



Australian Government

MSL916004 Maintain registration and statutory or legal compliance in work or functional area

Release: 1

MSL916004 Maintain registration and statutory or legal compliance in work or functional area

Modification History

Release 1. Supersedes and is equivalent to MSL916004A Maintain registration and statutory or legal compliance in work/functional area

Application

This unit of competency covers responsibility for the day-to-day operation of the work or functional area and its compliance with legislation and licensing, registration, ethical or accreditation requirements, e.g. National Association of Testing Authorities (NATA), and workplace policies and procedures.

This unit of competency is applicable to senior technical officers and laboratory supervisors in all industry sectors. While statutory or legal compliance is the responsibility of all personnel, supervisors have an important leadership role in promoting and monitoring workplace practices that enhance compliance. They work under broad supervision of scientists/medical staff/engineers.

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.

1	Interpret and communicate current legislation, codes and standards	1.1	Maintain knowledge of current and new requirements impacting on work/functional area
		1.2	Distribute clear information regarding the roles and responsibilities of teams and individuals to maintain the laboratory's statutory or legal compliance

- | | | | |
|---|--|-----|---|
| | | 1.3 | Explain the implications of non-conformance to all personnel within the work area |
| 2 | Ensure that work practices meet compliance requirements | 2.1 | Plan work practices to ensure compliance with relevant legislation and licensing, registration, ethical or accreditation requirements |
| | | 2.2 | Ensure that calibration and testing procedures are implemented so that equipment and methods are fit for purpose and reliable |
| | | 2.3 | Empower team members through coaching and mentoring to manage their responsibilities |
| 3 | Monitor, analyse, adjust and report performance | 3.1 | Ensure that actual and potential problems are identified, rectified and reported promptly to ensure workplace compliance |
| | | 3.2 | Analyse and supervise activities so that potential non-compliance is minimised |
| | | 3.3 | Recommend to designated personnel, strategies to improve compliance |
| | | 3.4 | Ensure that individuals/teams are informed of new and improved procedures |
| | | 3.5 | Maintain systems, records and reporting procedures according to legislative and licensing, registration, ethical or accreditation requirements and workplace procedures |
| 4 | Investigate, rectify and report non-conformance | 4.1 | Investigate and deal with non-conformance according to legislative and licensing, registration or accreditation requirements and workplace procedures |
| | | 4.2 | Provide on/off-the-job training for personnel to acquire and apply competencies to meet legislative and licensing, registration or ethical accreditation requirements |
| | | 4.3 | Re-design or adjust workplace practices to ensure that non-conformance is not repeated |

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 of more of:

- Australian and international standards covering the competence of testing and calibration laboratories, laboratory design and construction, laboratory safety, and quality and environmental management
- registration/licensing and/or National Association of Testing Authorities (NATA) accreditation requirements
- national work health and safety (WHS) standards and codes of practice, and national environment protection measures
- Australian and international standards, codes and guidelines covering measurement management, accuracy of measurement methods and results, expression of uncertainty (GUM) and principles of good laboratory practice (GLP)
- industry specific codes, guidelines, procedures and methods such as:
 - National Health and Medical Research Council (NHMRC) Guidelines
 - Association of Analytical Communities International (AOAC International) Official Methods of Analysis
 - Australian code of good manufacturing practice for medicinal products (GMP), and Therapeutic Goods Regulations
 - Australia New Zealand Food Standards (ANZFS) Code
 - Australian Dangerous Goods Code
 - gene technology regulations
 - animal welfare legislation and codes of practice
- legislation and regulations covering intellectual property (IP) and copyright, freedom of information, human rights and equal

opportunity, privacy and industrial relations

Workplace policy and procedures

Workplace policy and procedures include one or more of:

- operation of representative work groups/committees (ethics and WHS)
- audit requirements
- maintenance and confidentiality of laboratory records
- maintenance of certified reference materials
- maintenance of records of breaches

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 MSL916004A Maintain registration and statutory or legal compliance in work/functional area

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 MSL916004 Maintain registration and statutory or legal compliance in work or functional area

Modification History

Release 1. Supersedes and is equivalent to MSL916004A Maintain registration and statutory or legal compliance in work/functional area

Performance Evidence

Evidence of competence in this unit must satisfy all of the requirements of the elements and performance criteria, and include demonstration of:

- monitoring day-to-day operations of the work/functional area
- analysing results and long-term trends in data
- monitoring, analysing and changing work practices to ensure compliance with workplace requirements, legal requirements and relevant policies and procedures
- making improvements to rectify potential problems or instances of non-conformance
- providing information and training about roles, responsibilities and workplace procedures dealing with legal/statutory requirements
- providing coaching and mentoring support to personnel to change work practices
- communicating effectively with others who may have diverse work styles, cultures and perspectives
- keeping records complete, current and secure.

Knowledge Evidence

Must provide evidence that demonstrates knowledge of:

- workplace procedures governing document control, record management, communication and reporting, and internal and external audits
- scientific technical terminology used to describe legislative, licensing or registration requirements (e.g. traceability)
- legal, ethical and welfare issues associated with laboratory and technical work
- role, structure and responsibilities of ethics committees
- statutory and legal compliance requirements
- relevant work health and safety (WHS) and environment requirements.

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 must be assessed in a laboratory environment that either meets Australian standards for working laboratories or is accredited by the National Association of Testing Authorities (NATA) or the Royal College of Pathology, as appropriate.

- 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:
 - MSL915001 Provide information to customers
 - MSL916001 Develop and maintain laboratory documentation
 - MSL916003 Supervise laboratory operations in work or functional area
- Holistic assessment methods include:
 - review of verified records and reports generated by the candidate
 - feedback from managers regarding the candidate's ability to implement workplace compliance procedures
 - review of information developed by the candidate and provided to the work group about compliance requirements
 - observation of the candidate's interactions with personnel.
- Access is required to instruments, equipment, materials, workplace documentation, procedures and specifications associated with this unit, including, but not limited to:
 - laboratory equipped with appropriate equipment, instruments, services and consumables
 - relevant workplace policies, procedures, operational reports, financial reports and stock records
 - technical manuals, standard operating procedures (SOPs), quality manuals and quality system documentation.
- 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.

Links

Companion Volume implementation guides are found in VETNet -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=5c63a03b-4a6b-4ae5-9560-1e3c5f462baa>