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# **HOKLAS Supplementary Criteria No. 45**

## **Accreditation Requirements for Hong Kong Testing Laboratories to Undertake Product Testing to China Compulsory Certification System**

### **1. INTRODUCTION**

- 1.1 Pursuant to the Supplement VIII to the Mainland and Hong Kong Closer Economic Partnership Arrangement (CEPA) signed by the Mainland and the Hong Kong Special Administrative Region (HKSAR) governments on 13 December 2011, the scope of products to be tested by Hong Kong laboratories accredited by Hong Kong Accreditation Service (HKAS) to China Compulsory Certification (CCC) System requirements had been extended from four types of products under the Supplement VII to CEPA to all products listed in the directory of CCC products which are processed in Hong Kong.
- 1.2 The Agreement between the Mainland and Hong Kong on Achieving Basic Liberalization of Trade in Services in Guangdong under the framework of CEPA (Guangdong Agreement) was signed between the Mainland and HKSAR in December 2014. It includes measures allowing a testing laboratory in Hong Kong to collaborate with a designated Mainland certification body to undertake testing of products in the ‘audio and visual apparatus’ category of the CCC system that are designed and prototyped in Hong Kong, as well as processed or manufactured in Guangdong Province.
- 1.3 The Agreement on Trade in Services under CEPA (Agreement on Trade in Services) was signed between the Mainland and HKSAR in November 2015. It includes measures allowing a testing laboratory in Hong Kong to collaborate with a designated Mainland certification body to undertake testing of all products as listed in the directory of CCC products which are processed or manufactured in the China (Guangdong) Pilot Free Trade Zone, irrespective of where they are designed and prototyped.
- 1.4 In December 2018, by way of Exchange of Letters, the Agreement on Trade in Services was amended to extend the scope of CCC testing that can be undertaken by Hong Kong testing laboratories to cover all products processed/manufactured in the Mainland requiring CCC.
- 1.5 In November 2019, the Agreement concerning Amendment of the Agreement on Trade in Services (the Amendment Agreement) was signed between the Mainland and HKSAR to further extend the scope of CCC testing that can be undertaken by Hong Kong testing laboratories to cover all products requiring CCC processed or manufactured in any place (including places outside Mainland). The current directory of products that require CCC is listed in

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Appendix I. Testing laboratories can visit the CCC portal at the website of the Certification and Accreditation Administration of the People's Republic of China (CNCA) to search for the product directory under CCC and related CCC Implementation Rules.

- 1.6 This Supplementary Criteria explains the requirements for Hong Kong testing laboratories to undertake product testing to CCC as provided in the Amendment Agreement by CNCA.
- 1.7 Before providing CCC product testing service to the public, Hong Kong testing laboratories shall apply to HKAS for accreditation under Hong Kong Laboratory Accreditation Scheme (HOKLAS) to demonstrate their competence in CCC product testing and conformity with the competence requirements of the CNCA. HKAS accreditation will be granted with reference to product type (e.g. toys can be classified into electric toys, plastic toys metal toys and ride-on toys). Testing laboratories should draft the scope of accreditation sought based on their technical competence.

## **2. REQUIREMENTS AND PROCEDURE FOR QUALIFYING HONG KONG TESTING LABORATORIES**

- 2.1 Testing laboratories shall at all times comply with the following criteria:
  - A. HKAS 002 'Regulations for HKAS Accreditation',
  - B. ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories',
  - C. HKAS Policy Document No. 1 'HKAS Policy for Accreditation of Laboratories according to ISO/IEC 17025: 2017 under HOKLAS',
  - D. HOKLAS Supplementary Criteria No. 33 'Accreditation Regulations Specific for HOKLAS – Laboratory',
  - E. This Supplementary Criteria,
  - F. Other relevant HKAS and HOKLAS Supplementary Criteria,
  - G. Relevant requirements in the 'Measures for the Administration of Certification Bodies and Laboratories' under the China Compulsory Certification System 《強制性產品認證機構和實驗室管理辦法》, including requirements for qualification of a laboratory as specified in Article 10 (Appendix II),
  - H. all prevailing CCC Implementation Rules and applicable test standards,
  - I. Relevant latest revision of Guidance on the Application of Accreditation Criteria (認可準則應用說明) of the China National Accreditation Service for Conformity Assessment (CNAS) (Appendix III).
- 2.2 If there is any variation between the HKAS/HOKLAS Supplementary Criteria

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and the relevant CNAS Guidance, the applicant laboratory shall conform to the requirements of both documents.

- 2.3 An applicant laboratory shall be a legal entity in Hong Kong. The organisation structure of the laboratory shall ensure its impartiality and independence in undertaking the testing activities. The laboratory shall not have any serious violation of the ‘Regulations for HKAS Accreditation’ or other accreditation requirements within six months prior to submitting its application for accreditation.
- 2.4 The applicant laboratory shall have at least two years of experience in conducting the relevant test or shall have issued more than 20 reports for that test.
- 2.5 HKAS will conduct an on-site assessment to confirm the applicant laboratory’s conformity with the accreditation requirements and the competence requirements of the CNCA.
- 2.6 HKAS will issue a notification letter to grant accreditation to a laboratory confirmed to be satisfying the accreditation requirements and the competence requirements of the CNCA to undertake testing to CCC requirements. HKAS will only grant accreditation on condition that the products under test are covered under CCC. If any product under test within the laboratory’s accreditation scope is no longer covered under CCC, accreditation for the related testing activities will be terminated automatically. This accreditation condition will also be specified in the notification letter.
- 2.7 The accredited laboratory should seek collaboration with a CCC designated certification body in accordance with the procedures stated in Appendix IV. If the laboratory does not seek accreditation for all the required tests for the specified product type, HKAS will specify the limitation by indicating those products in the scope of accreditation of the laboratory. The laboratory shall indicate such limitation in its official document of collaboration with the CCC designated certification body. For example:
- Appliance for skin or hair care (0709)  
**<Excluding the following>**  
 - Detachable curler
- 2.8 CNCA announces the updated CCC requirements through its official website from time to time. Accredited laboratories shall visit this website regularly for continual conformity with the requirements of CNCA, including updating their testing standards. If any CCC Implementation Rule and/or test standard within the laboratory’s accreditation scope is no longer required by CNCA, accreditation for the related testing activities will be terminated automatically.

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### **3. SURVEILLANCE VISIT AND REASSESSMENT**

- 3.1 HKAS will conduct an on-site surveillance visit or a reassessment in each year to the accredited laboratory to confirm its continuing conformity with the accreditation requirements and the competence requirements of the CNCA.
- 3.2 If an accredited laboratory fails to demonstrate continuing conformity with the accreditation requirements or the competence requirements of the CNCA, HKAS will suspend the accreditation of such laboratory and notify CNCA accordingly.

### **4. CONTROL OF RECORDS**

- 4.1 An accredited laboratory shall determine the period for retention of its records with its collaboration certification body. The minimum retention period is four years.

### **5. PERSONNEL**

- 5.1 In addition to HKAS and CNAS requirements, laboratory personnel including HOKLAS approved signatories and test operators shall be trained on and conversant with the relevant CCC Implementation Rules and test standards.

### **6. EQUIPMENT AND FACILITIES**

- 6.1 An accredited laboratory shall have the required equipment and facilities, or shall obtain authorisation by the owner to use those required equipment and facilities. On-site assessments of HKAS may cover all sites where those authorised-to-use equipment and facilities are located.

### **7. HANDLING OF TEST ITEMS**

- 7.1 All samples shall be clearly identified.
- 7.2 The laboratories shall implement a system for identifying and recording the main test sample and other samples under the same unit of CCC application to ensure traceability of the samples and records.
- 7.3 The retention and disposal of tested samples shall conform to the relevant

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CCC Implementation Rules. If there is no specified requirement in the CCC Implementation Rules, the laboratory shall determine the sample retention and disposal requirement with its collaboration certification body.

## **8. TEST RECORDS**

- 8.1 All test reports shall be prepared in Simplified Chinese and signed by a HOKLAS approved signatory for the relevant test.
- 8.2 The accredited laboratory shall determine the report format together with its collaboration certification body.

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## **Appendix I**

### **Directory of Products that Require CCC \***

1. Electric cables and wiring
2. Electrical switches, protective devices and connection devices
3. Low voltage electrical equipment
4. Small power motors
5. Electric tools
6. Electric welding machines
7. Household and similar electrical appliances
8. Electronic product and safety accessory
9. Lighting apparatus
10. Motor vehicles and safety accessories
11. Agricultural machinery
12. Fire service equipment
13. Security system products
14. Construction materials
15. Children's products
16. Explosion-proof electrical products
17. Household gas appliances

\* The above directory may be updated from time to time by State Administration of Market Regulation. Testing laboratory shall refer to CCC portal at CNCA's website for the latest directory of products that require CCC.

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## **Appendix II**

**Article 10 of the ‘Measures for the Administration of Certification Bodies and Laboratories under the China Compulsory Certification System’  
(《強制性產品認證機構和實驗室管理辦法》第十條)**

(Note: There is only Chinese version. The above article in Chinese is available at CNCA’s website)

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### **Appendix III**

**China National Accreditation Service for Conformity Assessment (CNAS)  
Guidance on the Application of Accreditation Criteria  
(認可準則應用說明)**

1. CNAS-CL01-A002 - Guidance on the Application of Testing and Calibration Laboratories Competence Accreditation Criteria in the Field of Chemical Testing
2. CNAS-CL01-A003 - Guidance on the Application of Testing and Calibration Laboratories Competence Accreditation Criteria in the Field of Electrical Testing
3. CNAS-CL01-A004 - Guidance on the Application of Laboratory Competence Accreditation Criteria in the Field of Medical Device Testing
4. CNAS-CL01-A005 - Guidance on the Application of Testing and Calibration Laboratories Competence Accreditation Criteria in the Field of Automobile and Motorcycle Testing
5. CNAS-CL01-A008 - Guidance on the Application of Testing and Calibration Laboratories Competence Accreditation Criteria in the Field of Electromagnetic Compatibility Testing
6. CNAS-CL01-A009 - Guidance on the Application of Testing and Calibration Laboratories Competence Accreditation Criteria in the Field of Toy Testing
7. CNAS-CL01-A022 - Guidance on the Application of Laboratory Competence Accreditation Criteria in the Field of Building Materials Testing

(Note: The above guidance documents in Chinese may be downloaded from [www.cnas.org.cn](http://www.cnas.org.cn))

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#### **Appendix IV (Informative)**

##### **Procedure for a Hong Kong Accredited Laboratory to Collaborate with a CCC Designated Certification Body**

1. The accredited laboratory may propose its intention of collaboration with a CCC designated certification body.
2. The CCC designated certification body has the autonomy to arrange for discussion with the accredited laboratory based on the principle of consistency and validity of test results.
3. The CCC designated certification body concludes and signs collaboration agreement with the accredited laboratory.
4. The certification body will submit the signed agreement to CNCA for record.
5. CNCA will publish a directory of Hong Kong laboratories in collaboration with CCC designated certification bodies in its official website and then notify the relevant Mainland market regulation authorities.
6. Upon receiving notification from HKAS that a Hong Kong laboratory has no longer fulfilled the relevant requirements, CNCA will inform the concerned designated CCC certification body. The designated CCC certification body will review its collaboration with the concerned laboratory and report the result to CNCA. CNCA will announce the revised directory of Hong Kong laboratories in its website and then notify the relevant Mainland market regulation authorities.
7. If a Mainland market regulation authority reveals that a Hong Kong laboratory undertaking CCC testing activities has breached any laws and regulations on certification and accreditation, or implementation rules of the certification scheme, it will notify CNCA which will then notify HKAS.