

**Specification of Competency Standards**  
**for the Testing, Inspection and Certification Industry**  
**Unit of Competency**

Functional Area - Testing Quality Management

Title	Formulate laboratory quality management system
Code	105898L6
Range	This unit of competency (UoC) covers the abilities to formulate and design a quality management system in a testing / calibration laboratory according to its operational needs by interpreting the requirements in relevant international standards and laboratory accreditation scheme.
Level	6
Credit	6 (For Reference Only)
Competency	<p>Performance Requirements</p> <p>1. Possess knowledge of laboratory quality management system</p> <ul style="list-style-type: none"> <li>• Determine the scope of activities of the laboratory.</li> <li>• Analyse a broad range of resources requirements and their availabilities in the laboratory.</li> <li>• Interpret the requirements of laboratory quality management system in relevant international standards for testing / calibration laboratories.</li> <li>• Interpret the requirements of laboratory quality management system in relevant laboratory accreditation scheme.</li> </ul> <p>2. Formulate laboratory quality management system</p> <ul style="list-style-type: none"> <li>• Plan and design a quality management system to match with the scope of activities carried out by the laboratory in the following aspects: <ul style="list-style-type: none"> <li>○ document control,</li> <li>○ review of requests, tenders and contracts,</li> <li>○ subcontracting of tests and calibrations,</li> <li>○ purchasing services and supplies,</li> <li>○ service to customer and complaints handling,</li> <li>○ control of nonconforming work,</li> <li>○ improvement,</li> <li>○ corrective action and preventive action,</li> <li>○ control of records,</li> <li>○ internal audits,</li> <li>○ management reviews,</li> <li>○ personnel,</li> <li>○ accommodation and environmental conditions,</li> <li>○ test and calibration methods and method validation,</li> <li>○ equipment,</li> <li>○ measurement traceability,</li> <li>○ sampling,</li> <li>○ handling of test / calibration items,</li> <li>○ assuring the quality of test / calibration results,</li> <li>○ reporting the results.</li> </ul> </li> <li>• Develop the plan and procedures for implementing quality management system in the laboratory, including the following components: <ul style="list-style-type: none"> <li>○ objectives and tasks,</li> <li>○ responsibilities of personnel,</li> <li>○ timeline,</li> <li>○ budget and resource needs,</li> <li>○ benchmarks or performance indicators.</li> </ul> </li> </ul>

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	<p>3. Exhibit professionalism</p> <ul style="list-style-type: none"><li>• Ensure the quality management system is fit for the purpose and complies with the size and scope of the laboratory.</li><li>• Ensure the quality management system plan should be made available to all laboratory staff for its implementation.</li></ul>
Assessment Criteria	<p>The integrated outcome requirements of this UoC are the abilities to:</p> <ul style="list-style-type: none"><li>• formulate the quality management system for a laboratory by critically interpreting the requirements in relevant international standards and laboratory accreditation scheme,</li><li>• develop the plan and procedures for implementing the quality management system by determining the scope of activities of the laboratory in compliance with the organisation policy on quality management.</li></ul>
Remark	<p>The relevant international standards and laboratory accreditation scheme involved in this UoC are as follows:</p> <ul style="list-style-type: none"><li>• ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories</li><li>• HOKLAS 003 Technical Criteria for Laboratory Accreditation</li></ul>