Australian Government

Department of Education, Employment and Workplace Relations

MSL934002A Apply quality system and continuous improvement processes

Revision Number: 1

MSL934002A Apply quality system and continuous improvement processes

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the exercise of good laboratory practice 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.

Application of the Unit

Application of the unit	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. Industry representatives have provided case studies to illustrate the practical application of this unit of competency and to show its relevance in a workplace setting. These are found at the end of this unit of competency under the section 'This competency in practice'.

Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		

Employability Skills Information

Employability skills	This unit contains employability skills.

Elements and Performance Criteria Pre-Content

Elements describe the essential outcomes of a unit of competency.	Performance criteria describe the performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge section and the range statement. Assessment of performance is to be consistent with the evidence guide.

Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
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 energy work practices 1.6. Promote sustainable energy 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 continuous improvement strategies	5.1. Review all relevant features of work practice to identify possible contributing factors leading to sub-optimal performance 5.2. Identify options for removing or controlling the risk of sub-optimal performance

ELEMENT	PERFORMANCE CRITERIA
	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

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

This section describes the skills and knowledge required for this unit.

Required skills

Required skills include:

- applying problem solving techniques and strategies
- applying statistical analysis and statistical sampling procedures
- detecting non-conforming products or services in the work area
- documenting and reporting information about quality
- contributing effectively within a team to recognise and recommend improvements in productivity and quality
- implementing and monitoring improved practices and procedures

Required knowledge

Required knowledge includes:

- specifications for laboratory products and services in the candidate's work area
- quality requirements associated with the individual's job function and/or work area
- scientific and technical knowledge underpinning the processes, procedures, equipment and instrumentation associated with the candidate's work tasks and duties
- workplace procedures associated with the candidate's regular technical duties
- sustainable energy principles
- relevant health, safety and environment requirements
- layout of the enterprise, divisions and laboratory
- organisational structure of the enterprise
- lines of communication
- role of laboratory services to the enterprise and customers

Specific industry

Additional knowledge requirements may apply for different industry sectors. For example:

Biomedical sector:

- ethical requirements dealing with patient confidentiality
- animal welfare legislation and codes of practice
- guidelines for pre-transfusion testing
- gene technology regulations for large scale, small scale and planned release of genetically manipulated organisms

Evidence Guide

EVIDENCE GUIDE	
The Evidence Guide provides advice on assessment and must be read in conjunction with the performance criteria, required skills and knowledge, range statement and the Assessment Guidelines for the Training Package.	
Overview of assessment	
Critical aspects for assessment and evidence required to demonstrate competency in this unit	Assessors should ensure that candidates can: • use the enterprise's quality systems and business goals as a basis for decision making and action • apply all relevant procedures and regulatory requirements to ensure the quality and integrity of the products/services or data provided • apply and promote sustainable energy principles and work practices • detect non-conforming products or services in the work area • follow enterprise procedures for documenting and reporting information about quality • contribute effectively within a team to recognise and recommend improvements in productivity and quality • apply effective problem solving strategies • implement and monitor improved practices and procedures.
Context of and specific resources for assessment	This unit of competency is to be assessed in the workplace or simulated workplace environment. This unit of competency may be assessed with: • *MSL924001A Process and interpret data* • *MSL954001A Obtain representative samples in accordance with sampling plan* • *relevant MSL974000 series units of competency* • *relevant MSL975000 series units of competency*. Resources may include: • enterprise quality manual and procedures • quality control data/records • customer complaints and rectifications • candidate's supervisors and peers.
Method of assessment	The following assessment methods are suggested: • review of documentation completed by the candidate

EVIDENCE GUIDE	
	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. Those aspects of competency dealing with improvement processes could be assessed by the use of suitable simulations and/or a pilot plant and/or a range of case studies and scenarios. In all cases, practical assessment should be supported by questions to assess essential knowledge and those aspects of competency which are difficult to assess directly. Where applicable, reasonable adjustment must be made to work environments and training situations to accommodate ethnicity, age, gender, demographics and disability. Access must be provided to appropriate learning and/or assessment support when required. The language, literacy and numeracy demands of assessment should not be greater than those required to undertake the unit of competency in a work like environment.
This competency in practice	Industry representatives have provided the case studies below to illustrate the practical application of this unit of competency and to show its relevance in a workplace setting. **Manufacturing** A quality improvement team at a chemical manufacturing plant was asked to propose a way of minimising the cost of disposing of chromium rich waste. Using appropriate techniques, the team narrowed the alternatives down to the option of burning the waste stream. An experienced technician agreed that this was feasible, but suggested that because the waste was petroleum high in chromium the team should consider

EVIDENCE GUIDE	
	the environmental implications. Subsequent research indicated that the permitted chromium levels in the incinerated air waste stream would not exceed 10 ppm, which was less than the air emission standards for the plant. The technician analysed samples of the air waste stream and determined that the chromium levels were below the regulatory standards. He/she then supported the team's suggestion. **Environmental** The manager of an environmental testing laboratory believed that the team of laboratory technicians relied too much on external direction. As a result, the manager requested that whenever technicians asked for assistance they should also be ready to suggest a solution to the problem if at all possible. This strategy was implemented in a non-threatening manner and was accepted by the team. In time, the manager noted that many of the suggestions for solving problems and improving work practices that came from the team were effective and reasonable. Their skill in making realistic recommendations came from their familiarity with many of the issues that needed to be considered. It became the norm that the laboratory technicians were given public credit for suggesting successful strategies that improved safety, productivity and staff morale. **Food processing** A company that produces apple juice uses 30-35% hydrogen peroxide (H_2O_2) to sterilise packaging. A mist of atomised H_2O_2 is sprayed into pre-formed cartons and later removed with a jet of hot sterile air. The laboratory manager was concerned that some batches of product were not sterile after standing at room temperature for several days. The cause of the failure in the sterilisation procedure was not apparent and a technical officer was asked to investigate this problem. The technical officer examined each unit operation of juice manufacture and determined that the application of H_2O_2 was a critical sterilisation point where failure could occur. The concentration of H_2O_2 in the atomiser and in opened containers was unpredictable and several problems were found to contribute to this. H_2O_2 was left in the atomiser for up to several days between packaging runs. Containers of H_2O_2 were not always used sequentially, some being opened and then not used for a

EVIDENCE GUIDE	
	long time. The containers were stored at room temperature after opening and some may have become contaminated with atmospheric particulates that catalyse the breakdown of H_2O_2. The recommendations that emerged from the investigation were that: • fresh H_2O_2 should be used at the beginning of each packaging run • only one stock container of H_2O_2 should be open at any one time and stored chilled, with residuals discarded after 14 days • care should be taken to exclude foreign material from the opened vessels of H_2O_2 and the atomiser. In summary, the intolerance of the company to even low incidences of faulty product and the competency of the technical officer to investigate the processing stream resulted in increased product quality without significant cost.

Range Statement

RANGE STATEMENT	
The range statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Bold italicised wording, if used in the performance criteria, is detailed below. Essential operating conditions that may be present with training and assessment (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) may also be included.	
Codes of practice	Where reference is made to industry codes of practice, and/or Australian/international standards, it is expected the latest version will be used

Standards, **codes**, **procedures and/or enterprise requirements**	Standards, codes, procedures and/or enterprise requirements may include:
	• Australian and international standards, such as:
	  • AS ISO 17025-2005 General requirements for the competence of testing and calibration laboratories
	  • AS/NZS ISO 10005:2006 Quality management systems - Guidelines for quality plans
	  • AS/NZS ISO 10012:2004 Measurement management systems - Requirements for measurement processes and measuring equipment
	  • AS/NZS ISO 9000 Set:2008 Quality management systems set
	  • AS 1199 Sampling procedures and tables for inspection by attributes
	  • BS 5750 Quality systems
	• Australia New Zealand Food Standards (ANZFS) Code
	• Australian code of good manufacturing practice for medicinal products (GMP)
	• customer specific requirements/standards
	• enterprise and customer product specifications
	• National Association of Testing Authorities (NATA) Accreditation programs requirements
	• National Health and Medical Research Council (NHMRC) Guidelines
	• national measurement regulations and guidelines

RANGE STATEMENT	
	• principles of good laboratory practice (GLP) • quality manuals and procedures • Therapeutic Goods Regulations 1009
Quality control procedures	Quality control procedures may include: • standards imposed by regulatory and licensing bodies • enterprise quality procedures • 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
Methods for statistical analysis	Methods for statistical analysis may include: • means • median • mode • ranges • standard deviations • statistical sampling procedures
Problem solving techniques	Problem solving techniques may include: • identifying inputs and outputs • sequencing a process • identifying and rectifying a problem step • root cause analysis • implementing preventative strategies
Quality improvement tools and techniques	Quality improvement tools and techniques may include: • run charts, control charts, histograms and scattergrams to present routine quality control data • plan, do, check, act (PDCA) • Ishikawa fishbone diagrams and cause and effect diagrams • logic tree • similarity/difference analysis • Pareto charts and analysis

RANGE STATEMENT	
	• force field/strength weakness opportunities threats (SWOT) analysis
Sustainable energy principles and work practices	Sustainable energy principles and work practices may include: • 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
Communication	Communication may involve: • supervisors, managers and quality managers • administrative, laboratory and production personnel • internal/external contractors, customers and suppliers
Reporting	Reporting may include: • verbal responses • data entry into laboratory or enterprise database • brief written reports using enterprise proformas
Quality improvement opportunities	Quality improvement opportunities could include improved: • 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
Occupational health and safety (OHS) and environmental management requirements	OHS and environmental management requirements: • all operations must comply with enterprise OHS and environmental management

RANGE STATEMENT	
	requirements, which may be imposed through state/territory or federal legislation - these requirements must not be compromised at any time • all operations assume the potentially hazardous nature of samples and require standard precautions to be applied • where relevant, users should access and apply current industry understanding of infection control issued by the National Health and Medical Research Council (NHMRC) and State and Territory Departments of Health

Unit Sector(s)

Unit sector	Maintenance

Competency field

Competency field	

Co-requisite units

Co-requisite units		