

Annex II(H)
Management System Checklist
[for QMS certification (based on ISO/IEC 17021-3: 2017)]

The quality management system certification body shall complete the following checklist, which will be used for the assessment of the quality management system certification body's conformity with HKAS and HKCAS accreditation requirements.

This checklist consists of questions based on the requirements of ISO/IEC 17021-3: 2017. For further information, please refer to the corresponding document and clause as listed in the second column.

The quality management system certification body shall indicate in the 'QM Clause' column, for every question, the clause(s) in its management system manual, operation procedures or other related documentation which can demonstrate the quality management system certification body's conformity with the requirement.

The column headed 'OK' is for internal use of HKAS Executive.

A softcopy of this completed checklist shall be provided to HKAS Executive by email or other means.

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ISO/IEC 17021-3: 2017 Requirements	Clause	OK	QM/ Procedure Clause	Remarks / Questions to be asked at certification body
<p>Generic competence requirements</p> <p>Does your certification body define the competence requirements for each certification function as referenced in ISO/IEC 17021-1: 2015, Table A.1?</p> <p>When defining these competence requirements, does your certification body take into account all the requirements specified in ISO/IEC 17021-1, as well as those specified in Clauses 5 and 6 of ISO/IEC 17021-3: 2017 that are relevant for the QMS technical areas (see ISO/IEC 17021-1: 2015, 7.1.2), as defined by the certification body?</p>	4	<input type="checkbox"/> <input type="checkbox"/>		
<p>Competence requirements for QMS auditors and audit teams</p> <p>General</p> <p>Does your certification body ensure that an audit team is composed of auditors (and technical experts, as necessary) having the collective competence to undertake the audit that include the generic competence described in ISO/IEC 17021-1 and the QMS knowledge described in 5.2 to 5.4?</p> <p>Fundamental concepts and quality management principles</p> <p>Does each QMS auditor have knowledge of:</p> <ul style="list-style-type: none"> a) fundamental concepts and quality management principles and their application; b) terms and definitions related to quality management; c) the process approach including related monitoring and measurement; d) the role of leadership in an organisation and its impact on the QMS; e) application of risk based thinking including the determination of risks and opportunities; f) application of the PDCA (plan, do, check, act) cycle; 	5 5.1 5.2	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		

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ISO/IEC 17021-3: 2017 Requirements	Clause	OK	QM/ Procedure Clause	Remarks / Questions to be asked at certification body
<p>g) structures and interrelationships of documented information specific to quality management; and</p> <p>h) quality management related tools, methods, techniques and their application?</p> <p>Context of the organisation</p> <p>Does your certification body ensure that an audit team have business sector knowledge to determine whether an organisation has appropriately determined:</p> <p>a) the external and internal issues, relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its QMS;</p> <p>b) the needs and expectations of interested parties relevant to the organisation's QMS including the requirements for the products and services of the organisation; and</p> <p>c) the boundaries and applicability of the QMS to establish its scope?</p>	5.3	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
<p>Client products, services, processes and organisation</p> <p>Does your certification body ensure that an audit team have knowledge of:</p> <p>a) terminology and technology specific to the technical area;</p> <p>b) statutory and regulatory requirements applicable to the product or service specific to the technical area;</p> <p>c) characteristics of products, services and processes specific to the technical area;</p> <p>d) the infrastructure and environment for operation of processes affecting product and service quality;</p> <p>e) the provision of externally provided processes, products and services; and</p>	5.4	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		

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<p>f) the impact of organisation type, size, governance, structure, functions and relationships on development and implementation of the QMS, its documented information and certification activities?</p> <p>Competence requirements for other personnel</p> <p>General</p> <p>Do personnel involved in other certification functions have the collective competence sufficient to undertake those functions that includes the generic competence described in ISO/IEC 17021-1 and the QMS knowledge described in 6.2?</p> <p>Competence of personnel reviewing audit reports and making certification decisions</p> <p>Do personnel reviewing audit reports and making certification decisions have knowledge of:</p> <p>a) fundamental concepts and quality management principles;</p> <p>b) terms and definitions related to quality management;</p> <p>c) the process approach;</p> <p>d) the application of risk based thinking including the determination of risks and opportunities; and</p> <p>e) scopes and their applicability to an organisation's QMS?</p>	<p>6</p> <p>6.1</p> <p>6.2</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>		