

HOKLAS AP008

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)

This document provides information relating to the processing of an application for accreditation of a laboratory which provides Chinese medicine, chemical, forensic and pharmaceutical products testing services. Any laboratory which is interested in seeking HKAS accreditation is reminded to study related requirements carefully before submitting its application.

1. Accreditation Standard

The applicant laboratory shall comply with the accreditation requirements given in the following documents:

1a. **ISO/IEC 17025: 2017**

General Requirements for the Competence of Testing and Calibration Laboratories

Note: The applicant laboratory may purchase this standard through the Quality Services Division of the Innovation and Technology Commission (ITC).

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)

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

The applicant laboratory shall comply with the requirements of the following documents.

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. 6](#)

Code of Conduct

2f. [HOKLAS Supplementary Criteria No. 1](#)

Acceptability of Chemical Reference Materials and Commercial Standard Solutions Used for the Calibration of Equipment

- 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

Type of Tests	HOKLAS Supplementary Criteria
Microbiological Testing	HOKLAS Supplementary Criteria No. 8 'Chinese Medicine', 'Environmental Testing', 'Food', 'Miscellaneous', 'Pharmaceutical Products', 'Textiles and Garments' and 'Toys and Children's Products' - Microbiological Testing
Chemical Testing	HOKLAS Supplementary Criteria No. 20 'Chemical Testing', 'Chinese Medicine', 'Construction Materials', 'Miscellaneous', 'Pharmaceutical Products' and 'Toys and Children's Products' - Chemical Testing
Forensic Testing	HOKLAS Supplementary Criteria No. 42 'Forensic Testing' Test Category
DNA Sequencing (for species identification)	HOKLAS Supplementary Criteria No. 43 'Chinese Medicine' and 'Food' – Species Identification by DNA Sequencing for Authentication Purpose
Testing to the Hong Kong Chinese Materia Medica (HKCMM) Standards	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. 44 'Chinese Medicine' Test Category – Chemical and Physicochemical Testing to the Hong Kong Chinese Materia Medica (HKCMM) Standards
Testing of Composite Wood Products	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

The above documents are available at the website of HKAS (<https://www.itc.gov.hk/en/quality/hkas/publications/index.html>).

3. Application Process

The applicant laboratory is required to complete the following forms, submit them together with the required documents and pay an application fee (as detailed in [HOKLAS 006](#) - Schedule of Accreditation Fees for Organisations within the Hong Kong Special Administrative Region) to HKAS Executive for processing:

3a. [HOKLAS 005](#)

Application for Accreditation of a Laboratory, Proficiency Testing Provider (PTP) or Reference Material Producer (RMP) / Application for Extension of Scope of Accreditation of a Laboratory, PTP or RMP

3b. [HOKLAS 007](#)

Assessment / Reassessment Questionnaire for Non-medical Laboratories

- [HOKLAS 007 Annex I](#) – Scope of Accreditation Sought (for new application for accreditation or extension of scope of accreditation only)
- [HOKLAS 007 Annex II](#) – Checklist (Based on ISO/IEC 17025: 2017)

Detailed procedures for HKAS accreditation are given in [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
December 2024

HOKLAS AP008

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

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細心閱讀相關的認可要求。

1. 認可標準

申請認可資格的實驗所須符合載於以下文件的認可要求：

1a. [ISO/IEC 17025: 2017](#) (只有英文版本)

General Requirements for the Competence of Testing and Calibration Laboratories

備註：申請認可資格的實驗所可聯絡創新科技署轄下品質事務部，購買此標準。

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)

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須符合載於以下文件的認可要求：

2a. [HKAS 002C](#)

認可處認可規例

2b. [認可處補充準則第 1 號](#)

使用認可處認可標誌及聲稱具備認可處認可資格

2c. [認可處補充準則第 2 號](#)

不符合項及其評級

2d. [認可處補充準則第 4 號](#)

認可周期內進行實地覆審與監察訪問之間相隔的時間

2e. [認可處補充準則第 6 號](#)

紀律守則

2f. [HOKLAS Supplementary Criteria No. 1](#) (只有英文版本)

Acceptability of Chemical Reference Materials and Commercial Standard Solutions Used for the Calibration of Equipment

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）

測試種類	實驗所認可計劃補充準則
微生物測試	HOKLAS Supplementary Criteria No. 8 'Chinese Medicine', 'Environmental Testing', 'Food', 'Miscellaneous', 'Pharmaceutical Products', 'Textiles and Garments' and 'Toys and Children's Products' - Microbiological Testing
化學測試	HOKLAS Supplementary Criteria No. 20 'Chemical Testing', 'Chinese Medicine', 'Construction Materials', 'Miscellaneous', 'Pharmaceutical Products' and 'Toys and Children's Products' - Chemical Testing
法證測試	HOKLAS Supplementary Criteria No. 42 'Forensic Testing' Test Category
脫氧核糖核酸測序 (用於物種鑑定)	HOKLAS Supplementary Criteria No. 43 'Chinese Medicine' and 'Food' – Species Identification by DNA Sequencing for Authentication Purpose
香港中藥材標準測試	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. 44 'Chinese Medicine' Test Category – Chemical and Physicochemical Testing to the Hong Kong Chinese Materia Medica (HKCMM) Standards
複合木製品的測試	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以下表格（只有英文版本）並提交有關文件和按照 [HOKLAS 006](#)（只有英文版本）(Schedule of Accreditation Fees for Organisations within the Hong Kong Special Administrative Region) 繳付申請費用。

3a. [HOKLAS 005](#)

Application for Accreditation of a Laboratory, Proficiency Testing Provider (PTP) or Reference Material Producer (RMP) / Application for Extension of Scope of Accreditation of a Laboratory, PTP or RMP

3b. [HOKLAS 007 \(based on ISO/IEC 17025: 2017\)](#)

Assessment / Reassessment Questionnaire for Non-medical Laboratories

- [HOKLAS 007 Annex I](#) – Scope of Accreditation Sought (for new application for accreditation or extension of scope of accreditation only)
- [HOKLAS 007 Annex II](#) – Checklist (Based on ISO/IEC 17025: 2017)

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

2024 年 12 月