

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

Functional Area - Testing Operations

Title	Formulate method validation protocol
Code	105760L5
Range	This unit of competency (UoC) covers the ability to formulate validation protocol that can be adopted for test methods used in accredited testing laboratories. Validation protocol is a documented programme which provides a high degree of assurance that a specific test method will consistently produce a reliable result.
Level	5
Credit	2 (For Reference Only)
Competency	<p>Performance Requirements</p> <p>1. Possess knowledge of test method validation parameters and acceptance criteria</p> <ul style="list-style-type: none"> • Determine parameters of test method which should be validated and acceptance criteria for validating test method. • Justify those checks which should be considered to ensure performance characteristics of test method are scientifically sound, such as selectivity, linearity, range, sensitivity, limit of detection, limit of quantitation / practical quantitation limit, accuracy, precision, recovery, ruggedness, traceability, <p>2. Formulate method validation protocol</p> <ul style="list-style-type: none"> • Develop test method validation protocol in consultation with appropriate personnel. • Recommend appropriate mathematical/statistical treatment of data for presenting data and results in appropriate formats in compliance with the performance characteristics. • Verify formulated validation protocol. • Authorise and issue method validation protocol according to enterprise procedures. <p>3. Exhibit professionalism</p> <ul style="list-style-type: none"> • Ensure the formulated protocol can validate test methods that can consistently produce reliable results.
Assessment Criteria	<p>The integrated outcome requirement of this UoC is the ability to:</p> <ul style="list-style-type: none"> • formulate method validation protocol to validate test methods that are fit for purpose.
Remark	