



Australian Government

MSL977004 Develop or adapt analyses and procedures

Release: 1

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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.

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| 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/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 |
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| 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 |

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| 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 |
| | | | |
| 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 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/>