Australian Government

MSL976003A Evaluate and select appropriate test methods and/or procedures

Revision Number: 1

INDUSTRY SKILLS COUNCILS
Creating Australia's Future

MSL976003A Evaluate and select appropriate test methods and/or procedures

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the ability to evaluate and select test methods and/or procedures that are relevant to the current and evolving scope of the laboratory's operations. Selection of test methods and/or procedures may involve the appraisal of new and emerging technologies and may inform decision making about possible extension of the laboratory's scope. Alternatively, it may relate to existing testing requirements, 'one-off' tests, client's special requirements or new tests required to satisfy new legislative, accreditation, licensing or regulatory requirements.

Application of the Unit

Application of the unit	This unit of competency is applicable to senior technical officers, technical specialists and laboratory supervisors working in all industry sectors. They are required to demonstrate wide ranging, highly specialised technical skills. They are expected to execute sound judgement in the selection of appropriate methodology under the broad guidance of scientists/medical staff/engineers. All operations must comply with relevant standards, appropriate procedures and/or enterprise requirements. 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'.

Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		

Employability Skills Information

Employability skills	This unit contains employability skills.

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.

Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Determine sample characteristics and testing requirements	1.1. Confirm drivers for evaluation and selection of test methods and/or procedures 1.2. Examine sample documentation and/or consult with sample supplier to determine nature of samples 1.3. Identify sample characteristics which may affect testing requirements 1.4. Determine testing requirements and their compatibility with existing standard operating procedures (SOPs)
2. Evaluate possible test methods and/or procedures	2.1. Identify appropriate standards, reference materials, test methods and/or procedures which may be applicable 2.2. Assess suitability of available standards, reference materials, test methods and/or procedures against testing requirements 2.3. Identify environmental and occupational health and safety (OHS) risks 2.4. Identify the need for specific equipment, instrumentation, and/or specialised facilities 2.5. Estimate materials, personnel and possible training requirements
3. Recommend appropriate test methods and/or procedures	3.1. Select appropriate test methodology consistent with testing requirements and resource availability 3.2. Identify any changes to SOPs required prior to implementation of selected method and/or procedure 3.3. Recommend selected method and/or procedure to appropriate personnel and seek authorisation to proceed
4. Confirm and document selected methods and/or procedures	4.1. Obtain standards and/or reference materials for the method and/or procedure 4.2. Conduct tests to verify the performance of the method and/or procedure, standards and reference materials 4.3. Analyse the measurements and estimate uncertainties 4.4. Determine if legal traceability is required and develop appropriate chain of custody procedures 4.5. Document all safety, sample preparation, testing, data handling and reporting procedures 4.6. Submit all documentation to appropriate personnel

ELEMENT	PERFORMANCE CRITERIA
	for review and approval

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

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

Required skills

Required skills include:

- evaluating and selecting appropriate test methods and/or procedures to satisfy the range of testing situations normally encountered in the laboratory
- identifying reference standards or SOPs appropriate to testing requirements of the laboratory
- identifying standards that support compliance with regulatory and/or licensing requirements
- applying enterprise procedures to select appropriate standards
- using method performance analysis measures, such as accuracy, precision, uncertainty, linearity, selectivity, range, limit of detection and matrix characteristics in method selection
- documenting method selection procedures
- maintaining records of published methods
- following OHS procedures and principles of good laboratory practice (GLP)

Required knowledge

Required knowledge includes:

- principles, concepts and enterprise/regulatory requirements related to method selection
- regulatory/licensing testing requirements
- relative advantages/disadvantages of test methods for a range of testing situations
- cost advantages/disadvantages of enterprise test methods
- scientific/technical principles underpinning test method and their application to selection of testing methods for different materials
- metrological principles
- significance of normal, physiological or reference ranges
- enterprise and/or legal requirements for traceability
- enterprise/regulatory requirements regarding recording and reporting
- relevant health, safety and environment requirements

Specific industry

Additional knowledge requirements may apply for different industry sectors. For example:

Biomedical, biotechnology and food processing:

- effects of biologically inert or active chemicals, such as food and drug metabolites in test selection, testing and test data interpretation

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: • evaluate and select appropriate test methods and/or procedures to satisfy the range of testing situations normally encountered in the laboratory • identify reference standards or SOPs appropriate to testing requirements of the laboratory • identify standards that support compliance with regulatory and/or licensing requirements • apply enterprise procedures to select appropriate standards • use method performance measures, such as accuracy, precision, uncertainty, linearity, selectivity, range, limit of detection and matrix characteristics in method selection • clearly document method selection procedures • maintain records of published methods • follow OHS procedures and principles of GLP.
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* • *MSL916003A Supervise laboratory operations in work/functional area*. Resources may include: • standard laboratory equipped with appropriate equipment and reagents • SOPs and test methods • appropriate Australian and international regulatory standards.
Method of assessment	The following assessment methods are suggested: • completion of selection brief or selection proficiency test

EVIDENCE GUIDE	
	• review of records completed by the candidate over a period of time to confirm consistency in method selection • feedback from peers and supervisors • oral questioning to establish basis of selection of test methods and/or procedures. 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. **Biotechnology** The choice of analytical method for protein assay is influenced by the amount of protein likely to be present and the impurities present. During an extraction procedure, the yield of protein is monitored. At any stage there will be a range of substances used in the extraction. When the extraction is complete and the protein required has been isolated, the amount of protein recovered could range from bulk or gram quantities down to microgram quantities. The technical officer will check through the available methodologies and select procedures that will take account of the above problems. The Biuret assay is used for bulk assay protein, but will require reagent blanks to compensate for the impurities. At later stages of the monitoring, the Bradford reagent will be chosen because of its greater sensitivity and detection of smaller concentrations. It will be chosen over the Folins reagent because the Bradford reagent is not affected by buffer

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	reagents and detergent. **Biomedical** A technician is asked to detect, identify and quantify a blood group antibody using a range of physical, chemical and immunological tests. During the test evaluation and selection process he/she identifies performance parameters, such as test tolerance, sensitivity, specificity and reproducibility along with the effect of possible interfering serum pigments, such as dissolved haemoglobin and bilirubin. The technician prepares a report for the supervising scientist that explains the selection rationale, reports the performance test results and cites product information and recent literature to validate the test results and substantiate his/her conclusions and recommendations. **Food processing** A technician working in a food company must be able to select test methods appropriate to requirements. For example, if a quick determination of unsaturation in an oil mixture is required, the technician will probably use an appropriate method for determining the iodine value of the mix and compare this with specification. However, at a margarine manufacturing plant where the technician may be required to perform an analysis of fats and oils to determine the % saturated, % monounsaturated and % polyunsaturated components, then a gas chromatographic method would be run using appropriate computer software and the results checked against specification.

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 2243 Set:2006 Safety in laboratories set
	• 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
	• Australia New Zealand Food Standards (ANZFS) Code

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	• Australian code of good manufacturing practice for medicinal products (GMP) • Australian Dangerous Goods Code • Australian Quarantine and Inspection Service (AQIS) Export Control (Orders) Regulations 1982 and Import Guidelines • 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 GLP • quality manuals, equipment and procedures manuals • Therapeutic Goods Regulations 1009
Tests and procedures	Tests and procedures may be: • routine • infrequent • 'one-off' • quantitative or qualitative • identification or quantification of biological, chemical or physical activity • gross characteristics of a sample, including in vitro and in vivo • detection of chemical, physical or biological characteristics, features, markers or responses
Drivers for the evaluation and selection of test methods and/or procedures	Drivers for the evaluation and selection of test methods and/or procedures may include the: • new or amended legislation, regulation and licensing, accreditation requirements • public, political and commercial pressures • 'one-off' testing of potentially hazardous or contaminated materials following an

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	environmental emergency or incident • introduction of new reference standards, new or modified equipment and instruments • introduction of commercial products that are potentially hazardous • control of new, or changed, starting materials, in-process materials and products • troubleshooting of production, environmental and public health issues • environmental monitoring of new sites • investigation of customer's complaints • specialised testing of forensic, medical or veterinary samples • need to meet customer specific or changed requirements • development of new products
Factors which may influence method evaluation and selection	Factors which may influence method evaluation and selection • quantity and nature of sample available for testing • levels of detection required • type of matrix, possible contaminants and resulting interference • safety • availability of suitable equipment, instruments and availability of trained staff • cost • selectivity of method, range, accuracy, precision and acceptable uncertainty • whether it is appropriate/ethical to perform the test • balancing customer, enterprise and/or regulatory/licensing requirements
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

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	• 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

Competency field

Competency field	

Co-requisite units

Co-requisite units		