Hong Kong Institution of Certified Auditors

香港專業審核師學會

HKICA-CC03E

Certification Scheme of Medical Laboratory Auditors

Certification Criteria

The Secretary, Room 108, 1/F Sun Ling Plaza
30 On Kui Street, Fanling, New Territories

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FOREWORD

All public documents of Hong Kong Institution of Certified Auditors (HKICA) are issued in both Chinese and English version. The latest issue will be uploaded to the Scheme website.

Applicant can contact the Secretariat for information regarding the Certification Scheme for Medical Laboratory Auditors (CSMLA) by the following means:

Address: Room 108, 1/F Sun Ling Plaza, 30 On Kui Street, Fanling, New Territories
URL: http://www.hkica.org
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1. The HKICA was established in 2006. It is a non-profit making organization providing services to the quality, environmental, occupational health and safety, food safety, laboratory (including the medical laboratory) and other management systems auditing professionals. Its Executive Board comprises members from universities, public authorities, governmental organizations, certification bodies and management systems consultants in Hong Kong.

2. Its primary objectives are:
   (a) To promote the status of management system auditors to the public as a profession;

   (b) To establish a local based auditors registration system in accordance with ISO 19011:2018, ISO 15189:2012 and relevant management system standards and to maintain a database of all registered auditors in the HKICA website for the benefit of the industry;

   (c) To set up personnel certification schemes for different levels of management system auditors in accordance with the requirements of ISO/IEC 17024:2012, ISO 15189:2012, IPC-PL-11-006 and CNAS-CC03:2014;

   (d) To deliver auditing-related seminars and workshops which are of common interests to local auditing profession;

(e) To provide a focal point where registered auditors and certified auditors can get together for exchange of experience and knowledge and fostering of future developments in the related professions;

(f) To liaise with overseas equivalent bodies for reciprocal recognition of auditors certification schemes; and

(g) To approve auditing and related training courses for recognition by the auditing profession and the public in accordance with the international practice.

3. Background

3.1. Determined to avert the lack of recognition of professional status of the medical laboratory auditor, a CSMLA was established by HKICA in July 2018 with the following aims:

(a) To give professional recognition to the auditing practitioners so as to attract and retain talented and skilful personnel to enter into the medical laboratory auditing industry where HKG enjoys clear advantages and has good potential for further development;

(b) To set benchmarks for the upgrade of expertise and knowledge of the certification personnel;

(c) To improve the professional image of HKG medical laboratory industry and contribute to the building up of brand name for HKG medical laboratory testing services; and

(d) To become a renowned public personnel certification body in the Asia Pacific Region.

4. HKICA is a certification body in Hong Kong providing the certification service according to ISO/IEC 17024 for the medical laboratory auditor.

4.1. The benefits of certification include:

4.1.1. Recognition and prestige for the individual and creation of a competitive advantage over non-certified individuals in the same field;

4.1.2. Enhanced employment opportunities;

4.1.3. Establishment of a professional standard for individuals in a particular auditing field;

4.1.4. Assistance to employers in making more informed recruitment decisions;

4.1.5. A more productive and highly trained workforce for employers;

4.1.6. Enhanced professional impression on customers; and

4.1.7. Assistance to customers in making informed decisions about qualified auditors and prevention of using not yet competent and unfit practitioners as well as assurance of the accuracy and validity of auditing results.

5. This "Criteria" is established by HKICA based on IPC (BD-05-007) "Specification for the development of examinations as part of a certification scheme for MS auditors". The objective of the Scheme is to ensure the knowledge, competence and personal attributes of the medical laboratory auditors in meeting the quality requirements of auditing operations.

5.1. The mechanism of evaluation of competence of HKICA certified medical laboratory auditors as stipulated in this "criteria" is based on the concept and requirements of BS EN ISO/IEC 17024:2012 "Conformity assessment — General requirements for bodies operating certification of persons", CNAS-CC03:2014 "General requirements for bodies operating certification of persons (ISO/IEC 17024: 2012, IDT)" and ISO 19011:2018 "Guidelines for auditing management systems" and ISO 15189:2012 "Medical laboratories — Requirements for quality and competence".

1. SCOPE

1.1. This document prescribes procedures by which personnel may be examined and, if successful, certified as medical laboratory management system auditor.

2. REFERENCES

2.1. IPC (BD-05-007) “Specification for the development of examinations as part of a certification scheme for MS auditors”

2.2. IPC-PL-11-006 “Certification scheme for management system auditors”

2.3. IPC-PL-14-05 “Common requirements for IPC certification schemes”

2.4. ISO 19011: 2018 “Guidelines for auditing management systems”

2.5. ISO 9001:2015 “Quality management systems — Requirements”

2.6. ISO 15189:2012 “Medical laboratories — Requirements for quality and competence”

2.7. BS EN ISO/IEC 17024:2012 “Conformity assessment — General requirements for bodies operating certification of persons”

2.8. ISO/IEC 17021:2011 “Conformity assessment — General requirements for bodies providing audit and certification of management systems”

2.9. CNAS-CC03:2014 “General requirements for bodies operating certification of persons (ISO/IEC 17024: 2012, IDT)”

2.10. IPC_PL_11_006 “Certification Scheme for Management System Auditors”

2.11. IPC-PL-14-05 “Common requirements for IPC certification schemes”

3. TERMS AND DEFINITIONS

In view of any difference of the terms and definition giving below and other standards, the definitions as stipulated in this criteria will be followed.

3.1. **Certification process:** activities by which a certification body determines that a person fulfils **certification requirements** including application, assessment, decision on certification, recertification and use of **certificates** and logos/marks.

3.2. **Certification scheme competence:** and other requirements related to specific occupational or skilled categories of persons.

3.3. **Certification requirements:** set of specified requirements, including requirements of the scheme to be fulfilled in order to establish or maintain certification.

3.4. **Scheme owner:** organization responsible for developing and maintaining a **certification scheme.**

3.5. **Certificate:** document issued by a certification body under the provisions of this International Standard, indicating that the named person has fulfilled the **certification requirements.**

3.6. **Competence:** ability to apply knowledge and skills to achieve intended results.

3.7. **Qualification:** demonstrated education, training and work experience, where applicable.

3.8. **Assessment:** process that evaluates a person's fulfilment of the requirements of the **certification scheme.**

3.9. **Examination:** mechanism that is part of the **assessment** which measures a **candidate's competence** by one or more means, such as written, oral, practical and observational, as defined in the **certification scheme.**

3.10. **Examiner:** person competent to conduct and score an **examination**, where the examination requires professional judgement.

3.11. **Invigilator:** person authorized by the certification body who administers or supervises an **examination**, but does not evaluate the **competence** of the **candidate.**

3.12. **Personnel:** individuals, internal or external, of the certification body carrying out activities for the certification body.

3.13. **Applicant:** person who has submitted an application to be admitted into the **certification process.**

3.14. **Candidate applicant:** who has fulfilled specified prerequisites and has been admitted to the **certification process.**

3.15. **Impartiality:** presence of objectivity (Objectivity means that conflicts of interest do not exist, or are resolved, so as not to adversely influence subsequent activities of the certification body).

3.16. **Fairness:** equal opportunity for success provided to each **candidate** in the **certification process.**

3.17. **Validity:** evidence that the **assessment** measures what it is intended to measure, as defined by the **certification scheme.**

3.18. **Reliability:** indicator of the extent to which **examination** scores are consistent across different examination times and locations, different examination forms and different **examiners.**

3.19. **Appeal:** request by **applicant, candidate** or certified person for reconsideration of any decision made by the certification body related to her/his desired certification status.

3.20. **Complaint:** expression of dissatisfaction, other than **appeal**, by any individual or organization to a certification body, relating to the activities of that body or a certified person, where a response is expected.

3.21. **Interested party:** individual, group or organization affected by the performance of a certified person or the certification body.

3.22. **Surveillance:** periodic monitoring, during the periods of certification, of a certified person's performance to ensure continued compliance with the certification scheme.

3.23. **Continuing Professional Development Units** (CPDUs)
The CPDUs is the measuring unit used to quantify approved learning and professional service activities. Typically, one (1) CPDU is earned for every one (1) hour spent in a planned, structured learning experience or activity.

3.24. **Audit:** systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
Note 1: Audit as defined in this criteria refer only to external audit including those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations.
Note 2: When two or more management systems are audited together, this is termed a combined audit.
Note 3: When two or more auditing organizations cooperate to audit a single auditee, this is termed a joint audit.

3.25. **Audit criteria:** set of policies, procedures or requirements used for audits.

3.26. **Auditor:** person with the demonstrated personal attributes and competence to conduct an audit.

3.27. **IPC MS Auditor:** person with the demonstrated personal attributes and competence to initiate, plan, execute and report first and second party audits within quality or environment management in accordance with ISO 19011.

3.28. **IPC MS Lead Auditor:** person with the demonstrated personal attributes and competence to be an IPC Management System Auditors, and in addition are competent to lead an audit team of one or more additional auditors or technical experts. The lead auditors are able to initiate, plan, execute and report first-, second- and third-party audits within quality or environment management in accordance with ISO 19011 and ISO/IEC 17021-1 in the role as sole auditor, member of an audit team or as audit team leader.

3.29. **Audit team:** one or more auditors conducting an audit, supported if needed by technical experts.

Note 1: One auditor (excluding trainee auditor or Assistant Auditor) of the audit team is appointed as the audit team leader.
Note 2: The audit team may include trainee auditor or Assistant Auditor.

3.30. **Complete audit:** the entire audit process from preparation to reporting in accordance with ISO 19011 or ISO/IEC 17021.

3.31. **CNAS**: China National Accreditation Service for Conformity Assessment

3.32. **CCAA**: China Certification and Accreditation Association

3.33. **HKAS**: Hong Kong Accreditation Services

3.34. **HKICA**：Hong Kong Institution of Certified Auditors

3.35. **IPC:** International Personnel Certification Association

For any other terms not listed above, the relevant definitions in ISO/IEC 17000:2004 and the International Vocabulary of Basic and General Terms in Metrology apply.

4. SCOPE OF CERTIFICATION

4.1. Internal Auditor

Internal Auditors, evaluated by HKICA, are certified to possess the knowledge, skill and competence in taking the role as auditor and capable of conducting an audit independently. They can work under supervision of a Lead Auditor in leading an audit.

4.2. Lead Auditor

Lead Auditors, evaluated by HKICA, are certified to possess the knowledge, skill and competence in organizing and taking the role as Lead Auditor and capable of organizing, leading and communicating effectively with auditee. They are experienced auditor and should provide supervision and assistance to trainee auditors and Internal Auditors.

4.3. Auditing persons are normally certified by HKICA either as Internal Auditors and then advance to the next level.

5. CERTIFICATION CRITERIA

Candidate applicants shall have a combination of education, training and experience as stipulated in Sections 5.1 to 5.4 AND satisfying the assessment requirement in Section 5.5 to ensure that they fulfill the certification criteria.

5.1. Academic qualification, working experience and professional working experience:

5.1.1. Internal Auditor

Degree or equivalent in Medical Laboratory Sciences or Biomedical Sciences and three (3) years of professional experience in the medical laboratory.

5.1.2. Lead Auditor

Degree or above in Medical Laboratory Sciences or Biomedical Sciences and fifteen (15) years of working.

5.1.3. Only postgraduate experience is counted, research work is not acceptable.

5.1.4. The professional experience may be concurrent with working experience. Professional experience refers to implementation, operations, and/or auditing of the medical laboratory, which provides the practical knowledge necessary to effectively audit the laboratory.

Note: Applicants for certification shall provide documentary evidence of work experience; this evidence may be presented in the form of employer references giving information on work actually carried out and positions held.

5.2. Auditing experience

5.2.1. Internal Auditor shall have at least one (1) year of auditing experience.

5.2.2. The applicant for Lead Auditor shall possess at least six (6) years of auditing experience. The applicant shall have acted as a member or lead of an audit team on at least three (3) complete laboratory audits the total duration of which shall be ~~a~~ minimum of twelve (12) days auditing with a minimum of eight (8) days on site. All

auditing experience shall have been gained in the three-year period immediately prior to application.

5.3. **Knowledge and competence requirements**

Details of knowledge and competence requirements of different levels of certification are described in HKICA-CC04 "Certification Scheme for Medical Laboratory Auditors Examination syllabus". Fulfilling the examination requirements in Section 5.5 means that the knowledge and competence requirements are complied.

5.4. **Training**

5.4.1. The candidate for Internal Auditor must have successfully completed an internal auditor training course that contains at least 16 hours of training, for the specific scheme of medical laboratory management system (ISO 15189:2012). The training course must be conducted by a HKICA approved training organization; or training establishments approved by Certification Bodies that operate according to ISO/IEC 17024:2012, such as Exemplar Global as well as Professional Evaluation and Certification Board.

NOTE 1. The candidate must have successfully completed a HKICA approved foundation course that contains at least 8 hour of training prior to attempting the internal auditor training course.

5.4.2. The candidate for Lead Auditor must have successfully completed an internal auditor training course that contains at least 16 hour of training as well as lead auditor training course that contains an additional at least 16 hour, for the specific scheme of medical laboratory management system (ISO 15189:2012). The training course must be conducted by a HKICA approved training organization; or training establishments approved by Certification Bodies that operate according to ISO/IEC 17024:2012, such as Exemplar Global as well as Professional Evaluation and Certification Board.

5.4.3. Procedures for approval of training organization and training course is outlined in HKICA12 Approval of training organization and training course for Certification Scheme of Medical Laboratory Auditors Auditor".

5.5. **Examination requirements**

5.5.1. Internal Auditor

The candidate applicant shall obtain certificates of achievement (satisfactory results

in end-of-course evaluation) in training courses as given in Section 5.4.1.

5.5.2. Lead Auditor
The candidate applicant shall obtain certificates of achievement (satisfactory results in end-of-course evaluation) in training courses as given in Section 5.4.2.

5.5.3. The syllabus of examination for different level of applications are given in details in HKICA-CC04 “Certification Scheme for Medical Laboratory Auditors Examination Syllabus”.

5.6. **Code of Conduct**
All level shall declare and commit to abide by the Code of Conduct as stipulated by HKICA.

5.7. **Initial certification**

5.7.1. Applicants shall fulfill all criteria as stipulated in Sections 5.1 to 5.6 of this document. They shall be nominated either by working organization or HKICA-certified personnel.

5.7.2. The academic, working, professional working, auditing experience and training experience will be reviewed and assessed by the Qualification Board.

5.7.3. Applicant fulfill the examination requirements also considered as fulfilling the knowledge and competence requirements.

5.7.4. The personal attribute and ethics is certified either by the working organization or person nominating the applicant. The referee shall be a HKICA certified personnel with good reputation (excluding Internal and Assistant Auditor). The referee shall well familiar with the auditing experience and personal attributes of the applicant.

5.7.5. The Governing Council of HKICA will summarize the evaluation results of all the above certification criteria and make certification decision.

5.8. **Monitoring and Re-certification requirements**

5.8.1. Annual verification requirements:

a) Certified Internal Auditor must complete at least 10 CPDUs of which 5 CPDUs must be approved by HKICA;

b) Certified Lead Auditor must complete at least 20 CPDUs of which 10 CPDUs must be approved by HKICA.

5.8.2. Re-certification audit requirements:

a) Certified Internal Auditor must complete at least one (1) audit relating to the medical laboratory annually. If they cannot fulfill the audit requirements, they can attend approved training course and obtain certificate of achievement to demonstrate their continuing compliance with the certification criteria.

b) Certified Lead Auditor must complete at least two (2) audits relating to the medical laboratory annually. If they cannot fulfill the audit requirements, they can attend approved training course and obtain certificate of achievement to demonstrate their continuing compliance with the certification criteria.

5.8.3. Monitoring criteria：

a) HKICA monitors the performance and personal behavior and compliance of Code of Conduct of certified persons through complaints against the person, feedback of the nominated organizations and organizations being audited by the certified persons and annual verification evidence.

b) All personnel irrespective of levels certified shall undergo at least one (1) monitoring exercise within the three (3) year re-certification cycle.

c) Methods of monitoring:

i) Review of on-site evaluation report of accreditation body;

ii) Review of evaluation of performance and competence conducted by the Certification Body on the applicant (e.g. review of certification file, audit report and witness evaluation report etc)

iii) Results of interview assessment conducted by HKICA.

5.8.4. Certified personnel should take appropriate corrective actions if the following problems are encountered:

a) Complaints in relation to performance of their audit are not resolved;

b) Unsatisfactory results in on-site evaluation; or

c) Fail in interview assessment.

5.8.5. HKICA can conduct interview assessment in monitoring the audit activities and performance of certifies personnel, HKICA may suspend or terminate one's certification status in case there is no improvement of the above situations.

5.8.6. Re-certification follows the same procedures as initial certification.

6. CERTIFICATION PROCESS

6.1. Initial application

6.1.1. Applicants shall read and understand the requirements of this Certification Criteria.

6.1.2. Applicants can submit their application by email or by post with all necessary information including certificate of academic qualifications, certificate of achievement in training courses, audit log and any related documents together with the application fee. The application form is available for download from the HKICA website or available upon request. Applicants can also submit their application following the on-line application system and upload the required documents and fee.

6.1.3. Applicants shall provide complete and accurate information and evidence.

6.1.4. Applicants shall sign the declaration in the application form. They shall commit to abide to the requirements of the HKICA certification criteria particularly the criteria of Code of Conduct.

6.1.5. No applications can be confirmed until receipt of a correctly completed application form and the full fees.

6.1.6. In the event of false statements being discovered, any certificate awarded will be revoked and declared null and void.

6.1.7. Applicants shall apply in written form for request for accommodation of special needs for the certification process or release of information. The Certification Body shall provide assistant to the applicant as far as practicable.

6.1.8. Applicant for certification or certified persons shall pay the fee as stipulated in HKICA03 “Schedule of fees for person certification”. Once the certification process starts, the certification fee is non-refundable despite results of certification.

6.1.9. Recommendation on certification of a candidate shall be made solely on the basis of the information gathered during the certification process by the examiners.

6.1.10. The Governing Council (GC) of HKICA reviews the recommendation and concludes

the certification decision. Members of the GC shall not be involved in the examination and/or evaluation processes.

6.2. **Certification notice and certification certificate**

6.2.1. HKICA shall inform results of certification within fifteen (15) calendar days after certification decision by Governing Council.

6.2.2. HKICA shall upload the certification notice and issue certification/re-certification certificate, the certificate is valid for three (3) years. HKICA will inform the nominated organizations or the applicants of unsuccessful certification.

6.2.3. The certificates are signed by the President of the Certification Body and shall contain, as a minimum, the following information:

(a) Name of the certified person and certificate number (unique identification);
(b) Name and logo of the Certification Body (HKICA);
(c) Reference to the certification criteria HKICA-CC03 and year of issue on which the certification is based;
(d) The scope of certification, including level and limitations; and
(e) Effective date of certification and date of expiry.

6.2.4. Certified persons shall follow HKICA01E "Regulations for Certification Scheme of Quality Management System Auditors" Section 8 in the use of certificate and logo.

6.2.5. HKICA shall maintain sole ownership of the certificates. Certified persons shall stop use of the certificate during suspension or termination.

6.2.6. HKICA will upload the list of certified persons as public information to the website. The list includes:

(a) Name of certified person;
(b) Scope of certification and level;
(c) Certificate number; and
(d) Certification date and expiry date.

6.3. Monitoring and Re-certification

6.3.1. It is the policy of the Certification Body to set monitoring and re-certification criteria for certified auditor. The criteria is taken in the form of annual verification

(Section 5.8.1 of this document), audit in respective certified management system (Section 5.8.2 of this document), witness evaluation (Section 5.8.3 of this document), compliance with certification regulation and resolution of complaint against performance of the audit the auditor carried out.

6.3.2. Annual verification starts form the same month as certification in the following year. No verification is required for the first year of certification. Every year at the month of certification, the Secretariat will inform the certified auditors to pay for the annual fee and remind them to submit annual verification records.

6.3.3. If the certified personnel fail to submit and complete the annual verification, HKICA should follow Section 7 (Termination and suspension) of HKICA01E "Regulations for certification scheme of quality management auditors" to handle their certification status.

6.3.4. Candidates are required to re-certify before the period of certification validity, which is normally three (3) years from the date of issue of the certificate, has expired. The Operations Manager shall alert the candidate three months before expiration of the certification by email.

6.3.5. The candidate concerned shall go to the website and download the application form and shall submit payment and completed documentation, consisting of:

(a) Application form for re-certification HKICA-F01;
(b) Working experience in the past three (3) years;
(c) Monitoring records;
(d) Records of Continuing Professional Development (HKICA-F03 "Record log of professional development units"); and
(e) Audit logs (HKICA-F02 "Audit log"), if appropriate.

6.3.6. The form HKICA-F01 is available in the scheme website. Re-certified auditor can either fill in the form and send to the Secretariat or submit the application via the scheme on-line application system.

6.3.7. The Operations Manager will review the records of CPDU, monitoring records and audit log to determine whether the re-certification candidate fulfils the CPDU and audit number requirements for his level.

6.3.8. The Operations Manager should arrange interview assessment to monitor the audit activities and performance of a certified candidate if he cannot provide records of monitoring.

6.3.9. The same procedures as initial certification shall be followed for decision of re-certification.

7. APPEAL AND COMPLAINT

7.1. HKICA shall follow the procedures as stipulated in HKICA06E “Appeal and complaint procedure” to handle appeal and complaint.

7.2. Appellant shall submit their appeal in written form in HKICA-F04 “Appeal form” within thirty (30) days from related decision.

7.3. Appellant or complainant can download the document HKICA06E “Appeal and complaint procedure” and the form from the website. HKICA can provide the document and form upon request.

8. ACTIONS AGAINST CERTIFICATION STATUS

8.1. Actions against certification status

8.1.1. All certified persons shall ensure the information provided is valid and complete. In view of any false or fraud statement, HKICA will suspend or terminate the certification status in accordance with Section 7 of HKICA01E "Regulations for certification scheme of quality management system auditor".

8.1.2. The same procedures as Section 8.1.1 will be carried out in case the certified person fails to abide to Regulations as set by HKICA or fails to comply with the certification criteria. Warning, suspension, downgrade will be imposed. The final penalty is termination of certification status.

8.1.3. A certified auditing person may, on any personal reason by serving a written notice signed by the candidate, voluntarily suspends or terminates his/her certification for any or all of his/her certified activities.