HKAS Application Package
- Accreditation of Chinese Medicine, Chemical Testing, Forensic Testing and Pharmaceutical Products Testing Laboratories

(申請指南中文版本見第 4 頁)

Hong Kong Accreditation Service (HKAS) provides accreditation for conformity assessment bodies (including laboratories, reference material producers, proficiency testing providers, certification bodies, verification and validation bodies, and inspection bodies) located in Hong Kong through Hong Kong Laboratory Accreditation Scheme (HOKLAS), Hong Kong Certification Body Accreditation Scheme (HKCAS) and Hong Kong Inspection Body Accreditation Scheme (HKIAS).

This document provides information relating to accreditation application process. Laboratories interested in seeking HKAS accreditation for their Chinese medicine, chemical, forensic and pharmaceutical products testing services are encouraged to study this document before submitting an application.

1. Accreditation Standard

Applicant laboratories shall comply with following accreditation standard and Policy Document.

1a. ISO/IEC 17025: 2017
General Requirements for the Competence of Testing and Calibration Laboratories

The Quality Services Division of the Innovation and Technology Commission (ITC) provides standards sales service to general public. You may purchase the above international standard through the Division. For details, please visit the webpage of 'Standards Sales Service' of ITC (https://www.itc.gov.hk/en/quality/qsdiv/standards_sales.html).

1b. HKAS Policy Document No. 1
HKAS Policy for Accreditation of Laboratories according to ISO/IEC 17025: 2017 under HOKLAS (ISO/IEC 17025: 2017 HOKLAS Policy)

HKAS Policy Document No. 1 contains HKAS policy that serves as additional explanation of the requirements of ISO/IEC 17025: 2017. It shall be read in conjunction with ISO/IEC 17025: 2017.

2. Regulations for HKAS Accreditation and HKAS/HOKLAS Supplementary Criteria

Applicant laboratories shall also comply with following Regulations and HKAS/HOKLAS Supplementary Criteria as applicable.

2a. HKAS 002
Regulations for HKAS Accreditation

2b. HKAS Supplementary Criteria No. 1
Use of HKAS accreditation symbols and claims of accreditation status

2c. HKAS Supplementary Criteria No. 2
Nonconformities and their grading

2d. HKAS Supplementary Criteria No. 4
Interval between On-site Reassessment and Surveillance Visits of an Accreditation Cycle

2e. HKAS Supplementary Criteria No. 5
Internal Audits and Management Reviews

2f. HKAS Supplementary Criteria No. 6
Code of Conduct

2g. HOKLAS Supplementary Criteria No. 2
All Test Categories - Equipment Calibration and Verification

2h. HOKLAS Supplementary Criteria No. 33
Accreditation Regulations Specific for HOKLAS – Laboratory

2i. Other HOKLAS Supplementary Criteria: -

- HOKLAS Supplementary Criteria No. 1
  Acceptability of Chemical Reference Materials and Commercial Chemicals Used for the Calibration of Equipment

- HOKLAS Supplementary Criteria No. 8
  'Chinese Medicine', 'Environmental Testing', 'Food', 'Miscellaneous', 'Pharmaceutical Products', 'Textiles and Garments' and 'Toys and Children's Products' – Microbiological Testing

- HOKLAS Supplementary Criteria No. 20
  'Chemical Testing', 'Chinese Medicine', 'Construction Materials', 'Miscellaneous', 'Pharmaceutical Products' and 'Toys and Children's Products' – Chemical Testing

- HOKLAS Supplementary Criteria No. 40
  'Chinese Medicine' Test Category – Identification of Chinese Materia Medica by Microscopic Examination in accordance with the Hong Kong Chinese Materia Medica (HKCMM) Standards

- HOKLAS Supplementary Criteria No. 42
  'Forensic Testing' Test Category

- HOKLAS Supplementary Criteria No. 43
  'Chinese Medicine' and 'Food' – Species Identification by DNA Sequencing for Authentication Purpose

- HOKLAS Supplementary Criteria No. 44
  'Chinese Medicine' Test Category – Chemical and Physicochemical Testing to the Hong Kong Chinese Materia Medica (HKCMM) Standards

- 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

Above documents are available for free download from the website of HKAS (https://www.itc.gov.hk/en/quality/hkas/publications/index.html).

3. Application Process

Applicant laboratories are required to complete and submit following forms and documents for accreditation application.

3a. HOKLAS 005
Application for Laboratory Accreditation (including Proficiency Testing Providers and Reference Material Producers) / Extension of Scope of Accreditation

3b. HOKLAS 007 (based on ISO/IEC 17025: 2017)
Assessment / Reassessment Questionnaire for Non-medical Laboratories

- Annex I – Scope of Accreditation Sought (for new application for accreditation or extension of scope of accreditation only)
- Annex II – Checklist

3c. Management system and operation documents (as listed in HOKLAS 007 (based on ISO/IEC 17025: 2017))

In addition, applicant laboratories are required to pay application fee according to HOKLAS 006 (Schedule of Accreditation Fees for Organisations within the Hong Kong Special Administrative Region).

HKAS Executive will arrange a preliminary visit to the applicant laboratories within 21 working days upon receipt of application fee, properly completed application and necessary documents, as requested in relevant assessment and reassessment questionnaire. The date of actual initial assessment visit will be decided after the preliminary visit. It may take place within 3-5 months from the date of preliminary visit, depending on the readiness of the applicant laboratories. A maximum period of 6 months starting from the last date of the initial assessment visit is allowed for completion of remedial actions taken against the observations made by the assessment team during the assessment. Usually one year is allowed for the completion of whole process, from the date of receipt of the application to the granting of accreditation. If accreditation cannot be granted to the applicant laboratories within one year from the date of receipt of application, applicant laboratories may be required to pay the application fee again before the accreditation process can be resumed. For detailed accreditation process, please refer to HOKLAS IN003 [Application Procedures for HOKLAS Accreditation (Informative)].

Please contact Dr HO Chun-wah at 2829 4808 if you have any further queries.

HKAS Executive
October 2021

香港認可處申請指南
- 中藥、化學測試、科學鑑證及藥物測試實驗所的認可

香港認可處(認可處)透過香港實驗所認可計劃(HOKLAS)、香港認證機構認可計劃(HKCAS)及香港檢驗機構認可計劃(HKIAS)，向位於香港的合格評定機構(包括實驗所、標準物質生產者、能力驗證提供者、認證機構、核查和審定機構、及檢驗機構)提供認可服務。

本指南乃為有意申請認可處認可資格的中藥、化學測試、科學鑑證及藥物測試實驗所而設，內容包括有關申請認可資格的資訊。有興趣申請認可資格的實驗所在提交申請前應先閱讀本指南。

1. 認可標準

申請認可資格的實驗所須符合以下的認可標準及政策文件。

1a. ISO/IEC 17025: 2017
General Requirements for the Competence of Testing and Calibration Laboratories

創新科技署轄下品質事務部向公眾提供標準售賣服務。閣下可聯絡品質事務部，購買上述國際標準。詳情請瀏覽創新科技署「標準文件售賣服務」網頁
(https://www.itc.gov.hk/ch/quality/qsdiv/standards_sales.html)

1b. 香港認可處政策文件第1號
香港認可處在香港實驗所認可計劃下根據ISO/IEC 17025: 2017向實驗所提供認可服務的政策(香港實驗所認可計劃有關ISO/IEC 17025: 2017的政策)
香港認可處政策文件第1號列有香港認可處就ISO/IEC 17025: 2017規定的補充解釋。此文件必須與ISO/IEC 17025: 2017一併閱讀。

2. 認可規例及香港認可處/香港實驗所認可計劃補充準則

申請認可資格的實驗所亦須符合以下適用的認可規例及香港認可處/香港實驗所認可計劃補充準則。

2a. HKAS 002C
認可處認可規例

2b. HKAS Supplementary Criteria No. 1 (只有英文版本)
Use of HKAS accreditation symbols and claims of accreditation status

2c. 認可處補充準則第 2 號
不符合項及其評級

2d. HKAS Supplementary Criteria No. 4 (只有英文版本)
Interval between On-site Reassessment and Surveillance Visits of an Accreditation Cycle

2e. HKAS Supplementary Criteria No. 5 (只有英文版本)
Internal Audits and Management Reviews

2f. 認可處補充準則第六號
紀律守則

2g. HOKLAS Supplementary Criteria No. 2 (只有英文版本)
All Test Categories - Equipment Calibration and Verification

2h. 實驗所認可計劃補充準則第33號
實驗所認可計劃的認可規例－實驗所

2i. 其他實驗所認可計劃補充準則(只有英文版本): -

- HOKLAS Supplementary Criteria No. 1
  Acceptability of Chemical Reference Materials and Commercial Chemicals Used for the Calibration of Equipment

- HOKLAS Supplementary Criteria No. 8
  'Chinese Medicine', 'Environmental Testing', 'Food', 'Miscellaneous', 'Pharmaceutical Products', 'Textiles and Garments' and 'Toys and Children's Products' – Microbiological Testing

- HOKLAS Supplementary Criteria No. 20
  'Chemical Testing', 'Chinese Medicine', 'Construction Materials', 'Miscellaneous', 'Pharmaceutical Products' and 'Toys and Children's Products' – Chemical Testing

- HOKLAS Supplementary Criteria No. 40
  'Chinese Medicine' Test Category – Identification of Chinese Materia Medica by Microscopic Examination in accordance with the Hong Kong Chinese Materia Medica (HKCMM) Standards

- HOKLAS Supplementary Criteria No. 42
  'Forensic Testing' Test Category

- HOKLAS Supplementary Criteria No. 43
  'Chinese Medicine' and 'Food' – Species Identification by DNA Sequencing for Authentication Purpose

- HOKLAS Supplementary Criteria No. 44
  'Chinese Medicine' Test Category – Chemical and Physicochemical Testing to the Hong Kong Chinese Materia Medica (HKCMM) Standards

- 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

上述文件可於本處網頁免費下載

(https://www.itc.gov.hk/ch/quality/hkas/publications/index.html).

3. 申請程序

申請認可資格的實驗所須填妥並提交以下表格(只有英文版本)和文件。

3a. HOKLAS 005
Application for Laboratory Accreditation (including Proficiency Testing Providers and Reference Material Producers) / Extension of Scope of Accreditation

3b. HOKLAS 007 (based on ISO/IEC 17025: 2017)
Assessment / Reassessment Questionnaire for Non-medical Laboratories
- Annex I – Scope of Accreditation Sought (for new application for accreditation or extension of scope of accreditation only)
- Annex II – Checklist

3c. 管理體系及操作文件(表列於HOKLAS 007 (based on ISO/IEC 17025: 2017))

此外，申請認可資格的實驗所須按照HOKLAS 006 (Schedule of Accreditation Fees for Organisations within the Hong Kong Special Administrative Region) 繳付申請費用。

在收到實驗所的申請費用，填妥的申請表格和所須文件後21個工作天內，認可處執行機關會安排人員到該申請機構進行預訪。首次現場評審的日期會在預訪後，根據申請機構的準備程度決定。一般情況下，首次現場評審會於預訪後3至5個月內進行。在首次現場評審完成後，實驗所須在最後評審日起計的6個月內，就評審期間所發現的不符合規定項完成改正措施。由收到申請文件到獲得認可，整個過程一般須要在一年內完成。如申請的實驗所未能在一年內取得認可資格，則有可能須要重新繳交申請費用以延續申請。如需了解詳細的申請程序，請參閱HOKLAS IN003 [Application Procedures for HOKLAS Accreditation (Informative)](只有英文版本)。

如有任何疑問，歡迎聯絡本處何振華博士(電話: 2829 4808)查詢。

認可處執行機關
2021 年 10 月