Hong Kong Institution of Certified Auditors

香港專業審核師學會

HKICA-CC04E

Certification Scheme of Medical Laboratory Auditors

Examination Syllabus

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 of Medical Laboratory Auditors (CSMLA) by the following means:

Address: Room 108, 1/F Sun Ling Plaza, 30 On Kui Street, Fanling, New Territories
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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 medical laboratory) and other management systems auditing professions in Hong Kong. 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 medical laboratory auditors to the public as a profession;

   (b) to establish a local based auditors registration system in accordance with ISO 19011:2018 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 medical laboratory auditors in accordance with the requirements of ISO 15189:2012, ISO/IEC 17024:2012 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 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 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 auditing industry where Hong Kong enjoys clear advantages and has good potential for further development;

b) to set benchmarks for the upgrade of expertise and knowledge of the medical laboratory personnel;

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

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

4. The HKICA is a certification body in Hong Kong providing the certification service to ISO/IEC 17024 for 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;

4.1.7. Assistance to customers in making informed decisions about qualified auditors and prevention of using incompetent and unfit practitioners; and

4.1.8. Assurance of the accuracy and validity of auditing results.

1. SCOPE

1.1. This document prescribes procedures by which personnel may be examined and, if successful, certified as quality 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. 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 Continuing Professional Development Units (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 refers 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 of the audit team is appointed as the audit team leader.
Note 2: The audit team may include auditors-in-training 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. GENERAL

4.1. This document is developed based on HKICA-CC03E "Certification scheme of medical laboratory auditor – Certification criteria". It prescribes unify procedure in conducting oral and written examination by which personnel are assessed in an objective, impartial and comprehensive way in ensuring that they meet the Section 5.3 "Knowledge and competence requirements" of the certification criteria. This document applies for applicants for different levels.

5. EXAMINATION REQUIREMENTS

5.1. Written examination test subjects

5.1.1. Applicants for Certified Internal Auditor and Certified Lead Auditor shall obtain satisfactory results in the "Basic knowledge, auditing knowledge and techniques"

5.1.2. Candidates shall strictly abide by the examination rules (see Annex A), and consciously obey the instructions of invigilators and other examination staff.

5.2. Examination

5.2.1. The written examination is a closed book assessment. All examination papers are prepared by HKICA.

5.2.2. Duration of the "Basic knowledge, auditing knowledge and techniques" examination is one (1) hour.

5.2.3. Candidates are not allowed to carry any reference materials or standards for examination. HKICA shall provide ISO 9001:2015, ISO 15189:2012 and ISO 19011:2018 as reference.

5.3. Types of Examination questions and scores

5.3.1. "Basic knowledge, auditing knowledge and techniques" examination question types and weighing:

Scope of examination		Weighing (%)
ISO 15189 :2012 standard		50
Quality management system professional knowledge for medical laboratory		25
Quality Management system audit for medical laboratory		20
Personal attributes, code of conduct		5
Types of questions	Marks for each question	Sub-total marks
Multiple choice	30 x 3	90
True or False	15 x 2	30

5.3.2. The written examination is a combination of several of the following examination methods. Questions shall be within the area of competence described in this document.

a) Multiple choice questions: multiple choice is a form of assessment in which applicants are asked to select the right answer out of 4 to 5 possibilities.

b) True and false question: applicants are asked to determine the given statement is true or false.

5.3.3. All candidates shall adhere to the Examination Rules as given in Appendix 1.

5.4. Marking system

5.4.1. Model answer shall be set for each multiple choice and true/False questions. Marks will be given for correct answers and marks will not be deducted for wrong answer.

5.5. Evaluation of examination results

5.5.1. Total mark of "Basic knowledge, auditing knowledge and techniques" examination is 120 and the passing mark is 84.

5.6. Oral examination (interview evaluation)

5.6.1. Applicants

Applicants for lead auditor fulfilling the auditing criteria of HKICA-CC03 Clause 5.1.4 a) can apply for oral examination.

5.6.2. Examination syllabus and weighing

The examination syllabus follows the same content and weighing as this document Clause 5.5.3 “Management theory and application”.

Scope of examination	Weighing (%)
Integrated competence in quality management system audit for medical laboratory	55
Quality management system professional knowledge for medical laboratory	40
Personal attributes, code of conduct	5

5.6.3. The interview is conducted by a team of two (2) professional evaluators and will last for 45 minutes. The Operations Manager will liaise with the applicants and evaluators of the time and venue for conducting the interview.

5.6.4. All candidates shall follow the examination rules. Candidates should switch off the mobile. During interview, they cannot use any reference, electronic media such as mobile or notebook etc. Smoking is prohibited. Without permission of the evaluator, candidates cannot leave the examination venue.

5.7. Procedures for interview

5.7.1. Evaluators will assess the personal attributes and ethics of the candidates by observation during interview and on-site witness evaluation reports.

a) Evaluator will check and confirm the identity of the candidates, working and auditing experience (~ 5 minutes)

b) Integrated competence in quality management system audit (~ 25 minutes)

The evaluator will raise questions on either cases of HKICA or the real audit of the candidates. The interview is a combination of questioning, answering and counter interaction. The evaluators assess the auditing technique of the candidates and mark.

c) Quality management system professional knowledge (~ 15 minutes)

The evaluator will select questions from HKICA’s database. The interview is a combination of questioning, answering and counter interaction. The evaluators assess the knowledge of the candidate in this aspect and mark.

5.8. Examination frequency and location

5.8.1. Examination in principle is organized once every six (6) months. The certification body will also organize irregular examination depending on the need. Applicants will

be notified of unscheduled examination and they need to inform the Secretariat their intention in participation in such examination.

5.8.2. HKICA will announce in the scheme website the tentative examination date two months in advance. The examination venue will be announced one month ahead of the examination.

5.9. Examination Fees

5.9.1. Examination shall be paid in accordance with the fee structure as stipulated in HKICA03 "Schedule of fee for person certification".

5.9.2. The examination fee is non-refundable after the registration deadline no matter the applicant attends the examination or not.

5.10. Release of test results

5.10.1. HKICA will announce the list of personnel passing the examination within one (1) month from the examination. In case of legal holiday, the date will be postponed accordingly.

5.11. Cancellations, rescheduling, no shows

5.11.1. If candidate needs to cancel or reschedule an interview or an examination, he/she must do so no later than 48 hours before the scheduled appointment.

5.11.2. If he/she fails to notify the appropriate party within the specified time period and/or fails to meet a scheduled examination appointment, he/she forfeits the full certification fee and will have to pay the full certification fee in order to schedule another interview or examination.

5.11.3. There are times when extenuating circumstances (e.g. medical emergency, death in immediate family, illness in immediate family) may prevent a candidate from meeting a scheduled interview or examination appointment, resulting in a no show. Should such a situation arise, the candidate will be asked to provide explanations along with supporting documentation (e.g. accident report, medical documentation, death certificate). If he/she does not make contact within 72 hours following a missed appointment, fees will apply in order to schedule a new appointment. All claims will be reviewed on a case-by-case basis. The candidate is allowed a maximum of one (1) year, from the date of application is approved, to apply for re-examination.

6. EXAMINATION SYLLABUS

6.1. Quality management system standard

6.1.1. Development of the ISO 9000 series and ISO 15189.

6.1.2. Understand some of the terms and their interrelationship of ISO 9000 standard
the quality, requirements, quality management, products, quality planning, quality policy, quality objectives, processes, procedures, non-conformity, correction, corrective action and preventive action, continuous improvement, documentation, customer, customer satisfaction.

6.1.3. Understand the 12 basic principle of quality management systems

6.1.4. Understand the eight quality management principles.

6.1.5. Understand the concept of quality and process approach.

6.1.6. Understand the requirements of the ISO 9001 standard.

6.1.7. Understand the structure and scope of ISO 9004 standard and relation with the ISO 9001 standards.

6.1.8. Understand the ISO 9000 standards, normative standards and guidelines.

6.1.9. Understand the content of ISO 15189:2012 standards and guidelines.

6.2. Quality management system audit

6.2.1. Content of ISO 19011:2018 Subclauses 3, 4, 6.3 and 6.4.

6.2.2. Requirements of ISO/IEC 17021:2011 “Conformity assessment — General requirements for bodies providing audit and certification of management systems” Subclauses 9.1.2, 9.1.3, 9.2 to 9.6 in relation to audit and certification.

6.2.3. Understand the application of the principles, procedures and techniques of auditing;

a) Relate the auditee management system to the audit criteria;
b) Understand how to implement effective audit in the auditee organization's environment;
c) Understand the suitability and consequences of application of sampling technique during audit;
d) Maintain confidentiality and security of information; and
e) Practice personal attributes necessary for the effective and efficient conduct of a management system audit.

6.3. Quality management professional knowledge

6.3.1. Understand the quality management tools, methods and techniques:

a) Common statistical techniques and methods;
b) Measurement and monitoring techniques, measurement processes and measuring equipment;
c) Root Cause Analysis;
d) Monitoring and measuring customer satisfaction, complaint handling, code of conduct, dispute resolution;
e) Knowledge of the structure, layout, requirements and documentation of standards;
f) Quality planning;
g) Risk management;
h) Quality management evaluation (audit, evaluation and self-evaluation);
i) The characteristics of processes and products (including services); and
j) Continuous improvement, innovation and learning.

6.4. Personal attributes and behavior

6.4.1. Auditors at all levels should have the following personal attributes and behavior

a) Ethical, i.e. fair, truthful, sincere, honest and discreet;
b) Open-minded, i.e. willing to consider alternative ideas or points of view;
c) Diplomatic, i.e. tactful in dealing with people;
d) Observant, i.e. actively observing physical surroundings and activities;
e) Perceptive, i.e. aware of and able to understand situations;
f) Versatile, i.e. able to readily adapt to different situations;
g) Tenacious, i.e. persistent and focused on achieving objectives;
h) Decisive, i.e. able to reach timely conclusions based on logical reasoning and

analysis;

i) Self-reliant, i.e. able to act and function independently whilst interacting effectively with others;
j) Acting with fortitude, i.e. able to act responsibly and ethically, even though these actions may not always be popular and may sometimes result in disagreement or confrontation;
k) Open to improvement, i.e. willing to learn from situations, and striving for better audit results;
l) Culturally sensitive, i.e. observant and respectful to the culture of the auditee;
m) Collaborative, i.e. effectively interacting with others, including audit team members and the auditee's personnel; and
n) Healthy.

6.4.2. Auditors at all levels should work in accordance with the following principles:

a) **Integrity:** the foundation of professionalism
Auditors should perform the work with honesty, diligence, and responsibility.

b) **Fair presentation:** the obligation to report truthfully and accurately
Audit findings, audit conclusions and audit reports should reflect truthfully and accurately the audit activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the auditee should be reported.

c) **Due professional care:** the application of diligence and judgement in auditing
Auditors should exercise due care in accordance with the importance of the task they perform and the confidence placed in them by the audit client and other interested parties. An important factor in carrying out their work with due professional care is having the ability to make reasoned judgements in all audit situations.

d) Confidentiality: security of information
Auditors should exercise discretion in the use and protection of information acquired in the course of their duties.

e) Independence: the basis for the impartiality of the audit and objectivity of the audit conclusions
Auditors should be independent of the activity being audited wherever practicable,

and should in all cases act in a manner that is free from bias and conflict of interest. Auditors should maintain objectivity throughout the audit process to ensure that the audit findings and conclusions are based only on the audit evidence.

f) Evidence-based approach: the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process.
Audit evidence should be verifiable. It will in general be based on samples of the information available, since an audit is conducted during a finite period of time and with finite resources. An appropriate use of sampling should be applied, since this is closely related to the confidence that can be placed in the audit conclusions.

6.4.3. Understand HKICA11E "Regulations for certification scheme of medical laboratory auditors"

a) Section 6 “Obligations of certified persons”
b) Section 9 “Use of HKICA certificate and logo”
c) Knowledge in Prevention of Bribery Ordinance, Cap. 201 Chapter 9 particularly in corruption, acceptance of advantages and entertainment.

Appendix 1

Examination Rules

Candidates should strictly abide by the following examination rules and consciously obey the arrangement of examination invigilators and should not for any reason to obstruct examination invigilators in performing their duties, not interrupt examination and examination workplace.

1. Examination rules

1.1. Candidates should be ethical, i.e. fair, truthful, sincere, honest and discreet ethics, honesty and mutual respect.

1.2. Candidates should bring proof of identity documents and other provisions, to take the examination at the specified time and place.

1.3. The candidate should be required to produce relevant documents to the invigilator, and follow the seat number in seating. Identity documents and other related documents should be placed on the designated location for verification.

1.4. Candidates should only bring blue or black pen for answering. They are forbidden to carry a variety of communication tools (such as mobile phones, computers and other wireless reception, transmission equipment etc), electronic storage memory recorders, other equipment and other unnecessary items into the examination room.

1.5. Candidates should clearly fill in their candidate number, code of identity number in the specified location in the answer book.

1.6. Candidates should use blue or black pen to answer. Red and other color pen or pencil is not allowed. Candidates should answer the questions on the answer book provided or into the computer. Candidates are not allowed to make any mark on the answer sheet.

1.7. Candidates in the examination room must be kept quiet. They are not allowed to smoke, not to make noise, not to whisper, not to look around, not to gesture, not to copy or intentionally allow others to copy, not to make private copies of answer or examination papers or writing paper. They are not allowed to pass stationery, supplies within the examination room.

1.8. Candidates must remain silent and seated in their place at the end of the examination until response materials have been collected and checked, and an announcement is made permitting students to leave the examination room.

1.9. The candidate must not take away any examination paper, writing paper, answer book or test standards provided for the examination out of the examination room.

2. Violation of examination rules

2.1. Candidates, who do not comply with the examination rules or not obey the following arrangements, are identified as misconduct:

2.1.1. Carrying prohibited materials into the examination venue or not to place such materials at the specified location;

2.1.2. Not to take the examination in the prescribed seats;

2.1.3. Continue to answer before start or after signal of end of examination;

2.1.4. Peep, whisper, give signal or gesture in the examination process;

2.1.5. Make noise, smoke or other actions that would affect the implementation of the examination in the venue or other specified locations;

2.1.6. Leave the examination room without permission of invigilator during the examination;

2.1.7. Take away answer book, writing paper and test standard etc. out of the examination room;

2.1.8. Answer in pens not prohibited and to write the name, candidate number on locations other than specified or make any other marks on the answer paper; and

2.1.9. Other rules but not yet constitute cheating.

2.2. Candidates, who violate fairness and justice examination, improper means to obtain or attempt to obtain answers of questions, violate the following acts are identified as fraudulent examination:

2.2.1. Carry prohibited materials or electronic equipment containing the examination content for the examination;

2.2.2. Copy or assist others to copy answers or relevant information;

2.2.3. Use of communication equipment during the examination;

2.2.4. Take the examination by other person;

2.2.5. Intentionally destroy examination paper, answer book or test materials;

2.2.6. Give an identity code, candidate number not matching the original information;

2.2.7. Receive or exchange materials or examination or answer paper; and

2.2.8. Do any other actions that are considered as cheating.

2.3. Candidates who violate the examination rules may be disqualified and the result of that particular examination will be cancelled. Candidates, who cheat, will be disqualified and the results of all the subjects taken within that particular examination will be invalid. Candidates, who disrupt the examination workplace order, reject or impede the examination staff to fulfill management responsibilities, will be terminated of their participation in the examination and results of that subject concerned will be invalid.

2.4. In case the candidate violating the rules or cheating is an existing certified person, his/her certification status will be handled in accordance with HKICA01 “Regulations for certification scheme of quality management system auditors” Chapter 6.