



Australian Government

Department of Education, Employment and Workplace Relations

MSL977004A Develop or adapt analyses and procedures

Revision Number: 1

MSL977004A Develop or adapt analyses and procedures

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the ability to develop or adapt analyses and procedures to meet enterprise and/or regulatory requirements. New analyses 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.
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Application of the Unit

Application of the unit	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 enterprise requirements. The work may involve developing new testing methods or adapting existing methods to satisfy a testing need. Industry representatives have provided case studies to illustrate the practical application of this unit of competency and to show its relevance in a workplace setting. These can be found at the end of this unit of competency under the section 'This competency in practice'.
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Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		
	MSL976003A	<i>Evaluate and select appropriate test methods and/or procedures</i>

Employability Skills Information

Employability skills	This unit contains employability skills.
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Elements and Performance Criteria Pre-Content

Elements describe the essential outcomes of a unit of competency.	Performance criteria describe the performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge section and the range statement. Assessment of performance is to be consistent with the evidence guide.
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Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Determine gaps and deficiencies in present analyses and/or procedures	1.1. Identify opportunities to improve analyses and/or 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 enterprise 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 enterprise 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 occupational health and safety (OHS), environmental, regulatory and enterprise 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
4. Document and report new method/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

ELEMENT	PERFORMANCE CRITERIA
	4.4. Issue new method/procedure according to enterprise procedures

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

This section describes the skills and knowledge required for this unit.

Required skills

Required skills include:

- developing or adapting analyses and procedures to meet requirements
- interpreting a brief to determine testing requirements
- applying theoretical concepts and practical principles to develop or adapt methods
- evaluating existing testing procedures against new testing requirements
- using method performance analysis measures, such as accuracy, precision, uncertainty, linearity, selectivity, range, limit of detection and matrix characteristics
- researching alternative methods
- making recommendations for modification of existing procedures or development of new procedures
- following enterprise procedures to document and circulate new procedures

Required knowledge

Required knowledge includes:

- detailed knowledge of theoretical and practical basis of test/analysis
- principles and practices of operation of a range of testing equipment
- characteristics, capabilities and limitations of equipment
- relative advantages/disadvantages of different analytical methods
- theoretical procedures for method development
- method validation requirements
- enterprise and regulatory testing requirements
- relevant health, safety and environment requirements

Evidence Guide

EVIDENCE GUIDE

The Evidence Guide provides advice on assessment and must be read in conjunction with the performance criteria, required skills and knowledge, range statement and the Assessment Guidelines for the Training Package.

Overview of assessment

Critical aspects for assessment and evidence required to demonstrate competency in this unit

Assessors should ensure that candidates can:

- develop or adapt analyses and procedures to meet requirements
- interpret a brief to determine testing requirements
- apply theoretical concepts and practical principles to develop or adapt methods to meet requirements
- evaluate existing testing procedures against new testing requirements
- use appropriate procedures to research alternative methods
- use method performance measures, such as accuracy, precision, uncertainty, linearity, selectivity, range, limit of detection and matrix characteristics
- make recommendations for modification of existing procedures or development of new procedures based on sound principles
- follow enterprise procedures to document and circulate new procedures.

Context of and specific resources for assessment

This unit of competency is to be assessed in the workplace or simulated workplace environment.

This unit of competency may be assessed with:

- *MSL925002A Analyse measurements and estimate uncertainties*
- *MSL977001A Contribute to the development of products and applications*
- *MSL977002A Troubleshoot equipment and production processes*
- *MSL977003A Contribute to validation of test methods.*

Resources may include:

- standard laboratory equipped with appropriate equipment, reagents, samples and test methods
- online data search facilities.

EVIDENCE GUIDE**Method of assessment**

The following assessment methods are suggested:

- review of development or adaptation of methods completed by the candidate
- review of workplace development briefs completed by the candidate
- feedback from supervisors and/or clients
- oral or written questioning to assess underpinning knowledge of analyses, instrument operation, procedures and problem solving techniques.

In all cases, practical assessment should be supported by questions to assess underpinning knowledge and those aspects of competency which are difficult to assess directly

Where applicable, reasonable adjustment must be made to work environments and training situations to accommodate ethnicity, age, gender, demographics and disability.

Access must be provided to appropriate learning and/or assessment support when required.

The language, literacy and numeracy demands of assessment should not be greater than those required to undertake the unit of competency in a work like environment.

This competency in practice

Industry representatives have provided the case studies below to illustrate the practical application of this unit of competency and to show its relevance in a workplace setting.

Manufacturing

Technical specialists often have to apply their practical and theoretical knowledge of laboratory instrumentation to adapt or develop methods to solve specific problems. For example, a technical specialist in a consulting laboratory was asked to determine why heat-sealing bags were not sealing properly. Using infrared spectroscopy, the specialist ran spectra on several samples and noticed a difference in the coating on the bags which didn't seal compared with the coating on bags which sealed correctly. The spectra indicated that the coatings were different polymers. The technical specialist notified the supplier of the sealing problem and new bags were forwarded. To ensure that the problem didn't occur again,

EVIDENCE GUIDE

an infrared spectroscopy test method was developed to ensure that the correct polymer coating was on the new bags. As a result, production flowed smoothly when bags were delivered to the production line.

Biomedical

A laboratory manager determined that there is sufficient demand for a particular enzyme activity assay. Currently, this assay is performed manually by kinetic assay using a spectrometer. A senior technical officer has been given the task of converting the method to one that can be run on an automated biochemical analyser. The method will be translated to instructions regarding wavelength, absorbance increase or decrease, time of reading and intervals of the readings, sequence of addition of the reagents and sample, ratio of the volumes (they will be reduced in the automated procedure) and incubation conditions.

Food processing

The water activity of food is affected by temperature. The measurement of water activity takes considerable time, due in part to the time required for the sample to reach the specified test temperature in the instrument. A technician suggested that the test time could be reduced if the samples were presented to the instrument at the test temperature, rather than room temperature. She/he also raised concerns about water loss which could occur while raising the sample to test temperature. The technician planned an investigation and ran tests using standard Greenspan salts to compare results from normal testing with testing using pre-warm samples. Pre-warm samples held for 30 minutes in a pre-warm cabinet gave different results from the normal test method samples. However, samples held for 15 minutes in the pre-warm cabinet did not. A test method was subsequently introduced with samples being held for a maximum of 10 minutes in a pre-warm cabinet prior to being loaded into the water activity instrument. This gave excellent statistical correlation with the normal method and provided increased throughput of samples.

Range Statement

RANGE STATEMENT

The range statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Bold italicised wording, if used in the performance criteria, is detailed below. Essential operating conditions that may be present with training and assessment (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) may also be included.

Codes of practice

Where reference is made to industry codes of practice, and/or Australian/international standards, it is expected the latest version will be used

Standards, codes, procedures and/or enterprise requirements

Standards, codes, procedures and/or enterprise requirements may include:

- Australian and international standards, such as:
 - AS ISO 1000-1998 The international system of units (SI) and its application
 - AS ISO 17025-2005 General requirements for the competence of testing and calibration laboratories
 - AS/NZS ISO 10005:2006 Quality management systems - Guidelines for quality plans
 - AS/NZS ISO 10012:2004 Measurement management systems - Requirements for measurement processes and measuring equipment
 - AS/NZS ISO 14000 Set:2005 Environmental management standards set
 - AS/NZS ISO 9000 Set:2008 Quality management systems set
 - ISO 5725 Accuracy (trueness and precision) of measurement methods and results
 - ISO/IEC Guide 98-3:2008 Uncertainty of measurement - Part 3 Guide to the expression of uncertainty in measurement (GUM)
- Eurachem/CITAC Guide CG4 Quantifying uncertainty in analytical measurement
- appropriate journals and Internet sites
- Australia New Zealand Food Standards

RANGE STATEMENT	
	(ANZFS) Code • Australian code of good manufacturing practice for medicinal products (GMP) • Australian Quarantine and Inspection Service (AQIS) Export Control (Orders) Regulations 1982 and Import Guidelines • calibration and maintenance schedules • enterprise recording and reporting procedures • ethics committee requirements • gene technology regulations • intellectual property and copy right • material safety data sheets (MSDS) • material, production and product specifications • National Association of Testing Authorities (NATA) Accreditation programs requirements • national environment protection measures • National Health and Medical Research Council (NHMRC) Guidelines • national measurement regulations and guidelines • OHS national standards and codes of practice • principles of good laboratory practice (GLP) • production and laboratory schedules • quality manuals, equipment and procedures manuals • Therapeutic Goods Regulations 1009
New methods of analysis and related procedures	New methods of analysis and related procedures may be required to: • analyse raw materials • quality control or evaluate the stability of products • quality control or evaluate the stability of new formulations of existing products • use new technology • meet regulatory requirements • meet customer requirements • improve productivity • improve accuracy and precision
Analyses	Analyses may include: • non-instrumental methods, such as gravimetric,

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	titrimetric and qualitative tests • spectrometric methods, such as ultraviolet-visible (UV-VIS), infra red (IR) (including fourier transform infra red (FTIR)), near infra red (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
Procedures	Procedures are: • directions for conducting analyses • hard copy • online format
Concepts relating to method development	Concepts relating to method development include: • determining and defining development objectives • relating chemical and physical characteristic of sample to possible assay methods • evaluating criteria to choose appropriate analytical method • sample cleanup and preparation techniques • preparation, setup and calibration of testing equipment • choice of appropriate detection system ensuring accuracy/precision criteria are achieved • optimisation of analysis conditions • generating, recording and reporting data in format which assists procedure writing
Criteria for choice of method	Criteria for choice of method may include: • economic factors • safety considerations • resource factors, including equipment and personnel • regulatory, accreditation and registration

RANGE STATEMENT	
	considerations
Occupational health and safety (OHS) and environmental management requirements	OHS and environmental management requirements: - all operations must comply with enterprise OHS and environmental management requirements, which may be imposed through state/territory or federal legislation - these requirements must not be compromised at any time - all operations assume the potentially hazardous nature of samples and require standard precautions to be applied - where relevant, users should access and apply current industry understanding of infection control issued by the National Health and Medical Research Council (NHMRC) and State and Territory Departments of Health

Unit Sector(s)

Unit sector	Testing
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Competency field

Competency field	
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Co-requisite units

Co-requisite units		