



Australian Government

Department of Education, Employment and Workplace Relations

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

Release: 1

MSL936001A Maintain quality system and continuous improvement processes within work_functional area

Modification History

Not applicable.

Unit Descriptor

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

Application of the unit	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. 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 can be found at the end of this unit of competency under the section 'This competency in practice'.
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Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		

Employability Skills Information

Employability skills	This unit contains employability skills.
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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.
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Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Develop and maintain quality framework within work area	1.1. Distribute and explain information about the enterprise's quality system to personnel 1.2. Encourage personnel to participate in improvement processes and to assume responsibility and authority 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
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

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

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

Required skills

Required skills include:

- implementing and monitoring defined quality system requirements
- initiating continuous improvements within the work area
- applying effective problem identification and problem solving techniques
- strengthening customer service through a focus on continuous improvement
- implementing, monitoring and evaluating quality systems
- gaining commitment of individuals/teams to quality principles and practices
- implementing effective communication strategies
- encouraging ideas and feedback from team members when developing and refining techniques and processes
- analysing training needs and implementing training programs
- preparing and maintaining quality and audit documentation

Required knowledge

Required knowledge includes:

- communication/reporting protocols
- continuous improvement principles
- enterprise business goals and key performance indicators
- enterprise information systems management
- enterprise organisational structure, delegations and responsibilities
- policy and procedure development processes
- relevant health, safety and environment requirements
- relevant national and international quality standards and protocols
- standard operating procedures (SOPs) for the technical work performed in work area
- the enterprise quality system

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:

- implement and monitor defined quality system requirements and initiate continuous improvements within the work area
- apply effective problem identification and problem solving techniques
- strengthen customer service through a focus on continuous improvement
- implement, monitor and evaluate quality systems in the work area
- initiate quality processes to enhance the quality of performance of individuals and teams in the work area
- gain commitment of individuals/teams to quality principles and practices
- implement effective communication strategies
- encourage ideas and feedback from team members when developing and refining techniques and processes
- analyse training needs and implement training programs
- prepare and maintain quality and audit documentation.

Context of and specific resources for assessment

This unit of competency should be assessed in a laboratory environment that either meets Australian standards for working laboratories or is accredited by NATA or the Royal College of Pathology, as appropriate. Competency in this unit should be assessed over a sufficient period of time to enable the candidate to initiate and implement improvements.

This unit of competency may be assessed with:

- *MSL915001A Provide information to customers.*

Resources may include:

- quality manuals and documentation

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	- quality tools, such as Pareto charts, strengths, weakness, opportunities, threats (SWOT) analysis and plan, do, check, act (PDCA) - quality and customer data.
Method of assessment	The following assessment methods are suggested: - observation of the candidate leading a quality improvement team - review of verified reports of improvement initiatives and/or projects conducted by the candidate - feedback from peers, team members, supervisors, quality manager and customers - review of quality documentation prepared and maintained by the candidate - review of training places prepared by the candidate for personnel in the work area - review of audit processes and outcomes generated by the candidate - questions to assess underpinning knowledge of procedures and contingency management. In all cases, practical assessment should be supported by questions to assess underpinning 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 The laboratory supervisor with a pharmaceutical company had participated in the production of a company wide quality manual. This manual was distributed to the various work teams and an induction program for all workers was undertaken to familiarise

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them with the demands of the quality system. A transient, sharp improvement in laboratory operations was observed after which the quality metrics fell (although not to pre-quality system levels). The supervisor investigated this phenomenon and found that many of the analytical specifications determined by the company were detailed in the quality manual and nowhere else. Put simply, after an initial period during which laboratory personnel consulted the manual for guidance, there was a tendency for the personnel to rely more on their memories and less on the manual. The supervisor made it clear to personnel that 'guessing' procedures and methodologies was unacceptable. If they were uncertain of something they must consult the manual. Awareness of this problem allowed the supervisor to be more vigilant in monitoring laboratory operations and personnel eventually developed the habit of referring to the manual as required. A subsequent review of the manual went smoothly and efficiently. The staff were familiar with the manual's strengths and shortcomings and had made annotations for improvements that were readily incorporated during the review.

Environmental

Collection of botanical specimens for research purposes required personnel to record data at the time of collection in a prescribed format. A quality audit conducted by the laboratory supervisor indicated that some documentation was incomplete. The supervisor also found that sometimes documentation was completed later, from memory, rather than in the field. The supervisor met with the collectors involved, reinforced the enterprise protocols, explained the importance of diligent record keeping in achieving valid research outcomes and gained a renewed commitment to quality from the personnel. Subsequent quality audits indicated that the personnel had met their commitment and the research work was no longer jeopardised.

Food processing

The laboratory supervisor of a food processing company had noted over recent years that the requests of some customers were virtually impossible to fulfil. For example, one customer wanted a bleached flour which had not undergone any chemical treatment or adulteration for a particular market niche. Another customer wanted analytical results within an unrealistic

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timeframe. While none of these requests had caused serious friction between the company and its customers, the supervisor decided to take a proactive stance to address the not altogether unreasonable ignorance of some customers. After consulting with the laboratory manager, the supervisor invited all customers to tour the laboratory, during which the aims and limitations of the analytical procedures were explained. The tour gave customers the opportunity to assess their demands of the company and generate more realistic ideas for modifying the company's products to suit their needs. The outcomes of this exercise were that company-customer relations were improved, the future expectations of some customers were more practical and the company's ongoing program of product improvement was facilitated by customer input.

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 1199 Sampling procedures and tables for inspection by attributes
 - 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 ISO 10013-2003 Guidelines for quality management system documentation
 - AS/NZS ISO 9000 Set:2008 Quality management systems set
 - AS 1199 Sampling procedures and tables for inspection by attributes
- Association of Analytical Communities International (AOAC International) Official Methods of Analysis
- Australia New Zealand Food Standards (ANZFS) Code
- Australian code of good manufacturing practice for medicinal products (GMP)
- BS 5750 Quality systems
- Codex Alimentarius standards

RANGE STATEMENT	
	• customer specific requirements/standards • enterprise and customer product specifications • hazard analysis and critical control points (HACCP) principles • National Association of Testing Authorities (NATA) Accreditation programs requirements • National Health and Medical Research Council (NHMRC) Guidelines • national measurement regulations and guidelines • principles of good laboratory practice (GLP) • quality manuals and procedures • Therapeutic Goods Regulations 1009

RANGE STATEMENT	
Quality audits	Quality audits may include: • 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 (CRMs) • participation in external quality assurance programs
Communication	Communication may involve: • supervisors, managers and quality managers • laboratory and production personnel • customers and suppliers • auditors
Reporting	Reporting may include: • verbal responses • data entry into laboratory or enterprise databases • written reports
Documentation	Documentation may include: • sampling plans • enterprise quality manual • quality (certification or registration) requirements • audit documents • performance plans and reports • training records and/or plans • workplace procedures relating to occupational health and safety (OHS), equal opportunity (EO) and environmental legislative requirements • industrial awards and enterprise agreements
Occupational health and safety (OHS) and environmental management requirements	OHS and environmental management requirements: • all operations must comply with enterprise OHS and environmental management requirements, which may be imposed through state/territory or federal legislation - these

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	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
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Unit Sector(s)

Unit sector	Maintenance
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Competency field

Competency field	
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Co-requisite units

Co-requisite units		