



Australian Government

MSL977003 Contribute to validation of test methods

Release: 1

MSL977003 Contribute to validation of test methods

Modification History

Release 1. Supersedes and is equivalent to MSL977003A Contribute to validation of test methods

Application

This unit of competency covers the ability 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 of competency is applicable 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.

While no specific licensing or certification requirements apply to this unit at the time of publication, laboratory operations are governed by relevant legislation, regulations and/or external accreditation requirements. Local requirements should be checked.

Pre-requisite Unit

MSL976003 Evaluate and select appropriate test methods and/or procedures

Competency Field

Testing

Unit Sector

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 | 1.1 Confirm that latest editions of manufacturer specifications and operating instructions are present |
|--------------------------------|---|

	been qualified and validated	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	Ensure protocol is authorised by 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 record 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.

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

Range of Conditions

This field allows for different work environments and conditions that may affect performance. Essential operating conditions that may be present (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) are included.

Standards, codes, procedures and/or workplace requirements

Standards, codes, procedures and/or workplace requirements include the latest version of one or more of:

- Australian and international standards covering the requirements for the competence of testing and calibration laboratories, laboratory safety, quality and environmental management systems, and measurement management systems
- national work health and safety (WHS) standards and codes of practice, and national measurement regulations and guidelines
- Australian and international standards and guidelines covering specialised analysis, accuracy of measurement methods and results, expression of uncertainty, quantifying uncertainty, Association of Analytical Communities International (AOAC International) Official Methods of Analysis, Validation of Analytical Procedures, Validation of Characteristics of a Method of Analysis, and Validation of Compendial Methods
- specific codes, guidelines, procedures and methods, such as National Association of Testing Authorities (NATA) accreditation programs requirements, Australian code of good manufacturing practice for medicinal products (GMP), principles of good laboratory practice (GLP), Food Standards Australia New Zealand (FSANZ) Code, Australian Dangerous Goods Code, gene technology regulations, National Health and Medical Research Council (NHMRC) Guidelines, and Therapeutic Goods Regulations
- workplace documents, such as standard operating procedures (SOPs); quality and equipment manuals; calibration and maintenance schedules; material safety data sheets (MSDS) and safety procedures; material, production and product specifications; production and laboratory schedules; workplace recording and reporting procedures; waste minimisation and safe disposal procedures; cleaning, hygiene and personal hygiene requirements; stock records and inventory
- test methods and validation procedures

Validation

Validation includes one or more of the following:

- 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 include:

Validation protocols include one or more of the following:

- checks that are considered to ensure performance characteristics of test method are scientifically sound
- checks, such as:
 - 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

WHS and environmental management requirements

WHS and environmental management requirements include:

- complying with WHS and environmental management requirements at all times, which may be imposed through state/territory or federal legislation. These requirements must not be compromised at any time
- applying standard precautions relating to the potentially hazardous nature of samples
- accessing and applying current industry understanding of infection control issued by the National Health and Medical Research Council (NHMRC) and State and Territory Departments of Health, where relevant

Unit Mapping Information

Release 1. Supersedes and is equivalent to MSL977003A Contribute to validation of test methods

Links

Companion Volume implementation guides are found in VETNet -

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

Assessment Requirements for MSL977003 Contribute to validation of test methods

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Performance Evidence

Evidence of competence in this unit must satisfy all of the requirements of the elements and performance criteria, and include demonstration of:

- validating at least two (2) test methods using authorised protocols to ensure they are based on sound scientific principles and are fit for purpose
- conducting literature searches on background chemistry/physics/biology/immunology of materials to be evaluated, including likely impurities and degradation products
- conducting reliable qualification and validation checks of equipment and computer systems
- developing authorised validation test protocols in consultation with appropriate personnel
- starting up, setting up, optimising, calibrating and operating equipment to manufacturer specifications
- preparing test samples and standards for validation
- carefully checking the performance characteristics of the test method
- performing required calculations using appropriate equations, units, uncertainties and precision
- using relevant mathematical and statistical techniques to analyse results
- presenting large amounts of data, validation results and recommendations in appropriate formats for review and authorisation
- maintaining accurate and complete validation records
- communicating/reporting validation outcomes according to workplace procedures
- issuing validated method according to workplace procedures
- following workplace safety and environmental management procedures, and principles of good laboratory practice (GLP).

Knowledge Evidence

Must provide evidence that demonstrates knowledge of:

- principles, concepts and workplace/regulatory requirements related to method validation and reporting
- calculation steps, mathematical and statistical techniques used to analyse results
- traceability, including legal requirements for traceability
- principles and procedures of testing equipment operation
- characteristics, capabilities and limitations of equipment

- variables which should be validated and criteria for choice
- relevant hazards, work health and safety (WHS) and environment requirements.

Assessment Conditions

- Judgment of competence must be based on holistic assessment of the evidence. Assessment methods must confirm consistency of performance over time, rather than a single assessment event.
- This unit of competency is to be assessed in the workplace or a simulated workplace environment. A simulated workplace environment must reflect realistic operational workplace conditions that cover all aspects of workplace performance, including the environment, task skills, task management skills, contingency management skills and job role environment skills.
- Foundation skills are integral to competent performance of the unit and should not be assessed separately.
- Assessment processes and techniques must be appropriate to the language, literacy and numeracy requirements of the work being performed and the needs of the candidate.
- Knowledge evidence may be collected concurrently with performance evidence or through an independent process, such as workbooks, written assessments or interviews (provided a record is kept in each case).
- This unit of competency may be assessed with:
 - MSL977001 Contribute to the development of products and applications
 - MSL977002 Troubleshoot equipment and production processes
 - MSL977004 Develop or adapt analyses and procedures
 - MSL925002 Analyse measurements and estimate uncertainties
- Holistic assessment methods include:
 - review of at least two (2) validation reports completed by the candidate that each provide details of their contribution, including development of an authorised validation protocol, conduct of validation checks, presentation of validation data, results and recommendations and relevant records (e.g. approval, issuing of method and staff training needs)
 - feedback from supervisors about the candidate's ability to use authorised validation protocols to confirm whether or not test methods are based on sound scientific principles and are fit for the purpose, and prepare all relevant documentation for approval
 - oral or written questioning covering principles, concepts and workplace/regulatory requirements related to method validation and reporting.
- Access is required to instruments, equipment, materials, workplace documentation, procedures and specifications associated with this unit, including, but not limited to:
 - a standard laboratory equipped with appropriate equipment, instruments, reagents, samples and test methods
 - validation protocols.
- Assessors must satisfy the assessor competency requirements that are in place at the time of the assessment as set by the VET regulator.

- The assessor must demonstrate both technical competence and currency.
- Technical competence can be demonstrated through:
 - relevant VET or other qualification/Statement of Attainment AND/OR
 - relevant workplace experience.
- Currency can be demonstrated through:
 - performing the competency being assessed as part of current employment OR
 - having consulted with a laboratory about performing the competency being assessed within the last twelve months.

Links

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