



Australian Government

Assessment Requirements for MSL977003 Contribute to validation of test methods

Release: 1

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Modification History

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

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

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