



Australian Government

MSL934002 Apply quality system and continuous improvement processes

Release: 1

MSL934002 Apply quality system and continuous improvement processes

Modification History

Release 1. Supersedes and is equivalent to MSL934002A Apply quality system and continuous improvement processes

Application

This unit of competency covers the exercise of good laboratory practice (GLP) and effective participation in quality improvement teams. Personnel are required to ensure the quality and integrity of their own work, detect non-conformances and work with others to suggest improvements in productivity and quality.

This unit of competency is applicable to laboratory technicians working in all industry sectors who contribute to quality improvements in areas or processes associated with their own job function and/or specialisation. This unit of competency is relevant to experienced technical officers who may work individually or as part of a team.

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	Satisfy quality system requirements in daily work	1.1	Access information on quality system requirements for own job function
		1.2	Record and report quality control data in accordance with quality system
		1.3	Follow quality control procedures to ensure products or data are of a defined quality as an aid to acceptance or

		rejection
	1.4	Recognise and report non-conformances or problems
	1.5	Conduct work in accordance with sustainable work practices
	1.6	Promote sustainability principles and work practices to other workers
2	Analyse opportunities for corrective and/or optimisation action	2.1 Compare current work practices, procedures and process or equipment performance with requirements and/or historical data or records 2.2 Recognise variances that indicate abnormal or sub-optimal performance 2.3 Collect and/or evaluate batch and/or historical records to determine possible causes for sub-optimal performance 2.4 Use appropriate quality improvement techniques to rank the probabilities of possible causes
3	Recommend corrective and/or optimisation actions	3.1 Analyse causes to predict likely impacts of changes and decide on the appropriate actions 3.2 Identify required changes to standards and procedures and training 3.3 Report recommendations to designated personnel
4	Participate in the implementation of recommended actions	4.1 Implement approved actions and monitor performance following changes to evaluate results 4.2 Implement changes to systems and procedures to eliminate possible causes 4.3 Document outcomes of actions and communicate them to relevant personnel
5	Participate in the development of	5.1 Review all relevant features of work practice to identify possible contributing factors leading to sub-optimal

continuous improvement strategies		performance
	5.2	Identify options for removing or controlling the risk of sub-optimal performance
	5.3	Assess the adequacy of current controls, quality methods and systems
	5.4	Identify opportunities to continuously improve performance
	5.5	Develop recommendations for continual improvements of work practices, methods, procedures and equipment effectiveness
	5.6	Consult with appropriate personnel to refine recommendations before implementation of approved improvement strategies
	5.7	Document outcomes of strategies and communicate them to relevant personnel

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 requirements for the competence of testing and calibration laboratories, quality management systems and plans, measurement management, and sampling and testing • national work health and safety (WHS) standards and codes of practice, and National Association of Testing Authorities (NATA) accreditation program requirements • national measurement regulations and guidelines
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- specific codes, regulations guidelines, procedures and methods, such as Australia New Zealand Food Standards (ANZFS) Code, Australian code of good manufacturing practice for medicinal products (GMP), principles of good laboratory practice (GLP), National Health and Medical Research Council (NHMRC) Guidelines, and Therapeutic Goods Regulations
- 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 requirements/standards

Quality control procedures

Quality control procedures include one or more of:

- standards imposed by regulatory and licensing bodies
- working to a customer brief or batch card and associated quality procedures
- checklists to monitor job progress against agreed time, costs and quality standards
- preparation of sampling plans
- the use of hold points to evaluate conformance
- the use of inspection and test plans to check compliance

Sustainable work practices

Sustainable work practices include, but are not limited to, one or more of:

- examining work practices that use excessive electricity
- switching off equipment when not in use
- regularly cleaning filters
- insulating rooms and buildings to reduce energy use
- recycling and reusing materials wherever practicable
- minimising process waste

Quality improvement tools and techniques

Quality improvement tools and techniques include using one or more of:

- plan, do, check, act (PDCA)
- Ishikawa fishbone diagrams and cause and effect diagrams, logic tree, similarity/difference analysis, Pareto charts and analysis, force field/strength, weakness, opportunities, threats (SWOT) analysis

- run charts, control charts, histograms and scattergrams to present routine quality control data
- statistical analysis of quality control data, mean, median, mode, ranges and standard deviations

Communication

Communication includes interactions with one or more:

- supervisors, managers and quality managers
- administrative, laboratory and production personnel
- internal/external contractors, customers and suppliers

Quality improvement opportunities

Quality improvement opportunities include, but are not limited to, one or more of:

- production processes
- hygiene and sanitation procedures
- reductions in waste and re-work
- laboratory layout and work flow
- safety procedures
- communication with customers
- methods for sampling, testing and recording data

Documenting and reporting information about quality

Documenting and reporting information about quality includes, but are not limited to, one or more of:

- verbal responses
- data entry into laboratory or workplace database
- brief written reports using workplace proformas

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

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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 MSL934002 Apply quality system and continuous improvement processes

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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:
- applying relevant quality control procedures and regulatory requirements to ensure the quality and integrity of the products/services or data provided in work area
- applying and promoting sustainability principles and work practices in work area
- detecting non-conforming products or services and recognising opportunities for improvements in work area
- using at least three (3) quality improvement tools and techniques to analyse performance in work area
- applying effective problem-solving strategies, such as identifying inputs and outputs, sequencing a process, identifying and rectifying a problem step, and root cause analysis
- following workplace procedures for recording and reporting information about quality
- implementing and monitoring approved actions, changes and improvement strategies

consulting and working with other team members to suggest improvements in productivity and quality.

Knowledge Evidence

Must provide evidence that demonstrates knowledge of:

- business goals and quality requirements associated with job function and/or work area as a basis for decision making and action
- scientific and technical requirements of the processes, procedures, equipment and instrumentation associated with the candidate's work tasks and duties
- specifications for laboratory products and services in the work area
- sustainable energy principles
- workplace procedures associated with the candidate's regular technical duties
- layout of the workplace, divisions and laboratory
- organisational structure of the workplace
- lines of communication
- role of laboratory services to the workplace and customers
- 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 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:
 - MSL924001 Process and interpret data
 - MSL954001 Obtain representative samples in accordance with sampling plan
 - relevant MSL974000 series units of competency
 - relevant MSL975000 series units of competency
- Holistic assessment methods include:
 - review of documentation completed by the candidate as part of regular quality control
 - feedback from supervisors and/or customers regarding quality of products/services and/or data regularly provided by the candidate
 - observation of the candidate's performance and participation in quality improvement teams over time in the workplace
 - review of reports from quality improvement teams where the candidate's role is clearly outlined and verified
 - verified reports of improvements suggested and implemented by the candidate individually
 - use of suitable simulations and/or a pilot plant and/or a range of quality improvement case studies and scenarios.
- Access is required to instruments, equipment, materials, workplace documentation, procedures and specifications associated with this unit, including, but not limited to:
 - workplace quality manual and procedures, quality control data/records
 - customer complaints and rectifications.
- 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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