



Australian Government

MSL936002 Conduct an internal audit of the quality system

Release: 1

MSL936002 Conduct an internal audit of the quality system

Modification History

Release 1. Supersedes and is equivalent to MSL936002A Conduct an internal audit of the quality system

Application

This unit of competency covers the ability to prepare for, conduct and document an internal audit of aspects of the laboratory's quality system. It also covers the implementation of the identified corrective action and opportunities for improvement and the monitoring of their effectiveness.

This unit of competency is applicable to senior technical officers and laboratory supervisors working in all industry sectors. These people play a key role in the audit team due to their knowledge of the quality system and their broad technical expertise and specialised knowledge of procedures and technology. This unit of competency requires a thorough examination of various aspects of the quality system.

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	Prepare for internal audit	1.1	Analyse brief to determine the scope and detailed requirements of the planned audit
		1.2	Identify procedures and/or the work area to be audited, and collect relevant information and documentation

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| | | 1.3 | Brief relevant personnel and allocate roles and responsibilities |
| | | 1.4 | Develop a detailed audit plan in consultation with relevant personnel |
| | | 1.5 | Develop a checklist to identify conformance and non-conformance |
| 2 | Conduct audit | 2.1 | Identify the components and elements of the quality system and work area to be audited |
| | | 2.2 | Collaborate with relevant personnel to maximise continuous improvement and ownership of the audit process |
| | | 2.3 | Collect sufficient evidence to identify non-conforming aspects of the quality system |
| | | 2.4 | Analyse evidence to identify suitable corrective actions |
| 3 | Report findings | 3.1 | Document findings from the audit process in the required format |
| | | 3.2 | Present recommendations for corrective actions |
| | | 3.3 | Provide strategies for the implementation of the corrective actions |
| 4 | Complete corrective actions | 4.1 | Develop and implement an action plan to improve the quality system |
| | | 4.2 | Consult with relevant personnel regarding the necessary strategies to improve the quality system |
| | | 4.3 | Evaluate and report the effectiveness of the corrective action after an agreed time interval |
| | | 4.4 | Ensure that relevant certification is maintained |

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 of more of:

- Australian and international standards, codes and guidelines covering the competence of testing and calibration laboratories, laboratory design and construction, laboratory safety, quality management systems, documentation and plans, environmental management, measurement management, accuracy of measurement methods and results, expression of uncertainty (GUM) and principles of good laboratory practice (GLP)
- national standards and codes of practice for work health and safety (WHS), and national environment protection measures
- national measurement regulations and guidelines
- registration/licensing and/or National Association of Testing Authorities (NATA) accreditation requirements
- industry-specific codes, guidelines, procedures and methods, such as:
 - National Health and Medical Research Council (NHMRC) Guidelines
 - Association of Analytical Communities International (AOAC International) Official Methods of Analysis
 - Australian code of good manufacturing practice for medicinal products (GMP) and Therapeutic Goods Regulations
 - Australia New Zealand Food Standards (ANZFS) Code, and hazard analysis and critical control points (HACCP) principles
- 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 product specifications and quality requirements

Elements and components of a quality system

Elements and components of a quality system include, but are not limited to, one or more of:

- responsibilities of personnel within quality system
- contract review

- purchasing
- design control
- process control, control of customer-supplied product, product identification and traceability
- inspection and testing, control of inspection, measuring and test equipment, and inspection and test status
- statistical analysis, internal quality audits, and corrective and preventative action
- control of documents, data and quality records
- control of non-conforming product
- handling, storage, packaging, preservation and delivery
- training
- servicing

Information and documentation

Information and documentation include, but are not limited to, one or more of:

- workplace quality manuals
- documentation related to the quality elements being audited
- data records
- customer complaints
- training records
- certification documentation from clients/suppliers
- material/equipment specifications

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

MSA Training Package Implementation Guides - <http://mskills.org.au/training-packages/info/>