

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

Functional Area - Testing Operations

Title	Validate laboratory self-developed software
Code	105870L6
Range	This unit of competency (UoC) covers the abilities to validate self-developed software and programme for data manipulation of laboratory / on-site testing activities. This UoC also includes the abilities to establish procedures to validate self-developed software and develop mechanism to prevent unintentional disruption or amendment of the software.
Level	6
Credit	2 (For Reference Only)
Competency	<p>Performance Requirements</p> <ol style="list-style-type: none"> 1. Formulate validation procedures and protection mechanism for self-developed software <ul style="list-style-type: none"> • Develop and establish validation procedures to validate the software for ensuring validity of test results. • Develop, establish and implement mechanism for protecting integrity and confidentiality of data entry or collection, data storage, data transmission and data processing, e.g.: <ul style="list-style-type: none"> ○ access control by use of password, ○ read only file for authorised user, ○ track log of amendments of data entry, ○ rejection of data exceeding acceptable conditions, ○ permanent record of all cell formulas, logistics, ○ lock all cells of a spreadsheet except those input by the user. • Compose user procedures of the software to facilitate daily operation. 2. Validate laboratory self-developed software <ul style="list-style-type: none"> • Apply the user procedures to get access to the software. • Verify the self-developed software and programme, e.g.: <ul style="list-style-type: none"> ○ check output manually, ○ comparison with known results from known data, ○ input non-numerical data, nonsensical data or extreme values. • Distribute the validated software and programme to team or relevant personnel and confirm their competencies in using the software. • Monitor the usage and collect feedback from relevant personnel and consolidate any variations or potential disruptions. • Critically evaluate possible causes for the disruptions and modify the software to fit intended use with consultation of relevant personnel. • Document all changes made to software and control in accordance with document control system. • Re-validate laboratory self developed software regularly. 3. Exhibit professionalism <ul style="list-style-type: none"> • Ensure the self-developed software and programme are thoroughly validated before release for use. • Maintain the integrity and confidentiality of data in accordance with documented procedures and code of conduct.
Assessment Criteria	<p>The integrated outcome requirements of this UoC are the abilities to:</p> <ul style="list-style-type: none"> • formulate and establish procedures for validation of software and for protecting integrity and confidentiality of data entry or collection, data storage, data transmission and data processing, • validate laboratory self-developed software efficiently and accurately,

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	<ul style="list-style-type: none">• monitor and evaluate potential disruptions, modify and re-validate the software regularly.
Remark	