



Australian Government

MSL977005 Validate test methods

Release: 1

MSL977005 Validate test methods

Modification History

Release	Comments
Release 1	This version was released in <i>MSL Laboratory Operations Training Package Release 2.0</i>. Supersedes and equivalent to <i>MSL977003 Contribute to validation of test methods</i>. Prerequisites updated. Range of conditions removed. Assessment requirements amended.

Application

This unit of competency describes the skills and knowledge to validate test methods following defined protocols to ensure that they are based on sound scientific principles and are fit for the purpose for which they are to be used.

This unit applies to senior technical officers, laboratory supervisors and technical specialists working in all industry sectors. All operations are performed in accordance with laboratory and/or workplace procedures. Validation includes all those procedures which ascertain a method's technical soundness, performance and suitability for its intended use. Validation is a documented program which provides a high degree of assurance that a specific testing method will consistently produce a reliable result. The nature of the testing method may be physical, chemical, microbiological or a combination of these. The quality of the test method is built in during its design stage, validated in its development stage, and confirmed in its 'use' stage.

No licensing or certification requirements exist at the time of publication. However, regulations and/or external accreditation requirements for laboratory operations exist, so local requirements should be checked. Relevant legislation, industry standards and codes of practice within Australia must also be applied.

Pre-requisite Unit

MSL976005 Evaluate and select appropriate test methods and/or procedures

Competency Field

Testing

Elements and Performance Criteria

Elements describe the essential outcomes.

Performance criteria describe the performance needed to demonstrate achievement of the element.

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|---|---|-----|---|
| 1 | Confirm equipment has been qualified and validated | 1.1 | Confirm that latest editions of manufacturer specifications and operating instructions are present |
| | | 1.2 | Confirm that equipment, including computer systems, is installed according to manufacturer specifications |
| | | 1.3 | Confirm that equipment operating instructions exist and conform to manufacturer specifications |
| | | 1.4 | Confirm that equipment operates according to manufacturer design specifications |
| | | 1.5 | Verify that equipment calibration complies with appropriate standards |
| | | 1.6 | Confirm equipment and computer systems are validated |
| | | 1.7 | Confirm method has an acceptable level of uncertainty |
| | | | |
| 2 | Validate test method according to defined protocol | 2.1 | Develop validation test protocol in consultation with appropriate personnel |
| | | 2.2 | Seek authorisation from protocol from appropriate personnel |
| | | 2.3 | Validate test method according to validation protocol |
| | | | |
| 3 | Evaluate and record results | 3.1 | Evaluate validation results to confirm suitability of testing method |
| | | 3.2 | Obtain approval for evaluation recommendations from appropriate personnel |
| | | 3.3 | Record and file validation records |
| | | 3.4 | Issue validated method according to workplace procedures |
| | | 3.5 | Evaluate staff training needs and document appropriately |

3.6 Recommend update of relevant documentation as a result of the validation

Foundation Skills

This section describes those language, literacy, numeracy and employment skills that are essential to performance.

- Learning skills to conduct literature searches on background chemistry/physics/biology/immunology of materials to be evaluated, including likely impurities and degradation products
- Numeracy skills to:
 - optimise and calibrate equipment to manufacturer specifications
 - perform required calculations using appropriate equations, units, uncertainties and precision
 - use relevant mathematical and statistical techniques to analyse results
 - present large amounts of data, validation results and recommendations in appropriate formats for review and authorisation

Foundation skills essential to performance are explicit in the performance criteria of this unit of competency.

Unit Mapping Information

Equivalent to MSL977003 Contribute to validation of test methods, Release 1.

Links

Training Package Companion Volumes -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=5c63a03b-4a6b-4ae5-9560-1e3c5f462baa>

Assessment Requirements for MSL977005 Validate test methods

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Performance Evidence

There must be evidence the candidate has completed the tasks outlined in the elements and performance criteria of this unit, and:

- validated at least 2 test methods using authorised protocols to ensure they are based on sound scientific principles and are fit for purpose.

Knowledge Evidence

There must be evidence the candidate has knowledge of:

- principles, concepts and workplace/regulatory requirements related to method validation and reporting
- calculation steps, mathematical and statistical techniques used to analyse results
- principles and procedures of testing equipment operation
- characteristics, capabilities and limitations of equipment
- variables which should be validated and criteria for choice
- purposes of validation:
 - identification and impartial resolution of ethical issues, such as conflict of interest
 - ethical decision making
 - provision of products and services which match the operational and financial needs of stakeholders, including realistic quotes for work
 - accurate representation of skills, services, knowledge and qualifications of individuals and the organisation
 - acknowledgment of services and products developed by others, intellectual property (IP) and copyright
 - provision of unbiased, accurate and appropriately qualified information results
- validation protocols:

- checks that are considered to ensure performance characteristics of test method are scientifically sound
- checks, including:
 - selectivity
 - linearity
 - range
 - sensitivity
 - limit of detection
 - limit of quantitation
 - accuracy
 - precision
 - recovery
 - ruggedness
- assessment of the clarity and completeness of the description of the method
- workplace and/or legal traceability requirements
- awareness of environmental sustainability issues as they relate to the work task
- legal, ethical and work health and safety (WHS) requirements specific to the work task.

Assessment Conditions

Skills must have been demonstrated in the workplace or in a simulated environment that reflects workplace conditions and contingencies. The following conditions must be met for this unit:

- use of suitable facilities, equipment and resources, including:
 - a standard laboratory equipped with appropriate equipment, instruments, reagents, samples and test methods
 - validation protocols.

Assessors must satisfy the NVR/AQTF mandatory competency requirements for assessors.

Links

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<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=5c63a03b-4a6b-4ae5-9560-1e3c5f462baa>