

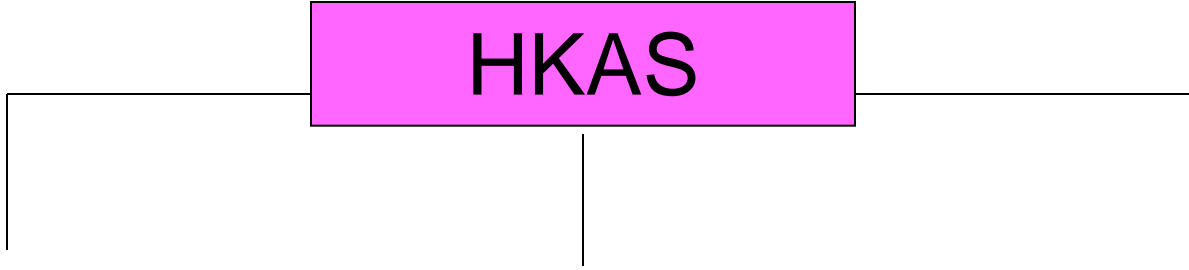


Hong Kong Accreditation Service 香港認可處

**Operates under Innovation and
Technology Commission
創新科技署**



Accreditation Schemes



Certification
HKCAS
Nov. 1998

17 Accredited
Certification
Bodies

Laboratory Testing
HOKLAS
May 1985

174 Accredited
Laboratories


Inspection
HKIAS
Dec. 1999

20 Accredited
Inspection
Bodies

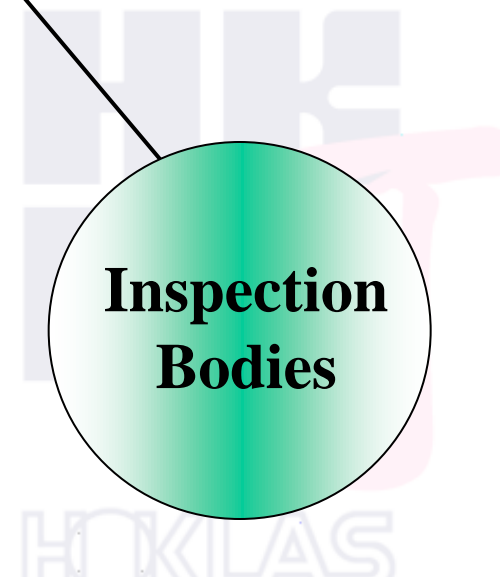
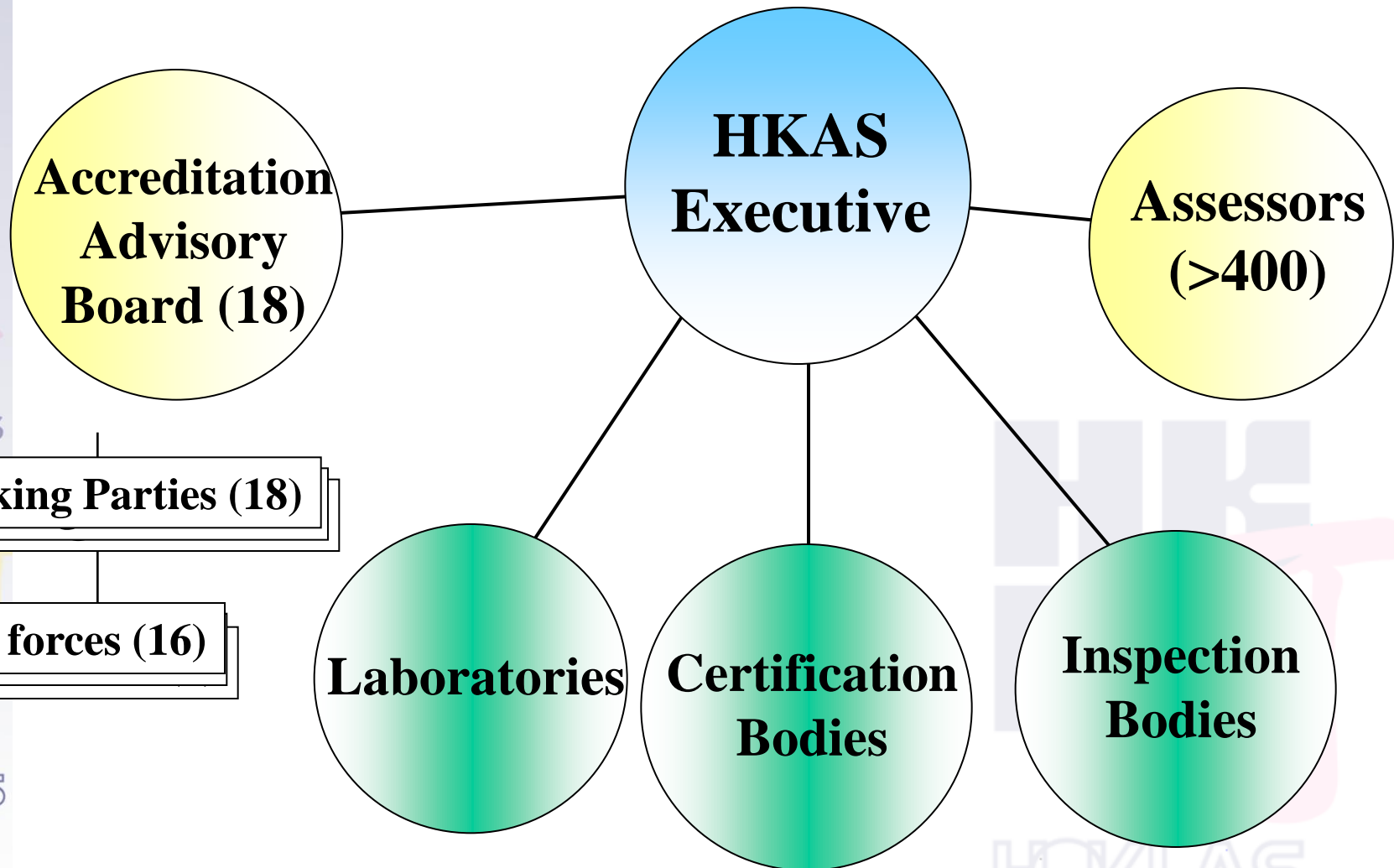




Features of HKAS Accreditation

- ✦ Voluntary
 - ✦ Based on international standards
 - ✦ Rigorous assessment and monitoring
 - ✦ International recognition
 - ✦ Independent and impartial
- 

HKAS Structure

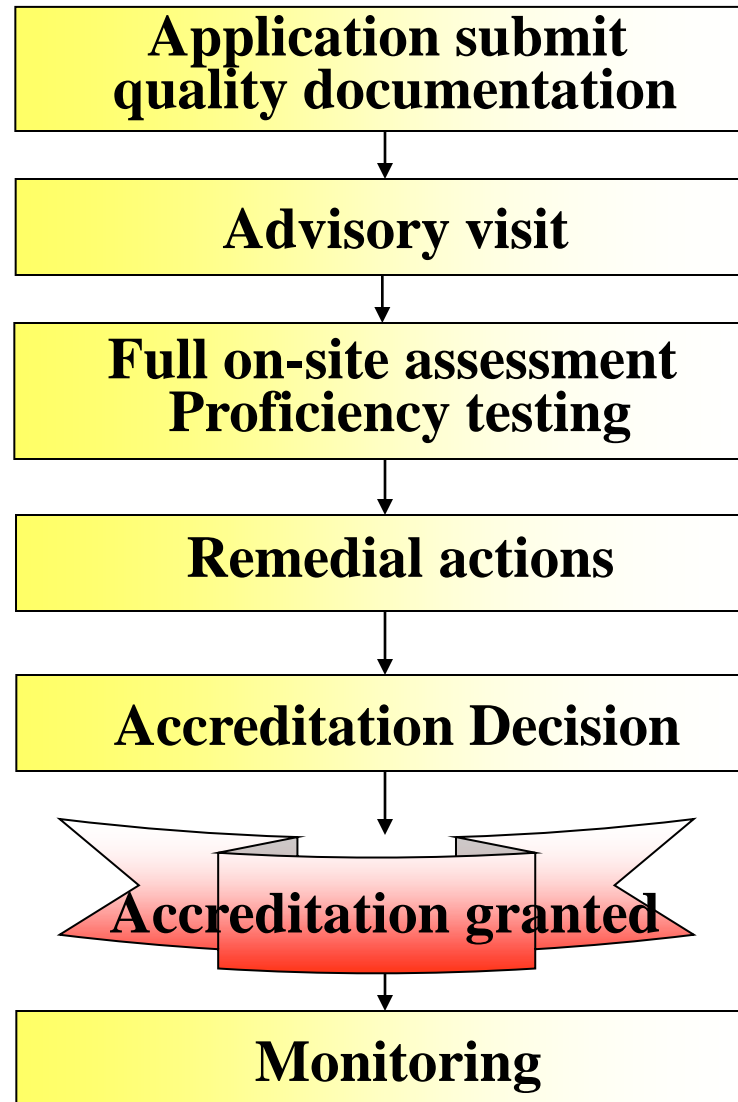


Accreditation

- **ISO/IEC 17000** *Conformity assessment – Vocabulary and general principles*

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks

Accreditation Process Flow chart



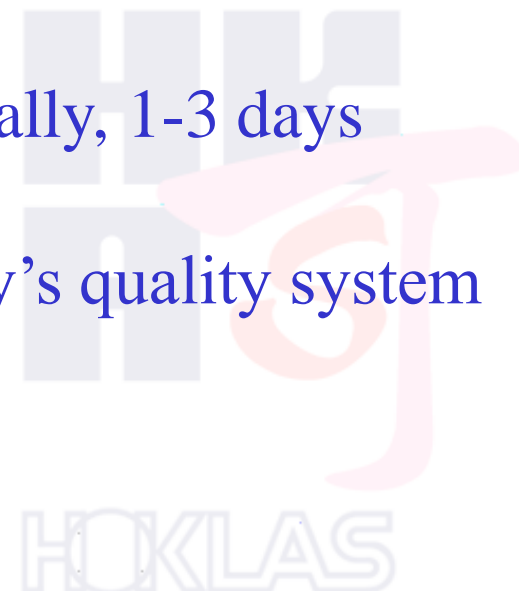
On-site Assessment

Performed by an assessment team that consists of:

- Lead assessor, normally HKAS officer
- technical assessors
- sometimes observers
- technical experts

Duration - depends on the scope, normally, 1-3 days

A rigorous assessment of the laboratory's quality system and technical competence.



On-site Assessment

Actual witnessing of demonstration of testing procedures and detailed review of documents and records.

Technical assessors are selected based on qualifications and experience in that particular field of testing

Assessors are independent with no conflict of interest

Assessors subject to Prevention of Bribery Ordinance.





Hong Kong Accreditation Service
香港認可處

Certificate of Accreditation
認可證書

This is to certify that
特此證明

CONFORMITY ASSESSMENT SERVICES LIMITED – AUTOPARTS VALIDATION

合格評定服務有限公司 - 汽車零件驗證實驗室

28, Laboratory Drive, Conformity Assessment Park, Lantau Island, Hong Kong

香港大嶼山·合格評定園·實驗所路二十八號

has been accepted by the HKAS Executive, on the recommendation of the Accreditation Advisory Board, as a
為香港認可處執行機關根據認可諮詢委員會建議而接受的

HOKLAS Accredited Laboratory
「香港實驗所認可計劃」認可實驗室

This laboratory meets the requirements of ISO / IEC 17025 : 2005 – General requirements for the competence of testing and calibration laboratories and it has been accredited for performing specific tests or calibrations as listed in the HOKLAS Directory of Accredited Laboratories within the test category of
此實驗所符合ISO / IEC 17025 : 2005 - 《測試及校正實驗所能力的通用規定》所訂的要求，獲認可進行載於香港實驗所認可計劃《認可實驗室名冊》內下述測試類別中的指定測試或校正工作

Calibration Services
校正服務

This laboratory is accredited in accordance with the recognised International Standard ISO / IEC 17025 : 2005.
本實驗所乃根據公認的國際標準 ISO / IEC 17025 : 2005 獲得認可。

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer joint ISO-ILAC-IAF Communiqué dated 18 June 2005).
這項認可資格顯示在指定範疇所需的技術能力及實驗所質量管理體系的運作
(見國際標準化組織、國際實驗所認可合作組織及國際認可論壇於二零零五年六月十八日的聯合公報)。

The common seal of the Hong Kong Accreditation Service is affixed hereto by the authority of the HKAS Executive
香港認可處根據認可處執行機關的權限在此蓋上通用印章

CHAN Sing Sing, Terence, Executive Administrator

執行幹事 陳成城

Issue Date : 5 January 2007

簽發日期：二零零七年一月五日

Registration Number : **HOKLAS 999**
註冊號碼：

Date of First Registration : 10 May 2006
首次註冊日期：二零零六年五月十六日



L000001



Monitoring of Accredited Laboratories

- Reassessments
- Surveillance
- Extensions
- Proficiency Testing
- Complaints

(www.itc.gov.hk/en/quality/hkas/about.htm)

Accreditation Requirements

Required to demonstrate that:-

- competent to perform the specific activities
- Implemented an effective quality system complying with accreditation criteria and
- In compliance with all the relevant regulations in HKAS 002

Regulations for HKAS Accreditation

HKAS 002 Regulations for HKAS Accreditation

5.1 An accredited organisation shall at all times:-

(a) Conform with the accreditation criteria, including accreditation regulations specified in this document, technical and non-technical requirements and other conditions as specified by HKAS Executive under its terms of accreditation. The accreditation regulations for specific accreditation schemes and programmes are listed in HKAS Supplementary Criteria No. 3....



Regulations for HKAS Accreditation

(b) Represent honestly and truthfully to any person concerned that it is only accredited for activities stated in its scope of accreditation;

(c) Pay the fees and charges as determined by HKAS Executive;

(d) Endeavour to ensure that the accreditation granted by HKAS is not used in a misleading manner: and

(e) Be a legal entity.



HOKLAS Supplementary Criteria No. 33

Accreditation Regulations Specific for HOKLAS – Laboratory

Section 3 Obligations of Accredited or Applicant Laboratories

3.1 HOKLAS Accreditation Criteria

HOKLAS Accreditation Criteria

An accredited laboratory shall at all times comply with the following HOKLAS accreditation criteria:-

HKAS 002 – *Regulations for HKAS Accreditation*

Relevant **HOKLAS** Supplementary Criteria

Relevant **HKAS** Supplementary Criteria, and



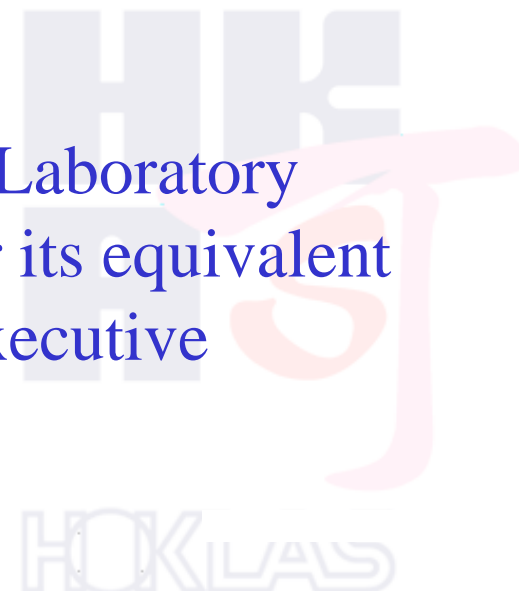
HOKLAS Accreditation Criteria

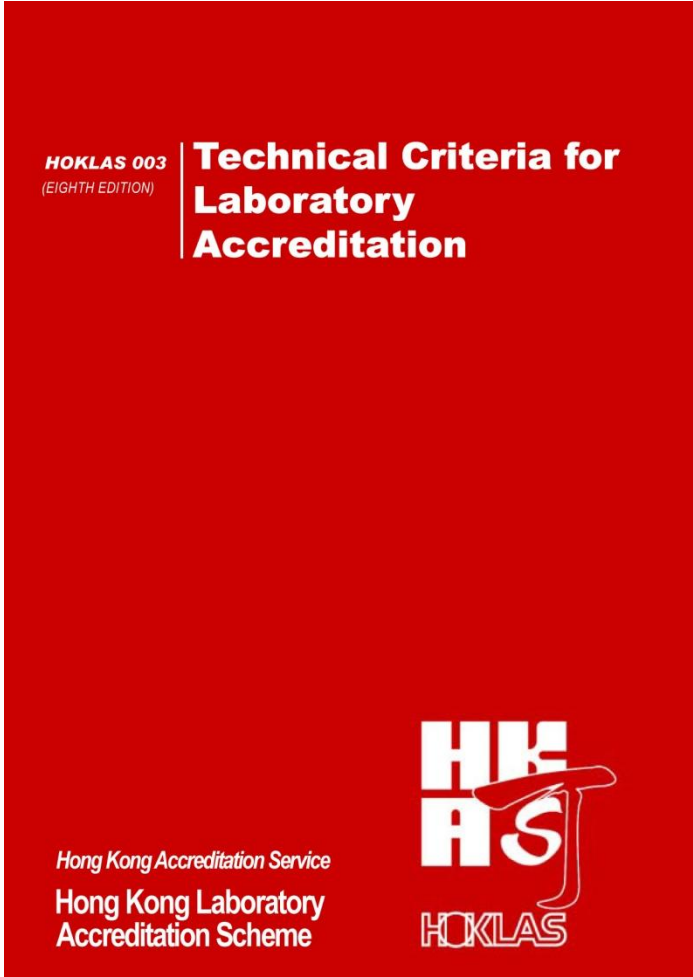
For non-medical laboratories:

HOKLAS 003 – Technical Criteria for Laboratory Accreditation or its equivalent as specified and published by HKAS Executive, or

For medical laboratories:

HOKLAS 015 – Technical Criteria for Laboratory Accreditation (Medical Laboratories) or its equivalent as specified and published by HKAS Executive





Technical criteria for Laboratory Accreditation

- **HOKLAS 003** *Technical Criteria for Laboratory Accreditation* (Ninth edition)
- Basis of technical criteria for laboratory accreditation - **ISO/IEC 17025 : 2005** *General requirements for the competence of testing and calibration laboratories*
- Sections 2 to 5 of **HOKLAS 003** are a verbatim reproduction of ISO/IEC 17025:2005



HOKLAS 003 Technical Criteria for Laboratory Accreditation

Section 1.4 Accreditation criteria

Applicant laboratories have to demonstrate conformity with the criteria in Sections 4 and 5 as well as the criteria in the relevant Supplementary Criteria and the regulations listed in HKAS 002 before accreditation can be granted, and accredited laboratories shall comply with the same criteria at all times for maintaining accreditation. Accredited and applicant laboratories may also be required to demonstrate to HKAS Executive that they can perform competently all the activities proposed for accreditation. Additionally, they shall maintain complete integrity and impartiality in all circumstances.



Technical criteria for Laboratory Accreditation

- **HOKLAS Supplementary Criteria No. 20** “*Chemical Testing*”, “*Chinese Medicine*”, “*Construction Materials*”, and “*Toys and Children’s Products*” – Chemical Testing





HOKLAS 015 Technical criteria for Laboratory Accreditation (Medical Laboratories)

- **HOKLAS 015** *Technical Criteria for Laboratory Accreditation (Medical Laboratories) (4th edition)*
- Basis of technical criteria for laboratory accreditation (medical laboratories) - **ISO 15189 : 2007** “*Medical laboratories – Particular requirements for quality and competence*”





HOKLAS 015 Technical criteria for Laboratory Accreditation (Medical Laboratories)

•**HOKLAS Supplementary Criteria 26** “*Medical Testing*” Test Category – Chemical Pathology

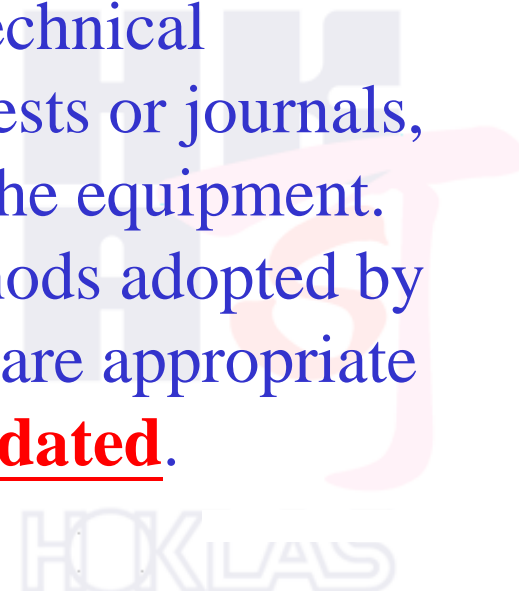




HOKLAS 003 Technical criteria for Laboratory Accreditation

5.4.2 Selection of methods

When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organisations, or in relevant scientific tests or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are **validated**.



HOKLAS 003 Technical criteria for Laboratory Accreditation

5.4.4 Non-standard methods

When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been **validated appropriately before use.**

Method Validation

5.4.5 Validation of methods

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

Method Validation

5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be **as extensive as is necessary** to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.



Method Validation

NOTE 1 Validation may include procedures for sampling, handling and transportation.



Method Validation

NOTE 2 The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:

- calibration using reference standards or reference materials;
- comparison of results achieved with other methods;
- interlaboratory comparisons;
- Systematic assessment of the factors influencing the results based on scientific understanding of the theoretical principles of the method and practical experience.

Method Validation

NOTE 3 When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.

Method Validation

5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' need.

Method Validation

NOTE 1 Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

NOTE 2 As method-development proceeds, regular review should be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorised.



Method Validation

NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

HOKLAS 015 Technical Criteria for Laboratory Accreditation (Medical Laboratories)

Clause 5.5.1 The laboratory shall use examination procedures, including those for selecting/taking sample portions, which meet the needs of the users of laboratory services and are appropriate for the examinations. Preferred procedures are those that have been published in established/authoritative textbooks, peer-reviewed tests or journals, or in international, national or regional guidelines. If in-house procedures are used they shall be appropriately **validated** for their intended use and fully documented.

HOKLAS 015 Technical Criteria for Laboratory Accreditation (Medical Laboratories)

Clause 5.5.2 The laboratory shall use only **validated** procedures for confirming that the examination procedures are suitable for the intended use. The validation shall be as extensive as are necessary to meet the needs in the given application or field of application. The laboratory shall record the results obtained and the procedure used for the validation.



Accreditation Criteria Documents

Except for **HOKLAS 003** and **HOKLAS 015**, all other accreditation criteria documents are available from our website at

<http://www.itc.gov.hk/en/quality/hkas/publication.htm>

Abridged version of **HOKLAS 003** and **HOKLAS 015** are also available.

Full version is only available for interested laboratories.



Accreditation Criteria Documents

ISO/IEC 17025:2005 and **ISO 15189:2007** are available for purchase from Product Standards Information Bureau (PSIB) at the following address:

36/F, Immigration Tower, 7 Gloucester Road, Wan Chai

Can also directly purchase from ISO website at

<http://www.iso.org>



International Recognition

- Recognised by 79 accreditation bodies in 63 economies (Feb 2011)
- Covers testing, medical testing, calibration, inspection, management system certification
- HKAS accreditation recognised internationally



ILAC/IAF MRA

- AUSTRIA 奧地利 *bmw f j*
- BELGIUM 比利時 *BELAC*
- BRAZIL CGCRE/ 巴西 *INMETRO*
- CROATIA 克羅地亞 *HAA*
- CZECH REPUBLIC 捷克共和國 *CAI*
- DENMARK 丹麥 *DANAK*
- EGYPT 埃及 *EGAC*
- ESTONIA 愛沙尼亞 *EAK*
- FINLAND 芬蘭 *FINAS*
- FRANCE 法國 *COFRAC*
- GERMANY 德國 *DAkkS*
- GREECE 希臘 *ESYD*
- HUNGARY 匈牙利 *NAT*
- ITALY ACCREDIA 義大利 *COPIA*
- IRELAND 愛爾蘭 *INAB*
- ISRAEL 以色列 *ISRAC*

UNITED KINGDOM
英國 *UKAS*

歐洲
區域集團
Regional
Group
Europe

LATVIA 拉脫維亞 *LATAK*

- TURKEY 土耳其 *TURKAK*
- TUNISIA 突尼斯 *TUNAC*
- SWITZERLAND 瑞士 *SAS*
- SOUTH AFRICA 南非 *SANAS*
- SWEDEN 瑞典 *SWEDAC*
- SPAIN 西班牙 *ENAC*
- SLOVENIA 斯洛文尼亞 *SA*
- SLOVAKIA 斯洛伐克 *SNAS*
- RUSSIAN FEDERATION 俄羅斯聯邦 *ACC Analitica*
- ROMANIA 羅馬尼亞 *RENAR*
- PORTUGAL 葡萄牙 *IPAC*
- POLAND 波蘭 *PCA*
- NORWAY 挪威 *NA*
- NETHERLANDS 荷蘭 *RvA*
- LITHUANIA 立陶宛 *LA*

CANADA 加拿大 *SCC CALA*

CHINA, PRC 中華人民共和國
CNAS

CHINESE TAIPEI 中華臺北 *TAF*

HONG KONG 香港 *HKAS*

INDIA *NABCB NABL*

INDONESIA 印尼 *KAN*

JAPAN *JAB IAJapan VLAC*

PAKISTAN 巴基斯坦 *PNAC*

PHILIPPINES 菲律賓 *PAO*

ARGENTINA 阿根廷 *OAA*

MEXICO 墨西哥 *EMA*

AUSTRALIA 澳大利亞 *NATA*

AUSTRALASIA 澳亞 *JAS-ANZ*

跨美
區域集團
Regional
Group
Inter-America

GUATEMALA 瓜地馬拉 *OGA*

VIETNAM 越南 *BOA*

USAASCLD/LAB 美國 *ACLASS A2LA, IAS, L-A-B IAS, NVLAP, PJLA*

THAILAND ONAC 泰國 *DS S DMSc*

SINGAPORE 新加坡 *SAC*

REP. OF KOREA 大韓民國 *KOLAS*

NEW ZEALAND 新西蘭 *IANZ*

MALAYSIA 馬來西亞 *DSM*

UNITED ARAB EMIRATES 阿拉伯聯合酋長國 *DAC*

CUBA 古巴 *ONARC*

COSTA RICA 哥斯大黎加 *ECA*

亞太
區域集團
Regional
Group
Asia-Pacific



Thank you

