

# HKAS

News Issue No. 63

Hong Kong Accreditation Service



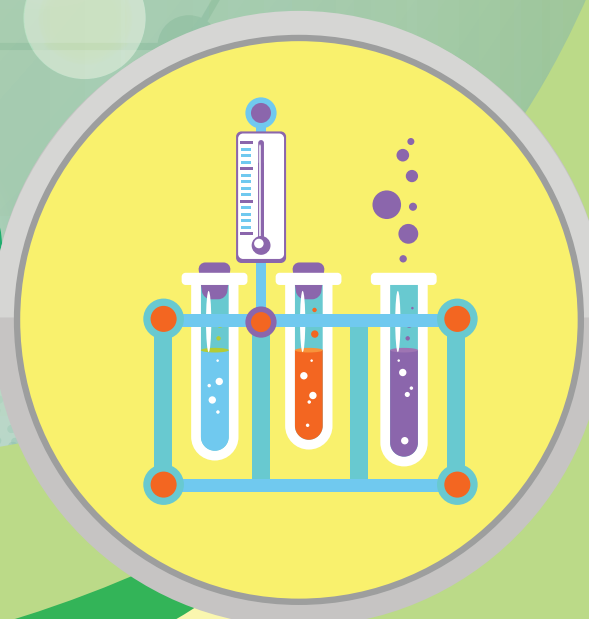
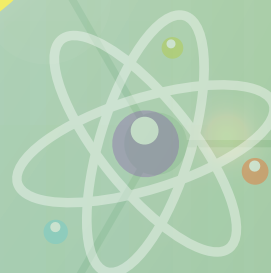
APRIL 2018

**P.7**  
Experience Sharing  
Seminar for  
Microbiological  
Testing Laboratories



**P.15**  
The 46<sup>th</sup> International  
Congress and Exposition  
on Noise Control  
Engineering  
(Inter-noise 2017)

**P.3**  
Publication of  
ISO/IEC  
17025:2017



# Contents

## News Issue No.63

Publication of ISO/IEC 17025:2017	3
Schedule for Implementation of ISO/IEC 17025: 2017 in Accreditation of Testing and Calibration Laboratories	4
Experience Sharing Seminar for Microbiological Testing Laboratories	7
Recognition of HKAS by US Environmental Protection Agency (EPA) under the EPA Toxic Substances Control Act Title VI Third-Party Certification Program	8
Seminar on Testing and Certification for Environmental Excellence	9
HKAS SC-06 – Code of Conduct Revised	9
Quick News	10
Chairman of EA Visits Hong Kong	11
Anti-corruption Workshops for HKAS Accredited Organisations	12
Experience Sharing Seminar for Chemical Testing Laboratories	13
Accredited Services in Demand	14
The 46 <sup>th</sup> International Congress and Exposition on Noise Control Engineering (Inter-noise 2017)	15
Assessment Feedback Seminar for Medical Testing Laboratories	16
New and Revised HKAS Documents	16
Proficiency Testing Updates	18
Accreditation Updates	19

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36/F, Immigration Tower,  
7 Gloucester Road, Wanchai,  
Hong Kong  
Tel: 2829 4840  
Fax: 2824 1302  
Email: [hkas@itc.gov.hk](mailto:hkas@itc.gov.hk)  
Website: [www.hkas.gov.hk](http://www.hkas.gov.hk)

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# Publication of ISO/IEC 17025:2017

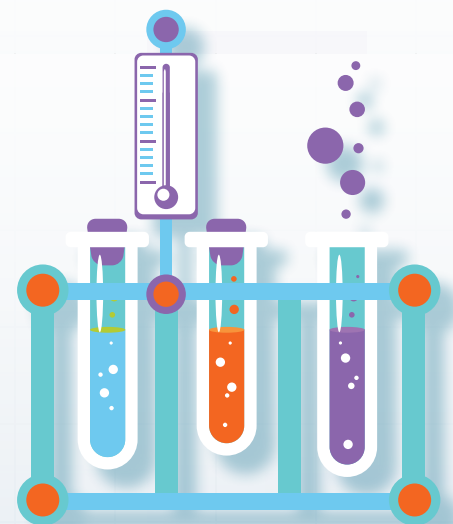
Revision of the international standard, ISO/IEC 17025:2005 on 'General requirements for the competence of testing and calibration laboratories' has been completed. ISO/IEC 17025:2017 was published in November 2017. In accordance with the International Laboratory Accreditation Cooperation (ILAC) Resolution GA 20.15 of the 20th ILAC General Assembly held in New Delhi in November 2016, a transition period of three years from the date of publication has been adopted by the ILAC. At the end of the transition period, i.e. November 2020, accreditation of a laboratory to ISO/IEC 17025:2005 will no longer be recognised under the ILAC Mutual Recognition Arrangement (MRA). Laboratories currently accredited by HKAS have to complete the transition to the new standard before the transition deadline. Accredited laboratories are urged to prepare their own transition plan promptly. HKAS has held seminars to explain the details of the schedule for implementation of ISO/IEC 17025:2017 for accreditation of testing and calibration laboratories to both laboratories and assessors.

ISO/IEC 17025:2017 specifies the general requirements for the competence, impartiality and consistent operation of laboratories and has been developed with the objective of promoting confidence in the operation of laboratories. The document contains requirements for laboratories to demonstrate their abilities to operate competently and impartially, and to consistently deliver technically valid test and calibration results. Laboratories that conform to this document will also operate generally in accordance with the principles of ISO 9001.

The main change in ISO/IEC 17025:2017 comparing with ISO/IEC 17025:2005 is in its structure. The content does not change much and the requirements are principally the same. It is a policy of ISO that ISO/CASCO standards follow a common structure, and there are also common elements (common set of words) which are the same for different conformity assessment standards including those for testing, certification and inspection bodies. The common elements are 'Confidentiality', 'Impartiality', 'Complaints' and 'Management system requirements'. In ISO/IEC 17025:2017, there is a slight change to the scope to make it clearer for the users. A definition of 'laboratory' is added to include bodies performing sampling, testing and/ or calibration.

To align with ISO 9001, ISO/IEC 17025:2017 introduces the concept of risk-based thinking which enables some reduction in prescriptive requirements and their replacement by performance-based requirements. The new standard requires laboratories to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative impacts. The laboratory is responsible for deciding which risks and opportunities need to be addressed.

ISO/IEC 17025:2017 also focuses more on logical process for laboratory activities, reduces the required amount of documentation, and puts emphasis on impartiality, information technology and traceability. There is also a new requirement on decision rule, requiring laboratories to clearly define, document and agree with their clients on the rule to apply when making decision on conformity with a specified requirement, e.g. to state pass or fail in a statement of conformity, for the test or calibration to be conducted.



# Schedule for Implementation of ISO/IEC 17025:2017 in Accreditation of Testing and Calibration Laboratories

As the date of publication of ISO/IEC 17025:2017 was November 2017 and the transition period was adopted as three years, the deadline for laboratories to conform to ISO/IEC 17025:2017 is 30 November 2020. All HKAS accreditations to ISO/IEC 17025:2005 will become invalid after 30 November 2020. HKAS policies and supplementary criteria relevant to ISO/IEC 17025:2017 will be issued in due course.

## 1. Laboratories applying for initial accreditation

### Application for accreditation

Starting from 1 July 2018, HKAS Executive will accept applications for accreditation to ISO/IEC 17025:2017. HKAS Executive recommends that new applications for accreditation should be made to this accreditation standard. Initial applications for accreditation to ISO/IEC 17025:2005 (HOKLAS 003:2015) will not be accepted after 31 December 2018.

### Initial applications based on ISO/IEC 17025:2005

Between 1 July 2018 and 31 December 2018, nonconformities against the requirements of ISO/IEC 17025:2005 will be raised as 'Nonconformities (NCs)'. Obvious nonconformities against the requirements of ISO/IEC 17025:2017 will be raised as 'Recommendations'\*. Accreditation to ISO/IEC 17025:2005 will be granted when the applicant laboratory has rectified all critical and significant NCs to the satisfaction of HKAS Executive and has committed to rectify all minor NCs prior to the next reassessment.

To ensure a smooth transition to ISO/IEC 17025:2017, all new laboratories accredited to ISO/IEC 17025:2005 shall prepare a transition plan detailing the changes to their management system and the time frame for implementation of the requirements of ISO/IEC 17025:2017. The transition plan shall be furnished with basic information as shown in the example on Page 6. The transition plan shall be submitted to HKAS Executive within one month from the date of obtaining accreditation.

If accreditation cannot be granted to an applicant laboratory within one year after the date of receipt of the application, HKAS Executive will suspend processing the application. The applicant laboratory shall implement all the requirements of ISO/IEC 17025:2017 (and submit the required application fee as appropriate) before HKAS Executive restarts the accreditation process and a fresh assessment to confirm conformity with all requirements to ISO/IEC 17025:2017 shall be conducted.

### Initial applications based on ISO/IEC 17025:2017

All nonconformities against the requirements of ISO/IEC 17025:2017 will be raised as NCs. The applicant laboratory shall provide a plan for resolving all NCs identified in the assessment to HKAS Executive within one month of the assessment. Accreditation to ISO/IEC 17025:2017 will be granted when the applicant laboratory has rectified all critical and significant NCs to the satisfaction of HKAS Executive and has committed to rectify all minor NCs prior to the next reassessment.

## 2. Accredited Laboratories

To ensure a smooth transition to ISO/IEC 17025:2017, an accredited laboratory shall prepare a transition plan detailing the changes to its management system and the time frame for implementation of the requirements of ISO/IEC 17025:2017. The transition plan shall be submitted to HKAS Executive by 1 September 2018 (or within one month from the date of obtaining accreditation to ISO/IEC 17025:2005 for any newly accredited laboratories). All on-site assessments by HKAS for confirming conformity with ISO/IEC 17025:2017 shall be completed by 1 May 2020. Such on-site assessments, which will incur additional assessment time and corresponding assessment fee by themselves, could be conducted either: (i) together with routine surveillance visits / reassessments; or (ii) earlier as additional assessments, which could be combined with ad-hoc assessment(s) for extension of scope of accreditation as appropriate. The transition plan to be submitted shall include all the aspects required and the proposed dates of all on-site assessment visits to be conducted by HKAS by 1 May 2020 to confirm transition of all test categories. Please refer to the example given on Page 6 on the expected information to be provided in the transition plan.

From 1 July 2018 onwards, laboratories may decide to have their reassessments, assessments for extension of scope of accreditation and surveillance visits of laboratories to be based on the requirements of ISO/IEC 17025:2005 or ISO/IEC 17025:2017. If ISO/IEC 17025:2005 is to be used, obvious nonconformities against the new requirements of ISO/IEC 17025:2017 found in the assessments will be raised as 'Recommendations'\*. HKAS Executive will agree with an accredited laboratory when assessment to ISO/IEC 17025:2017 is to be started, with due regard to the transition plan submitted by the laboratory. If ISO/IEC 17025:2017 is to be used, all nonconformities against the requirements of ISO/IEC 17025:2017 will be raised as NCs. Accreditation to ISO/IEC 17025:2017 will be granted when the laboratory has rectified all critical and significant NCs to the satisfaction of HKAS Executive and has committed to rectify all minor NCs prior to the next reassessment.

## 3. Issue of Certificate of Accreditation referring to ISO/IEC 17025:2017

A certificate of accreditation referring to ISO/IEC 17025:2017 for each test category after transition will be issued free of charge to an accredited laboratory when conformity with ISO/IEC 17025:2017 requirements for all activities under the test category concerned has been demonstrated to the satisfaction of HKAS Executive.

Note: \* Addressing the 'Recommendations' raised does not imply conformity with ISO/IEC 17025:2017. Conformity of the accredited laboratory to ISO/IEC 17025:2017 will be assessed on-site when the laboratory confirms that the new requirements of ISO/IEC 17025:2017 are fully implemented.

## Example of a transition plan:

Laboratory Name:		<<Name of laboratory>>
Transition due date proposed by the laboratory		2 April 2019
Monitoring Plan		A
Gap analysis		Before <<Date>>
Management system manuals updated to meet ISO/IEC 17025:2017 requirements		Before <<Date>>
Technical manuals (for Test Categories A, B, C) updated to meet ISO/IEC 17025:2017 requirements		Before <<Date>>
Technical manuals (for Test Categories D, E, F) updated to meet ISO/IEC 17025:2017 requirements		Before <<Date>>
Implementation of the revised management system for all Test Categories		From <<Date>>
Completion of internal audit of the updated system with internal audit report ready for assessment team's review		Before <<Date>> (this date shall be earlier than the proposed transition assessment date of 2 April 2019)
	Due dates for scheduled assessments	Accreditation standard to be used
Reassessment for Test Categories A, B, C	2 April 2018	ISO/IEC 17025:2005
Reassessment for Test Categories D, E, F	16 August 2018	ISO/IEC 17025:2005
Surveillance visit for Test Categories A, B, C (1st transition assessment)	2 April 2019	ISO/IEC 17025:2017
Surveillance visit for Test Categories D, E, F (2nd transition assessment**)	16 August 2019	ISO/IEC 17025:2017
Reassessment for Test Categories A, B, C	2 April 2020	ISO/IEC 17025:2017
Reassessment for Test Categories D, E, F	16 August 2020	ISO/IEC 17025:2017

\*\*All transition assessments shall be completed by 1 May 2020.

## Important dates

Important dates	Event
1 July 2018 (tentative)	HKAS starts to accept applications for accreditation to ISO/IEC 17025:2017
1 September 2018	Last day for accredited laboratories to submit transition plan to ISO/IEC 17025:2017
1 July 2018 to 31 December 2018	Assessments for initial applications may be based on either ISO/IEC 17025:2005 or ISO/IEC 17025:2017
31 December 2018	Last day to accept initial application based on ISO/IEC 17025:2005
Starting from 1 July 2018	Assessment of accredited laboratories may be based on either ISO/IEC 17025:2005 or ISO/IEC 17025:2017, as agreed with HKAS Executive
1 May 2020	Assessment of all accredited laboratories for transition to ISO/IEC 17025:2017 shall be completed
From 1 December 2020	All HKAS accreditations to ISO/IEC 17025:2005 become invalid

# Experience Sharing Seminar for Microbiological Testing Laboratories

HKAS regularly organises experience sharing seminars for assessors and laboratory personnel. These seminars provide a good opportunity for them to exchange views, knowledge and expertise, as well as helping us to harmonise application of accreditation criteria. An experience sharing seminar for microbiological testing laboratories was conducted on 16 November 2017. Eighty representatives from laboratories and assessors joined the seminar.

Dr John Ho, HKAS Senior Accreditation Officer, started by briefing participants on the revised accreditation requirements on Code of Conduct. Two experienced technical assessors in microbiological testing, Dr W C Yam and Mr Danny Cheung, were then invited to share their assessment experience with participants.



Dr John Ho briefs participants on the Code of Conduct requirements

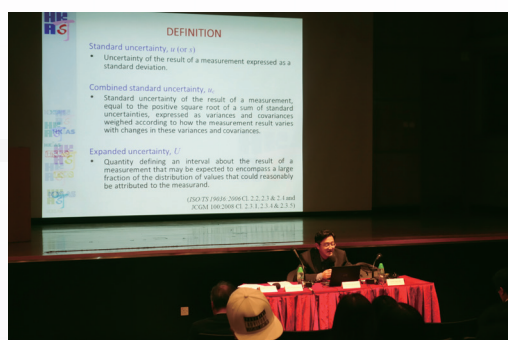


Dr W C Yam shares his experience in sampling airborne microorganisms

Mr Cheung continued the discussion by giving a presentation on the testing of several specific pathogens viz. *Legionella*, *Vibrio cholerae* and *Shigella*, with a detailed explanation of the standard methods used, their limitations, results reporting requirements, as well as specific properties of the pathogens.



Mr Danny Cheung introduces the common methods used for testing specific pathogens



Mr Edmund Tse explains MU estimation in microbiological testing

In the last session, Mr Edmund Tse, HKAS Accreditation Officer, briefed participants on the accreditation criteria for estimating measurement uncertainty (MU) in microbiological testing, followed by an overview of the common approaches used for MU estimation in microbiological testing. The discussion emphasised a global (top-down) approach for estimating MU, building on a MU model in which two essential MU components viz. the distributional and operational components were involved.

Feedback from participants showed that most of them found the seminar informative and useful. In view of the positive responses, HKAS will continue its effort to organise similar experience sharing seminars in the future.

# Recognition of HKAS by US Environmental Protection Agency (EPA) under the EPA Toxic Substances Control Act Title VI Third-Party Certification Program

The US Environmental Protection Agency (EPA) published in the Federal Register a final rule in December 2016 (<https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0244-0013>) requiring composite wood products produced domestically or imported into the US to meet specified formaldehyde emission standards. This final rule led to a Third-Party Certification Programme viz. the EPA Toxic Substances Control Act (TSCA) Title VI Third-Party Certification Program that helps ensure that composite wood panel producers comply with the formaldehyde emission standards for composite wood products pursuant to the requirements of the Formaldehyde Standards for Composite Wood Products Act, or TSCA Title VI. Under the Programme, recognised Third-Party Certifiers (TPCs) will carry out product certification and regularly inspect composite wood panel producers, and conduct, oversee and verify formaldehyde emission tests. According to the rule, an accreditation body (AB) must enter into a recognition arrangement with EPA in order to become a recognised AB under the Programme for accrediting TPCs and related testing laboratories.

Being a signatory member to both ILAC MRA for testing and inspection and IAF MLA for product certification, HKAS has been admitted by the EPA to the Third-Party Certification Program and become a recognised product and laboratory AB to provide related accreditation service. For details, please contact our Senior Accreditation Officer, Dr John Ho, at [cwho@itc.gov.hk](mailto:cwho@itc.gov.hk) or 2829 4808.





# Seminar on Testing and Certification for Environmental Excellence

In recent years, there has been increasing awareness of environmental protection. Many companies and organisations are therefore becoming more conscious of green management and energy conservation. Local testing and certification industry has also stepped up to provide more support in this regard. For example, laboratories conduct testing on water and air samples to help monitor environmental pollution, certification bodies also offer third party certification services for management systems relating to environment responsibility and energy usage in accordance with international standards.



To introduce how testing and certification services can help improve the environment, Hong Kong Council for Testing and Certification and Hong Kong Accreditation Service co-organised a seminar on 18 December 2017. The seminar aimed for practitioners from property and facility management companies, personnel responsible for building management, tenants in commercial buildings as well as users of environmental testing and certification services.

Speakers of the seminar include representatives from testing and certification organisations, who shared their insights on the benefits of using different accredited environmental testing, inspection and certification services. A commercial company that was certified for various environment-related management system standards was invited to share its experience on how certification service helps accomplish objectives for energy conservation and green management. An officer of Hong Kong Accreditation Service also talked about the important role of accreditation in ensuring the quality of testing and certification services at the seminar.

## HKAS SC-06 – Code of Conduct Revised

HKAS Supplementary Criteria No. 6 Code of Conduct was revised and published on 2 January 2018.

### Key changes are:

Clause number	Change
2.2	The contents of the code of conduct should follow the Corruption Prevention Guide for Testing and Certification Industry prepared by the ICAC as far as practicable.
2.2 (a)	The code of conduct shall address solicitation of advantages explicitly.
2.3	CAB should seek professional advice from the ICAC with regard to the adequacy of the code of conduct.
3.2	CAB should arrange all personnel to attend integrity management training courses organised by the ICAC as far as possible.
3.5	CAB failing to report any impropriety or unlawful act would render imposed suspension by HKAS.

HKAS assessment teams will review the updated code of conduct and assess the implementation of the above actions during assessments.

## Quick News

### APLAC-PAC Project Steering Committee meeting in Hong Kong

HKAS hosted the meeting of the Joint APLAC-PAC Project Steering Committee in December 2017. The committee is responsible for overseeing the process of merging APLAC and PAC to become the Asia Pacific Accreditation Cooperation (APAC), a new accreditation cooperation body for the region. During the meeting, the Constitution, regulations, membership structure and fee model of the new regional body as well as other key issues regarding the merger and the transition were discussed. It is anticipated that APAC will be established on 1 January 2019. The mid-year meeting of the APLAC Board of Management was also held in Hong Kong back to back with the Project Steering Committee meeting.



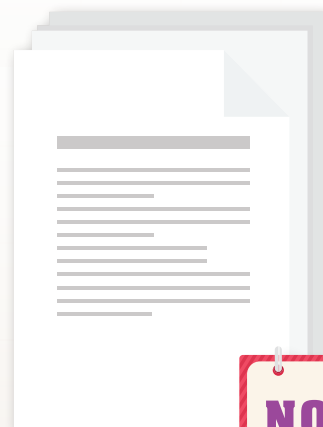
### New Accreditation Service for Scene of Crime Investigation

HKAS now offers accreditation service for scene of crime investigation under the Hong Kong Inspection Body Accreditation Scheme (HKIAS). The accreditation criteria for organisations carrying out crime scene inspection are ISO/IEC 17020 (i.e. HKIAS 003), HKIAS Supplementary Criteria No. 7 and other relevant HKAS and HKIAS requirements. To learn more about this new service, please contact our Senior Accreditation Officer, Dr Daria Wong, at 2829 4801 or [chwong@itc.gov.hk](mailto:chwong@itc.gov.hk).

### Publication of ISO/IEC 17011:2017

ISO/IEC 17011:2017, Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies, was published in November 2017. This document specifies requirements for the competence, consistent operation and impartiality of accreditation bodies (ABs) assessing and accrediting conformity assessment bodies.

According to the ISO/IEC 17011:2017 Transition Plan issued by IAF and ILAC, all signatory ABs, including HKAS, shall complete the transition to the new standard by November 2020.



# Chairman of EA Visits Hong Kong

HKAS invited Dr Thomas Facklam, the Chairman of the European Co-operation for Accreditation, to visit Hong Kong on 4 – 8 December 2017 through the Government's Sponsored Visitor Programme. The aim of this programme is to allow guests from overseas to experience Hong Kong first hand, so that they can better understand the economic and social development of Hong Kong in recent years.

During the week of his stay, Dr Facklam visited a number of government departments such as Department of Justice, the Independent Commission Against Corruption, Electrical and Mechanical Services Department, Standards and Calibration Laboratory (SCL), etc. He also met with stakeholders of the testing and certification industry, including HKAS and its Accreditation Advisory Board, HKAS accredited conformity assessment bodies, the Hong Kong Council for Testing and Certification, the Hong Kong Science and Technology Park, as well as the Open University of Hong Kong. He had in-depth discussions with representatives of these organisations and obtained a good overview about Hong Kong. They also exchanged information on fast-growing areas as well as fields with high potential to develop in testing and certification industry worldwide.

At the end of the programme, Dr Facklam expressed his enjoyment of the visit and the fruitful interactions with various parties. He thanked the Hong Kong Government for such a valuable experience. HKAS would also like to thank the receiving parties for their hospitality and kind assistance during Dr Facklam's visit.



Dr Facklam meets with colleagues of HKAS and SCL



Dr Facklam visits the teaching laboratory at the Open University of Hong Kong



Visit to the Data Studio of the Hong Kong Science and Technology Park

# Anti-corruption Workshops for HKAS Accredited Organisations

Professional integrity is one of the core values of Hong Kong's testing and certification industry. A high level of credibility gives users of testing and certification services extra confidence, thereby enhancing the industry's competitiveness in the international market. To encourage practitioners to uphold a high level of professional ethics, HKAS invited ICAC to organise two anti-corruption workshops for staff of accredited organisations on 22 January 2018.

The first workshop on 'Professional Integrity and Hong Kong's Anti-bribery Legislation' was offered to frontline staff, while the second workshop on 'Professional Integrity and Managing Staff Integrity' was mainly for managerial staff. Both workshops were delivered by Mr Wallace Chu, Senior Community Relations Officer of the Hong Kong Business Ethics Development Centre of ICAC.

During the talks, Mr Chu shared with participants about the risks and consequences of corruption and malpractices in the industry, as well as how to identify ethical dilemma as a defence against corruption. He also talked about the importance of implementing an adequate Code of Conduct for all staff in an organisation.

Nearly 250 participants from accredited organisations attended the workshops. Due to the overwhelming response, HKAS will liaise with ICAC to organise similar training again in the near future.



# Experience Sharing Seminar for Chemical Testing Laboratories

An experience sharing seminar for chemical testing laboratories accredited under HOKLAS was held on 19 December 2017. About 120 participants including practitioners from over 50 accredited laboratories and technical assessors joined the seminar.

The seminar consisted of two parts. In the first part, Dr John Ho, HKAS Senior Accreditation Officer, provided a refresher session to participants on the HKAS accreditation requirements on Code of Conduct, including a few updates in HKAS Supplementary Criteria No. 6 and HOKLAS Supplementary Criteria No. 33. Then, Ms Sandra Ho, an experienced technical assessor and practitioner in the field for over 35 years and altogether having conducted over 200 assessments for HKAS, shared with us her insights on one of the key aspects in the new edition of ISO/IEC 17025 – risk-based thinking. She explained in detail the new requirement in ISO/IEC 17025:2017 concerning ‘actions to address risks and opportunities’ and the approach to conduct risk assessment in a laboratory context. The discussion was supplemented with examples of common operational risks in laboratories, together with the associated risk management protocols.

In the second part of the seminar, HKAS Accreditation Officers, Dr William Ho and Mr Edmund Tse, shared with participants common nonconformities identified in assessments relevant to chemical testing and accreditation requirements for ensuring the validity of test results. The use of the Shewhart control charts to assist in statistical control of testing process was also discussed.

Participants actively took part in discussions with the speakers throughout the seminar. They generally found the seminar very useful. In view of the good response, HKAS will continue to organise similar activities in the future.



Dr John Ho briefs participants on the accreditation requirements on Code of Conduct



Ms Sandra Ho introduces the management of risks and opportunities



Dr William Ho shares common assessment findings for chemical testing laboratories



Mr Edmund Tse introduces how Shewhart control charts could be applied to statistical control of testing process



Participants in the Experience Sharing Seminar for Chemical Testing Laboratories

# Accredited Services in Demand

In the 23<sup>rd</sup> meeting of the Users of HKAS Accredited Services Liaison Group on 15 November 2017, users explored the availability of the following accredited activities:

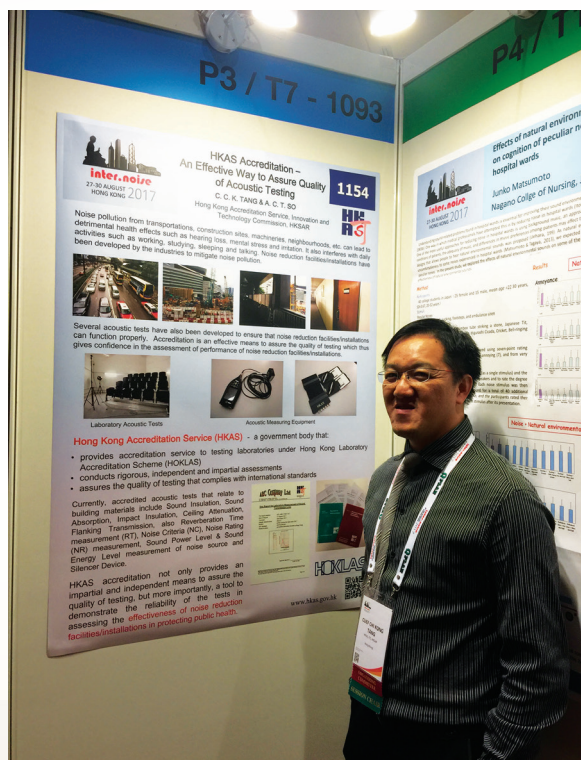
- 1) Leaching test for six heavy metals (lead, cadmium, chromium, nickel, copper and antimony) in products for use in contact with drinking water in accordance with AS/NZS 4020.
- 2) GB standards for toys and baby products:
  - GB 4806.1-2016 食品安全国家标准 食品接触材料及制品通用安全要求
  - GB 4806.2-2015 食品安全国家标准 奶嘴
  - GB 4806.5-2016 食品安全国家标准 玻璃制品
  - GB 4806.6-2016 食品安全国家标准 食品接触用塑料树脂
  - GB 4806.7-2016 食品安全国家标准 食品接触用塑料材料及制品
  - GB 4806.9-2016 食品安全国家标准 食品接触用金属材料及制品
  - GB 4806.10-2016 食品安全国家标准 食品接触用涂料及涂层
  - GB 4806.11-2016 食品安全国家标准 食品接触用橡胶材料及制品
  - GB 9685-2016 食品安全国家标准 食品接触材料及制品用添加剂使用标准
  - GB 31604.10-2016 食品安全国家标准 食品接触材料及制品 2,2-二(4-羟基苯基)丙烷(双酚A)迁移量的测定
  - GB 28482-2012 婴幼儿安抚奶嘴安全要求
  - GB 6675.1-2014 玩具安全 第1部分:基本规范
  - GB 6675.2-2014 玩具安全 第2部分:机械与物理性能
  - GB 6675.3-2014 玩具安全 第3部分:易燃性能
  - GB 6675.4-2014 玩具安全 第4部分:特定元素的迁移
- 3) Calibration of heat soak ovens
- 4) Testing in accordance with ASTM C1279, BS EN 14179-1, BS EN 12600 and BS EN 1288-3
- 5) Inspection in accordance with BS EN 14179-1

Accredited conformity assessment bodies may consider seeking accreditation from Hong Kong Accreditation Service if interested.

# The 46<sup>th</sup> International Congress and Exposition on Noise Control Engineering (Inter-noise 2017)

Noise pollution is posing health problems to many people in Hong Kong. To mitigate the negative influence, noise reduction facilities/installations have been developed by the industries. Several acoustic tests have also been developed to ensure that these noise reduction facilities/installations can function properly. Since these tests are crucial for verifying the effectiveness of such noise reduction facilities/installations, highly accurate and reliable test results are required. Accreditation provides an effective means to assure the quality of testing and thus give confidence in the verification process. HKAS took this opportunity to participate in the congress and presented the importance of quality assurance in acoustic testing.

Our Accreditation Officer, Ir Dr Clief Tang, had a poster presentation on 'HKAS Accreditation - An Effective Way to Assure Quality of Acoustic Testing' in the congress. Common acoustic tests used in Hong Kong and the accreditation of acoustic tests by Hong Kong Accreditation Service under the Hong Kong Laboratory Accreditation Scheme (HOKLAS) were introduced. Fruitful discussions among participants were held and valuable suggestions were shared which certainly would broaden the awareness of good quality testing on acoustics.



Ir Dr Clief Tang presents in the poster session

For more information about accreditation services in relation to construction, please contact our Senior Accreditation Officer, Ir Chan Wai-keung (tel:2829 4812 / email:wk.chan@itc.gov.hk) or Ir Joshua Lee (tel:2829 4870 / email:joshua.lee@itc.gov.hk).

# Assessment Feedback Seminar for Medical Testing Laboratories

The 9<sup>th</sup> Assessment Feedback Seminar for Medical Testing Laboratories was held at Hong Kong Museum of History on 12 January 2018. This half-yearly event aims to provide a platform for exchange of experience and knowledge, and to harmonise accreditation requirements.

This seminar consisted of three sessions. The first session was a highlight of selected findings recorded in assessments of the past six months.

Some common nonconformities

- the internal audit plan did not cover all elements of ISO 15189;
- quality indicators to monitor and evaluate performance covering pre-examination, examination and post-examination processes were not established;
- correction factors were not updated after calibration of equipment;
- missing the required statement in HOKLAS endorsed report as stipulated in HOKLAS SC-33

In the second session, some noteworthy points, including proper use of the accreditation symbol and claims of accreditation status, issue of revised documents and forms, were elaborated. The last session was a discussion on feedback from both laboratories and assessors.

This seminar attracted 104 medical testing laboratory professionals and assessors. All participants engaged in the discussion actively and provided positive feedback to the seminar.



Dr Alex Chan, Accreditation Officer of HKAS, presents previous assessment findings, points to note, and feedback to the audience

## 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
HKAS SC-05	HKAS Supplementary Criteria No. 5 'Internal Audits and Management Reviews'	Issue 3	Nov-2017	Nov-2017
HKAS SC-06	HKAS Supplementary Criteria No. 6 'Code of Conduct'	Issue 4	Jan-2018	Jan-2018
HKCAS 007	Assessment / Reassessment Questionnaire (for Management System Certification Bodies)	Feb 2018	Feb 2018	Feb 2018



Document Code	HKAS published document	Version	Publication Date	Implementation Date
*HKCAS 007-A1	Scope of Accreditation Sought (for New Application for Accreditation or Extension of Scope of Accreditation only)	Feb 2018	Feb 2018	Feb 2018
*HKCAS 007-A2A	Management System Checklist (for any Management System Certification)	Feb 2018	Feb 2018	Feb 2018
*HKCAS 007-A2B	Management System Checklist (for Management System Certification in respect of a Certification Scheme)	Feb 2018	Feb 2018	Feb 2018
*HKCAS 007-A2C	Management System Checklist (for EnMS Certification)	Feb 2018	Feb 2018	Feb 2018
*HKCAS 007-A2D1	Management System Checklist [for EMS Certification (based on ISO/IEC TS 17021-2: 2012)]	Feb 2018	Feb 2018	Feb 2018
*HKCAS 007-A2D2	Management System Checklist [for EMS Certification (based on ISO/IEC 17021-2: 2016)]	Feb 2018	Feb 2018	Feb 2018
*HKCAS 007-A2E	Management System Checklist (for FSMS Certification)	Feb 2018	Feb 2018	Feb 2018
*HKCAS 007-A2F	Management System Checklist (for ISMS Certification)	Feb 2018	Feb 2018	Feb 2018
*HKCAS 007-A2G	Management System Checklist (for OHSMS Certification)	Feb 2018	Feb 2018	Feb 2018
*HKCAS 007-A2H1	Management System Checklist [for QMS Certification (based on ISO/IEC TS 17021-3: 2013)]	Feb 2018	Feb 2018	Feb 2018
*HKCAS 007-A2H2	Management System Checklist [for QMS Certification (based on ISO/IEC 17021-3: 2017)]	Feb 2018	Feb 2018	Feb 2018
*HKCAS 007-A2J	Management System Checklist (for RCHE-MS Certification)	Feb 2018	Feb 2018	Feb 2018
HKCAS AP001	HKCAS Application Package 001 'Accreditation of Management System Certification Bodies 管理體系認證機構的認可'	Feb 2018	Feb 2018	Feb 2018
HKCAS IN001	Application Procedures for HKCAS Accreditation (Informative)	Issue 2	Feb 2018	Feb 2018
HKCAS SC-04	HKCAS Supplementary Criteria No. 4 'Accreditation Regulations Specific for HKCAS - Certification Body'	Issue 14	Feb 2018	Feb 2018
HKCAS SC-07	HKCAS Supplementary Criteria No. 7 "Accreditation Programme for Occupational Health and Safety Management System Certification"	Issue 4	Nov-2017	Nov-2017
HKCAS SC-09	HKCAS Supplementary Criteria No. 9 'Accreditation of Greenhouse Gas Validation and Verification Bodies – Verification of Greenhouse Gas Assertions at Organisation Level, and Validation and/or Verification of Greenhouse Gas Assertions at Project Level'	Issue 4	Nov-2017	Nov-2017
HKCAS SC-13	HKCAS Supplementary Criteria No. 13 'Accreditation of Greenhouse Gas Verification Bodies – Verification of Carbon Footprint of a Product Study Report'	Issue 2	Nov-2017	Nov-2017
*HKIAS AP004	HKIAS Application Package 004 'Accreditation of Inspection Body for Scene of Crime Investigation 罪案現場勘查的認可'	Dec 2017	Dec 2017	Dec 2017
*HKIAS SC-07	HKIAS Supplementary Criteria No.7 'Scene of Crime Investigation'	Issue 1	Dec 2017	Dec 2017
HOKLAS 007	Assessment / Reassessment Questionnaire for Non-medical Laboratories	Mar 2018	Mar 2018	Mar 2018
HOKLAS SC-06	HOKLAS Supplementary Criteria No. 6 "Environmental Testing" Test Category – Chemical Testing	Issue 8	Dec-2017	Dec-2017
HOKLAS SC-08	HOKLAS Supplementary Criteria No. 8 "“Chinese Medicine”, “Environmental Testing”, “Food”, “Miscellaneous”, “Pharmaceutical Products” and “Toys and Children’s Products - Microbiological Testing "	Issue 8	Dec-2017	Dec-2017
HOKLAS SC-21	HOKLAS Supplementary Criteria No. 21 "'Food' - Detection and quantification of Genetically Modified Organisms (GMO) in food by Polymerase Chain Reaction (PCR)"	Issue 5	Dec-2017	Dec-2017
HOKLAS SC-37	HOKLAS Supplementary Criteria No. 37 "Food" Test Category - Chemical Testing	Issue 5	Dec-2017	Dec-2017
HOKLAS SC-43	HOKLAS Supplementary Criteria No. 43 "“Chinese Medicine” and “Food”- Species Identification by DNA Sequencing for Authentication Purpose'	Issue 5	Dec-2017	Dec-2017

Document Code	HKAS published document	Version	Publication Date	Implementation Date
HOKLAS SC-44	HOKLAS Supplementary Criteria No. 44 "Chinese Medicine" Test Category – Chemical and Physicochemical Testing to the Hong Kong Chinese Materia Medica (HKCMM) Standards	Issue 3	Dec-2017	Dec-2017
HOKLAS SC-50	HOKLAS Supplementary Criteria No. 50 "Environmental Testing" Test Category – Sampling and On-site Measurement for Air Quality Monitoring '	Issue 2	Dec-2017	Dec-2017
*HOKLAS 017C: 2016	能力驗證提供者認可技術準則 (ISO/IEC 17043:2010 - 《合格評定 - 能力驗證的一般規定》, MOD (縮略本)	Sep 2016	Sep 2016	Sep 2016
*HKCAS SC-15	HKCAS Supplementary Criteria No. 15 'Accreditation of US Environmental Protection Agency (EPA) Toxic Substances Control Act (TSCA) Title VI Third-Party Certifiers Certifying Production of Composite Wood Products for Compliance with EPA TSCA Title VI Formaldehyde Emission Standards	Issue 1	Feb-2018	Mar-2018
*HKCAS 006#	Schedule of Fees for Accreditation of Certification Bodies and Validation / Verification Bodies within the Hong Kong Special Administrative Region (Effective from 30 March 2018)	Mar 2018	Mar 2018	Mar 2018
*HKIAS 006#	Schedule of Accreditation Fees for Inspection Bodies within the Hong Kong Special Administrative Region (Effective from 30 March 2018)	Mar 2018	Mar 2018	Mar 2018
*HOKLAS 006#	Schedule of Accreditation Fees for Organisations within the Hong Kong Special Administrative Region (Effective from 30 March 2018)	Mar 2018	Mar 2018	Mar 2018
*HOKLAS 013#	Schedule of Accreditation Fees for Organisations outside of the Hong Kong Special Administrative Region (Effective from 30 March 2018)	Mar 2018	Mar 2018	Mar 2018
HKCAS 020-1:2013	Technical Criteria for Accreditation of Greenhouse Gas Validation and Verification Bodies - Part 1 (ISO 14065:2013, Greenhouse gases - Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition, MOD) (Abridged Version)	1 <sup>st</sup> Ed Amd 2	Mar-2018	Mar-2018
*HOKLAS SC-53	HOKLAS Supplementary Criteria No. 53 'Chemical Testing' Test Category – Accreditation of Laboratories for Testing of Composite Wood Products for Formaldehyde Emission to Support the US Environmental Protection Agency (EPA) Toxic Substances Control Act (TSCA) Title VI Third-Party Certification Program	Issue 1	Mar-2018	Mar-2018
HKAS SC-01	HKAS Supplementary Criteria No. 1 Use of HKAS accreditation symbols and claims of accreditation status	Issue 11	Mar 2018	Mar 2018

\*New publication

## Proficiency Testing Updates

An update on the proficiency testing programmes organised by HKAS is given below (as at 31 Mar 2018):

Test Category	Programme	Status
Construction Materials	HCM/2017/01 - Determination of Density and Fineness of Cement	Final report issued in Mar 2018. Fourteen laboratories participated.
Toy and Children's Products Environmental Testing	HTC/2017/01 – Analysis of Chromium (VI)	Interim report under preparation. Twenty laboratories participated with results returned.

Progress in programmes organised by regional cooperations of accreditation bodies

Test Category	Programme and Organiser	Status
Calibration Service	APLAC M021 – Volume Organised by KAN, Indonesia	Final report was issued in Dec 2017. Three laboratories participated.
	APLAC M027 – Calibration of E2 Weights Organised by KAN/Puslit KIM LIPI	Final report was issued in Dec 2017. Two laboratories participated.



Test Category	Programme and Organiser	Status
Chinese Medicine	APMP-APLAC T106 – Organochlorine Pesticides in Ginseng Root Organised by GLHK, Hong Kong	Final report to be issued in second half of 2018. Four laboratories participated.
Food	APMP-APLAC T105 – Nutritional Elements (Iron and Zinc) in Wheat Flour Organised by KRIS, Korea	Final report was issued in Nov 2017. One laboratory participated.
	APMP-APLAC T107 – Elements in Food Supplement Organised by GLHK, Hong Kong	Final report to be issued in first half of 2018. Two laboratories participated.
	APLAC T108 – Benzo[a]pyrene in Olive Oil Organised by NIM, China	Samples distributed in Dec 2017. Results submitted in Mar 2018. Three laboratories nominated for participation.

## Accreditation Updates

### New Accreditation Granted (31 October 2017 to 31 March 2018)

One laboratory has been accredited since the last issue of HKAS News. The name, registration number and accredited areas are summarised below. HKAS wishes to congratulate the laboratory on its success in obtaining accreditation.

#### HOKLAS

Registration No.	Name of Conformity Assessment Body	Test Category Granted	Clientele
HOKLAS 273	IDEAL Test Consultants Ltd.	Calibration Services Construction Materials	Public

### Accreditation Suspended

#### Voluntary Suspension (as at 31 March 2018)

#### HOKLAS

Registration No.	Name of Conformity Assessment Body	Test Category and Test Area	Effective Date (dd.mm.yyyy)
009	SGS Hong Kong Limited	<b>Testing Required By The China Compulsory Certification (CCC) System :</b> Electrical and Electronic Products <b>Electrical and Electronic Products : All tests</b>	16.08.2017
010	CEDD – Public Works Laboratories	<b>Construction Materials :</b> Playground equipment	31.08.2017
036	UL VS Hong Kong Limited	<b>Testing Required By The China Compulsory Certification (CCC) System :</b> All tests	03.10.2017
048	K. Wah Asphalt Limited - Tai Sheung Tok Depot Laboratory	<b>Construction Materials :</b> All tests	01.06.2017
125	SGS IECC Limited	<b>Electrical and Electronic Products : All tests</b>	16.08.2017
156	Hong Kong Gems Laboratory Company Limited	<b>Physical and Mechanical Testing :</b> All tests	24.12.2017
165	Jewellery Trade Laboratory Limited	<b>Physical and Mechanical Testing : All tests</b>	01.05.2017
188	NGTC (HK) Ltd.	<b>Physical and Mechanical Testing : All tests</b>	09.02.2018
235	TÜV SÜD Hong Kong Limited	<b>Chemical Testing : All tests</b>	05.04.2017
235	TÜV SÜD Hong Kong Limited	<b>Electrical and Electronic Products : All tests</b> <b>Testing Required By The China Compulsory Certification (CCC) System : All tests</b>	10.04.2017
242	Chemical Laboratory (HK) Pte Limited	<b>Food : All tests</b>	30.04.2017
246	Vocational Training Council - Hong Kong Institute of Vocational Education (Tuen Mun) - Testing and Calibration Centre	<b>Calibration Services : All Calibration</b>	12.01.2018

## Imposed Suspensions (as at 31 March 2018)

### HOKLAS

Registration No.	Name of Laboratory	Test Category and Test Area	Effective Date (dd.mm.yyyy)
818S	PHC Medical Diagnostic Centre Ltd.	<b>Medical Testing</b> : All tests	24.11.2017

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.

### Accreditation Terminated

#### Voluntary Termination (31 October 2017 to 31 March 2018)

### HOKLAS

Registration No.	Name of Laboratory	Test Category and Test Area	Effective Date (dd.mm.yyyy)
058	Bureau Veritas Hong Kong Limited - Kowloon Bay Office	<b>Food</b> : Preservatives	24.11.2017
195	ICQ (HK) Limited	<b>Toys and Children Products</b> : All tests	31.10.2017
204	The Lab (Asia) Limited	<b>Construction Materials</b> : All tests in Dong Guan Laboratory	10.11.2017

### HKIAS

Registration No.	Name of Inspection Body	Inspection Field	Effective Date (dd.mm.yyyy)
024#	Health, Safety and Environment Office, The Hong Kong University of Science and Technology	Indoor Air Quality	19-01-2018

# Accreditation of all activities of the conformity assessment body is terminated.

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.

