

Hong Kong Laboratory Accreditation Scheme

香港實驗所認可計劃



Introduction

簡介

Hong Kong Laboratory Accreditation Scheme (HOKLAS) is administered by Hong Kong Accreditation Service (HKAS). Its operation is based on international standard and the accreditation provided is independent and impartial. All HKAS' accreditation schemes, including HOKLAS, are open for voluntary participation. Through vigorous on-site assessments and regular surveillance, the accredited organisation's management system and technical competence for specific activities are critically evaluated.

香港實驗所認可計劃（實驗所認可計劃）由香港認可處（認可處）管理，並按照國際標準運作，提供獨立公正的認可服務。認可處轄下的所有認可計劃（包括實驗所認可計劃），均屬自願參與性質。認可處會透過進行嚴謹的實地評審和定期監察，審慎評估獲認可機構的管理體系及進行特定活動的技術能力。

Accreditation of Non-Medical Testing and Calibration Laboratories

為非醫務實驗所和校正實驗所提供的認可服務

Laboratory accreditation offers formal recognition of a laboratory's competence in performing specific tests or calibrations and provides assurance on the reliability of the associated results. It also ensures that a laboratory implements a compliant management system. In Hong Kong, laboratory accreditation has a history dating back to 1985 when HOKLAS was first established under the former Industry Department. HKAS was then established in 1998 through the expansion of HOKLAS. To date, HKAS has accredited over 200 non-medical laboratories, which offer testing and calibration services across a wide spectrum of technical disciplines.

實驗所認可服務旨在正式承認實驗所進行特定測試或校正工作的能力，以保證相關結果的可靠性，並確保該實驗所實施符合規定的管理系統。香港的實驗所認可服務歷史可追溯至 1985 年，當時前工業署首度推出實驗所認可計劃。隨着該計劃的擴展，認可處在 1998 年成立。時至今日，認可處已為超過 200 間在多個技術領域提供測試和校正服務的非醫務實驗所發出認可資格。

Accreditation criteria

認可準則

Accreditation criteria for laboratories (non-medical) are in accordance with ISO/IEC 17025 'General requirements for the competence of testing and calibration laboratories'. In addition, laboratories shall comply with HKAS and HOKLAS regulations, policies and relevant supplementary criteria for specific technical disciplines. During the accreditation process, laboratories need to demonstrate their conformity with the accreditation criteria to HKAS assessment teams through on-site assessments, during which representative laboratory activities within the scope of accreditation will be selected for witnessing.

適用於實驗所（非醫務）的認可準則是根據 ISO/IEC 17025《測試及校正實驗所能力的通用規定》而制定。此外，實驗所亦須遵守認可處及實驗所認可計劃就特定技術領域訂定的規例、政策及相關補充準則。在認可過程中，認可處評審小組會進行實地評審，揀選在認可範圍內具代表性的實驗所活動以作視察，期間實驗所需向評審小組證明已符合相關認可準則。

Scope of accreditation service 認可服務範圍

HKAS currently provides accreditation service to laboratories (non-medical) for the following 15 test categories:
認可處目前為實驗所（非醫務）提供以下 15 個測試類別的認可服務：

- Calibration Services
校正服務
- Chemical Testing
化學測試
- Chinese Medicine
中藥
- Construction Materials
建築材料
- Electrical and Electronic Products
電氣及電子產品
- Environmental Testing
環境測試
- Food
食品
- Forensic Testing
科學鑑證
- Miscellaneous
雜類
- Pharmaceutical Products
藥物
- Physical and Mechanical Testing
物理及機械測試
- Textiles and Garments
紡織品及成衣
- Toys and Children's Products
玩具及兒童產品
- Testing Required by the China Compulsory Certification
中國強制性產品認證制度規定的檢測
- Veterinary Testing
獸醫化驗



As the need arises, HKAS may extend its service to cover other test categories.
如有需要，認可處會把服務擴展至其他測試類別。

Accreditation of Medical Testing Laboratories 為醫務化驗所提供的認可服務

Launched in February 2004, the HOKLAS medical testing accreditation programme serves as an effective gateway for medical testing laboratories to demonstrate their technical competence and be recognised by various clients such as clinicians, patients, regulators, *in vitro* medical device manufacturers, etc.

實驗所認可計劃下的醫務化驗認可方案在 2004 年 2 月推出，旨在為醫務化驗所提供有效的途徑展示其技術能力，以獲得醫生、病人、監管者及體外醫療儀器製造商等不同客戶的認同。

Accreditation criteria 認可準則

Medical testing laboratories are assessed against the requirements of the international standard ISO 15189 'Medical laboratories – Requirements for quality and competence'. In addition, laboratories shall comply with HKAS and HOKLAS regulations, policies and relevant supplementary criteria.

認可處會按照國際標準 ISO 15189《醫務化驗所－質量和能力的專用要求》的規定評審醫務化驗所。此外，化驗所亦須遵守認可處及實驗所認可計劃的規例、政策及相關補充準則。

Scope of accreditation service 認可服務範圍

HKAS provides accreditation service to medical testing laboratories in the following disciplines:
認可處為醫務化驗所提供以下領域的認可服務：

- Anatomical Pathology
解剖病理學
- Chemical Pathology
化學病理學
- Clinical Microbiology & Infection
臨床微生物學及傳染病
- Haematology
血液學
- Immunology
免疫學
- Medical Genetics
醫學遺傳學



Accreditation of Proficiency Testing Providers 為能力驗證提供者提供的認可服務

Proficiency testing is a very useful tool for demonstrating, assessing and monitoring the performance of laboratories and inspection bodies for specific tests or measurements. To provide formal recognition to competent proficiency testing providers (PTPs) based on international standard, HKAS launched the accreditation programme for PTPs under HOKLAS in 2008.

能力驗證於證明、評審和監察實驗所和檢驗機構在特定測試或測量活動上的表現方面發揮很大功用。認可處在 2008 年於實驗所認可計劃下推出為能力驗證提供者而設的認可方案，按照國際標準正式承認合資格的能力驗證提供者。



Accreditation criteria 認可準則

PTPs obtaining accreditation must operate in accordance with the technical and management system requirements in ISO/IEC 17043 'Conformity assessment - General requirements for proficiency testing'. They also need to follow applicable HKAS regulations, policies and supplementary criteria.

獲發認可資格的能力驗證提供者必須按照 ISO/IEC 17043 《合格評定－能力驗證的通用要求》內有關技術和管理體系的規定營運，亦須遵守適用的認可處規例、政策及補充準則。

Scope of accreditation service 認可服務範圍

HKAS currently offers accreditation service for PTPs that organise proficiency testing schemes for chemical testing, medical testing, calibration, electronic and electrical products, microbiological examination, as well as physical and mechanical testing. As the need arises, the programme may be extended to cover providers of schemes in other technical disciplines.

認可處目前提供的認可服務，適用於就化學測試、醫務化驗、校正、電氣及電子產品、微生物檢查，以及物理及機械測試提供能力驗證計劃的能力驗證提供者。如有需要，認可計劃的涵蓋範圍可擴展至其他技術領域的能力驗證計劃提供者。

Accreditation of Reference Material Producers 為標準物質生產者提供的認可服務

Reference materials are important tools for disseminating metrological traceability and ensuring the quality of measurement results. Accreditation of reference material producers (RMPs) enhances the confidence and acceptance of the reference materials they produce. HKAS began to offer accreditation for RMPs in 2010 under HOKLAS.

標準物質是推廣計量溯源性和確保測量結果質素的重要工具。標準物質生產者獲發認可資格，可以促使各界信賴和接納其生產的標準物質。認可處從 2010 年開始根據實驗所認可計劃為標準物質生產者提供認可服務。

Accreditation criteria 認可準則

RMPs applying for accreditation shall establish a management system and demonstrate conformity to the international standard ISO 17034 'General requirements for the competence of reference material producers'. They also have to comply with HKAS and HOKLAS regulations, policies and relevant supplementary criteria.

申請認可資格的標準物質生產者須制定管理體系，並證明其已符合國際標準 ISO 17034 《標準物質生產者能力的通用要求》，以及認可處及實驗所認可計劃的規例、政策及相關補充準則。

Scope of accreditation service 認可服務範圍

HKAS offers accreditation service for RMPs of certified and non-certified reference materials. 認可處為有證標準物質和非有證標準物質的生產者提供認可服務。

Benefits of accreditation 取得認可資格的好處

Accredited laboratories enjoy the following advantages:
獲認可實驗所可享有以下優勢：

- Formal recognition of competence
其能力獲正式承認
- A benchmark for performance
確立表現基準
- Boost of corporate image for service promotion
提升企業形象，有助推廣業務
- Wider acceptance of test and calibration results, reference materials and proficiency testing schemes
促使各界更廣泛接納其測試及校正結果、標準物質和能力驗證計劃

Users of accredited service also gain the following benefits:
使用獲認可服務亦有以下好處：

- Reliable test results
取得可靠的測試結果
- Confidence in laboratory service
對實驗所提供的服務更具信心
- Cost savings in export of goods due to cross-border recognition of test results
因測試結果獲跨境承認而節省貨物出口成本

International recognition 國際承認

HKAS makes every effort to promote the acceptance of test and calibration results from accredited laboratories. Locally, endorsed reports and certificates issued by HKAS accredited laboratories are widely accepted by the general trade and industry as a proof of conformity. They are also recognised by the government in its acquisition of services and law enforcement. Internationally, acceptance is promoted through mutual recognition arrangements (MRA) established among accreditation bodies worldwide. HKAS is active in the regional and international laboratory accreditation community. HKAS is a signatory to both the International Laboratory Accreditation Cooperation (ILAC) and Asia Pacific Accreditation Cooperation (APAC) MRAs, which covers HKAS accreditation on testing, calibration, reference material production and proficiency testing provision.

Under these MRAs, the accreditation by HKAS is recognised as equivalent to an accreditation by other signatories in over 100 economies globally. Endorsed test reports and certificates issued by HKAS accredited laboratories are therefore recognised worldwide, including the major trading partners of Hong Kong. These cross-border recognition arrangements effectively reduce the need for repetitive testing and calibration, thereby facilitating trade between Hong Kong and other economies.

認可處致力推動各界接納獲認可實驗所發出的測試和校正結果。本地方面，獲認可處認可的實驗所發出的認許報告及證書得到一般工商界廣泛接納，用以證明其符合規定，同時亦在政府採購物料和執法時獲承認。國際方面，認可處與世界各地的認可機構達成相互承認安排，以期推動各界接納認可結果。認可處在區域和國際間的實驗所認可組織內相當活躍，亦是國際實驗所認可合作組織 (ILAC) 和亞太認可合作組織 (APAC) 相互承認安排的簽署成員，該兩項安排涵蓋認可處在測試、校正、標準物質生產和提供能力驗證方面的認可服務。

根據上述相互承認安排，認可處發出的認可資格獲全球逾 100 個經濟體的其他簽署成員承認為等同的認可資格。因此，獲認可處認可的實驗所發出的認許測試報告和證書獲得國際承認，當中包括香港的主要貿易伙伴。這些跨境承認安排有效減少重複測試和校正的需要，促進香港與其他經濟體的貿易往來。

Information and enquiry 相關資訊與查詢

All HKAS and HOKLAS publications can be downloaded from the HKAS website (www.hkas.gov.hk). Laboratories interested in applying for HOKLAS accreditation are also encouraged to study the application packages available at the HKAS website. Further query may be directed to the responsible officer of HKAS Executive as listed there.

For more information on the services offered by HKAS accredited laboratories, please visit the Directory of Accredited Conformity Assessment Bodies at the HKAS website or contact HKAS Executive (email to: HKAS@itc.gov.hk).

認可處及實驗所認可計劃的所有刊物均可於認可處網站 (www.hkas.gov.hk) 下載。有意申請實驗所認可計劃認可資格的實驗所，宜先閱覽認可處網站所載的申請指南。如有查詢，請與網站載列的認可處執行機關負責人員聯絡。

欲知更多獲認可處認可的實驗所提供的服務詳情，請瀏覽認可處網站內的獲認可合格評定機構名冊或聯絡認可處執行機關（電郵：HKAS@itc.gov.hk）。