



**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.

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

### 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**

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## **Links**

MSA Training Package Implementation Guides - <http://mskills.org.au/training-packages/info/>