineering in Civil and Structural Engineering from The University of Hong Kong in 1993 and Master of Science together with the Diploma of the Imperial College in Soil Mechanics and Environmental Geotechnics from Imperial College London in 2001. He has more than 20 years of experience in geotechnical engineering. In HKAS, Ir Lee is responsible for the accreditation of testing laboratories, inspection bodies and product certification bodies in construction field.



Ir Joshua LEE Weng

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## First Certification Body Accredited to Food Safety Management System (FSMS) Certification

HKAS is very pleased to announce that in March 2017, the first accreditation for FSMS certification was granted to Hong Kong Quality Assurance Agency (HKQAA). HKAS wishes to congratulate them on their success in obtaining accreditation.

HKAS launched the service on accreditation of Food Safety Management System certification bodies (FSMS CB) under the Hong Kong Certification Body Accreditation Scheme (HKCAS) in March 2011. The technical criteria for accreditation of FSMS CB are ISO/IEC 17021-1:2015, ISO TS/22003: 2013 and HKCAS supplementary criteria (HKCAS SC-06).

For enquires about the accreditation of FSMS certification, please contact our Senior Accreditation Officer, Mr Shum Wai-leung, at 2829 4806 or [wshum@itc.gov.hk](mailto:wshum@itc.gov.hk).

## HKAS Extended PAC MLA and IAF MLA to Food Safety Management System Certification

Following the granting of the first accreditation of Food Safety Management System (FSMS) certification to an existing accredited certification body in March 2017, HKAS submitted an application for extending the scope of Pacific Accreditation Cooperation Multilateral Arrangement (MLA) on 29 March 2017. As HKAS has been a PAC MLA for Quality Management System and Environmental Management System Certifications for years, PAC adopted documentation review as the evaluation method in assessing this application. In June 2017, HKAS successfully extended its PAC MLA to FSMS certification.

Subsequent to the admission of PAC MLA on FSMS certification, HKAS also submitted the application for extending the scope of IAF MLA to cover FSMS on 28 June 2017. As PAC is a recognised regional cooperation for accreditation of FSMS, IAF has extended HKAS MLA to cover FSMS certification on 7 July 2017 through documentation review.

## New Accreditation Service for Veterinary Testing Laboratories

HKAS now offers accreditation service for veterinary testing laboratories under the Hong Kong Laboratory Accreditation Scheme (HOKLAS). The accreditation criteria for veterinary testing laboratories are ISO/IEC 17025 (i.e. HOKLAS 003), HOKLAS Supplementary Criteria No. 52 'Veterinary Testing' Test Category and other relevant HKAS/HOKLAS requirements.

To know more about this new service, please contact our Senior Accreditation Officer, Dr Lillian Chow, at 2829 4816 or [lsnchow@itc.gov.hk](mailto:lsnchow@itc.gov.hk).



**IAF Chair presents the IAF  
MLA certificate to HKAS at  
2017 IAF General Assembly  
in Vancouver**

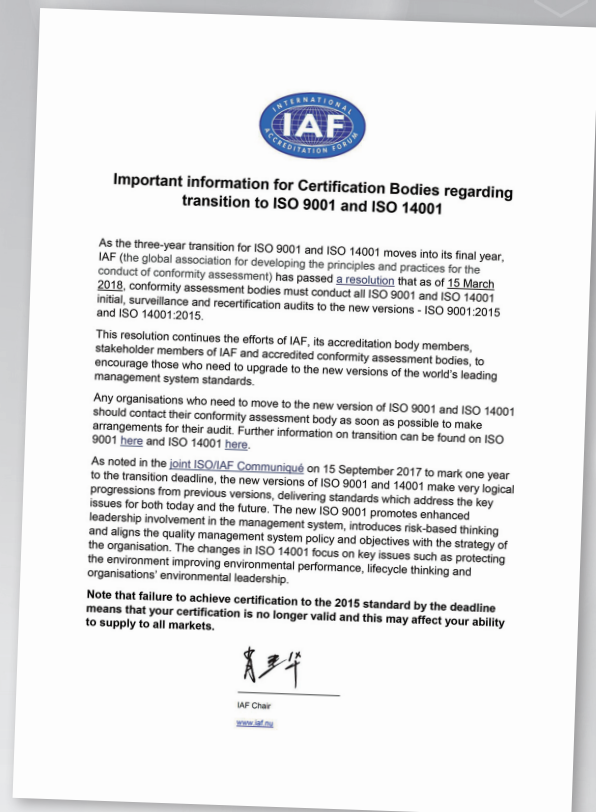
# Important Information for Certification Bodies Regarding Transition to ISO 9001 and ISO 14001

As the three-year transition for ISO 9001 and ISO 14001 moves into its final year, IAF (the global association for developing the principles and practices for the conduct of conformity assessment) has passed a resolution that as of 15 March 2018, conformity assessment bodies must conduct all ISO 9001 and ISO 14001 initial, surveillance and recertification audits to the new versions - ISO 9001:2015 and ISO 14001:2015.

This resolution continues the efforts of IAF, its accreditation body members, stakeholder members of IAF and accredited conformity assessment bodies, to encourage those who need to upgrade to the new versions of the world's leading management system standards.

Any organisations who need to move to the new version of ISO 9001 and ISO 14001 should contact their conformity assessment bodies as soon as possible to make arrangements for their audit.

As noted in the joint ISO/IAF Communiqué on 15 September 2017 to mark one year to the transition deadline, the new versions of ISO 9001 and 14001 make very logical progressions from previous versions, delivering standards which address the key



issues for both today and the future. The new ISO 9001 promotes enhanced leadership involvement in the management system, introduces risk-based thinking and aligns the quality management system policy and objectives with the strategy of the organisation. The changes in ISO 14001 focus on key issues such as protecting the environment, improving environmental performance, lifecycle thinking and organisations' environmental leadership.



Note that failure to achieve certification to the 2015 standard by the deadline means that your certification is no longer valid and this may affect your ability to supply to all markets.

## Seminar on Common Findings Related to Management Requirements for Medical Testing Laboratories



*More than 120 participants, including laboratory personnel and technical assessors, attend the two seminars at the Queen Elizabeth Stadium*

HOKLAS 015 (5th Edition) – Technical Criteria for Laboratory Accreditation (Medical Laboratories) is the fundamental accreditation criteria document for medical testing laboratories. While a medical laboratory needs to demonstrate conformity with both technical and management requirements stipulated in the document before accreditation is granted and shall comply with the same criteria at all times for maintaining accreditation, it is important for the laboratory personnel to fully understand all requirements in the standard.

On 2 and 30 June 2017, two repeated seminars sharing common findings related to management requirements of HOKLAS 015 (5th Edition) for medical laboratories were held at the Queen Elizabeth Stadium. Since

the adoption of HOKLAS 015 (5th Edition) as the accreditation criteria for medical laboratories on 1 October 2014, these were the first HKAS seminars ever focusing only on management requirements. Laboratory personnel, in particular quality managers, and technical assessors were invited to the seminars. Both seminars were delivered by Ms Bella Ho, Senior Accreditation Officer, and Dr Alex Chan, Accreditation Officer, HKAS.

Each seminar was divided into two sessions. The first session was an open forum to discuss issues encountered in implementing the management requirements of ISO 15189:2012. Common nonconformities found against each management requirement were fully explained. In particular, Ms Ho elaborated on the requirements of internal



*Ms Bella Ho holds an open forum to discuss issues encountered in implementation of the management requirements of ISO 15189*

*Dr Alex Chan presents an analysis of the common findings on management requirements being observed in medical laboratories*

audit with illustrated examples. Emphasis was put on distinguishing between vertical and horizontal audits and elaborating on what is expected of a good internal audit report. In the second session, Dr Chan shared some common management system findings in assessments. Among all the management

requirements, (1) cl. 4.3 on document control, (2) cl. 4.14 on evaluation and audits, and (3) cl. 4.2 on quality management system had been cited the most in assessment reports. Through explanation and discussion in these seminars, laboratories have a better understanding of the management requirements and will further promote their fulfillment of the relevant requirements.



*Participants actively engage in the open forum*

Altogether, more than 120 participants from 33 organisations attended the two seminars. All participants actively engaged in the discussion and highly appreciated the detailed presentations and meticulous data analysis.



# Seminar on Construction Testing, Inspection and Certification

The theme of World Accreditation Day 2017 focuses on how accreditation supports professionals in the construction industry, ranging from contractors, manufacturers, designers, architects, engineers, to regulators. To raise the awareness of accreditation and promulgate this year's theme, HKAS organised a seminar in relation to construction testing, inspection and certification on 26 May 2017.

Ir Dr Eric Lim Chaw-hyon from Safety, Accident & Failure Experts Ltd. was invited to talk about the requirements on effective heat soak method and the rationale behind. After that, Ir Prof Wong Yuk-lung, Head of Department of Civil Engineering of Chu Hai College of Higher Education, also Vice-President of Hong Kong Concrete Institute, shared his valuable experience on a product conformity certification scheme for aggregates for concrete. Ir Kenneth Pak, Senior Project Officer of Engineering Discipline In-service Training Office of Vocational Training Council presented the use of time lapse ground penetration radar (GPR) as a monitoring measure for excavation and lateral support works. Lastly, Ir Dr Fiona Chan, Accreditation Officer of HKAS gave a presentation on the accreditation services provided by HKAS.



(From left to right) Ir Kenneth Pak, Ir Dr Fiona Chan, Ir Prof Wong Yuk-lung and Ir Dr Eric Lim

About 90 participants, including practitioners from the testing and certification industry, users of testing and certification services, and counterparts from other government departments, attended the seminar. The participants were engaged in very interactive and fruitful discussions on matters relating to heat-soaked glass inspection, product certification for aggregates for concrete and time lapse GPR. Positive feedback was received and most of the participants found the seminar very practical and useful.

For more information about accreditation services in construction, please contact our Senior Accreditation Officers, Ir Chan Wai-keung (tel: 2829 4812 / email: wk.chan@itc.gov.hk) or Ir Joshua Lee (tel: 28294870 / email: joshua.lee@itc.gov.hk).



## Quick Note to Applicant and Accredited Organisations

When lodging an application of accreditation or extension of scope of accreditation, the applicant organisation shall ensure that the application fee is submitted together with other application documents. HKAS will only process the application when the application form, relevant documents and the application fee are all received.

Assessment fee shall be paid on time. It is an accredited organisation's obligation to pay the fees and charges as determined by HKAS Executive. HKAS reserves the right not to proceed with the on-site assessment in case of delay in payment. Failing of doing so may also lead to imposed suspension or termination of the accredited organisations.

An applicant organisation shall maintain complete integrity at any point in the application and assessment process. If there is evidence of fraudulent behaviour, if the applicant organisation intentionally provides false information or if the applicant organisation conceals information, HKAS Executive shall reject the application or terminate the assessment process. The resulting application and assessment fees paid are not refundable.

## New and Revised HKAS Documents

Since the last issue of HKAS News, a number of HKAS, HOKLAS, HKIAS and HKCAS documents have been revised or newly published. These are shown in the following table with their respective dates of implementation. The supplementary criteria are mandatory documents and HKAS accredited organisations are advised to study them carefully and adjust their management system and/or operation procedures accordingly on or before the implementation dates. These documents are available at our website at [www.hkas.gov.hk](http://www.hkas.gov.hk).

Document Code	HKAS published document	Version	Publication Date	Implementation Date
HKCAS 006	HKCAS 006 Schedule of Fees for Accreditation of Certification Bodies and Validation / Verification Bodies in Hong Kong	Oct 2017	Oct-2017	Oct-2017
HKCAS 023	HKCAS 023 Technical Criteria for Accreditation of Product Certification Bodies (Abridged Version)	2017	Jul-2017	Jul-2017
*HKCAS IN001	HKCAS IN001 Application Procedures for HKCAS Accreditation (Informative)	Issue 1	Oct-2017	Oct-2017
HKCAS SC-04	HKCAS SC-04 HKCAS Supplementary Criteria No. 4 'Accreditation Regulations Specific for HKCAS - Certification Body'	Issue 12	Jul-2017	Jul-2017
HKIAS 003C:2017	HKIAS 003C:2017 檢驗機構認可技術準則 (ISO/IEC 17020:2012 – 《合格評定 – 各類檢驗機構的運作規定》, MOD) 縮略本	2017	Sep-2017	Sep-2017
*HKIAS IN001	HKIAS IN001 Application Procedures for HKIAS Accreditation (Informative)	Issue 1	Oct-2017	Oct-2017

Document Code	HKAS published document	Version	Publication Date	Implementation Date
HKIAS SC-04	HKIAS SC-04 HKIAS Supplementary Criteria No. 4 'Indoor Air Quality Inspection'	Issue 6	Jul-2017	Jul-2017
HKIAS SC-05	HKIAS SC-05 HKIAS Supplementary Criteria No. 5 'Accreditation Regulations Specific for HKIAS - Inspection Body'	Issue 4	Oct-2017	Oct-2017
HOKLAS 021	HOKLAS 021 General Checklist for HOKLAS Supplementary Criteria for Medical Laboratories	Oct 2017	Oct-2017	Oct-2017
HOKLAS AP009	HOKLAS AP009 HOKLAS Application Package 009 'Accreditation of Medical Laboratories 醫務化驗所的認可'	Jul 2017	Jul-2017	Jul-2017
*HOKLAS AP015	HOKLAS AP015 HOKLAS Application Package 015 'Accreditation of Veterinary Testing Laboratories 獸醫化驗所的認可'	Oct 2017	Oct-2017	Oct-2017
*HOKLAS IN003	HOKLAS IN003 Application Procedures for HOKLAS Accreditation (Informative)	Issue 1	Oct-2017	Oct-2017
HOKLAS SC-09	HOKLAS SC-09 HOKLAS Supplementary Criteria No. 9 "Physical and Mechanical Testing" and 'Toys and Children's Products' Test Categories - Physical and Mechanical Tests"	Issue 6	Aug-2017	Aug-2017
HOKLAS SC-20	HOKLAS SC-20 HOKLAS Supplementary Criteria No. 20 "Chemical Testing", "Chinese Medicine", "Construction Materials", "Miscellaneous", "Pharmaceutical Products" and "Toys and Children's Products" - Chemical Testing	Issue 8	Aug-2017	Aug-2017
HOKLAS SC-22	HOKLAS Supplementary Criteria No. 22 "'Textiles and Garments' Test Category"	Issue 5	Jun-2017	Sep-2017
HOKLAS SC-30	HOKLAS SC-30 HOKLAS Supplementary Criteria No. 30 "Medical Testing" Test Category - Molecular Genetics"	Issue 9	Jul-2017	Jul-2017
HOKLAS SC-33	HOKLAS SC-33 HOKLAS Supplementary Criteria No. 33 'Accreditation Regulations Specific for HOKLAS - Laboratory'	Issue 5	Oct-2017	Oct-2017
HOKLAS SC-35	HOKLAS SC-35 HOKLAS Supplementary Criteria No. 35 "Medical Testing" Test Category - Cytogenomics"	Issue 3	Jul-2017	Jul-2017
HOKLAS SC-45	HOKLAS SC-45 HOKLAS Supplementary Criteria No. 45 'Accreditation Requirements for Hong Kong Testing Laboratories to Undertake Product Testing to China Compulsory Certification System'	Issue 5	Sep-2017	Sep-2017
HOKLAS SC-45C	HOKLAS SC-45C 實驗所認可計劃補充準則第 45 號 - 中國強制性產品認證制度產品檢測的認可要求	第五版	Sep-2017	Sep-2017
HOKLAS SC-46	HOKLAS SC-46 HOKLAS Supplementary Criteria No. 46 'Electrical and Electronic Products' Test Category – Accreditation of ENERGY STAR® Program Laboratory for Testing Electrical and Electronic Products	Issue 3	Jul-2017	Jul-2017
*HOKLAS SC-51	HOKLAS SC-51 HOKLAS Supplementary Criteria No. 51 'Chemical Testing' - Doping Control Testing Laboratories	Issue 1	Aug-2017	Aug-2017
*HOKLAS SC-52	HOKLAS SC-52 HOKLAS Supplementary Criteria No. 52 "Veterinary Testing" Test Category"	Issue 1	Oct-2017	Oct-2017

\*New publication

# Proficiency Testing Updates

An update on the proficiency testing programmes organised by HKAS is given below (as at 31 Oct 2017):

Test Category	Programme	Status
Construction Materials	HCM/2017/01 - Determination of Density and Fineness of Cement	Data Analysis in progress. Fourteen laboratories participated.
Toy and Children's Products Environmental Testing	HTC/2017/01 - Analysis of Chromium (VI)	Sample dispatched in Oct 2017. Twenty laboratories participated.

## Progress in programmes organised by regional cooperations of accreditation bodies

Test Category	Programme and Organiser	Status
Chinese Medicine	APMP-APLAC T106 - Organochlorine Pesticides in Ginseng Root Organised by GLHK, Hong Kong	Interim report was issued in Jun 2017. Four laboratories participated.
Food	APLAC T103 - Determination of Acesulfame Potassium and Sucralose in Cake Mix Flour Organised by SAC, Singapore	Report was issued in Mar 2017 and will be finalised after review. One laboratory participated.
	APMP-APLAC T107 - Elements in Food Supplement Organised by GLHK, Hong Kong	Interim report was issued in Jun 2017. Two laboratories participated.
	APMP-APLAC T105 - Nutritional Elements (Iron and Zinc) in Wheat Flour Organised by KRIS, Korea	Interim report was issued in Dec 2016. One laboratory participated.
Calibration Service	APLAC M027 - Calibration of E2 Weights Organised by KAN/Puslit KIM LIPI	Draft Final report was issued in Jun 2017 for comments. Two laboratories participated.

# Accreditation Updates

## New Accreditation Granted (15 June 2017 to 31 October 2017)

Ten laboratories have been accredited since the last issue of HKAS News. Their names, registration numbers and accredited areas are summarised below. HKAS wishes to congratulate them on their success in obtaining accreditation.

### HOKLAS

Registration No.	Name of Conformity Assessment Body	Test Category Granted	Clientele
HOKLAS 267	Appleone Calibration Laboratory Limited	Calibration Services	In-house laboratory, normally not available for public testing
HOKLAS 268	Lidl Hong Kong Limited - Quality Laboratory	Electrical and Electronic Products Physical and Mechanical Testing Textiles and Garments Toy and Children's Products	In-house laboratory, normally not available for public testing
HOKLAS 269	SgT Lab Testing Limited	Textiles and Garments	Public
HOKLAS 270	Hong Kong Police Force - Identification Bureau	Forensic Testing	In-house laboratory, normally not available for public testing
HOKLAS 271	Advanced - Technical Testing Services Co., (H.K.) Ltd.	Construction Materials	Public
HOKLAS 272	Balun Technology International Limited	Electrical and Electronic Products	Public
HOKLAS 822S	KingMed Diagnostics (Hong Kong) Limited	Medical Testing	Private physicians, medical centres

## HKCAS

Registration No.	Name of Conformity Assessment Body	Activity Granted	Clientele
HKCAS 027	Green Council Ltd. - Green Council Certification Scheme	Energy management system certification Environmental management system certification Occupational health and safety management system certification Quality management system certification	Public

## HKIAS

Registration No.	Name of Conformity Assessment Body	Test Category Granted	Type#
HKIAS 030	Jesee (HK) Engineering Services Co., Ltd	Construction Products	A
HKIAS 031	Geotechnics & Concrete Engineering (Hong Kong) Ltd.	Construction Products	A

#Type:

A: Provides 'third party' inspection service to the public

## Accreditation Suspended

### Voluntary Suspension (as at 31 October 2017)

## HOKLAS

Registration No.	Name of Conformity Assessment Body	Test Category Granted	Effective Date (dd.mm.yyyy)
009	SGS Hong Kong Limited	Testing Required By The China Compulsory Certification (CCC) System -- Electrical and Electronic Products Electrical and Electronic Products -- All tests	16.08.2017
010	CEDD – Public Works Laboratories	Construction Materials -- Playground equipment	31.08.2017
036	UL VS Hong Kong Limited	Testing Required By The China Compulsory Certification (CCC) System -- All tests	03.10.2017
048	K. Wah Asphalt Limited - Tai Sheung Tok Depot Laboratory	Construction Materials -- All tests	01.06.2017
058	Bureau Veritas Hong Kong Limited - Kowloon Bay Office	Food -- Preservatives	09.01.2017
125	SGS IECC Limited	Electrical and Electronic Products -- All tests	16.08.2017
165	Jewellery Trade Laboratory Limited	Physical and Mechanical Testing -- All tests	01.05.2017
235	TÜV SÜD Hong Kong Limited	Chemical Testing -- All tests	05.04.2017
235	TÜV SÜD Hong Kong Limited	Electrical and Electronic Products -- All tests Testing Required By The China Compulsory Certification (CCC) System -- All tests	10.04.2017
242	Chemical Laboratory (HK) Pte Limited	Food -- All tests	30.04.2017

## HKIAS

Registration No.	Name of Conformity Assessment Body	Inspection Field Granted	Effective Date (dd.mm.yyyy)
024	Health, Safety and Environment Office, The Hong Kong University of Science and Technology	Indoor Air Quality	31.03.2017

The above list only shows those accredited organisations with the whole test category / area suspended or terminated. In addition, the list does not display those suspended and terminated activities individually. Readers are advised to refer to the scope of accreditation displayed on HKAS website for the latest accreditation of the specific activities of an accredited organisation.