



Australian Government

Department of Education, Employment and Workplace Relations

MSL977003A Contribute to validation of test methods

Revision Number: 1

MSL977003A Contribute to validation of test methods

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the ability to validate test methods following defined protocols to ensure that they are based on sound scientific principles and are fit for the purpose for which they are to be used.
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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 are performed in accordance with laboratory and/or enterprise procedures. Validation includes all those procedures which ascertain a method's technical soundness, performance and suitability for its intended use. Validation is a documented program which provides a high degree of assurance that a specific testing method will consistently produce a reliable result. The nature of the testing method may be physical, chemical, microbiological or a combination of these. The quality of the test method is built in during its design stage, validated in its development stage, and confirmed in its 'use' stage. 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. Confirm equipment, including computer systems, has been qualified and validated	1.1. Confirm that latest editions of manufacturer's specifications and operating instructions are present 1.2. Confirm that equipment is installed according to manufacturer's specifications 1.3. Confirm that equipment operating instructions exist and conform to manufacturer's specifications 1.4. Confirm that equipment operates according to manufacturer's design specifications 1.5. Verify that equipment calibration complies with appropriate standards 1.6. Confirm equipment/computer systems are validated 1.7. Confirm method has an acceptable level of uncertainty
2. Validate test method according to defined protocol	2.1. Develop validation test protocol in consultation with appropriate personnel 2.2. Ensure protocol is authorised by appropriate personnel 2.3. Validate test method according to validation protocol
3. Evaluate and record results	3.1. Evaluate validation results to confirm suitability of testing method 3.2. Obtain approval for evaluation recommendations from appropriate personnel 3.3. Record and file validation records 3.4. Issue validated method according to enterprise procedures 3.5. Evaluate staff training needs and record appropriately 3.6. Recommend update of relevant documentation as a result of the validation

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

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

Required skills

Required skills include:

- validating test methods as fit for purpose following a validation protocol established in consultation with appropriate personnel
- conducting literature searches on background chemistry/physics/biology/immunology of materials to be evaluated, including likely impurities and degradation products
- starting up, setting up/optimising, calibrating and operating equipment to manufacturer's specifications
- preparing test samples and standards for validation
- carrying out validation tests according to the validation protocol
- applying theoretical knowledge and appropriate statistics to interpret validation data and reach correct conclusions
- recording results and communicating recommendations according to enterprise procedures
- arranging large amounts of data into logical format so other technical personnel can review and reach the same valid conclusions
- following occupational health and safety (OHS) and environmental management procedures and principles of good laboratory practice (GLP)

Required knowledge

Required knowledge includes:

- principles, concepts and enterprise/regulatory requirements related to method validation
- traceability, including legal requirements for traceability
- principles and procedures of testing equipment operation
- characteristics, capabilities and limitations of equipment
- variables which should be validated and criteria for choice
- mathematical/statistical evaluation of results and present data and results in appropriate formats
- enterprise/regulatory requirement regarding validation and reporting
- 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:

- validate test methods as fit for purpose following a validation protocol established in consultation with appropriate personnel
- conduct literature searches on background chemistry/physics/biology/immunology of materials to be evaluated, including likely impurities and degradation products
- start up, set up/optimize, calibrate and operate equipment to manufacturer's specifications
- prepare test samples and standards for validation
- carry out validation tests according to the validation protocol
- apply theoretical knowledge and appropriate statistics to interpret validation data and reach correct conclusions
- record results and communicate recommendations according to enterprise procedures
- arrange large amounts of data into logical format so other technical personnel can review and reach the same valid conclusions
- follow OHS and environmental management 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:

- *MSL977001A Contribute to the development of products and applications*
- *MSL977002A Troubleshoot equipment and production processes*
- *MSL977004A Develop or adapt analyses and procedures*
- *MSL925002A Analyse measurements and estimate uncertainties.*

EVIDENCE GUIDE	
	Resources may include: • standard laboratory equipped with appropriate equipment, reagents, samples and test methods • validation protocol.
Method of assessment	The following assessment methods are suggested: • completion of validation brief or validation proficiency test • review of workplace validation briefs completed by the candidate • feedback from supervisors and/or clients • oral or written questioning to assess underpinning knowledge of equipment operation, methods and 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 A technical specialist was developing a method for testing samples taken while monitoring a workplace for glutaraldehyde, a toxic chemical. The samples were collected in air monitoring cassettes and on glass fibre filters impregnated with 2,4-dinitrophenylhydrazine. The filters were desorbed with acetonitrile and the DNPH derivative analysed by highperformance liquid chromatography (HPLC) at 365nm. The new method was

EVIDENCE GUIDE

validated by checking and documenting factors, such as selectivity, linearity, range, limit of detection, accuracy, precision, recovery and ruggedness. Although this involved considerable work, the specialist was confident that the testing method would deliver reliable results after completing the validation.

Biomedical

A number of pituitary hormone assays are to be converted from radioimmunoassay (RIA) to enzyme linked immunosorbent assay (ELISA). Both configurations of assays are available in kit form but the laboratory manager would like the new procedures validated. The task has been given to a senior technical officer. The project involves comparison of the average and variance of results obtained for a number of quality control sera. The variance and precision of the signal output (counts per minute for RIA, absorbance for ELISA) are examined as well as sensitivity estimates for both assays. All investigations are documented and reported in the laboratory notes for accreditation audit purposes.

Food processing

A food research laboratory uses the following instrumental techniques:

- ultraviolet-visible (UV-VIS) spectrometer for colour analysis
- HPLC for food preservative analysis
- inductively coupled plasma-atomic emission spectrometry and flame atomic absorption analysis for metal contaminant analysis.

Each of the above methods is validated to assure that it is based on sound scientific principles and will deliver results appropriate to requirements. Factors, such as accuracy, linearity, range, limit of detection, precision, recovery, ruggedness and selectivity are evaluated and documented. This investigation provides confidence that methods are used within their limits of detection, are linear and selective over the required range, and deliver suitable accuracy and precision. The investigation is documented, according to enterprise requirements, and provides detailed reference for accreditation, audit and future laboratory use.

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 10013-2003 Guidelines for quality management system documentation
 - 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
- *Guidelines for collaborative study procedures*

RANGE STATEMENT	
	<i>to validate characteristics of a method of analysis</i>, Fourth (Final) Draft; J. of Anal. Chem., Vol 72, No 4, 694-704 • ICH Q2A: Validation of Analytical Procedures - Guideline for industry • United States Pharmacopoeia (USB) General chapter - Validation of Compendial Methods (1225) • OHS national standards and codes of practice • principles of good laboratory practice (GLP) • Australia New Zealand Food Standards (ANZFS) Code • 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 • gene technology regulations • maintenance and confidentiality of records • 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 • Therapeutic Goods Regulations 1009
Test methods requiring validation	Test methods requiring validation may include: • identification and impartial resolution of ethical issues, such as conflict of interest • ethical decision making • provision of products and services which match the operational and financial needs of stakeholders, including realistic quotes for work • accurate representation of skills, services, knowledge and qualifications of individuals and the organisation • acknowledgment of services and products developed by others, intellectual property and copyright

RANGE STATEMENT	
	• provision of unbiased, accurate and appropriately qualified information results
Validation protocols include:	Validation protocols include: • those checks which should be considered to ensure performance characteristics of test method are scientifically sound • examples of checks include: • selectivity • linearity • range • sensitivity • limit of detection • limit of quantitation • accuracy • precision • recovery • ruggedness • an assessment of the clarity and completeness of the description of the method
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		