



Australian Government

MSL977004 Develop or adapt analyses and procedures

Release: 1

MSL977004 Develop or adapt analyses and procedures

Modification History

Release 1. Supersedes and is equivalent to MSL977004A Develop or adapt analyses and procedures

Application

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

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	Determine gaps and deficiencies in present methods and	1.1	Identify opportunities to improve analyses and procedures
		1.2	Identify requirements for new analyses and procedures to meet testing briefs

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| procedures | | 1.3 | Define the scope of analysis required by the improvement or new testing brief |
| | | 1.4 | Establish that existing workplace test methods/procedures do not meet requirements |
| | | 1.5 | Prepare development proposal |
| | | 1.6 | Confirm development requirements and development proposal with appropriate personnel |
| | | 1.7 | Obtain authorisation to proceed |
| | | | |
| 2 | Research and propose alternatives | 2.1 | Source relevant documented methods/procedures |
| | | 2.2 | Review relevant documented methods/procedures according to workplace procedures |
| | | 2.3 | Consult with relevant technical personnel regarding project development issues |
| | | 2.4 | Evaluate resource requirements for proposed methods/procedures |
| | | 2.5 | Ensure that methods/procedures meet work health and safety (WHS), environmental, regulatory and workplace requirements |
| | | 2.6 | Document development requirements, timelines and proposed methods/procedures |
| | | 2.7 | Obtain authorisation to proceed |
| | | | |
| 3 | Evaluate alternatives, develop analyses and recommend methods and procedures | 3.1 | Investigate possible alternative methods and procedures and choose appropriate method/procedure |
| | | 3.2 | Develop and/or adapt analytical method or test procedure to meet requirements |
| | | 3.3 | Trial method/procedure against test method/procedure requirements |
| | | 3.4 | Validate method/procedure |
| | | 3.5 | Maintain records to substantiate and justify chosen method/procedure |

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| 4 | Document and report new methods and procedure | 4.1 | Prepare and/or update analytical method/procedure and associated standard operating procedures (SOPs) |
| | | 4.2 | Obtain final approval for new method/procedure |
| | | 4.3 | Withdraw, document and archive superseded method/procedure |
| | | 4.4 | Issue new method/procedure according to workplace procedures |

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 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, and Association of Analytical Communities International (AOAC International) Official Methods of Analysis
- 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 methods and procedures; 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

New methods and related procedures

New methods of analysis and related procedures are required for one or more of the following reasons:

- analysis of raw materials
- quality control or evaluation of the stability of products
- quality control or evaluation of the stability of new formulations of existing products
- introduction of new technology
- to meet regulatory requirements
- to meet customer requirements
- improvement of productivity
- improvement of accuracy and precision

Analyses

Analyses include, but are not limited to, one or more of:

- non-instrumental methods, such as gravimetric, titrimetric and qualitative tests
- spectrometric methods, such as ultraviolet-visible (UV-VIS), infrared (IR) (including Fourier transform infrared (FTIR)), near infrared (NIR), atomic absorption (AA) and fluorescence
- chromatographic methods, such as thin layer, paper, gas chromatography (GC), high performance liquid chromatography (HPLC), ion chromatography (IC) and electrophoresis
- electrochemical methods, such as ion-selective electrodes and polarography
- assays based on biological properties or cell properties for enzyme antibody activity

WHS and environmental management

WHS and environmental management requirements include:

- complying with WHS and environmental management

requirements

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 MSL977004A Develop or adapt analyses and procedures

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 MSL977004 Develop or adapt analyses and procedures

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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:

- developing or adapting at least one (1) method of analysis and all related methods and procedures to meet workplace and regulatory requirements
- interpreting briefs to determine testing requirements
- preparing authorised development proposals, including gap/deficiency analysis, details of development requirements, timelines and proposed methods and procedures
- applying theoretical concepts and practical principles to develop or adapt methods and procedures to meet requirements
- researching alternative methods
- evaluating existing testing methods and procedures against new testing requirements
- trialling and validating methods and procedures
- applying method performance measures, such as accuracy, precision, uncertainty, linearity, selectivity, range, limit of detection and matrix characteristics
- generating, recording and reporting data in formats which assist procedure writing
- recommending modifications of existing methods and procedures or development of new methods and procedures based on sound principles
- preparing and/or updating analytical methods and procedures
- documenting and issuing approved new method/procedure in accordance with workplace procedures
- following workplace safety and environmental management procedures.

Knowledge Evidence

Must provide evidence that demonstrates 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/procedure, including:
 - economic factors
 - safety considerations
 - resource factors, including equipment and personnel
 - regulatory, accreditation and registration considerations
- detailed theoretical and practical basis of tests/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
- procedures and requirements for method and procedure development, validation and approval
- workplace and regulatory testing requirements
- 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:
 - MSL925002 Analyse measurements and estimate uncertainties
 - MSL977001 Contribute to the development of products and applications
 - MSL977002 Troubleshoot equipment and production processes
 - MSL977003 Contribute to validation of test methods
- Holistic assessment methods include:
 - review of documentation completed by the candidate that provides details of gap/deficiency analysis, authorised development proposal, research and evaluation of alternatives, recommendations, validation of method/procedure and relevant records (e.g. approval, issuing of method/procedure)

- feedback from supervisors about the candidate's ability to develop or adapt methods and procedures to meet workplace and/or regulatory requirements and prepare all relevant documentation for approval
- oral or written questioning covering concepts, principles and processes for selection and development of methods/procedures, technical aspects of method/procedure, and validation and approval procedures.
- 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, and SOPs
 - online data search facilities.
- 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.

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