Australian Government

Department of Education, Employment and Workplace Relations

MSL916004A Maintain registration and statutory or legal compliance in work/functional area

Release: 1

INDUSTRY SKILLS COUNCILS
Creating Australia's Future

MSL916004A Maintain registration and statutory or legal compliance in 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 its compliance with legislation and licensing, registration, ethical or accreditation requirements (e.g. National Association of Testing Authorities (NATA)) and enterprise policies and procedures.

Application of the Unit

Application of the unit	This unit of competency is applicable to senior technical officers and laboratory supervisors in all industry sectors. While statutory or legal compliance is the responsibility of all personnel, supervisors have an important leadership role in promoting and monitoring workplace practices which enhance compliance. They work under broad supervision of 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'.

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. Interpret and communicate current legislation, codes and standards	1.1. Maintain knowledge of current and new requirements impacting on work/functional area 1.2. Distribute clear information regarding the roles and responsibilities of teams and individuals to maintain the laboratory's statutory or legal compliance 1.3. Explain the implications of non-conformance to all personnel within the work area
2. Ensure that work practices meet compliance requirements	2.1. Plan work practices to ensure compliance with relevant legislation and licensing, registration, ethical or accreditation requirements 2.2. Ensure that the calibration system is implemented to meet traceability requirements 2.3. Ensure that testing procedures are implemented so that methods and equipment are fit for purpose 2.4. Implement systems to ensure the accuracy of measuring equipment 2.5. Empower team members through coaching and mentoring to manage their responsibilities
3. Monitor, analyse, adjust and report performance	3.1. Ensure that actual and potential problems are identified, rectified and reported promptly to ensure workplace compliance 3.2. Analyse and supervise activities so that potential non-compliance is minimised 3.3. Recommend to designated personnel strategies to improve compliance 3.4. Ensure that individuals/teams are informed of new and improved procedures 3.5. Maintain systems, records and reporting procedures according to legislative and licensing, registration, ethical or accreditation requirements and workplace procedures
4. Investigate, rectify and report non-conformance	4.1. Investigate and deal with non-conformance according to legislative and licensing, registration or accreditation requirements and workplace procedures 4.2. Provide on/off job training for personnel to acquire and apply competencies to meet legislative and licensing, registration or ethical accreditation requirements 4.3. Re-design or adjust workplace practices to ensure that non-conformance is not repeated

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

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

Required skills

Required skills include:

- ensuring work practices are conducted in an ethical and professional manner
- monitoring and analysing work practices to ensure compliance and taking appropriate action to rectify potential problems or instances of non-conformance
- detailed analysis of results and long term data trends
- providing information and training on roles and responsibilities and enterprise procedures dealing with legal/statutory requirements
- communicating appropriately with all customers (internal and external)
- negotiating changes to work processes and procedures to meet statutory or legal requirements
- developing and introducing practices to improve the work environment
- providing coaching and mentoring support to personnel to change work practices
- keeping required records complete, current and secure

Required knowledge

Required knowledge includes:

- enterprise procedures governing document control, record management, communication and reporting, and internal and external audits
- scientific technical terminology used to describe legislative, licensing, or registration requirements (e.g. traceability)
- legal, ethical and welfare issues associated with laboratory and technical work
- role, structure and responsibilities of ethics committees
- statutory and legal compliance requirements
- relevant health, safety and environment requirements

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 candidate can: • ensure work practices are conducted in an ethical and professional manner • supervise laboratory operations to ensure that the work or functional area complies with legislation and laboratory licensing, registration or accreditation requirements (e.g. NATA) and the enterprise's policies and procedures • monitor and analyse work practices to ensure compliance and take appropriate actions to rectify potential problems or instances of non-conformance • provide information and training on roles and responsibilities and enterprise procedures dealing with legal/statutory requirements • communicate appropriately with all customers (internal and external) and be aware of cultural and social contexts • negotiate changes to work processes and procedures to meet statutory or legal requirements • develop and introduce practices to improve the work environment • provide coaching and mentoring support to personnel to change work practices • keep required records complete, current and secure.
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. This unit of competency may be assessed with: • *MSL915001A Provide information to customers* • *MSL916001A Develop and maintain laboratory documentation* • *MSL916003A Supervise laboratory operations in work/functional area*

EVIDENCE GUIDE	
	• *TAADEL301C Provide training through instruction and demonstration of work skills*. Resources may include: • laboratory equipped with appropriate equipment, instruments, services and consumables • relevant enterprise policies, procedures, operational reports, financial reports and stock records • technical manuals, standard operating procedures (SOPs), quality manuals and quality system documentation.
Method of assessment	The following assessment methods are suggested: • observation of the candidate's interactions with personnel • review of verified records and reports generated by the candidate • feedback from managers regarding the candidate's ability to implement relevant enterprise procedures • review of information developed by the candidate and provided to the workgroup. 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. **Biomedical** A pathology laboratory is preparing for NATA assessment. The role of one laboratory supervisor is to organise information sessions to inform personnel about the standards and codes to be followed for accreditation.

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	These cover issues, such as working with biological, chemical and radiation hazards, the use of safety equipment, the disposal of waste, ethics committee requirements and patient confidentiality. Training is provided to ensure all personnel are equipped with sufficient knowledge and skills to fulfil their responsibilities in line with the relevant codes and standards. The thorough preparation of the laboratory personnel by the laboratory supervisor assists the laboratory to gain NATA accreditation. **Environmental** A laboratory supervisor is asked to do an internal audit of a work area as part of an analytical laboratory's preparation for a NATA assessment. The supervisor checks items, such as the currency of the quality manual and laboratory documentation, the storage of reference standards and compares the documentation of test results with NATA requirements. As a result of this internal audit, the supervisor is confident that the forthcoming NATA assessment will show that the work area complies with all requirements. **Food processing** A team of technical assistants performs a common set of food analyses that are essential to the operations of a food processing company. After a period of rapid staff turnover, their supervisor noticed that the degree of variance in the analytical results has increased. An internal proficiency study confirmed that this rise was not due to compositional differences between samples. The supervisor sought to overcome this problem by first discussing it with the team. The supervisor realised that some of the recently employed technical assistants did not fully understand some analytical procedures. Furthermore, each member of the team, for various reasons, has a distinct preference for performing some procedures over others and this appeared to influence their competency to conduct all other analyses. In consultation with the team, the supervisor made several changes to the way they work. A more structured induction of new staff was introduced and where possible each technician was allocated the analyses that they preferred and were most competent to perform. The supervisor also instigated a review of the analytical methods involved and identified the critical steps in each assay as defined by the laboratory's accreditation authority. Particular attention was paid to steps regularly

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	misunderstood by one or more technicians in the past and a series of 'critical operating procedures' were developed. These procedures, together with the SOPs, were clearly displayed in the area where the relevant assay was conducted. Overall, these actions by the laboratory supervisor improved the work performance and satisfaction of the staff, maintained the laboratory's standards of compliance and enhanced the level of communication and cooperation with the team.

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 1000-1998 The international system of units (SI) and its application
	• 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 2982.1:1997 Laboratory design and construction - General requirements
	• 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 14000 Set:2005 Environmental management standards set
	  • AS/NZS ISO 9000 Set:2008 Quality management systems set
	  • ISO 5725 Accuracy (trueness and precision) of measurement methods and results
	  • ISO/IEC Guide 98-3:2008 Uncertainty of measurement - Part 3 Guide to the expression of uncertainty in measurement

RANGE STATEMENT	
	(GUM) • animal welfare legislation and codes of practice • Eurachem/CITAC Guide CG4 Quantifying uncertainty in analytical measurement • occupational health and safety (OHS) national standards and codes of practice • principles of good laboratory practice (GLP) • Australia New Zealand Food Standards (ANZFS) Code • Australian code of good manufacturing practice for medicinal products (GMP) • Australian Dangerous Goods Code • Anti-discrimination Acts • Australian Quarantine and Inspection Service (AQIS) Export Control (Orders) Regulations 1982 and Import Guidelines • dispute resolution • ethics committee requirements • freedom of information • gene technology regulations • general duty of care • Human Rights and Equal Opportunity Commission Act 1986 • intellectual property and copyright • maintenance and confidentiality of records • maintenance of certified reference materials and regulation 80 certificates • maintenance of records of breaches • National Association of Testing Authorities (NATA) Accreditation programs requirements • national environment protection measures • National Health and Medical Research Council (NHMRC) Guidelines • national measurement regulations and guidelines • natural justice • privacy legislation • representative work groups/committees • Therapeutic Goods Regulations 1009 • workers' compensation, WorkCover and industrial relations

RANGE STATEMENT	
Ethical considerations	Ethical considerations may include: • identification and impartial resolution of ethical issues, such as conflict of interest • ethical decision making • provision of products and services which match the operational and financial needs of stakeholders, including realistic quotes for work • accurate representation of skills, services, knowledge and qualifications of individuals and the organisation • acknowledgment of services and products developed by others, intellectual property and copyright • provision of unbiased, accurate and appropriately qualified information results
Communication	Communication may involve: • managers and supervisors • laboratory and production staff • regulating authorities • provision of information and training • explanation of legislation, codes, standards and work practices
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		