

# HKAS



News Issue No. 74

December 2023

Hong Kong Accreditation Service



P.3 The World Accreditation Day Forum 2023

P.4 HKAS Assessor Forum 2023

# CONTENTS

Issue No.74

<b>The World Accreditation Day Forum 2023</b>	<b>3</b>
<b>HKAS Assessor Forum 2023</b>	<b>4</b>
<b>Briefing Sessions on Updated Requirements in ISO/IEC 17043:2023</b>	<b>5</b>
<b>Technical Seminar on Statistics for Quantitative Interlaboratory Comparisons for Chemical Testing Laboratories</b>	<b>6</b>
<b>Experience Sharing Seminar on Food Chemical Testing</b>	<b>7</b>
<b>Liaison with Stakeholders in the Construction Industry</b>	<b>9</b>
<b>Media Briefing on "Digitisation and Automation of Public Works Laboratories"</b>	<b>10</b>
<b>New HKAS Fee Schedules</b>	<b>10</b>
<b>First Accreditation on Scene of Crime Investigation</b>	<b>11</b>
<b>Task Force on Polymerase Chain Reaction (PCR) Testing</b>	<b>11</b>
<b>Peer Evaluation of HKAS by APAC</b>	<b>12</b>
<b>Updates from ILAC, IAF and APAC</b>	<b>12</b>
<b>New Accreditation Granted, Suspended and Terminated</b>	<b>15</b>
<b>New and Revised HKAS Documents</b>	<b>16</b>
<b>Proficiency Testing Updates</b>	<b>16</b>

**36/F, Immigration Tower,  
7 Gloucester Road, Wanchai, Hong Kong**  
**Tel: 2829 4841 Fax: 2824 1302**  
**Email: [hkas@itc.gov.hk](mailto:hkas@itc.gov.hk)**  
**Website: [www.hkas.gov.hk](http://www.hkas.gov.hk)**

Every care has been taken to check the accuracy of the information included in this newsletter. However, HKAS Executive does not guarantee its accuracy and readers should note that if they make use of such information, they do so at their own risk. The views and opinions in the articles provided by third parties do not reflect those of HKAS Executive.

# The World Accreditation Day Forum 2023



Mr LAU Wai-ming, Assistant Commissioner for Innovation and Technology (Quality Services) giving welcoming remarks.

**H**ong Kong Accreditation Service, in collaboration with the Hong Kong Council for Testing and Certification, organised a forum on 16 June 2023 to celebrate the World Accreditation Day (WAD). The theme of the WAD this year was Accreditation: Supporting the Future of Global Trade.

Different technical regulations in different regions around the world create technical barriers to trade. Mutual Recognition Arrangements (MRA) / Multilateral Recognition Arrangements (MLA) promote international trade by accepting conformity assessment results (e.g. test reports, certificates) across international borders. Through these MRA / MLA, an accreditation body will recognise conformity assessment results issued by laboratories, inspection bodies and certification bodies accredited by its MRA / MLA partners. Hence, global trade can be facilitated and the cost and time of repeated testing and certification can be reduced. In line with the theme of this year's World Accreditation Day, we were delighted to have four guest speakers from different sectors, namely the manufacturing sector, the conformity assessment body sector, users of accredited services and government departments, to share their views on how accreditation benefited their sectors. The forum attracted about 150 participants, including professionals and practitioners from the testing and certification industry, academics, users of conformity assessment services and officials from other governmental departments.

At the beginning of the forum, Mr LAU Wai-ming, Assistant Commissioner for Innovation and Technology (Quality Services) delivered the welcoming

remarks. Mr LAU pointed out that the globally mutual recognition arrangements of accreditation and the application of international standards could eliminate the need for repetition of conformity assessments, reduce costs and facilitate free trade across borders. He added that accreditation could ensure professional and reliable services provided by the accredited conformity assessment bodies.

## Market Expansion with International Accreditation

The first speaker of the forum was Dr Ralph CHOW, Chief Executive Officer of The Chinese Manufacturers' Association of Hong Kong. In the talk, Dr CHOW shared with participants the recent market trend and challenges that the Hong Kong manufacturing industry was facing. He also emphasised that accreditation played an essential role in supporting Hong Kong's manufacturers. He added that the endorsed test reports and certificates issued by accredited conformity assessment bodies were beneficial to Hong Kong's exports.

## How Accreditation Supports Global Supply Chain - Ensuring Quality, Safety & Sustainability

The next speaker, Ms Miranda KWAN, Director of Knowledge Solutions of SGS Hong Kong Limited, shared the recent key challenges in global supply chain. She emphasised the benefits of accreditation



Forum celebrating WAD 2023 in Hong Kong (from left to right: Mr Wilson SHUM, Ms Miranda KWAN, Mr LAU Wai-ming, Dr Ralph CHOW, Ir Amund WONG and Dr CHAN Wing-han).

in global supply chain, including improving customer confidence, company image and cost savings. By sharing some case studies, Ms KWAN illustrated how accreditation and conformity assessment activities contributed to business growth. She concluded that accreditation could provide a framework for compliance with international standards and regulations, and promote best practices in quality control, safety and sustainability.

### **Building the Three-runway System of Hong Kong International Airport - The Importance of Accreditation and Conformity Assessment**

Ir Amund WONG, General Manager of Technical Services Infrastructure of the Airport Authority Hong Kong, was the next speaker onstage. His talk was about how accreditation supported the development of Three-runway System of the Hong Kong International Airport. In the presentation, Ir WONG introduced the accredited test activities that were carried out for the Three-runway System by their onsite laboratories. He emphasised the importance of accreditation in ensuring the quality of test results. He also shared the benefits of having laboratories set up onsite, which enabled prompt testing services for a large volume of samples.

### **Applied Research of the Government Chinese Medicines Testing Institute**

The last speaker of the forum was Dr CHAN Wing-han, Senior Chemist (Government Chinese Medicines Testing Institute) of the Department of Health of the HKSAR Government. Dr CHAN introduced the development of Chinese medicine in Hong Kong. Then, she gave an overview of the Government Chinese Medicines Testing Institute (GCMTI), which had recently obtained HOKLAS accreditation. Dr CHAN also presented how the work of the Institute supported Chinese medicine trade and promoted standardisation of Chinese medicine testing in Hong Kong.

In the last session of the Forum, the four speakers were invited to join the question and answer session on stage. Participants raised interesting questions and shared their views with the speakers. The session was interactive and fruitful.



WAD Forum 2023

## **HKAS Assessor Forum 2023**

**A**ssessors and technical experts are indispensable partners of HKAS. Without their valuable support, it would not be possible for HKAS to provide professional accreditation service. Every year, HKAS organises the Assessor Forum to share with participants the progress of HKAS' work and the latest development of HKAS. In the past three years, HKAS organised Assessor Forums remotely in relation to the COVID-19 epidemic. This year, HKAS resumed a physical Forum, which was held on 16 June 2023. It attracted more than 170 assessors and technical experts.

### **Assessor Forum**

Mr Wilson SHUM Wai-leung, Executive Administrator of HKAS, opened the Assessor Forum by reporting the work of HKAS in the period from October 2022 to April 2023 as well as introducing new developments in coming years. Mr SHUM first reported the latest figures of organisations accredited, followed by the performance of the accredited organisations and



Assessor Forum 2023

their feedback on HKAS assessments. Then, he shared about the international activities and work of HKAS with participants. Finally, he wholeheartedly expressed his appreciation to all assessors and technical experts for their dedication and continuous support over the past years.

### **Certificate Presentation Ceremony**

Following the update from Mr SHUM, Professor Paul LAM, SBS, JP, Chairman of the HKAS Accreditation



Mr SHUM Wai-leung sharing the update and development of HKAS to participants.

Registration Number	Name of Newly Accredited Organisations
HOKLAS305	Acurweight Technology Limited
HOKLAS867P	Hospital Authority – Queen Elizabeth Hospital, Department of Pathology
HOKLAS868P	In Touch, Limited – Histopathology Laboratory
HOKLAS306	Sartorius Hong Kong Limited - Calibration Laboratory



Assessors receiving the Certificates of Appreciation

Advisory Board, presented certificates of accreditation to four conformity assessment bodies that were newly accredited in the period from October 2022 to April 2023. In addition, twelve assessors were awarded the certificate of appreciation for their significant contribution to HKAS assessments, including three who had served more than 250 assessment days. After the ceremony of certificate presentation, all participants were assigned a discussion group according to their expertise for further discussions relating to specific technical fields and topics.

Certificate of Appreciation	Name of Assessors
For more than 250 assessment days	Ir SHIU Chi-yan
	Ir SHIU Chi-yung
	Dr MAN Tim-on
For more than 200 assessment days	Mr CHAN Tak-kin
	Mr NG Kam-kwong
	Ir YAM Wing-wa
For more than 150 assessment days	Mr LEE Lun-tai
	Ir YAN Yui-kuen
For more than 100 assessment days	Dr William HO Dan-dan
	Ms Heidi IU Yan-ping
For more than 50 assessment days	Ms Bella HO Shiu-wun
	Mr AU YEUNG Chi-yuen

## Briefing Sessions on Updated Requirements in ISO/IEC 17043:2023

ISO/IEC 17043:2023 for the accreditation of proficiency testing providers (PTPs) was published in May 2023. In order to make sure our technical assessors, experts, accredited PTPs and other interested organisations are conversant with the changes in the standard, three briefing sessions on ‘Updated Requirements in ISO/IEC 17043:2023 for Accreditation of Proficiency Testing Providers’ were conducted in September and October 2023.

Each briefing session started with a comprehensive summary on the major updates in the 2023 edition, followed with a thorough gap analysis, especially on subtle differences between the 2010 and 2023 editions.

Some main changes in ISO/IEC 17043:2023 are summarised below:

- To include a risk-based thinking/approach in the Management System requirements, and have much more description of the requirements for impartiality.
- To include other types of conformity assessment activities (inspection and sampling) for which PT may apply, in addition to testing and calibration.

- Requirements for subcontractors have been included in “external providers of products and services”, and the term ‘subcontractor’ was removed.
- New requirements for monitoring the validity of the scheme processes were added.
- To require that a description of the process for handling complaints / appeals shall be publicly available.

In the second part of the briefing sessions, the transition arrangement was introduced. Participants were briefed on how to prepare for an assessment based on ISO/IEC 17043:2023. At the end of each briefing session, there was a Q&A session in which participants clarified the intent of the requirements and discussed how the transition could fit into the routine assessment schedule.

PTP assessors and 35 representatives from accredited PTPs and other interested organisations attended the briefing sessions. Participants were particularly impressed with the detailed walkthrough of the new standard.

# Technical Seminar on Statistics for Quantitative Interlaboratory Comparisons for Chemical Testing Laboratories



Dr John HO (right), Senior Accreditation Officer, HKAS, and Mr Edmund TSE (left), Accreditation Officer, HKAS, at the Technical Seminar on Statistics for Quantitative Interlaboratory Comparisons for Chemical Testing Laboratories

On 3 July 2023, HKAS organised a technical seminar on statistics for quantitative interlaboratory comparisons for HKAS accredited laboratories performing chemical testing. The seminar was well attended by over 100 participants, including representatives from 35 accredited laboratories, technical assessors and experts. Mr Edmund TSE, Accreditation Officer of HKAS, was the speaker of the seminar.

According to our observations in assessments, quite a number of interlaboratory comparison exercises, especially those organised by laboratories themselves for accreditation purposes, e.g. for demonstration of technical competence, performance monitoring or external quality control, had only limited numbers of participants (mostly 2-3). The methods of data analysis the organisers used sometimes relied on consensus statistics, which are appropriate only for processing data from large numbers of laboratories (e.g. >30). Besides, the International Laboratory Accreditation Cooperation (ILAC) policy document on proficiency testing (PT) viz. ILAC P9:06.2014 'ILAC Policy for Participation in Proficiency Testing Activities' was being revised. The latest draft of the document required accredited laboratories to provide evidence of competence of the organisers of both PT schemes and interlaboratory comparisons they had participated to demonstrate the organisers' conformity with the relevant requirements of ISO/IEC 17043:2023, including requirements on data analysis. This seminar was arranged to share with

our laboratories the common statistical data analysis techniques used for interlaboratory comparisons with both small and large number of laboratories in hope of enhancing their understanding and correct application of the techniques as well as preparing laboratories for complying with the new requirements to be introduced in the upcoming ILAC P9.

The seminar was divided into three parts: -

## I. Use of Robust Algorithms

In the first part, consensus statistical techniques for data analysis, mainly the robust algorithms given in ISO 13528:2022 for interlaboratory comparisons among large number of laboratories, were introduced. The concept of normal and standard normal distributions, consensus statistics and various robust statistical techniques for estimating the population mean and population standard deviation (i.e. robust location and dispersion estimators) as follows were introduced:

Location estimator	Dispersion estimator
Median	Normalised interquartile range (nIQR)
Median	Scaled median absolute deviation (MADe)
$x^*$ of Algorithm A (Huber)	$s^*$ of Algorithm A (Huber)
$x^*$ of Q/Hampel	$s^*$ of Q/Hampel (Q)

Details of calculation of the various estimators were explained. The characteristics, assumptions, limitations and relative efficiency of different statistical techniques were also discussed.

## II. Use of Significance Tests

The significance tests commonly adopted for interlaboratory comparisons among small number of laboratories, including the application of ANOVA and t-tests for results comparison, were presented in this part. Various significance tests, viz. two-sample independent t-test with equal variance, Welch's t-test, ANOVA with equal within-group variance, two-sample independent t-test, including their characteristics, calculation, assumption and limitations, were introduced. Besides, tests for detecting departure from normality by graphical evaluation, viz. normal

quantile-quantile (Q-Q) plot, box-and-whisker plot, kernel density plot, were also mentioned. A supplementary statistical test to verify departure from normality, viz. Shapiro-Wilk test, was further discussed. The use of Grubbs' test and Rosner's test for outlier rejection in PT was also explained.

### III. Organising Comparison with Limited Number of Participants

Part III of the seminar focused on the organisation of PT schemes with a small number of participants. The recommended strategies for establishing assigned values and setting evaluation criteria were introduced. In PT schemes with small numbers of participants, assigned values are mainly determined by methods that are independent of the participants' results, e.g. by metrologically valid procedures, using certified value of a CRM or formulation. Performance evaluation is essentially based on external criteria or criteria based on fitness for purpose, e.g. maximum permissible level established by regulator, benchmark performance specifications or interlaboratory variability from a general model (Horwitz / Thompson).

After the presentation, a Q&A session was also held

to offer participants an opportunity to ask questions relating to the statistical techniques introduced.

Participants found the seminar informative, practical and very useful. Some participants even found the duration of the seminar too short to cover everything they needed to know and wished HKAS to organise similar seminars and provide more examples. HKAS will take into the account the comments received when organising similar workshops or seminars in the future.



Q & A Session

## Experience Sharing Seminar on Food Chemical Testing

**O**n 7 September 2023, the Government Laboratory (GL) and HKAS jointly organised the Experience Sharing Seminar on Food Chemical Testing for our food testing laboratories. We were glad to see over 50 participants from 17 accredited laboratories and our technical assessors joining the event.

In the first session of the seminar, we were delighted to have two experts from GL, namely Dr POON Ka-fai and Dr LEE Wan-wann, to share their experience in testing of food contaminants and introduce the role of GL in supporting the testing industry.

Dr POON Ka-fai's presentation topic was 'Determination of ethylene oxide in selected food items'. Ethylene oxide is a versatile chemical and is widely used as a raw material in the production of a number of useful products such as antifreeze and cosmetics. The chemical also has a number of direct uses on its own, for example, as preservatives

and fumigants. Nevertheless, ethylene oxide is classified as carcinogenic by a number of regulatory bodies and its use has been banned in some regions (e.g. Europe). Its residue and its marker residue, 2-chloroethanol, are tightly controlled in food items under the European Regulation. The volatile nature of the chemical presents a particular challenge to its analysis. Dr POON introduced the methods of analysis of ethylene oxide in selected food items. He explained in detail the precautions to be taken to prevent unintended loss of the compound during sample preparation (e.g. the use of dry ice in sample blending). He also highlighted the key parameters and the extra techniques required (e.g. use of programmable temperature vaporizer) in the GC-MS analysis of the target analyte. During the Q&A session, there were extensive discussions on the testing process, particularly about sample preparation. Dr POON took the opportunity to provide further information about the test to participants.

Dr LEE Wan-waan introduced to participants the proficiency testing (PT) service of GL, with particular emphasis on the organisation of PT schemes with metrological traceable reference values (MTRV) for food testing. GL has been providing PT service since 1987 to assist laboratories in demonstrating and developing technical competence. So far, GL has organised about 80 PT activities. The main characteristics of GL's PT services are:

- provision of PTs which are not available on the market to support the testing and certification industry in Hong Kong;
- organising regional/international PT schemes, such as the Asia Pacific Metrology Programme – Asia Pacific Accreditation Cooperation (APMP-APAC) Joint PT Programme to different economies;
- providing PT schemes with MTRV.

The GL has been accredited for its PT activities under HOKLAS since 2009 according to ISO/IEC 17043. The PT activities accredited span multiple technical disciplines, including Chinese medicine, environmental testing, food and biological matrix. Dr LEE further introduced the methods used by GL to determine the MTRV, such as by using consensus values from expert



Dr KOO Chi-kin, Accreditation Officer, HKAS

laboratories such as NMIs and DIs, by formulation, and by using reference methods such as isotope dilution mass spectrometry. Dr LEE highlighted the benefits of PT schemes with MTRV, which enable more meaningful performance evaluation and allow assessment of bias and metrological comparability of participants' results. She shared the data of some past PTs organised by GL to demonstrate how PT schemes with MTRV revealed underlying performance problems of participants.

In the second session of the seminar, Dr KOO Chi-kin, Accreditation Officer of HKAS, shared the common nonconformities identified by HKAS in the assessment of food testing laboratories. The nonconformities presented were mainly technical in nature, relating to laboratory personnel, equipment, environmental conditions and facilities, method validation and verification, handling of test items, evaluation of measurement uncertainty, QC requirements, results reporting, etc. Nonconformities concerning both food and food container testing were discussed. Dr KOO also provided a highlight of the requirements in HOKLAS SC-37 for method validation.

The seminar was well received by the participants. Most of them found the seminar contents informative and useful. In view of the good responses, HKAS will continue to collaborate with GL to organise similar seminars in the future.



Dr POON Ka-fai, Chemist, GL



Dr LEE Wan-waan, Chemist, GL



Q&A Sessions



# Liaison with Stakeholders in the Construction Industry

**H**KAS frequently engages with different works departments (including Development Bureau, Buildings Department, Housing Department and Water Supplies Department), accredited organisations and stakeholders (including conformity assessment bodies, associations and product scheme owners) in the construction industry through meetings to promote and enhance testing, inspection and certification services for construction materials, as well as to harmonise practices in the field.

## Meetings with Association of Construction Materials Laboratories Limited (ACML)

This year, HKAS had two meetings with the ACML. The representative of Development Bureau was also invited to join the meeting held in September 2023 to provide updated information on electronic test report submission in line with 'Construction 2.0'.



Mr Anthony SO, Project Assistant Secretary of Development Bureau (fifth left), Ir Dr Fiona CHAN, Senior Accreditation Officer (sixth left), Accreditation Officers, and participants in the meeting with ACML

## Sharing Sessions for Welding Inspection

HKAS also organised sharing sessions on welding inspection on 29 May and 13 November 2023. Representatives of all HKIAS accredited inspection bodies under the construction products inspection field joined the sessions. The Buildings Department had recently incorporated BS EN ISO 14732:2013

in the 2023 edition of the Code of Practice for the Structural Use of Steel 2011. HKAS officers therefore shared comments of technical assessors on the standard, such as the type of welding and functional knowledge. Some interesting scenarios for re-qualification were also discussed.

## Sharing Session for Nondestructive Testing of Welds and Metallic Materials

HKAS has accredited a number of laboratories for performing nondestructive testing (NDT) of welds and/or metallic materials. A sharing session was conducted on 4 October 2023 for NDT laboratories to update them the latest development in the field.

In the session, the following technical aspects were covered:

- Presentation of scope of HOKLAS accreditation for NDT
- Decision rule for reporting of conformity statements
- Qualification of HOKLAS approved signatory
- Harmonisation of testing practice of NDT (including photographic records and holding time for final NDT)

Over 80 participants from 35 accredited laboratories joined this sharing session. The sharing session was well received by the participants. In view of the good response, HKAS will continue to organise similar events in the future.



Dr Clief TANG, Accreditation Officer (third right) speaking in the Sharing Session

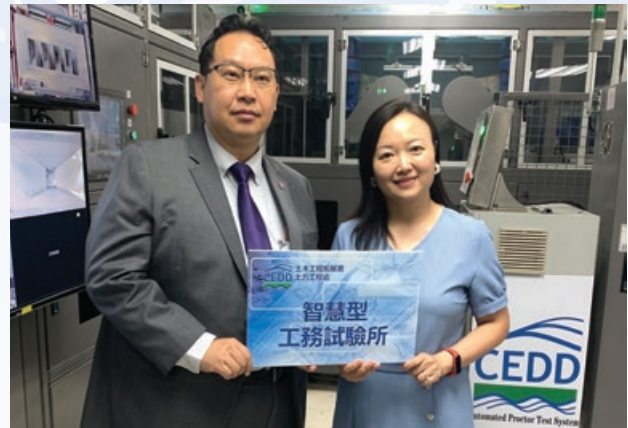
# Media Briefing on "Digitisation and Automation of Public Works Laboratories"

Going digital is no doubt an important initiative to enhance the efficiency and effectiveness of administration of public works contracts including construction site management. To facilitate digitalisation of construction sites' records and promote paperless culture, Public Works Laboratories (PWL) of the Civil Engineering and Development Department (CEDD) and their contract laboratories have started to issue test certificates/reports in electronic format since 1 August 2023. A media briefing on "Digitisation and Automation of Public Works Laboratories" was therefore held by CEDD's Geotechnical Engineering Office (GEO) on 7 September 2023 to introduce the new measures.

HKAS was also invited to join this media briefing. Before PWL launched the use of electronic test reports, HKAS assessment team had assessed the laboratory on-site to confirm that the electronic report and its transmission comply with relevant accreditation requirements.

At the media briefing, an automated system newly

developed by PWL for soil testing was also showcased. This system adopted advanced automation and robotic technologies, coupling with the application of computer vision analysis. It enabled the whole testing process to be fully automatic, which significantly enhanced the efficiency of the testing service.



(From right to left) Ir Jenny F YEUNG, Deputy Head of Geotechnical Engineering Office (Planning and Standards) of CEDD, and Mr Wilson WL SHUM, Executive Administrator of HKAS

## New HKAS Fee Schedules will be effective from 5 January 2024

HKAS fees were last adjusted in 2018 and the government has frozen all fee review exercises from 2019 to 2021. When this moratorium ended on 31 December 2021, all government departments, including HKAS, resumed the regular review and adjustment of fees and charges.

After taking into account the operating costs of HKAS, the inflation rate between these years and the current business environment, HKAS decided to increase all accreditation fees by 3% starting from **5 January 2024**. These fees include application fees, assessment fees, annual subscription fees and fees for additional certificates of accreditation. The new fee schedules are now available at the HKAS website.

Please note that:

- a. All initial applications and applications for extension of scope of accreditation received by HKAS on or after 5 January 2024 will be charged based on the new fee schedules. If the application is submitted by post, the post stamp date will be considered as the date of receipt.
- b. If an organisation intends to submit an application based on the old fee schedules, please ensure that

the correct application form (e.g. HOKLAS 005), completed assessment questionnaire (e.g. HOKLAS 007 and HOKLAS 007-A1) and payment reach HKAS before 5 January 2024. Otherwise, the application will be charged by the new fee schedules.

- c. Assessment fees for any assessment of which date(s) and team composition are confirmed on or after 5 January 2024, as marked by the issuance of the confirmation letter by HKAS, will be calculated based on the new schedules.
- d. If an organisation has notified HKAS of a change in its information that will lead to the issuance of new certificate(s) of accreditation, the charge of such certificate(s) will be based on the new fee schedules if the notification letter for confirming the change is issued on or after 5 January 2024.
- e. Payment for all other requests for additional certificates of accreditation received by HKAS on or after 5 January 2024 shall be made as per the new fee schedules.

HKAS will continue to review its fees regularly according to the Government's policy and notify all accredited organisations in due course when there are changes.

# HKAS granted first accreditation on Scene of Crime Investigation

In August 2023, HKAS granted accreditation to Government Laboratory – Forensic Science Division on its activities at the scenes of crime. The organisation is accredited under HKIAS for the location and recovery of various types of crime scene exhibits, including

bloodstain, latent DNA, glass, fibre, tool mark and shoeprint. This is the first accreditation granted on Scene of Crime Investigation since HKAS launched this service in 2017.



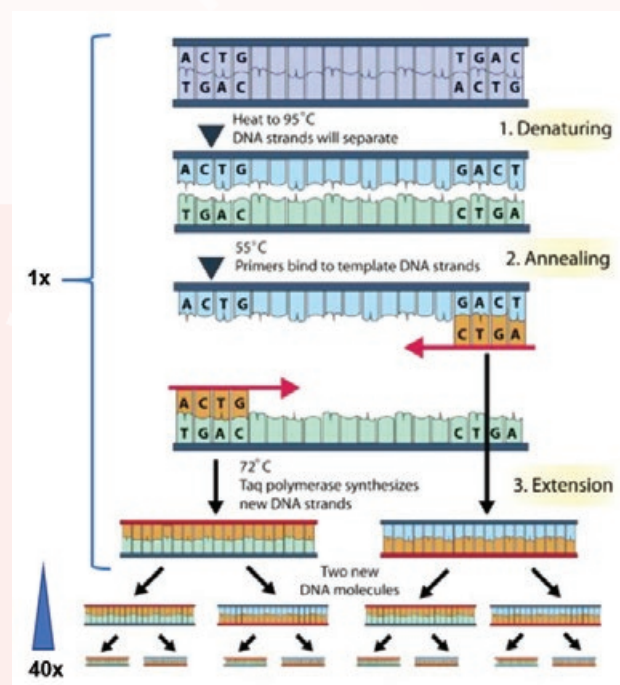
## Task Force on Polymerase Chain Reaction (PCR) Testing

HKAS has been providing accreditation service to laboratories for performing analysis of genetically modified food by the polymerase chain reaction (PCR) technique since 2005. The relevant accreditation criteria are provided in HOKLAS Supplementary Criteria No. 21 'Chemical Testing' and 'Food' – Polymerase Chain Reaction (PCR) Testing.

PCR is a laboratory technique for rapidly producing millions to billions of copies of a specific segment of DNA, which can then be studied in greater detail. Given the wide applicability of the technique, particularly in gene detection, more and more laboratories are interested in adopting the technique to meet specific needs of their clients.

About a year ago, we received an accreditation request from a local laboratory performing a new field of PCR tests, viz. detection of gene doping in sporting animals through analysis of their blood (e.g. horse blood) for the presence of certain transgenes by the PCR technique. The aim of the tests was to detect the illegal use of genetic modification technology for athletic performance-enhancement in the relevant sporting events.

Our experience in this new field of PCR tests was rather limited. Upon consultation with the Chairman of our Accreditation Advisory Board (AAB) Working Party on Biological and Chemical Testing, we decided to form a new Task Force under the Working Party to provide the necessary technical support. A new Task Force on PCR Testing was therefore established on 2 August 2022. The Task Force (TF) is chaired by Mr Danny CHEUNG, a Working Party member, and consists of experts from local universities and forensic testing laboratories as members. Mr CHEUNG is an expert in microbiological and molecular testing, and has been a technical assessor under HOKLAS for over 23 years. The primary assignment of the TF was to



Schematic diagram of PCR (courtesy of the Government Laboratory)

expand the HOKLAS Supplementary Criteria No. 21 (Issue No. 6) 'Food' - Detection and Quantification of GMO in food by PCR to make it applicable to the detection of gene doping, in addition to GMO. After working diligently over ten months, holding 4 rounds of document circulations and 2 online meetings, the TF finally came up with a revised HOKLAS Supplementary Criteria No. 21 titled 'Chemical Testing' and 'Food' – Polymerase Chain Reaction (PCR) Testing'. The criteria document was published on 31 July 2023. We would like to express our sincere thanks to Mr CHEUNG and all TF members for their contributions and efforts.

Laboratories that are interested in applying for the related accreditation are welcome to contact HKAS Executive.

# Peer Evaluation of HKAS by APAC

**H**KAS is a signatory to the Mutual/Multilateral Recognition Arrangement (MRA/MLA) of Asia Pacific Accreditation Cooperation (APAC), International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC). In order to maintain the signatory statuses, HKAS must operate in accordance with ISO/IEC 17011 and mandatory requirements set out by these organisations. APAC will evaluate HKAS once every 4 years to ensure that relevant criteria are met.

The latest peer evaluation of HKAS was conducted online in June, August 2022 and February 2023. The peer evaluation team comprised 8 members from different economies in the Asia Pacific region, who are all experienced assessors in their respective accreditation bodies. During the evaluation,

evaluators not only assessed the management system and operation of HKAS, but also witnessed some accreditation assessments of our accredited organisations. HKAS would like to take this opportunity to thank all organisations that allowed their assessments to be witnessed for their kind assistance.

Based on the recommendation from the evaluation team, the APAC MRA Council has approved the signatory status of HKAS for (i) all existing MRA scopes; and (ii) the extension to cover the validation and verification of environmental information based on ISO/IEC 17029:2019 and ISO 14065: 2020. According to the APAC Secretary, HKAS is the first APAC member to be recognised for this new scope and sub-scope.

## Updates from ILAC, IAF and APAC

**T**he International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF) jointly organized the ILAC-IAF Annual Meetings in November 2023 at Montreal, Canada. The followings are some updates from the meetings:

### ILAC ([www.ilac.org](http://www.ilac.org))

1. Revision of ILAC P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities has been finalised and it will soon be published. This document sets out the policy for accreditation bodies (ABs) on the use of proficiency testing (PT) activities in the accreditation process. It provides PT and interlaboratory comparison (ILC) requirements for accreditation of all conformity assessment bodies (CABs) performing testing or calibration activities (i.e. testing, sampling, calibration and medical laboratories, inspection bodies, biobanks, PT providers and reference material producers) and is based on the requirements for ensuring the validity of results in ISO/IEC 17025:2017 and ISO 15189:2022. It contains three Informative Appendices, where the Appendix C is derived from the EA document EA 4/18. The policy requires participation in PT or ILC prior to gaining accreditation and specifies how the AB addresses PT and ILC in accreditation assessments.

HKAS held an experience sharing seminar on 23 November 2023 to introduce details of this new

ILAC P9 to accredited CABs.

2. ISO 15189:2022 Medical laboratories — Requirements for quality and competence was published in December 2022. ILAC has adopted a resolution (GA 26.08) to endorse a transition period of 3 years from the date of publication of the standard. Feedback was sought in the ILAC Accreditation Committee (AIC) on the implementation of ISO 15189:2022 as to whether any harmonisation issues have been encountered. Only a few ABs have started assessing to the recent revision thus far, and they reported that CABs seemed to like the less prescriptive format of the new standard. It was also noted that ILAC G26:11/2018 Guidance for the Implementation of a Medical Accreditation Scheme would be subject to revision in early 2024. The revision would be limited to the few items that were impacted by the revised ISO 15189:2022, as well as for updating a few referred documents that were out of date.
3. ISO/IEC 17043:2023 Conformity assessment — General requirements for the competence of proficiency testing providers was published in May 2023. ILAC has adopted a resolution (GA 26.09) to endorse a transition period of 3 years from the date of publication of the standard. The new ISO/IEC 17043:2023 has not been fully implemented yet by most ILAC members so the AIC is still

awaiting user-issues to arise as assessments occur. Some members voiced potential concerns over the new surveillance requirements as well as normative references to ISO 17034 and ISO/IEC 17025 regarding a harmonised view on relevant requirements. The Stakeholder Forum also cited that the new requirement (CI 7.3.2.3) on homogeneity and stability was stricter in that an assessment must now be undertaken for every round of PT. However, it was explained that the assessment could be quick and easy in some cases.

4. The International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM4) is being revised in the Joint Committee for Guide in Metrology Working Group 2 (JCGM WG2). A second Committee Draft (CD 2) has released earlier and was circulated to ILAC AIC members for comment between August and September 2023. The comments received were reviewed by a small working group under ILAC AIC, of which HKAS was also a member, and the collated comments were provided to JCGM WG2 for consideration on 25 October 2023 via the ILAC Secretariat.
5. Systematic review of the accreditation standard for inspection bodies, ISO/IEC 17020:2012 Conformity assessment — Requirements for the operation of various types of bodies performing inspection, is being undertaken. A working draft (WD) of the standard ISO/IEC WD 17020 is being developed by Working Group 31 (WG 31) of the ISO Committee on conformity assessment (ISO/CASCO). A CD is expected to be circulated for comment by April 2024. According to the present work plan of WG31, the revised standard is expected to be published in November 2025.

### IAF ([www.iaf.nu](http://www.iaf.nu))

6. In IAF, there is a mechanism for various stakeholders including accreditation bodies, certification bodies and users of accredited services to submit papers to the technical committee (TC) for discussion. Most issues are clarification on application of accreditation standards and IAF mandatory documents. In the last TC meeting, four papers related to HKAS' operation were discussed: -
  - (i) The first discussion paper was about the proposed actions taken by IAF in response to the additions to Appendix 2 of Annex SL of the Consolidated ISO Supplement to ISO/IEC Directives, Part 1 approved by ISO Technical Management Board, i.e. adding new text "The organization shall determine whether climate change is a relevant issue"

under 4.1 and "Relevant interested parties can have requirements related to climate change" as a note under 4.2. The IAF TC in general agreed with the positions recommended by the Working Group (WG) on Management System Certification, which were to carry out the suggested actions, i) IAF, ISO and ISO/CASCO should start their communication soon to address the minor changes in the High Level Structure of the Management System Standard (MSS); ii) to open communication channels to make sure that IAF is addressing the changes at an appropriate level that ISO was thinking; iii) to request ISO to provide an impact assessment to IAF to find out if ISO understands the impact of the change to the MSS; 4) to issue an ID or MD in order to minimise the impact and address the consistency among ABs and CABs according to IAF PR7.

- (ii) The second discussion paper was related to the status/binding effect of the TC decision log. IAF TC agreed with the proposed change to the use of the TC decision log, making them mandatory going forward unless the IAF Member presents a valid justification for not doing so to the IAF TC. The AB must also communicate the rationale for its decision to not implement the specific TC decision to its CABs. This proposal will be submitted to the IAF Executive Committee for confirmation.
- (iii) The third discussion paper was about the introduction of an Informative Document (ID) on remote audit methods for management systems. The IAF TC tasked the WG Digital to create a forum on the IAF website to discuss the recommendations regarding the introduction of the ID to the IAF suite of documents.
- (iv) The fourth paper was related to the "employment status" of the certification decision maker, on whether the person can be individually contracted under any form of legally enforceable contract or hired through a labour contract as an employee of the certification body. The IAF TC confirmed that the person assigned by the certification body to make a certification decision shall be employed by, or shall be under legally enforceable arrangement with the certification body or an entity under the organisational control of the certification body. The structure of the certification body needs to be considered within the legal

context of the country the body is located in based on its regulations. The intent of the requirement is to make sure the certification body is legally responsible for its certification decisions.

7. IAF implements a set of amended principles of the IAF CertSearch Certificate Database following the ballot conducted in August 2022. IAF Database Management Committee (DMC) has developed a MD outlining the process for managing data upload and data maintenance, with appropriate exemptions and sanctions where requirements are not met. The MD was issued in October 2023 with a one-year implementation period. To assist CBs in understanding the operation of the database, monthly technical support webinars will be held in the fourth week of each month for CBs.

The 'Single International Organisation for Accreditation' project

8. At the 19th IAF/ILAC Joint GA that took place in Frankfurt in 2019, a resolution was passed to establish a single international organization for accreditation. A Joint IAF/ILAC Steering Committee (SC) for establishing a single international organisation for accreditation (the New Body Incorporated, NBI) was set up to identify the main principles that would form the basis of the NBI and other main issues such as membership rules, voting rules, cost/benefits and secretariat. The SC would execute the project for establishing the NBI (namely the One Organisation Project, OOP) with the support from a contractor reporting to the JEC.

In the Joint GA this year, a representative of the contractor made a progress report of the OOP. Some unresolved issues of the Project identified earlier were also discussed in this meeting. The issues mainly surrounded the comments received from members on the draft Constitution and General Rules of the NBI, which were circulated for IAF and ILAC members' comment during May to July 2023, e.g., about the place of registration of the NBI, detailed structure of the NBI, stakeholder member categories and voting rights. Taking members' comments into account, the contractor would further revise the draft Constitution and General Rules of the NBI and circulate the revised draft of the documents for members' comment again. In view of this additional round of document circulation, some delay in the project implementation was anticipated and the roadmap of the OOP might have to be revised. According to the existing roadmap, the NBI would be established in Q4 2025.

## APAC ([www.apac-accreditation.org](http://www.apac-accreditation.org))

9. The APAC Annual Meetings were held between 25 and 30 June 2023 in Anaheim, USA. Matters relating to accreditation of conformity assessment bodies in the Asia Pacific region were discussed in various committees' meetings and the General Assembly. HKAS representatives attended the meetings in person this time.
10. APAC has 56 Full Members and Signatories to its MRA from 32 economies. Five new signatories were added since 2022's General Assembly. APAC also has 11 Associates Members and 14 Affiliates.
11. APAC published a new technical guidance document in 2023, which is TEC1-002 'APAC Guidance on the assessment of metrological traceability of measurements made with multi-turn coils used to calibrate clamp-style current meters'.
12. APAC's Communication and Promotion Committee published two brochures in 2023 to promote the use of accredited certification services. The brochures cover business continuity management system (ISO 22301) and information security management system (ISO/IEC 27001).
13. APAC Mutual Recognition Arrangement (MRA) Council approved the addition of new sub-groups under the MRAs for management systems certification and product certification. The new management system sub-scopes are:
  - ISO/IEC 17021-13, ISO 37301 Compliance Management Systems
  - ISO 20000-6, ISO 20000-1 Information Technology Service Management Systems
  - ISO 21001 Educational Organization Management Systems
  - ISO/IEC 17021-5, ISO 55001 Asset Management Systems
  - ISO/IEC 17021-11, ISO 41001 Facility Management Systems
  - ISO/IEC 17021-15, ISO 7101 Healthcare Organization Management Systems
  - International Aerospace Quality Group (IAQG) Industry Controlled Other Party (ICOP) Certification Scheme

The new product certification sub-groups cover schemes on Brand Reputation through Compliance Global Standard (BRCGS) and International Featured Standards (IFS).

# New Accreditation Granted

From 16 May 2023 to 31 October 2023, five organisations have been accredited. The name, registration number and accredited areas are summarised below. HKAS wishes to congratulate the CABs on their success in obtaining accreditation.

## HOKLAS

Registration No.	Name of Conformity Assessment Body	Test Category Granted	Clientele
HOKLAS869S	Codex Genetics Limited	Medical Testing	Private physicians, medical centres, private and public hospitals and other medically related institutions
HOKLAS307	東莞兆閱帷幕牆有限公司	Construction Materials	Public
HOKLAS308	KAS Quality Service (Guangzhou) Co., Ltd	Construction Materials	Public

## HKCAS

Registration No.	Name of Conformity Assessment Body	Certification Service Granted	Clientele
HKCAS032	The Lab (Asia) Limited	Product Certification	Public

## HKIAS

Registration No.	Name of Conformity Assessment Body	Inspection Field Granted	Clientele
HKIAS037	Government Laboratory - Forensic Science Division	Scene of Crime Investigation	Government Departments

## Suspended Accreditation Imposed Suspension (as at 31 Oct 2023)

### HOKLAS

Registration No.	Name of Conformity Assessment Body	Test Category and Test Area Suspended	Effective Date (dd.mm.yyyy)
864S	ProCare Medical Laboratory Centre Limited	<b>Medical Testing</b> - Chemical Pathology - Haematology	07.07.2023

## Voluntary Suspension (as at 31 Oct 2023)

### HOKLAS

Registration	Name of Conformity Assessment Body	Test Category and Test Area Suspended	Effective Date
138	Nutek Systems (HK) Limited	<b>Construction Materials</b> - Metallic Materials	21.09.2023
#217	Meyer Aluminium Limited - Material Laboratory	<b>Chemical Testing</b> - All tests <b>Physical and Mechanical Testing</b> - All tests	01.01.2023
#833P	Hospital Authority - Kwong Wah Hospital, Department of Pathology	<b>Medical Testing</b> - All tests	08.03.2023
849S	Precious Blood Hospital (Caritas) - Clinical Pathology Laboratory	<b>Medical Testing</b> - Medical Genetics (Molecular Genetics)	01.10.2023
#864S	ProCare Medical Laboratory Centre Limited	<b>Medical Testing</b> - Clinical Microbiology and Infection	16.10.2023
#866S	New Life Laboratory Testing Limited	<b>Medical Testing</b> - All tests	26.04.2023

## HKCAS

Registration No.	Name of Certification Body	Certification Service Suspended	Effective Date (dd.mm.yyyy)
#031	Fraser Certification Services Ltd.	<b>Environmental Management System</b> <b>Occupational Health and Safety Management System</b> <b>Quality Management System</b>	14.03.2023

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

## Terminated Accreditation

### Voluntary Termination (16 May 2023 to 31 October 2023)

## HOKLAS

Registration No.	Name of Conformity Assessment Body	Test Category and Test Area Terminated	Effective Date (dd.mm.yyyy)
039	Hong Kong Productivity Council - Green Living Laboratory	<b>Environmental Testing</b> - Consumer Products - volatile organic compounds	10.08.2023
083	Wellab Limited	<b>Chinese Medicine</b> - All tests <b>Food</b> - Additives – All tests	30.06.2023
#166	Department of Health, Centre for Health Protection, Public Health Laboratory Services Branch, Microbiology Division, Non-Clinical Microbiology Laboratory	<b>Environmental Testing</b> - All tests <b>Food</b> - All tests	01.09.2023
#280	Hong Kong Rope Safety Laboratory Limited	<b>Construction Materials</b> - Metallic Materials	17.07.2023
#294	Gain Up Corporation Limited - Gain Up Testing Laboratory	<b>Electrical and Electronic Products</b> - All tests	01.08.2023
#809S	Department of Health - Clinical Genetic Service, Neonatal Screening and Genetic Laboratory	<b>Medical Testing</b> - All tests	01.07.2023
#848S	Health Hope International Medical Laboratory Limited	<b>Medical Testing</b> - All tests	01.09.2023
#857S	CaTAGene Limited	<b>Medical Testing</b> - All tests	31.07.2023

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

Note: The above lists show only those accredited organisations with the whole test category / area suspended or terminated. In addition, the lists do 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.

## New and Revised HKAS Documents

New and revised HKAS, HOKLAS, HKIAS and HKCAS documents are available under "Publications", "HKAS Recently Revised and New Publications in Previous Six Months" at our website at [www.hkas.gov.hk](http://www.hkas.gov.hk).

## Proficiency Testing Updates

Test Category	Programme and Organiser	Status
Food	APMP-APLAC T111 –Event-specific quantitative analysis for genetically modified (GM) Maize Line MON87427 Organised by NIM, China	Final Report issued in June 2023 One laboratory was nominated to participate. Results are satisfactory