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

0 Introduction

(a) This criteria document serves to clarify and supplement the requirements of ISO/IEC 17025: 2017 and HKAS Policy Document No. 1 for the accreditation of identification of Chinese Materia Medica by microscopic examination in accordance with the Hong Kong Chinese Materia Medica (HKCMM) Standards under the test category of ‘Chinese Medicine’. This criteria document shall be read in conjunction with ISO/IEC 17025: 2017, HKAS Policy Document No. 1 and the relevant HKAS and HOKLAS supplementary criteria documents.

(b) Both the organoleptic examination and microscopic examination are important methods to determine the authenticity and quality of Chinese Materia Medica (CMM). Organoleptic examination involves inspection through visual examination, feeling, smelling and tasting of products while microscopic identification covers the use of microscope to identify crude drug slides of transverse or longitudinal sections, powder, surface and disintegrated tissue of CMM samples. It should be noted that HKCMM Standards also specify tests other than microscopic examination for identification purpose. A more complete identification can be achieved if the other tests specified for identification, such as chromatographic analysis, are also performed.

(c) The following sections set out specific technical criteria for microscopic examination of CMM according to HKCMM Standards. Technical criteria pertaining to specified tests other than microscopic examination in HKCMM Standards are covered in HOKLAS Supplementary Criteria No. 44. This document also provides guidance for selected aspects. In areas not covered in this document, the requirements stipulated in ISO/IEC 17025: 2017, HKAS Policy Document No. 1, HKAS 002 and other relevant criteria documents shall apply.

(d) Laboratories should note that complying with this document might not necessarily meet all the requirements of the HKCMM Standards. The HKCMM Standards may have specific requirements for each CMM which shall also be met when conducting the concerned tests/examinations.

1 Scope

(No additional explanation)

2 Normative reference

(No additional explanation)

3 Terms and definition

(No additional explanation)

4 General requirements

(No additional explanation)

5 Structural requirements

5.1 The technical management of the laboratory shall include at least a staff member who has in-depth knowledge of and extensive hands-on experience in the identification of CMM in accordance with HKCMM Standards. This person is also responsible for the technical operation of the laboratory with respect to microscopic identification and the training of staff members for routine examination of CMM.

6 Resource requirements

6.1 General

(No additional explanation)

6.2 Personnel

(a) The minimum qualification and experience necessary for all posts within the laboratory shall be defined. The qualifications and experience shall be appropriate to the duties and responsibilities of the respective posts concerned.

(b) Microscopic examination shall be performed by formally trained and authorised staff members. Training programme and materials shall be documented and authorised. The programme shall include the training in the technique for microscopic examination, procedures in sample preparation, staining techniques, use of microscope, taking of photographs, identification, data handling and other quality control techniques. Records of initial training and continuing competence monitoring, including all associated raw data, shall be maintained.

(c) As microscopic examination requires the analysts to distinguish colours of different components in the sample slides, colour vision defects may prevent them from properly performing this task. Therefore, analysts and approved signatories shall undergo a colour defect check to ensure the reliability of the examination results. Those qualified analysts to carry out examination are also required to participate in the laboratory's performance monitoring programmes according to the requirements specified therein. A list of all qualified analysts shall be maintained.

(d) Both the analysts and approved signatories shall have the minimum qualification and experience stated below. In addition, the approved signatory shall meet the requirements given in HKAS 002, ISO/IEC 17025: 2017, HKAS Policy Document No. 1 and other relevant criteria documents.

(e) Analysts and approved signatories

(i) Analysts and approved signatories shall either have

(1) a Bachelor's degree or above in Pharmacy of Chinese Medicine or equivalent, plus one year relevant working experience; or

(2) a Bachelor's degree or above in Chinese Medicine and have attended and passed a training course, provided by a recognized tertiary institute, on the identification and authentication of CMM covering both theory and laboratory training, plus two years relevant working experience; or

(3) a Bachelor's degree or above in a relevant science subject and have attended and passed a training course, provided by a recognised tertiary institute, on the identification and authentication of CMM covering both theory and laboratory training, plus three years relevant working experience.

Note: An outline of a typical training course for the purpose of clause 6.2 (e)(i)(2) and 6.2 (e)(i)(3) is shown in the Appendix.

(ii) Irrespective of the person's academic qualifications, the nominee shall have at least six months experience in the area of examination for which signatory approval is sought.

(iii) In all cases, candidates shall demonstrate his/her technical competence in the area of examination under consideration to the assessors before signatory approval can be granted.

6.3 Facilities and environmental conditions

(a) The laboratory shall provide appropriate environmental conditions and controls necessary for particular examinations, including temperature, humidity, freedom from vibration, freedom from airborne and dust-borne contamination, special lighting, etc. Environmental conditions that influence the validity of the results shall be controlled continuously, monitored and recorded. Acceptable ranges for environmental conditions such as temperature and humidity shall be defined and documented. Cases where environmental conditions fall outside the acceptable ranges shall be recorded and the effects, if any, on examination results shall be evaluated. Suitable corrective actions shall be taken to rectify the situation as soon as possible.

(b) Laboratories shall lay down procedures and precautions to be taken to prevent contamination or interference on laboratory activities from the environment. Particular attention should be given to, for example, the presence of dust in the laboratory environment for microscopic identification. Precautions shall be taken to avoid the ingress of dust as far as possible. Good housekeeping is essential to minimise contamination or interference by air-borne particulates.

6.4 Equipment

(a) All critical chemicals and consumables having significant effect on the examination results shall be verified to ensure conformity with specified requirements before use.

6.5 Metrological traceability

(a) HOKLAS Supplementary Criteria No. 2 'All Test Categories – Equipment Calibration and Verification' gives detailed requirements and recommendations for equipment calibration and verification. Calibration of equipment critical to examination results shall be traceable to the International System of Units (SI). Where traceability of measurements to SI units is not technically possible, Cl. 6.5.3 of ISO/IEC 17025: 2017 shall be followed. For microscopic examination, proper calibration of the camera for taking photographs of slides, including but not limited to image colour and dimension calibration, shall be conducted.

(b) CMM samples used as controls shall only be accepted after strict botanical taxonomy identification with the original plant for reference. Apart from accurately identifying the original plants of CMM samples, it should be noted that the microscopic features of the examination object might show variation by its origin, growth environment, time of harvest/collection and post processing. Therefore, the place of origin, collection time and processing methods shall be recorded. Photographs in the HKCMM Standards may serve as the reference. However, the laboratories shall be equipped with laboratory control samples or slides relevant to the scope of accreditation. The laboratory shall have established that these control samples contain features conforming to the HKCMM Standards.

6.6 Externally provided products and services

(No additional explanation)

7 Process requirements

7.1 Review of requests, tenders and contracts

(No additional explanation)

7.2 Selection, verification and validation of methods

(a) Selection of test methods

(i) The laboratory shall document all methods and procedures concerning sampling, sample handling and storage, preparation of specimens, specimen examination and, as appropriate, recording of images, etc.

(ii) Laboratories shall adopt methods as given in the HKCMM Standards only.

(b) Verification of methods

(i) Laboratories shall carry out the examination in strict accordance with HKCMM Standards. They shall verify their competence to perform the examination by, for example, participation in proficiency testing programmes as far as possible. They shall also verify their performance using positive control and negative control (e.g. habitually alternatives or commonly confused herbs) samples. They have to demonstrate their ability to avoid false positive identification.

(ii) Quality of tissue slides is essential to microscopic identification. Appropriate methods for preparation of specimen slides shall be chosen on the basis of the nature of the examination object.

7.3 Sampling

(a) Sampling from sample lot or site is not covered by this document. Customers taking their own samples shall be made aware of proper storage, sampling and transportation procedures.

(b) Recommended sampling procedure given in HKCMM Standards for selecting CMM samples for examination shall be followed. However, it should be noted that the results of examination should relate to the samples as examined only.

7.4 Handling of test or calibration items

(a) Laboratories shall examine and record the condition and appearance of the samples upon receipt. Items to be checked should include, where appropriate, number, amount of sample, colour, batch number, etc. Any deviations of test item from specified conditions or the customers' supplied information shall be handled in accordance with Cl. 7.4.3 of ISO/IEC 17025: 2017.

(b) Samples for examination shall be suitably stored as soon as practicable upon receipt. Laboratories shall define the storage conditions for different types of samples, particularly for perishable samples. For dried CMM samples, in order to prevent deterioration and mould growth, they shall be stored under an environment with low humidity. The temperature of the sample storage, if critical, shall also be controlled. The environmental conditions for sample storage shall be monitored and recorded to demonstrate that the

requirements are fulfilled

(c) Frequently, it is necessary to split the samples for testing of different properties. It is essential that such sub-samples represent the original samples and that their identities are maintained at all times.

(d) Access to the sample storage shall be controlled and only authorised persons shall have access to the sample storage. The storage area should be locked after office hours of the laboratory.

7.5 Technical records

(a) Results for the examination on each and every microscopic feature specified in HKCMM Standards for the CMM being examined shall be recorded. The records shall contain sufficient details to ensure that the examination could be repeated in the same conditions and sample locations as far as possible. Photographs of the original samples and photomicrographs of the microscopic features shall be taken and included as part of the records. Worksheets used in the laboratory shall include provision for recording the above information, details of the equipment used, reference controls used and names of the responsible analysts.

(b) All records including photographs and photomicrographs (in hardcopy and electronic format), specimen slides and original samples shall be kept for at least four years after the issue of the results.

7.6 Evaluation of measurement uncertainty

(No additional explanation)

7.7 Ensuring the validity of results

(a) The laboratory shall include the analysis of laboratory samples of positive control and negative control (e.g. habitually alternatives or commonly confused samples), re-examining of the same sample and the comparison of the examination results performed by independent personnel. When in doubt, the results must be cross checked by independent qualified personnel.

(b) Laboratories shall document their quality control plans and procedures. The plans shall include frequency of performing quality control samples, their acceptance criteria and actions to be taken in cases of acceptance criteria not being met.

(c) Results for the examination on each and every microscopic feature specified in HKCMM Standards for the examined CMM shall be reviewed critically by the approved signatory (or by a second person if the approved signatory is the one performing the original examination) before being reported. Detailed review records shall be kept. In case of doubt, the approved signatory (or the second person) shall repeat the examination, with the assistance of the original examiner as appropriate, to verify the results.

(d) Laboratories shall also define the minimum retraining period for the operators. All operators shall participate in internal proficiency testing programme by examining blind samples at a minimum frequency of once in every six months to ascertain their continuing competence.

(e) Laboratories shall participate in external proficiency testing programme or inter-laboratory comparison studies once every year for each type of CMM samples.

7.8 Reporting of results

(a) A description of the samples as received shall normally be given in reports. The description shall include, where relevant to the interpretation of examination results, a description of the number/set, appearance and amount of samples, type of container and condition when received. Any deviation from the customer's information or abnormality shall be reported. If there is a possibility that the examination results may be affected by the deviation, it shall be in the report.

(b) The sample preparation procedure shall be given if it is required for the proper interpretation of examination results.

(c) When a statement on the positive identification of the sample is given in the report, the statement shall only be made by stating that the sample conforms to specifications of HKCMM Standards for the microscopic identification of a particular CMM. Any such statement without mentioning of conformity with the specifications of HKCMM Standards shall not be made. The results of organoleptic examination should also be considered when interpreting the microscopic examination results. An example of the statement is as follows:

"The sample was found to conform to the specifications of Hong Kong Chinese Materia Medica Standards for the microscopic identification of

Radix Ginseng" – if only microscopic examination was performed.

(d) There may be cases where positive identification cannot be ascertained solely using microscopic examination. In such case, a statement of conformity shall not be made. Nonetheless, in all cases, it may be necessary to supplement microscopic examination with other identification means given in HKCMM Standards in order to provide additional confidence in the identity of the sample.

7.9 Complaints

(No additional explanation)

7.10 Nonconforming work

(No additional explanation)

7.11 Control of data and information management

(No additional explanation)

8 Management system requirements

(No additional explanation)

Appendix
(Informative)

A typical training course on the "Identification and Authentication of Chinese Materia Medica (CMM)" shall, as a minimum, comprise the following: -

I. Theory (not less than 70 hours)

(a) Background and basic principles on the identification and authentication of CMM. Emphasis should be placed on confusion clarification and discrimination for authenticity and quality through organoleptic examination.

(b) Knowledge on the sources of CMM and the various steps involved in their preparation such as collection, processing and storage.

(c) Sampling and reference for CMM identification and authentication.

(d) Background and basic principles on the microscopic examination of CMM.

(e) Characteristics for microscopic identification of different types/parts of CMM such as radix, rhizome, caulis, lignum, cortex, folium, flower, fruit and seed, as well as their identification in mixtures.

II. Practical (not less than 20 hours)

(a) Morphological and organoleptic examination of CMM specimens as well as their source plants.

(b) Processing of CMM for microscopic examination.

(c) Microscopic examination and identification of different types of CMM and mixtures.

III. Assessment

(a) Continuous assessment through regular assignments, laboratory reports, etc.

(b) Qualifying examination.