MSL916001A Develop and maintain laboratory documentation

INDUSTRY
SKILLS
COUNCILS
Creating Australia's Future

MSL916001A Develop and maintain laboratory documentation

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the ability to develop and maintain relevant documentation and systems in response to identified information requirements or changes in laboratory policy or external accreditation requirements. It includes the analysis of specialised technical requirements and the development and/or amendment of workplace documents, procedures and record keeping systems using established workplace procedures. Final responsibility for documentation and systems generally rests with professional scientific/medical/engineering staff who have the appropriate signatory status or legal delegation.

Application of the Unit

Application of the unit	This unit of competency is applicable to technical officers and laboratory supervisors working in all industry sectors.
	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'.

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. Recognise documentation needs/deficiencies	1.1. Evaluate current documentation to identify instances where documentation is needed or deficient
	1.2. Analyse development opportunities and discuss with appropriate personnel to assess and confirm requirements
2. Develop/revise documentation	2.1. Specify documentation need and set/prioritise objectives
	2.2. Analyse existing documentation/records in accordance with specified requirements
	2.3. Develop/amend documentation as a draft in accordance with review requirements
	2.4. Issue documentation to appropriate personnel for review
	2.5. Edit documentation to ensure that the initial identified need/deficiency and review requirements are satisfied
	2.6. Recall superseded documentation and issue new documentation in accordance with document control procedures
3. Implement and evaluate new laboratory documentation	3.1. Brief personnel on new/revised documentation to ensure successful implementation of new procedures
	3.2. Monitor and evaluate implementation of new/revised documentation and amend documents or provide training, if required

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

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

Required skills

Required skills include:

- analysing, drafting and amending enterprise documentation in accordance with specifications
- completing documentation in a clear and concise manner that is easily understood by others and in accordance with enterprise requirements/ specifications
- recognising problems in systems and documentation
- using internal and external information sources efficiently
- critically analysing information
- preparing documentation that is accurate, free from editorial errors and omissions and easily understood by the intended audience
- obtaining and including relevant feedback on draft documentation
- communicating information and developments in the appropriate manner
- completing the preparation and distribution of documents in the given time

Required knowledge

Required knowledge includes:

- documentation development and tracking
- records management and maintenance
- quality systems and continuous improvement
- organisational structure, delegations and responsibilities
- communication protocols and reporting
- scientific, technical and workplace terminology
- occupational health and safety (OHS), environmental and other relevant legislative requirements, regulations and codes
- enterprise standard operating procedures (SOPs)
- technical developments in the sector (current methodologies, ranges and interpretations)
- relevant health, safety and environment requirements
- the laboratory's business goals and key performance indicators

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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: • analyse, draft and amend enterprise documentation in accordance with specifications • complete documentation in a clear and concise manner that is easily understood by others and in accordance with enterprise requirements/ specifications • recognise problems in systems and documentation • use internal and external information sources efficiently • critically analyse information • prepare documentation that is accurate, free from editorial errors and omissions, and in accordance with requirements • prepare documentation that is easily understood by the intended audience • obtain and include relevant feedback on draft documentation • communicate information and developments in the appropriate manner • complete the preparation and distribution of documents in the given time.
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: • *MSL916004A Maintain registration and statutory or legal compliance in work/functional area* • *MSL936001A Maintain quality system and continuous improvement processes within work/functional area* • *MSL946001A Implement and monitor OHS and environmental management systems*. Resources may include: • information directories and databases

EVIDENCE GUIDE

	enterprise documents and procedures.
Method of assessment	The following assessment methods are suggested: • examination of a range of relevant enterprise documentation developed by the candidate • feedback from peers and supervisors that enterprise procedures were followed and that the documentation is accurate and user friendly. 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. **Environmental** A water sample thought to contain cadmium had been logged for analysis. Later that day, the technician designated to perform the analysis advised the laboratory supervisor that the procedures had not yet been revised to suit the newly installed analytical equipment. The supervisor created a draft procedure document for the revised procedure and passed it, with an explanation of the reasons for the change, to the appropriate personnel for authorisation. The draft document was approved and the supervisor issued the revised procedures as a control document. The supervisor notified all relevant personnel of the change, removed the old procedures, replaced it with the new document and entered the change in the document control register. **Food processing**

EVIDENCE GUIDE	
	Two senior technicians in the laboratory of a food processing company hazard analysis and critical control points (HACCP) team suggested extensive changes to the way the laboratory functioned so that it better supported the HACCP system. The technicians reviewed the existing HACCP documentation and legislation and revised the laboratory documentation that was relevant to the HACCP system. They also organised in-house training to provide each member of the laboratory team with the knowledge and skills essential for successful implementation of this system. Overall, the adoption of a HACCP plan by the company proceeded with relatively few problems, in part because of the involvement of the laboratory staff and the training provided by the company.

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 10013-2003 Guidelines for quality management system documentation
	   • AS ISO 17025-2005 General requirements for the competence of testing and calibration laboratories
	   • AS/NZS 2243 Set:2006 Safety in laboratories set
	   • AS/NZS ISO 10005:2006 Quality management systems - Guidelines for quality plans
	   • AS/NZS ISO 14000 Set:2005 Environmental management standards set
	   • AS/NZS ISO 9000 Set:2008 Quality management systems set
	   • Australia New Zealand Food Standards (ANZFS) Code
	• Australian code of good manufacturing practice for medicinal products (GMP)
	• Australian Dangerous Goods Code
	• gene technology regulations
	• OHS national standards and codes of practice
	• principles of good laboratory practice (GLP)
	• testing procedures and specific method collections for industry sectors:
	   • Association of Analytical Communities International (AOAC International) Official Methods of Analysis

RANGE STATEMENT	
Workplace documentation	Workplace documentation may include: • workplace procedures, SOPs and operating manuals • test procedures • sampling procedures (sampling, preparation, labelling, storage, transport and disposal) • evaluation of materials or products • instructions for equipment installation, commissioning, calibration and maintenance • safety requirements for equipment, materials or products • cleaning, hygiene and personal hygiene requirements • methods for extraction or manufacture of a product • risk evaluation, monitoring or control procedures • compliance/non-compliance reports • quality system and continued improvement processes • incident and accident/injury reports • permits • schematics/work flows/laboratory layouts • instructions to comply with new legislation, standards, guidelines and codes • stock records/inventory • training program contents • waste minimisation and disposal
Items of equipment and systems	Items of equipment and systems may include: • online information systems, databases, record and filing systems • computer equipment
Communication	Communication may be with: • supervisors and managers (laboratory, quality and customer service) • other laboratory or production personnel • members of the public, customers and suppliers • external auditors, regulation and licensing/accreditation authorities, such as

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RANGE STATEMENT	
	National Association of Testing Authorities (NATA)
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 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	Communication/organisation

Competency field

Competency field	

Co-requisite units

Co-requisite units		

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