



Australian Government

MSL936001 Maintain quality system and continuous improvement processes within work or functional area

Release: 1

MSL936001 Maintain quality system and continuous improvement processes within work or functional area

Modification History

Release 1. Supersedes and is equivalent to MSL936001A Maintain quality system and continuous improvement processes within work/functional area

Application

This unit of competency covers responsibility for the day-to-day operation of the work or functional area and ensuring that quality system requirements are met and continuous improvements are initiated.

This unit of competency is applicable to senior technical officers and laboratory supervisors working in all industry sectors. Quality audits and evaluations for the work area may be undertaken as an individual or as part of a team under broad direction from 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

Quality

Unit Sector

Elements and Performance Criteria

Elements describe the essential outcomes.

Performance criteria describe the performance needed to demonstrate achievement of the element.

1	Develop and maintain quality framework within work area	1.1	Distribute and explain information about the workplace's quality system to personnel
		1.2	Encourage personnel to participate in improvement processes and to assume responsibility for quality outputs
		1.3	Allocate responsibilities for quality within work area in

			accordance with quality system
		1.4	Provide coaching and mentoring to ensure that personnel are able to meet their responsibilities and quality requirements
2	Maintain quality documentation	2.1	Identify required quality documentation, including records of improvement plans and initiatives
		2.2	Prepare and maintain quality documentation and keep accurate data records
		2.3	Maintain document control system for work area
		2.4	Contribute to the development and revision of quality manuals and work instructions for the work area
		2.5	Develop and implement inspection and test plans for quality controlled products
3	Provide training in quality systems and improvement processes	3.1	Analyse roles, duties and current competency of relevant personnel
		3.2	Identify training needs in relation to quality system and continuous improvement processes
		3.3	Identify opportunities for skills development and/or training programs to meet needs
		3.4	Initiate and monitor training and skills development programs
		3.5	Maintain accurate training records
4	Optimise and report performance	4.1	Review performance outcomes to identify ways in which planning and operations could be improved
		4.2	Enhance customer service through the use of quality improvement techniques and processes
		4.3	Adjust plans and communicate these to personnel involved in their development and implementation

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| 5 | Evaluate relevant components of quality system | 5.1 | Undertake regular audits of components of the quality system that relate to the work area |
| | | 5.2 | Implement improvements in the quality system in accordance with own level of responsibility and workplace procedures |

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, codes and guidelines covering the competence of testing and calibration laboratories, laboratory design and construction, laboratory safety, quality management systems, documentation and plans, environmental management, measurement management, accuracy of measurement methods and results, expression of uncertainty (GUM) and principles of good laboratory practice (GLP)
- national standards and codes of practice for work health and safety (WHS), and national environment protection measures
- national measurement regulations and guidelines
- registration/licensing and/or National Association of Testing Authorities (NATA) accreditation requirements
- 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
- gene technology regulations
- animal welfare legislation and codes of practice
- workplace documents, such as standard operating procedures (SOPs); quality and equipment manuals; calibration and maintenance schedules; material safety data sheets (MSDS) and safety procedures; material, production and product specifications; production and laboratory schedules; workplace recording and reporting procedures; and waste minimisation and safe disposal procedures
- customer-specific product specifications and quality requirements

Quality audits

Quality audits include one or more of:

- regular checks of laboratory procedures
- daily and weekly checks of specimen reception, instrumentation and results for control and standard samples to identify non-conformance and problem areas
- maintenance of appropriate certified reference materials
- participation in external quality assurance programs

Communication

Communication includes one or more of:

- liaising with supervisors, managers and quality managers, laboratory and production staff, customers and suppliers
- providing information, coaching and/or training about quality systems and plans, standards, codes and work practices
- recording information and preparing reports
- liaising with auditors and reporting to regulating authorities

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 MSL936001A Maintain quality system and continuous improvement processes within 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 MSL936001 Maintain quality system and continuous improvement processes within work or functional area

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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:
- ensuring that the quality system requirements of day-to-day operations in the work area are met
- implementing, monitoring and evaluating quality system requirements and initiating continuous improvements within the work area
- applying effective problem identification, problem solving and quality improvement techniques
- gaining commitment of individuals and teams to apply quality principles and practices
- using quality improvement techniques to enhance internal and external customer service
- encouraging ideas and feedback from team members when developing and refining techniques and processes
- analysing training needs and implementing coaching and/or training programs to enhance the performance of individuals and teams
- communicating effectively with supervisors, managers, laboratory and/or production personnel and customers about quality requirements

preparing and maintaining quality and audit documentation.

Knowledge Evidence

Must provide evidence that demonstrates knowledge of:

- workplace business goals and key performance indicators (KPIs)
- workplace organisational structure, delegations and responsibilities, and information management systems
- relevant sections of national and international quality standards, codes and protocols that apply in work area
- workplace quality system, plans and documentation
- continuous/quality improvement techniques, such as Pareto charts; strengths, weakness, opportunities, threats (SWOT) analysis; and plan, do, check, act (PDCA)
- standard operating procedures (SOPs) for the technical work performed in work area
- workplace policy and procedure development processes
- workplace communication, recording and reporting procedures
- 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
 - MSL916004 Maintain registration and statutory or legal compliance in work or functional area
 - MSL916001 Develop and maintain laboratory documentation
- Holistic assessment methods include:
 - review of quality documentation prepared and maintained by the candidate
 - review of verified reports of improvement initiatives and/or projects conducted by the candidate
 - review of audit processes and outcomes generated by the candidate
 - review of information and training resources prepared by the candidate for personnel in the work area
 - feedback from peers and team members about the candidates ability to encourage participation and provide useful information, coaching and training
 - feedback from supervisors, managers and/or customers that the quality system requirements of day-to-day operations are met in the work area
 - observation of the candidate leading a quality improvement team
 - questions to assess required knowledge of quality systems, documentation, quality tools, continuous improvement processes and relevant workplace procedures.
- Access is required to all instruments, equipment, materials, workplace documentation, procedures and specifications associated with this unit, including, but not limited to:
 - documentation, such as sampling plans, workplace quality manual, quality (certification or registration) requirements, quality and customer data, audit documents, performance plans and reports, and training records and/or plans
 - workplace procedures relating to WHS, equal opportunity, environmental legislative requirements, and industrial awards and workplace agreements.
- 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 competence 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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