



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
		1.3	Brief relevant personnel and allocate roles and responsibilities

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| | | 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

Elements and components of a quality system include, but are not

components of a quality system

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

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

Links

Companion Volume implementation guides are found in VETNet -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=5c63a03b-4a6b-4ae5-9560-1e3c5f462baa>

Assessment Requirements for MSL936002 Conduct an internal audit of the quality system

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Performance Evidence

- Evidence of competence in this unit must satisfy all of the requirements of the elements and performance criteria, and include demonstration of:
- preparing for, conducting and documenting at least one (1) internal audit of aspects of the laboratory's quality system in accordance with workplace procedures
- collecting and analysing all necessary data, relevant documentation and records
- applying effective problem identification, problem solving and quality improvement techniques
- encouraging suggestions and feedback from team members to develop improved work practices or processes
- documenting audit findings accurately and recommending logical corrective actions to address non-conformance items
- communicating effectively with supervisors, managers, laboratory and/or production personnel before, during and after the audit
- implementing identified corrective actions and opportunities for improvement and monitoring and evaluating their effectiveness

maintaining and reporting quality and audit documentation.

Knowledge Evidence

Must provide evidence that demonstrates knowledge of:

- workplace quality system, plans and documentation and relevant national and international quality standards and protocols that apply in work area
- workplace organisational structure, delegations and responsibilities, and information management systems
- importance of identifying, reporting and addressing non-conformance
- laboratory's business goals and key performance indicators (KPIs)
- audit process and documentation
- problem-solving techniques to identify causes and options to remedy problems
- continuous improvement principles and techniques, such as:
 - run charts, control charts, histograms and scattergrams to present quality control data
 - plan, do, check, act (PDCA)
 - Ishikawa fishbone diagrams; cause and effect diagrams; logic tree; similarity/difference analysis; Pareto charts and analysis; force field/strengths, weaknesses, opportunities, threats (SWOT) analysis

- process capability
- standard operating procedures (SOPs) for the technical work performed in work area
- workplace communication, recording and reporting procedures
- work health and safety (WHS) and environment requirements.

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

- incorporating food safety and/or hazard analysis and critical control points (HACCP) plan requirements into audit
- monitoring and verifying critical control limits.

Assessment Conditions

- Judgement of competence must be based on holistic assessment of the evidence. Competency must be assessed within the context of a team-based internal quality audit and assessed over a sufficient period of time to enable the candidate to prepare and conduct the audit, report the findings and implement and evaluate any corrective action.
- This unit of competency is to be assessed in the workplace or a simulated workplace environment, and assessment evidence must be relevant to the particular workplace context. A simulated workplace environment must reflect realistic operational workplace conditions that cover all aspects of workplace performance, including the environment, task skills, task management skills, contingency management skills and job role environment skills.
- Foundation skills are integral to competent performance of the unit and should not be assessed separately.
- Assessment processes and techniques must be appropriate to the language, literacy and numeracy requirements of the work being performed and the needs of the candidate.
- Knowledge evidence may be collected concurrently with performance evidence or through an independent process, such as workbooks, written assessments or interviews (provided a record is kept in each case).
- This unit of competency may be assessed with:
 - MSL916002 Manage and develop teams
 - MSL936001 Maintain quality system and continuous improvement processes within work or functional area
- Holistic assessment methods include:
 - review of audit plan, checklists, data, findings and recommendations prepared by the candidate as part of the internal audit process
 - feedback from audit team members about the candidate's ability to encourage participation and provide useful information and clear instructions
 - feedback from managers about implementation of the internal audit and the usefulness of the findings and recommendations
 - questions to assess required knowledge of quality systems, internal audit process, quality improvement techniques and relevant workplace procedures
 - observation of the candidate's performance at key audit stages.

- Access is required to all instruments, equipment, materials, workplace documentation, procedures and specifications associated with this unit, including, but not limited to:
 - documentation, such as audit documents, workplace quality manual and HACCP plans, and quality (certification or registration) requirements
 - safety procedures, SOPs and work instructions.
- Assessors must satisfy the assessor competency requirements that are in place at the time of the assessment as set by the VET regulator.
- The assessor must demonstrate both technical competence and currency.
- Technical competence can be demonstrated through:
 - relevant VET or other qualification/Statement of Attainment AND/OR
 - relevant workplace experience.
- Currency can be demonstrated through:
 - performing the competency being assessed as part of current employment OR
 - having consulted with a laboratory about performing the competency being assessed within the last twelve months.

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