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

- 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