

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

Functional Area - Testing Operations

Title	Validate laboratory information management system
Code	105869L6
Range	This unit of competency (UoC) covers the abilities to validate laboratory information management system (LIMS) for laboratory / on-site testing activities to meet operational requirements. This UoC also includes the abilities to perform the validation tasks individually or in a team context by exercising appropriate judgement on resource requirements and to monitor, critically evaluate and determine measures to control potential operational variations and discrepancies.
Level	6
Credit	4 (For Reference Only)
Competency	<p>Performance Requirements</p> <p>1. Determine the validation plan and resources availability</p> <ul style="list-style-type: none"> • Use a wide range of computer hardware and software concepts, relevant numbering systems (binary, decimal and hexadecimal) and technical terminology to communicate effectively with relevant personnel. • Explain the workflow and operation of different sectors within the laboratory and integration of laboratory processes with computer information systems. • Apply a broad range of data types and information in laboratory / on-site testing activities. • Consolidate information from manuals, specification sheets, diagnostic equipment and software and verify compatibility of existing workstation with system to be developed. • Determine communication hardware, hardware configuration, digitisation requirements, operational considerations and constraints, administrator, level of accessibility and protection mechanism. • Determine the personnel, information and equipment required to deliver the validation work. <p>2. Perform validation of LIMS in consultation with relevant personnel</p> <ul style="list-style-type: none"> • Validate the applications of the LIMS, e.g.: <ul style="list-style-type: none"> ○ transforming information to electronic data, ○ acquiring experimental data, ○ transforming electronic data stream to digital domain, ○ programming, interrogating and capturing data from stand alone monitoring equipment and non-automated laboratory processes, ○ routing interconnections and communication of data to and between computerised systems, ○ tracking amendments of data entry, ○ rejection of data exceeding acceptable conditions. • Develop standard operating procedures (SOPs) for interfaced systems stating constraints and authorisation. • Manage the implementation of automated laboratory and/or field system and ensure the competence of personnel in using the system. • Monitor the implementation and resolve troubles identified with consultation with relevant personnel. • Critically evaluate the applicability of the LIMS and establish measures to control and rectify potential operational variations and discrepancies. <p>3. Exhibit professionalism</p>

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	<ul style="list-style-type: none">• Ensure the LIMS is properly debugged and validated to meet the operational requirements.• Maintain the integrity and confidentiality of laboratory information and data.
Assessment Criteria	<p>The integrated outcome requirements of this UoC are the abilities to:</p> <ul style="list-style-type: none">• formulate validation plan and determine resource availability,• validate the LIMS to ensure its compliance with operational specifications,• monitor the applicability of LIMS, critically evaluate potential variations and implement measures efficiently in response to potential discrepancies.
Remark	