

Medical Laboratory Accreditation Boosts User's Confidence

醫務化驗所認可 提升用家信心

Nowadays, doctors not only rely on a stethoscope and body check, but also medical laboratory testing to make clinical diagnosis of patients. Medical tests ranging from blood tests, urine tests, and examination of patient's respiratory secretions, etc. provide important information on the patients' health condition, facilitating doctors to make medical decisions. Accurate and reliable test results are thus of utmost importance, and contributes directly to the quality of medical service. In this issue, we are delighted to invite Dr QUE Tak-lun, Chief of Service (Clinical Pathology), New Territories West Cluster, Hospital Authority, and Chairman of the Working Party on Medical Testing, Accreditation Advisory Board, to share with us his experience in obtaining medical laboratory accreditation and how it could help enhance the competence and professionalism of medical laboratories.

Accreditation upholds professional standards

Accreditation offers formal third-party recognition for medical laboratories which conform to international standards in carrying out specific testing activities. Dr Que pointed out, "There is no way to assess the competence of medical laboratories if each of them follows different testing standards and procedures. Accreditation is really important as it provides unified standard and requirements for medical laboratories to follow, upholding the professionalism of medical testing."

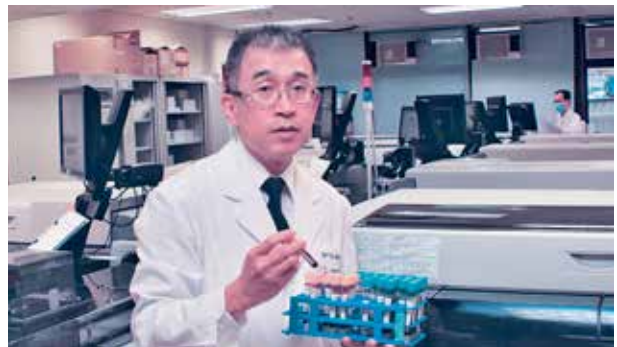
In 2004, Hong Kong Laboratory Accreditation Scheme (HOKLAS), operated by the Hong Kong Accreditation Service (HKAS) of the Government, extended its coverage to medical testing. Dr Que called it a revolutionary move as Hong Kong has eventually had its own accreditation scheme for voluntary participation by local medical laboratories. Medical laboratories applying for accreditation will undergo rigorous assessment by independent assessors of HKAS to ensure they are conforming to the ISO standard ISO 15189:2012 "Medical laboratories - Requirements for quality and competence". Therefore, the standard of operation and quality of test results of accredited medical laboratories are assured.

今時今日，醫生不再單憑聽診和身體檢查為病人臨床診斷，還會利用醫務化驗來診斷病情。醫務化驗種類繁多，包括血液測試、尿液測試和呼吸道分泌物化驗等多個範疇，協助醫生了解病人的健康狀況，為治療提供指引。因此，一份準確可靠的化驗報告至關重要，亦直接影響醫療服務的質素。今期，我們很榮幸邀請到醫院管理局新界西醫院聯網病理學部部門主管兼認可諮詢委員會醫務化驗工作小組主席郭德麟醫生，分享獲取醫務化驗所認可的經驗，以及認可資格如何提高醫務化驗所的競爭力 and 專業水平。

認可提高專業水平

認可可是由第三方證明一間醫務化驗所進行的特定測試項目符合國際標準。郭醫生指出：「如果每間醫務化驗所各自遵循不同的化驗標準和程序，就無法評估它們的能力。而認可為醫務化驗所提供了一套統一的標準和要求，從而提高醫務化驗所的專業水平。」

政府轄下的香港認可處所管理的「香港實驗所認可計劃」(HOKLAS)，在2004年開始為本港醫務化驗所提供認可服務。郭醫生稱之為革命性的突破，只因香港終於擁有自家的認可計劃，供本地醫務化驗所自願參與。申請認可的醫



Dr QUE Tak-lun, Chief of Service (Clinical Pathology), New Territories West Cluster, Hospital Authority, and Chairman of the Working Party on Medical Testing, Accreditation Advisory Board
醫院管理局新界西醫院聯網病理學部部門主管兼認可諮詢委員會醫務化驗工作小組主席郭德麟醫生

Quality control of laboratory equipment

To be accredited, medical laboratories have to meet a number of management and technical requirements. Laboratory equipment is one of the major assessment areas. Dr Que said, "Nowadays, there is heavy demand for different types of medical tests like chemical pathology tests, haematology tests and microbiology tests. For instance, Tuen Mun Hospital handles over 20 million tests involving 4 million samples every year. When dealing with such a huge volume of tests, we need to ensure the equipment used meets the technical specifications and requirements consistently." To achieve this, equipment of accredited medical laboratories needs to be calibrated against reference materials to ensure accuracy. Validation of equipment is required to verify whether it performs according to its intended purpose. Appropriate quality control procedures should also be adopted to ensure the test is properly processed.

Minimise possible errors by documentation

Currently, a wide variety of medical tests provided by the Department of Clinical Pathology of Tuen Mun Hospital are accredited under HOKLAS. Dr Que considered the standardisation and documentation of work procedures and records the biggest challenges they encountered in the process of obtaining accreditation. Dr Que explained, "To meet the requirements of ISO 15189, we have to make sure every test is done properly and records are kept. We also need to promulgate specific guidelines on work procedures. For example, the temperature of refrigerators in medical laboratories is always monitored. To avoid cross contamination, frontline staff is given strict guidelines on what items can be put together." He admitted that, in the beginning, maintaining all the records and documentations

have brought much pressure upon the department. However, noting that these steps are crucial for reducing operational ambiguity and facilitating reviews for improvement and risk management, he considered all the efforts are worthwhile.

Quality assurance for users

Through accreditation, the competence of medical laboratories is fully endorsed and recognised. Dr Que remarked, "Using services from accredited medical laboratories can ensure that the test results are generated according to international standards and thus are trustworthy. The public can visit the website of HKAS (www.hkas.gov.hk) to find out which medical laboratory is accredited for a specific test, as every test is assessed and accredited independently."



務化驗所會由香港認可處的獨立評審團隊進行嚴格評審，以確保其符合國際標準ISO 15189:2012《醫務化驗所一質量及能力的要求》。因此，獲認可醫務化驗所的操作水平和化驗結果皆有保證。

化驗設備的品質控制

要獲取認可，醫務化驗所必須符合眾多管理和技術要求，而化驗所設備是主要的評核範疇之一。郭醫生說：「今時今日，市民對不同類型的醫務化驗如化學病理測試、血科測試和微生物測試等，需求很大。以屯門醫院為例，每年需要處理超過2,000萬個測試，當中涉及多達400萬個樣本。在處理如此大量的化驗工作時，我們必須確保使用的設備能符合技術規格和要求。」為達此目標，獲認可的醫務化驗所使用的設備必須利用標準物質進行校正，以保證其準確性，亦須檢查設備能否按其擬定用途運作。化驗所須採用適當的品質控制程序，才能確保化驗服務正常運作。

文件記錄減出錯

現時，屯門醫院臨床病理部提供的多項醫務化驗，均取得香港認可處認可。郭醫生認為申請認可過程中所遇到的最大挑戰，無疑是要將所有工作程序及文書紀錄標準化及作文件紀錄。他解釋：「為了符合ISO 15189的要求，我們必須確保每項測試都妥善完成和記錄完整。我們還須制定各項工作流程的具體指引，例如醫務化驗所必須時刻監測雪櫃的溫度。為避免交叉污染，我們亦向前線人員發出指引，嚴格限制在雪櫃內同一分隔不可同時擺放病人樣本及試劑。」他承認在推行認可的初期，這些記錄文件要求確為部門帶來一定壓力，但當理解到實行有關措施可令操作流程更為清晰，而且能夠幫助化驗所持續改善和進行風險管理，他認為所付出的努力都十分值得。

用家獲品質保證

醫務化驗所的能力通過認可得到充分肯定和廣泛認受。郭醫生表示：「使用認可醫務化驗所提供的服務，可以確保化驗結果是以國際從業標準所得，因而值得信賴。由於每項測試須經獨立評審方能獲發認可，市民可瀏覽香港認可處的網頁（www.hkas.gov.hk），查詢醫務化驗所獲認可資格的化驗項目。」

Tackling Cybersecurity in Smart City

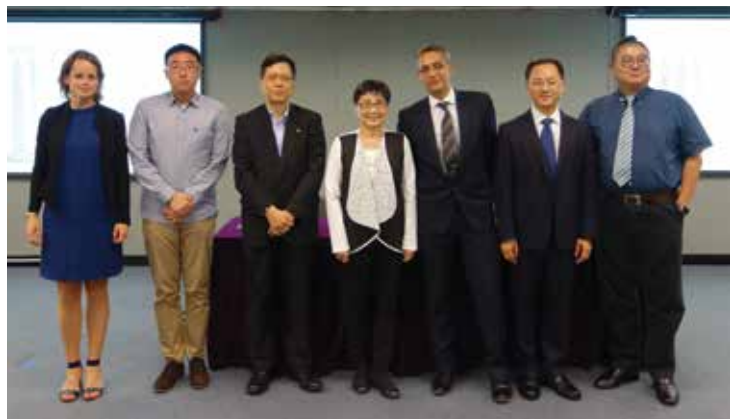
智慧城市應對 網絡安全問題

Nowadays, smart technology applications have become an inseparable part of our daily life. The transmission of digital data has never been more frequent and it is practically ubiquitous. While we are enjoying the convenience brought by these new applications, there is increasing public concern about the associated information security risks.

On 12 July 2018, HKCTC and the Hong Kong Accreditation Service co-organised a "Seminar on Cybersecurity Testing". The seminar started with an analysis of the risks encountered in this smart world by Mr Ronald Pong, a Council Member of the Smart City Consortium, and an introduction on the needs of Internet of Things (IoT) security assessment by Mr Bernard Kan, Senior Consultant of Hong Kong Productivity Council. Then, Dr Shi Hongsong, Director of Research Laboratory on IT Security Evaluation, China Information Technology Security Evaluation Center, introduced the development and applications of common criteria for IT security evaluation.

In the second part of the seminar, Mr Wang Junshu, Testing Engineer, The Fifth Electronics Research Institute of the Ministry of Industry and Information Technology, provided some practical examples on testing of IT products to ISO/IEC 15408. After that, Ms Gonda Lamberink, Senior Business Development Manager of UL International Ltd. briefed the attendees on the standards developed in safeguarding smart products and IT systems from security threats and cyber attacks. Lastly, Mr Jon Murthy, Chairperson of the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF) Communications and Marketing Committee, shared some experience and the challenges encountered in the development of accreditation service for cybersecurity evaluation in Europe.

The seminar has enabled the participants to interact with speakers and deepen their understanding of the need for enhanced IT security and the corresponding solutions.



A group photo of speakers and organiser 講者及主辦機構嘉賓合照

今時今日，我們的日常生活已離不開各式各樣的智能應用技術，而當中涉及的數碼數據傳輸更是前所未有的頻繁，可謂「無處不在」。當大家享受這些應用技術所帶來的便利，同時亦增加了大眾對相關資訊保安風險的關注。

香港檢測和認證局與香港認可處於2018年7月12日合辦了「網絡安全測試研討會」。研討會首先由智慧城市聯盟理事會成員龐博文先生，向大家分析在智能世界中可能面對的網絡危機，而香港生產力促進局高級顧問簡正修先生則介紹了物聯網（IoT）的資訊保安評估需要。隨後，中國信息安全測評中心檢測技術實驗室主任石竝松博士與參加者詳細講解信息安全通用評估準則(CC)的開發和應用。

在研討會的下半部，工業和信息化部電子第五研究所測試工程師王俊舒先生分享了一些資訊產品測試的實際例子，讓大家了解符合國際標準 ISO/IEC 15408 的要求。接著，UL安全國際檢定有限公司高級業務開發經理 Gonda Lamberink 介紹針對智能產品及資訊系統而發展的標準，以保護其免受安全威脅和網絡攻擊。最後，國際實驗所認可合作組織（ILAC）及國際認可論壇（IAF）行銷傳播委員會主席 Jon Murthy 分享了在歐洲發展網絡安全評估認可服務的經驗和所遇到的挑戰。

是次研討會為參加者提供與講者互動的機會，令他們明白到提升資訊保安的需要，加深對相應解決方案的了解。

Construction Materials Testing, Inspection and Certification Anchor Hong Kong's Infrastructure

建材檢測認證為基建質素把關

In recent years, a myriad of infrastructure and construction projects in Hong Kong are being carried out, keeping the city in pace with other metropolis in the world. Local testing and certification sector has been providing essential support to uphold the quality of works and projects. New testing and inspection technologies are being explored to make continuous improvement in assuring the quality and safety of buildings and infrastructures. Concurrently, product certification schemes for different types of construction materials, ranging from ceramic tiles to repair mortars, have been developed to help safeguard the quality of construction materials.

To keep stakeholders abreast of the latest development in different areas of construction materials testing, inspection and certification, HKCTC and the Hong Kong Accreditation Service (HKAS) jointly organised a seminar on 26 January 2018. The seminar was met with encouraging response, attracting over 180 attendees from the construction sector, suppliers and manufacturers of construction materials, as well as practitioners of the testing and certification sector.

This year, the seminar has invited speakers from government department, research and development institute and tertiary institutions to share with the audience a wide range of subjects, including the latest requirements in the testing of cores taken from cement stabilised soil, the latest development in underground utility imaging and diagnosis, the newly developed C-100 high strength concrete, as well as the application of product certification in construction projects.

For more details about the presentations of the speakers, please visit the HKCTC's website at www.hkctc.gov.hk/en/work_seminars.html.



(From left) Ir Dr Jeffrey Lam, Technical Manager, Nano and Advanced Materials Institute Limited, Ir Dr Wallace Lai, Assistant Professor, Department of Land Surveying and Geo-Informatics, The Hong Kong Polytechnic University, Prof. Albert Yu, Chairman, HKCTC, Ir Prof. Joseph Mak, Head of Department of Civil Engineering, Chu Hai College of Higher Education, Ir Prof. Philip Chung, Deputy Head of Geotechnical Engineering Office (Planning & Standards), Civil Engineering and Development Department, and Ms Jane Lee, Secretary-General, HKCTC

(左起) 納米及先進材料研發院有限公司技術經理林悅基博士工程師、香港理工大學土地測量及地理資訊學系助理教授賴偉樂博士工程師、香港檢測和認證局主席于常海教授、珠海學院土木工程學系系主任麥耀榮教授工程師、土木工程拓展署土力工程處副處長(規劃及標準)鍾偉強教授工程師，以及香港檢測和認證局秘書長李詩昕女士

與眾多世界大都會一樣，香港多項基建及建築工程項目進行得如火如荼。本地的檢測和認證業一直為確保工程項目質素提供重要支援，業界與機構更不斷開發嶄新的檢測技術，持續協助提升樓宇和基建的安全及質素。與此同時，不同建材產品的認證計劃，包括瓷磚及修葺用砂漿等，亦能為建材產品的質素把關。

為讓各持分者進一步了解建材檢測認證方面的最新發展，香港檢測和認證局聯同香港認可處於2018年1月26日合辦了一場研討會。研討會反應熱烈，吸引了超過180名人士出席，包括建築業界人士、建材供應商及生產商，以及檢測和認證業的從業員。

今年，研討會邀請了來自政府部門、科研機構及大專院校的講者，分享多個與建材檢測認證相關的題目，包括水泥加固土樣芯試驗的最新要求、地下設施成像和診斷技術的最新發展、C-100高強度混凝土的發展和特性，以及產品認證在不同建築工程上的應用。

有關研討會演講的詳情，請瀏覽香港檢測和認證局網頁：
www.hkctc.gov.hk/tc/work_seminars.html



Promoting Hong Kong's Testing and Certification Services at Belt and Road Summit

參與「一帶一路高峰論壇」 推廣香港檢測認證服務

Jointly organised by the Government of the Hong Kong Special Administrative Region and the Hong Kong Trade Development Council (HKTDC), the 3rd Belt and Road Summit held on 28 June 2018 received some 5,000 participants from 55 countries and regions. More than 80 government and business leaders from Hong Kong, the Mainland and countries around the world exchanged views on multilateral co-operation and new business opportunities arising from the Belt and Road Initiative.

During the Summit, HKCTC has set up an exhibition booth to showcase the strength of Hong Kong's testing and certification sector to worldwide business leaders and industry experts, thereby exploring more development opportunities for our testing and certification bodies along the Belt and Road countries. We will continue to make use of the HKTDC's platform to promote Hong Kong's testing and certification services.



由香港特別行政區政府及香港貿易發展局（貿發局）合辦的第三屆「一帶一路高峰論壇」，於2018年6月28日假座香港會議展覽中心舉行，吸引了來自55個國家及地區約5,000人參與。超過80位香港、內地及世界各國官員及商界領袖，於論壇上共同探討「一帶一路」帶來的全新商機，就促進區域合作蓬勃發展交流意見。

在論壇期間，香港檢測和認證局設置了展覽攤位，向各地商界翹楚及行業領袖展示香港檢測認證業的優勢，期望為本地檢測認證機構於一帶一路沿線國家開拓更多發展機遇。我們會繼續透過貿發局的平台，推廣香港的檢測認證服務。

Establishment of Panel on Manpower Development

The testing and certification sector is built upon a workforce of professionals with high integrity and technical expertise. HKCTC has been putting much focus in attracting new blood to the sector and enhancing capability of testing and certification practitioners. Recently, HKCTC has established the Panel on Manpower Development to consider ways to strengthen manpower resource for the sector. The Panel held a brainstorming session on 10 July 2018, during which Panel members and human resource executives of testing and certification organisations exchanged views on the challenges faced in attracting talent and the possible way forward. The Panel also met with representatives of Labour Department on 9 October 2018 to discuss the manpower needs of the testing and certification sector and explore means to help the sector recruit the needed labour. In the coming year, the Panel will further consider different initiatives to help attract and nurture talent for the sector.

成立人力發展小組

香港的檢測和認證業建基於一羣具有高度誠信及良好技術知識的專業人員。香港檢測和認證局一直致力為行業吸納新血，並持續提升從業員的能力。最近，香港檢測和認證局成立了人力發展小組，以探討如何加強行業的人力資源發展。小組於2018年7月10日舉行了集思會，一眾小組成員和檢測認證機構的人力資源行政人員於會中，討論行業吸引人才所遇到的挑戰，並就未來可發展的路向交換意見。小組亦於2018年10月9日與勞工處的代表會面，雙方討論有關行業人力需求的問題，並探討協助行業招聘人手的方法。來年，小組將考慮不同方案，幫助行業吸引和培養人才。



Brainstorming Session Held on 10 July 2018
2018年7月10日舉行的集思會

Summer Workshops to Arouse Students' Interest in Testing

暑期工作坊提升學生對檢測的興趣



Students visited laboratories in summer 2017
2017年暑期參觀活動



Summer laboratory workshops in 2018
2018年暑期實驗室工作坊

To raise students' understanding and interest in the testing and certification sector, HKCTC launched a brand new summer activity programme for secondary school students last year. Arrangements were made for the participating students to visit the Standards and Calibration Laboratory, Government Laboratory, and the laboratories at the Hong Kong Productivity Council and Hong Kong Science Park. These visits were well attended and the schools have passed us very positive feedback.

Riding on last year's success, we continued the summer activity programme this year and have organised six sessions of laboratory workshops for senior secondary students studying chemistry during the period between late June and early July 2018. Participating students were given opportunities to conduct the experiments of the "Teaching Kit on Chemical Testing for New Senior Secondary Curriculum", a kit launched by HKCTC to introduce the basic chemical testing concepts. Through providing students' with more hands-on practical experience, we wish to apprise them of the importance of testing in our daily life, hence arousing their interest in joining the sector in the future.

All sessions were completed successfully, attracting some 200 students from 15 secondary schools. The feedback received from participating students were equally motivating, with over 80% expressed that the workshops had raised their interest in chemical testing and deepened their understanding of the testing and certification industry. In the light of the overwhelming response from schools, we plan to re-run these workshops in the next academic year.

The teaching kit, comprising a teachers' guide and a student laboratory manual, is available at the HKCTC website at www.hkctc.gov.hk/en/work.html#d.

香港檢測和認證局去年首次推出暑期活動計劃，為中學生安排參觀不同政府及公營機構檢測設施，包括標準及校正實驗所、政府化驗所、香港生產力促進局和香港科學園的實驗室，希望藉此加強學生對檢測認證業的興趣和了解。活動反應熱烈，學校對活動的評價亦甚高。

本局今年再接再厲，推出新一輪的暑期活動。我們於2018年6月尾至7月初期間，為正修讀化學的高中生舉辦了六場實驗室工作坊。參與的學生在指導下，進行了本局推出的新高中化學課程教材套中的實驗，學習基本化學測試概念。我們希望能夠透過提供更多實踐的機會，向學生展示測試在日常生活中的重要性，從而提高他們將來投身行業的興趣。

我們很高興全部實驗室工作坊均圓滿結束。活動共吸引了約200名來自15間中學的學生參加，參加者對活動給予肯定，超過八成受訪學生表示工作坊有助提升他們對化學測試的興趣，以及加深他們對檢測認證業的了解。鑑於活動反應非常踴躍，我們會於明年再舉辦同類的實驗室工作坊。

有關新高中化學課程教材套包括教師指引及學生實驗手冊，已上載至本局的網頁：www.hkctc.gov.hk/tc/work.html#d

Statistics of Testing and Certification Activities

檢測認證活動統計數字

The 2016 statistics of the testing and certification activities in Hong Kong have been released earlier this year. Key data are set out at the charts and diagrams below. For more details, please visit HKCTC website (www.hkctc.gov.hk).

2016年香港檢測和認證活動的統計數字經已公布，主要數據如下。詳情請瀏覽香港檢測和認證局網站(www.hkctc.gov.hk)。

Number of Establishments and Persons Engaged in Testing and Certification Activities (2016)

2016年從事檢測和認證活動機構的數目及就業人數

Category 類別	Number of establishments 機構單位數目	Number of persons engaged 就業人數
Private independent establishments 私營獨立機構	670	13 960
Manufacturers and exporters engaging 100 persons or more and with in-house laboratories for testing services 人數達100人以上並設有內部實驗室進行測試活動的製造商和出口商	45	660
Laboratories in government departments / public organisations (including those in the hospitals of the Hospital Authority and those accredited by Hong Kong Accreditation Service in local universities) 政府部門／公共機構內的實驗室(包括醫院管理局轄下醫院的實驗室和本地大學內獲香港認可處認可的實驗室)	55	3 380
Total 總數	770	18 000

Private Independent Establishments with Major Economic Activities in Testing, Inspection and Certification Services (2016)

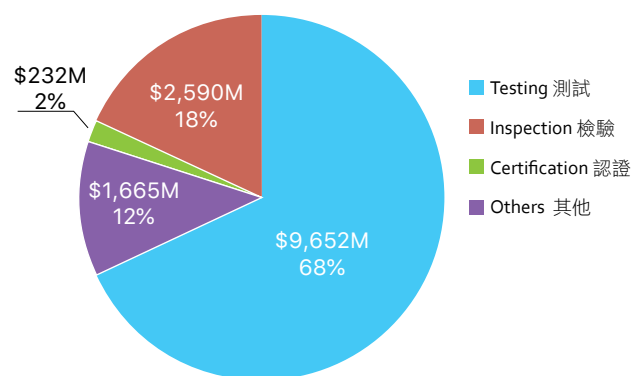
2016年從事測試、檢驗和認證活動的私營獨立機構單位的業務收益

Number of establishments 機構單位數目	Number of persons engaged 就業人數	Business receipts (HK\$Million) 業務收益(百萬港元)	Value added (HK\$Million) 增加價值(百萬港元)
670	13 960	14,138	7,325

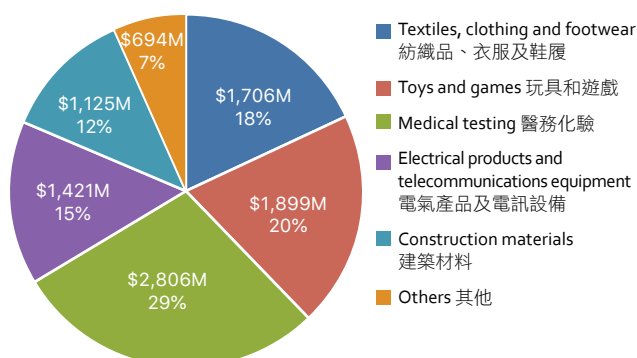
Business Receipts of Private Independent Establishments (2016)

2016年私營獨立機構單位業務收益

By Type of Service 按服務類別



By Type of Products/Services Tested 按產品/服務類別



Ethics Corner 誠信錦囊

To maintain their integrity and impartiality in all circumstances, testing and certification organisations should ensure all personnel working for them act

- lawfully – to abide by the laws of Hong Kong, including the Prevention of Bribery Ordinance (Cap. 201);
- professionally – to maintain the same quality standard for activities performed, no matter whether or not the HKAS endorsed report is issued; and
- honestly – no making of misleading statements on, for instance, accreditation status or activities performance of the organisation.

在任何情況下，檢測認證機構都必須行事持正和公正無私，為此，機構須確保全體人員

- 守法 — 恪守香港法例，包括香港法例第201章《防止賄賂條例》；
- 專業 — 不論香港認可處認許報告是否用作匯報檢測活動結果，機構應確保檢測活動能保持同樣的質量水平；及
- 真誠 — 不作出具誤導性的聲明，例如機構的認可資格或檢測活動表現。

Upcoming Activities 活動預告

HKCTC will be participating in various trade fairs to promote Hong Kong's testing and certification services to local and overseas buyers/manufacturers in different business areas. You are most welcome to visit the booth of HKCTC at the following upcoming trade fairs:

香港檢測和認證局不時參與各種貿易展覽會，向不同行業的本地及海外買家/製造商推廣本港的測試及認證服務。以下是我們即將參加的貿易展覽會，歡迎前來參觀我們的攤位。

At Hong Kong Convention and Exhibition Centre 於香港會議展覽中心舉行

Name of Trade Fairs 貿易展覽會名稱	Fair Dates 展期
Hong Kong International Lighting Fair (Autumn Edition) 香港國際秋季燈飾展	27 – 30.10.2018
Hong Kong Optical Fair 香港眼鏡展	7 – 9.11.2018
SmartBiz Expo 創智營商博覽	5 – 7.12.2018
Hong Kong Toys & Games Fair 香港玩具展	7 – 10.1.2019
Hong Kong Fashion Week for Fall/Winter 香港時裝節秋冬系列	14 – 17.1.2019
Hong Kong International Jewellery Show 香港國際珠寶展	28.2 – 4.3.2019

At Asia World-Expo 於亞洲國際博覽館舉行

Name of Trade Fairs 貿易展覽會名稱	Fair Dates 展期
Eco-Expo Asia 國際環保博覽	25 – 28.10.2018

HKCTC will also participate at the following trade fairs outside Hong Kong
香港檢測和認證局亦會參與以下外地貿易展覽會：

Name of Trade Fairs 貿易展覽會名稱	Location 地點	Fair Dates 展期
China Hi-tech Fair 中國國際高新技術成果交易會	Shenzhen 深圳	14 – 18.11.2018
Spielwarenmesse International Toy Fair 紐倫堡國際玩具展覽會	Nuremberg, Germany 德國紐倫堡	30.1 – 3.2.2019

If you are interested in subscribing our newsletter, please send your contact information to us by e-mail or fax listed below. If you wish to update your information or do not wish to receive our newsletter in the future, please also contact us by email or fax.

如果您有興趣訂閱本通訊，歡迎以電郵或傳真通知我們聯絡方法。如果您希望修改個人資料或不欲收到本通訊，亦請以電郵或傳真聯絡我們。

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