Appendix 8: General requirements of ISO/IEC 17024:2012 Applying to the Management of the CMC Certification Scheme in Member Institutes

This document assists Member Institutes prepare for external audit when applying for accreditation as a ISO/IEC 17024 Certifying Body.

General requirements of ISO/IEC 17024:2012 applying to the management of the CMC Certification Scheme in Member Institutes.

1 Management Organisation, Structure and System, Responsibility and Authority

ISO/IEC17024:2012 Clause 4.1, 4.2, 5.1, 5.2 & 10.2.1

The member institute shall be a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for its certification activities.

The member institute shall be responsible for, shall retain authority for, and shall not delegate, its decisions relating to certification, including the granting, maintaining, recertifying, expanding and reducing the scope of the certification, and suspending or withdrawing the certification.

The member institute shall document its organizational structure, describing the duties, responsibilities and authorities of management, certification personnel and any committee. When the member institute is a defined part of a legal entity, documentation of the organizational structure shall include the line of authority and the relationship to other parts within the same legal entity.

The party/parties or individuals responsible for the following shall be identified:

a) policies and procedures relating to the operation of the member institute;
b) implementation of the policies and procedures;
c) finances of the member institute;
d) resources for certification activities;
e) development and maintenance of the certification schemes;
f) assessment activities;
g) decisions on certification, including the granting, maintaining, recertifying, expanding, reducing, suspending or withdrawing of the certification;
h) contractual arrangements.

If completion of training is a specified requirement of a certification scheme, the recognition/approval of training by the member institute shall not compromise impartiality or reduce the assessment and certification requirements. The member institute shall provide information regarding education and training if they are used as pre-requisites for being eligible for certification. However, the member institute shall not state or imply that certification would be simpler, easier or less expensive if any specified education/training services are used.

A member institute that is part of a legal entity offering training shall:

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a) identify and document the associated threats to its impartiality on an ongoing basis: the body shall have a documented process to demonstrate how it eliminates or minimizes those threats;
b) demonstrate that all processes performed by the member institute are independent of training to ensure that confidentiality, information security and impartiality are not compromised;
c) not give the impression that the use of both services would provide any advantage to the applicant;
d) not require the candidates to complete the member institute's own education or training as an exclusive prerequisite when alternative education or training with an equivalent outcome exists;
e) ensure that personnel do not serve as an examiner of a specific candidate they have trained for a period of two years from the date of the conclusion of the training activities: this interval may be shortened if the member institute demonstrates it does not compromise impartiality.

The member institute shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this CMC Certification Scheme.

The member institute's top management shall establish and document policies and objectives for its activities.

The top management shall provide evidence of its commitment to the development and implementation of the management system in accordance with the requirements of this CMC Certification Scheme. The top management shall ensure that the policies are understood, implemented and maintained at all levels of the member institute's organization.

The member institute's top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that include:

a) ensuring that processes and procedures needed for the management system are established, implemented and maintained;
b) reporting to top management on the performance of the management system and any need for improvement.

2 Management of Impartiality including Training Activities

ISO/IEC 17024:2012 Clause 4.3

The member institute’s CMC Certification activities shall be structured and managed so as to safeguard impartiality. This shall include balanced involvement of interested parties.

The member institute shall document its structure, policies and procedures to manage impartiality and to ensure that the certification activities are undertaken impartially.

The member institute shall have top management commitment to impartiality in certification activities.

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The member institute shall have a statement publicly accessible without request that it understands the importance of impartiality in carrying out its certification activities, manages conflict of interest and ensures the objectivity of its certification activities.

The member institute shall act impartially in relation to its applicants, candidates and certified persons.

Policies and procedures for certification of persons shall be fair among all applicants, candidates and certified persons.

Certification shall not be restricted on the grounds of undue financial or other limiting conditions, such as membership of an association or group. The member institute shall not use procedures to unfairly impede or inhibit access by applicants and candidates.

The member institute shall be responsible for the impartiality of its certification activities and shall not allow commercial, financial or other pressures to compromise impartiality.

The member institute shall identify threats to its impartiality on an ongoing basis. This shall include those threats that arise from its activities, from its related bodies, from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a body with a threat to impartiality.

NOTE 1 A relationship that threatens the impartiality of the body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding) and payment of a sales commission or other inducement for the referral of new applicants, etc.

NOTE 2 Threats to impartiality can be either actual or perceived.

NOTE 3 A related body is one which is linked to the member institute by common ownership, in whole or part, and has common members of the board of directors, contractual arrangements, common names, common staff, informal understanding or other means, such that the related body has a vested interest in any certification decision or has a potential ability to influence the process.

The member institute shall analyse, document and eliminate or minimize the potential conflict of interests arising from its certification activities. The member institute shall document and be able to demonstrate how it eliminates, minimizes or manages such threats. All potential sources of conflict of interest that are identified, whether they arise from within the member institute, such as assigning responsibilities to personnel, or from the activities of other persons, bodies or organizations, shall be covered.

3 Management of Finance and Liability

ISO/IEC 17024:2012 Clause 4.4

The member institute shall have the financial resources necessary for the operation of the CMC Certification process and have adequate arrangements (e.g. insurance or reserves) to cover associated liabilities.
4 Resources – Internal and Outsourced Personnel, Facilities

ISO/IEC 17024:2012 Clause 6

The member institute shall manage and be responsible for the performance of all personnel involved in the certification process.

The member institute shall have sufficient personnel available with the necessary competence to perform certification functions relating to the type, range and volume of work performed.

The member institute shall define the competence requirements for personnel involved in the certification process. Personnel shall have competence for their specific tasks and responsibilities.

The member institute shall provide its personnel with documented instructions describing their duties and responsibilities. These instructions shall be kept up-to-date.

The member institute shall maintain up-to-date personnel records, including relevant information, e.g. qualifications, training, experience, professional affiliations, professional status, competence and known conflicts of interest.

Personnel acting on the member institute’s behalf shall keep confidential all information obtained or created during the performance of the body’s certification activities, except as required by law or where authorized by the applicant, candidate or certified person.

The member institute shall require its personnel to sign a document by which they commit themselves to comply with the rules defined by the member institute, including those relating to confidentiality, impartiality and conflict of interests.

**NOTE** Where permitted by law, other methods, including electronic signature, are acceptable.

When a member institute certifies a person it employs, the member institute shall adopt procedures to maintain impartiality.

The member institute shall require its personnel who are involved in the certification activities to declare any potential conflict of interest in any candidate.

Examiners shall meet the requirements of the member institute. The selection and approval processes shall ensure that examiners:

a) understand the relevant certification scheme;
b) are able to apply the examination procedures and documents;
c) have competence in the field to be examined;
d) are fluent, both in writing and orally, in the language of examination; in circumstances where an interpreter or a translator is used, the member institute shall have procedures in place to ensure that it does not affect the validity of the examination;
e) have identified any known conflicts of interest to ensure impartial judgements are made.

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The member institute shall monitor the performance of the examiners and the reliability of the examiners' judgements. Where deficiencies are found, corrective actions shall be taken. *NOTE* Monitoring procedures for examiners can include, for example, on-site observation, review of examiners' reports, feedback from candidates.

If an examiner has a potential conflict of interest in the examination of a candidate, the member institute shall undertake measures to ensure that the confidentiality and impartiality of the examination are not compromised. These measures shall be recorded.

The member institute shall have a documented description of the responsibilities and qualifications of other personnel involved in the assessment process (e.g. invigilators).

If other personnel involved in the assessment have a potential conflict of interest in the examination of a candidate, the member institute shall undertake measures to ensure that confidentiality and impartiality of the examination is not compromised. These measures shall be recorded.

The member institute shall have a legally enforceable agreement covering the arrangements, including confidentiality and conflict of interests, with each body that provides outsourced work related to the certification process. *NOTE* For the purposes of this International Standard, the terms "outsourcing" and "subcontracting" are considered to be synonyms.

When a member institute outsources work related to certification, the member institute shall:

a) take full responsibility for all outsourced work;

b) ensure that the body conducting outsourced work is competent and complies with the applicable provisions of this International Standard;

c) assess and monitor the performance of the bodies conducting outsourced work in accordance with its documented procedures;

d) have records to demonstrate that the bodies conducting outsourced work meet all requirements relevant to the outsourced work;

e) maintain a list of the bodies conducting outsourced work.

The member institute shall use adequate premises, including examination sites, equipment and resources for carrying out its certification activities.

### 5 Control of Documents

ISO/IEC 17024:2012 Clause 10.2.2 & 10.2.3

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Applicable requirements of the member institute’s CMC Certification Scheme shall be documented. The member institute shall ensure that the management system documentation is provided to all relevant personnel.

The member institute shall establish procedures to control the documents (internal and external) that relate to the fulfilment of this CMC Certification Scheme. The procedures shall define the controls needed to:

a) approve documents for adequacy prior to issue;

b) review and update as necessary and re-approve documents;

c) ensure that changes and the current revision status of documents are identified;

d) ensure that relevant versions of applicable documents are provided at points of use;

e) ensure that documents remain legible and readily identifiable;

f) ensure that documents of external origin are identified and their distribution controlled;

g) prevent the unintended use of obsolete documents and apply suitable identification if they are retained for any purpose.

NOTE Documentation can be in any form or type of medium.

The member institute shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this CMC Certification Scheme.

The member institute shall establish procedures for retaining records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements.

6 CMC Examination Records

ISO/IEC 17024:2012 Clause 7 & 10.2.4

The member institute shall maintain records of applicants, candidates and certified persons.

The records shall include a means to confirm the status of a certified person. The records shall demonstrate that the certification or recertification process has been effectively fulfilled, particularly with respect to application forms, assessment reports (which include examination records) and other documents relating to granting, maintaining, recertifying, expanding and reducing the scope, and suspending or withdrawing certification.

The records shall be identified, managed and disposed of in such a way as to ensure the integrity of the process and the confidentiality of the information. The records shall be kept for an appropriate period of time, for a minimum of one full certification cycle, or as required by recognition arrangements, contractual, legal or other obligations.
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The member institute shall have enforceable arrangements to require that the certified person informs the member institute, without delay, of matters that can affect the capability of the certified person to continue to fulfil the certification requirements.

The member institute shall verify and provide information, upon request, as to whether an individual holds a current, valid certification and the scope of that certification, except where the law requires such information not to be disclosed.

The member institute shall make publicly available without request information regarding the scope of the certification scheme and a general description of the certification process.

All pre-requisites of the certification scheme shall be listed and the list shall be made publicly available without request.

Information provided by the member institute, including advertising, shall be accurate and not misleading.

The member institute shall establish documented policies and procedures for the maintenance and release of information.

The member institute shall, through legally enforceable agreements, keep confidential all information obtained during the certification process. These agreements shall cover all personnel.

The member institute shall ensure that information obtained during the certification process, or from sources other than the applicant, candidate or certified person, is not disclosed to an unauthorized party without the written consent of the individual (applicant, candidate or certified person), except where the law requires such information to be disclosed.

When the member institute is required by law to release confidential information, the person concerned shall, unless prohibited by law, be notified as to what information will be provided.

The member institute shall ensure that the activities of related bodies do not compromise confidentiality.

The member institute shall develop and document policies and procedures necessary to ensure security throughout the entire certification process and shall have measures in place to take corrective actions when security breaches occur.

Security policies and procedures shall include provisions to ensure the security of examination materials, taking into account the following:

a) the locations of the materials (e.g. transportation, electronic delivery, disposal, storage, examination centre);

b) the nature of the materials (e.g. electronic, paper, test equipment);

c) the steps in the examination process (e.g. development, administration, results reporting);

d) the threats arising from repeated use of examination materials.

Certification bodies shall prevent fraudulent examination practices by:

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a) requiring candidates to sign a non-disclosure agreement or other agreement indicating their commitment not to release confidential examination materials or participate in fraudulent test-taking practices;

b) requiring an invigilator or examiner to be present;

c) confirming the identity of the candidate;

d) implementing procedures to prevent any unauthorized aids from being brought into the examination area;

e) preventing candidates from gaining access to unauthorized aids during the examination;

f) monitoring examination results for indications of cheating.
Internal Auditing and Management Review

ISO/IEC 17024:2012 Clause 10.2.5 & 10.2.6

The member institute's top management shall establish procedures to review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this CMC Certification Scheme. These reviews shall be conducted at least once every 12 months and shall be documented.

The input to the management review shall include information related to the following:

a) results of internal and external audits (e.g. accreditation body assessment);
b) feedback from applicants, candidates, certified persons and interested parties related to the fulfilment of this International Standard;
c) safeguarding impartiality;
d) the status of preventive and corrective actions;
e) follow-up actions from previous management reviews;
f) the fulfilment of objectives;
g) changes that could affect the management system;
h) appeals and complaints.

The output from the management review shall include as a minimum decisions and actions related to the following:

a) improvement of the effectiveness of the management system and its processes;
b) improvement of the certification services related to the fulfilment of this CMC Certification Scheme;
c) resource needs.

The member institute shall establish procedures for internal audits to verify that it fulfils the requirements of this International Standard and that the management system is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits.

Internal audits shall be performed at least once every 12 months. The frequency of internal audits may be reduced if the member institute demonstrates that its management system continues to be effectively implemented in accordance with this International Standard and has proven stability.

The member institute shall ensure that:

a) internal audits are conducted by competent personnel, knowledgeable in the certification process, auditing and the requirements of this International Standard;
b) auditors do not audit their own work;
c) personnel responsible for the area audited are informed of the outcome of the audit;
d) any actions resulting from internal audits are taken in a timely and appropriate manner;

e) any opportunities for improvement are identified.

### 8 Corrective and Preventive Action

ISO/IEC 17024:2012 Clause 10.2.7 & 10.2.8

The member institute shall establish (a) procedure(s) for identification and management of nonconformities in its operations. The member institute shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the impact of the problems encountered. The procedures shall define requirements for the following:

a) identifying nonconformities;
b) determining the causes of nonconformity;
c) correcting nonconformities;
d) evaluating the need for actions to ensure that nonconformities do not recur;
e) determining and implementing the actions needed in a timely manner;
f) recording the results of actions taken;
g) reviewing the effectiveness of corrective actions.

The member institute shall establish (a) procedure(s) for taking preventive actions to eliminate the causes of potential nonconformities. Preventive actions taken shall be appropriate to the probable impact of the potential problems. The procedures for preventive actions shall define requirements for the following:

a) identifying potential nonconformities and their causes;
b) evaluating the need for action to prevent the occurrence of nonconformities;
c) determining and implementing the action needed;
d) recording the results of actions taken;
e) reviewing the effectiveness of the preventive actions taken.
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