

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

Functional Area - Testing Operations

Title	Prepare method validation reports
Code	105763L5
Range	This unit of competency (UoC) covers the abilities to prepare method validation reports to ascertain a test method's technical soundness, performance and suitability for its intended use in testing laboratories.
Level	5
Credit	2 (For Reference Only)
Competency	<p>Performance Requirements</p> <ol style="list-style-type: none"> 1. Possess the knowledge of statistics for analysing validation results for reporting <ul style="list-style-type: none"> • Identify mathematical/statistical techniques available for evaluation of validation results. • Explain enterprise/regulatory requirements regarding validation and reporting. 2. Prepare method validation reports <ul style="list-style-type: none"> • Apply theoretical knowledge and appropriate statistical techniques to interpret validation data and reach correct conclusions. • Evaluate validation results to confirm suitability of test method. • Interpret validation data and present the results in appropriate reporting formats according to standard operating procedures. • Make conclusions and recommendations in validation reports and file validation records based on the results. • Issue validated method according to standard operating procedures. 3. Exhibit professionalism <ul style="list-style-type: none"> • Ensure the technical soundness, performance and suitability of the validated test method fit for its intended use.
Assessment Criteria	<p>The integrated outcome requirements of this UoC are the abilities to:</p> <ul style="list-style-type: none"> • interpret validation data and reach correct conclusions by applying theoretical knowledge and appropriate statistical techniques, • prepare method validation reports to record validation results and communicate recommendations according to standard operating procedures.
Remark	