



Australian Government

MSL977012 Develop or adapt analyses and procedures

Release: 1

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Modification History

Release 1. Supersedes and equivalent to MSL977008 Develop or adapt analyses and procedures. Minor changes to Performance Criteria. Performance Evidence simplified.

Application

This unit of competency describes the skills and knowledge to develop or adapt analyses, including methods and procedures, to meet workplace and/or regulatory requirements. New analyses, methods and associated procedures may be required to meet a customer's brief, analyse new products or raw materials, improve laboratory efficiency or meet changing regulatory requirements.

This unit applies to senior technical officers, laboratory supervisors and technical specialists working in all industry sectors. All operations must comply with relevant standards, appropriate procedures and/or workplace requirements. The work may involve developing new testing methods or adapting existing methods to satisfy a testing need.

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

MSL976006 Evaluate and select appropriate test methods and/or procedures

Competency Field

Testing

Elements and Performance Criteria

Elements	Performance Criteria
Elements describe the essential outcomes.	Performance criteria describe the performance needed to demonstrate achievement of the element.
1. Determine gaps and deficiencies in present methods and procedures	1.1 Identify opportunities to improve analyses and procedures 1.2 Identify requirements for new analyses and procedures to meet testing briefs 1.3 Define the scope of analysis required by the improvement or new testing brief 1.4 Establish that existing workplace test methods and procedures do not

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	meet requirements 1.5 Prepare development proposal based on information reviewed 1.6 Confirm development requirements and development proposal with appropriate personnel 1.7 Obtain authorisation to proceed in accordance with workplace procedures
2. Research and propose alternatives	2.1 Source relevant documented methods and procedures 2.2 Review relevant documented methods and procedures in accordance with workplace procedures 2.3 Consult with relevant technical personnel regarding project development issues 2.4 Evaluate resource requirements for proposed changes 2.5 Ensure that proposed changes meet work health and safety (WHS), environmental, regulatory and workplace requirements 2.6 Document development requirements, timelines and proposed methods and procedures 2.7 Obtain authorisation to proceed in accordance with workplace procedures
3. Evaluate alternatives, develop analyses and recommend methods and procedures	3.1 Investigate possible alternatives and choose appropriate method/procedure 3.2 Develop and/or adapt analytical method or test procedure to meet requirements 3.3 Trial method and procedure against requirements 3.4 Validate method and procedure against workplace requirements 3.5 Maintain records to substantiate and justify chosen approach
4. Document and report new methods and procedure	4.1 Prepare and/or update analytical method/procedure and associated laboratory documentation 4.2 Obtain final approval for new method/procedure 4.3 Identify and respond to situations where withdrawal, documentation and archiving of superseded methods and/or procedures is required 4.4 Issue new method and procedures in accordance with workplace procedures

Foundation Skills

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

- Learning skills to applying theoretical concepts and practical principles to develop or adapt methods and procedures to meet requirements
- Numeracy skills to apply method performance measures, such as accuracy, precision, uncertainty, linearity, selectivity, range, limit of detection and matrix characteristics.

Other foundation skills essential to performance are explicit in the performance criteria of this unit.

Unit Mapping Information

Supersedes and is equivalent to MSL977008 Develop or adapt analyses and procedures.

Links

MSL Laboratory Operations Companion Volume Implementation Guide is available from VETNet -

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

Assessment Requirements for MSL977012 Develop or adapt analyses and procedures

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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:

- developed or adapted a method of analysis of an item or process, and all related methods and procedures to meet workplace and regulatory requirements, for at least 1 of the following:
 - non-instrumental method
 - spectrometric method
 - chromatographic method
 - electrochemical method
 - assays based on biological properties or cell properties for enzyme antibody activity
 - any complex method.

Knowledge Evidence

There must be evidence the candidate has knowledge of:

- concepts relating to method and procedure development, including:
 - determining and defining development objectives
 - relating chemical and physical characteristic of sample to possible assay methods
 - evaluating criteria to choose appropriate analytical method
 - sample clean-up and preparation techniques
 - preparation, set-up and calibration of testing equipment
 - choice of appropriate detection system ensuring accuracy/precision criteria are achieved
 - optimisation of analysis conditions
- criteria for choice of method and procedure, including:
 - economic factors
 - safety considerations
 - resource factors, including equipment and personnel
 - regulatory, accreditation and registration considerations
- detailed theoretical and practical basis of analyses relevant to job role

- operating principles and practices and characteristics, capabilities and limitations of testing equipment used
- relative advantages and disadvantages of different testing methods
- reasons for new methods of analysis and related procedures being developed, including:
 - analysis of raw materials
 - introduction of new technology
 - quality control or evaluation of the stability of new formulations of existing products
 - quality control or evaluation of the stability of products
 - to meet regulatory requirements
- procedures and requirements for method and procedure development, validation and approval
- 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
 - workplace procedures
 - online data search facilities.

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

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