



Australian Government

MSL916001 Develop and maintain laboratory documentation

Release: 1

MSL916001 Develop and maintain laboratory documentation

Modification History

Release 1. Supersedes and is equivalent to MSL916001A Develop and maintain laboratory documentation

Application

This unit of competency covers the ability to develop and maintain relevant documentation and systems in response to identified information requirements or changes in laboratory policy or external accreditation requirements. It includes the analysis of specialised technical requirements and the development and/or amendment of workplace documents, procedures and record keeping systems using established workplace procedures. Final responsibility for documentation and systems generally rests with professional scientific/medical/engineering staff who have the appropriate signatory status or legal delegation.

This unit of competency is applicable to technical officers and laboratory supervisors working in all industry sectors.

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

Nil

Competency Field

Communication/organisation

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 | Recognise documentation needs/deficiencies | 1.1 | Evaluate current documentation to identify instances where documentation is needed or deficient |
| | | 1.2 | Analyse development opportunities and discuss with appropriate personnel to assess and confirm requirements |

2	Develop/revise documentation	2.1	Specify documentation need and set/prioritise objectives
		2.2	Analyse existing documentation/records in accordance with specified requirements
		2.3	Develop/amend documentation as a draft in accordance with review requirements
		2.4	Issue documentation to appropriate personnel for review
		2.5	Edit documentation to ensure that the initial identified need/deficiency and review requirements are satisfied
		2.6	Recall superseded documentation and issue new documentation in accordance with document control procedures
3	Implement and evaluate new laboratory documentation	3.1	Brief personnel on new/revised documentation to ensure successful implementation of new procedures
		3.2	Monitor and evaluate implementation of new/revised documentation and amend documents or provide training, if required

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 competence of testing and calibration laboratories, laboratory safety, and quality and environmental management
- work health and safety (WHS) national standards and codes of

practice

- registration/licensing and/or National Association of Testing Authorities (NATA) accreditation requirements
- codes, guidelines, procedures and specific method collections for industry sectors such as:
 - Association of Analytical Communities International (AOAC International) Official Methods of Analysis
 - Australian code of good manufacturing practice for medicinal products (GMP), principles of good laboratory practice (GLP)
 - Australia New Zealand Food Standards (ANZFS) Code
 - Australian Dangerous Goods Code
 - gene technology regulations

Workplace documentation

Workplace documentation includes one or more of:

- instructions to comply with new legislation, standards, guidelines, codes and permits
- plans covering management of laboratory services, quality, environment, training and maintenance
- workplace procedures; standard operating procedures (SOPs) and operating manuals; instructions for equipment installation, commissioning, calibration and maintenance; and waste minimisation and disposal
- safety requirements for equipment, materials or products; risk evaluation, monitoring or control procedures; and incident and accident/injury reports
- test procedures, sampling procedures (sampling, preparation, labelling, storage, transport and disposal), methods for extraction or manufacture of a product, and procedures for evaluation of materials or products
- compliance/non-compliance reports, quality system and continued improvement processes
- cleaning, hygiene and personal hygiene requirements
- schematics/workflows/laboratory layouts
- stock records/inventory
- training program contents

Record keeping systems

Record keeping systems include:

- online information systems, databases, record and filing systems

Personnel

Personnel include one or more of:

- supervisors and managers (laboratory, quality and customer service), and laboratory or production personnel
- members of the public, customers and suppliers
- external auditors, regulation and licensing/accreditation authorities, such as National Association of Testing Authorities (NATA), if within limits of responsibility and authority

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

Release 1. Supersedes and is equivalent to MSL916001A Develop and maintain laboratory documentation

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 MSL916001 Develop and maintain laboratory documentation

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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:

- recognising problems in workplace documentation and systems
- analysing, developing and maintaining workplace documentation and systems in response to identified information requirements or changes in laboratory policy or external accreditation requirements
- developing and amending workplace documents and systems using established workplace procedures
- producing documentation that is accurate and meets specifications, free from editorial errors and omissions, and understood by others
- using internal and external information sources efficiently
- critically analysing information
- obtaining and incorporating relevant feedback on draft documentation
- communicating information and developments effectively
- completing the preparation and distribution of documentation in the given timeframe.

Knowledge Evidence

Must provide evidence that demonstrates knowledge of:

- the laboratory's business goals, key performance indicators (KPIs), organisational structure, delegations and responsibilities
- how work health and safety (WHS), environmental, registration/accreditation and other legislative requirements, regulations and codes govern laboratory documentation
- standard operating procedures (SOPs) relevant to the laboratory's operations and scope of testing
- scientific, technical and workplace terminology; and technical developments in the sector (such as current methodologies, ranges and interpretations)
- workplace procedures for developing/amending and tracking documentation; records management and maintenance
- workplace communication protocols and reporting.

Assessment Conditions

- Judgement 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:
 - MSL916004 Maintain registration and statutory or legal compliance in work or functional area
 - MSL936001 Maintain quality system and continuous improvement processes within work or functional area
 - MSL946001 Implement and monitor WHS and environmental management systems
- Holistic assessment methods include:
 - examination of workplace documentation amended and developed by the candidate
 - feedback from peers and supervisors that documentation developed by the candidate is accurate and user friendly and that workplace procedures were followed.
- Access is required to instruments, equipment, materials, workplace documentation, procedures and specifications associated with this unit, including, but not limited to:
 - information directories and databases
 - workplace documents and procedures.
- 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 competency 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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