



Australian Government

Department of Education, Employment and Workplace Relations

MSL936002A Conduct an internal audit of the quality system

Revision Number: 1

MSL936002A Conduct an internal audit of the quality system

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the ability to prepare for, carry out 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.
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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. 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 represents a thorough examination of various aspects of the quality system. 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. 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 documentation 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. Explain the components 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 systems 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

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

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

Required skills

Required skill include:

- preparing and conducting an audit of the quality system following enterprise procedures
- implementing corrective action and monitoring its effectiveness
- implementing effective communication strategies
- collecting and analysing all necessary data/documentation/records
- encouraging suggestions and feedback from team members when developing and refining processes
- monitoring and reviewing the team's performance
- applying effective problem identification and problem solving techniques
- preparing and maintaining quality and audit documentation
- making recommendations based on the findings of non-conformance items
- initiating and evaluating corrective action and making appropriate adjustments

Required knowledge

Required knowledge includes:

- enterprise quality system, relevant national and international quality standards and protocols
- audit process
- continuous improvement principles
- importance of identifying and reporting non-conformance
- documentation processes
- problem solving techniques to identify causes and options to remedy problems
- workplace communication reporting requirements and procedures
- enterprise organisational structure, responsibilities and delegations
- relevant health, safety and environment requirements
- laboratory's business goals and key performance indicators

Specific industry

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

Food processing:

- incorporate food safety and/or hazard analysis and critical control points (HACCP) plan requirements into audit
- monitor and verify critical control limits

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:

- prepare and conduct an audit of the quality system following enterprise procedures
- implement corrective action and monitor its effectiveness
- implement effective communication strategies before, during and after an audit
- collect and analyse all necessary data/documentation/records
- encourage suggestions and feedback from team members when developing and refining processes
- monitor and review the team's performance
- apply effective problem identification and problem solving techniques
- prepare and maintain quality and audit documentation
- make recommendations based on the findings of non-conformance items
- initiate and evaluate corrective action and make appropriate adjustments.

Context of and specific resources for assessment

This unit of competency is to be assessed in the workplace or simulated environment. Ideally, competency should be assessed within the context of a team based internal quality audit. Competency in this unit should be 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 may be assessed with:

- *MSL916002A Manage and develop teams*
- *MSL936001A Maintain quality system and continuous improvement processes within work/functional area.*

Resources may include:

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	• quality manuals and documentation • quality system requirements.
Method of assessment	The following assessment methods are suggested: • observation of the candidate's performance at key points during the audit • review of data and reports obtained from audit records • review of documentation completed by the candidate as part of the development of the audit process • feedback from team members • feedback from management regarding the implementation of the internal audit. 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. Questioning techniques should suit the language and 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 A new laboratory is being planned and the senior technical officer has been included in the steering committee to prepare the brief. The committee has decided that the preparation of the brief will include an audit of the safety and operating standards of the current laboratory. The aim of the audit will be to compare the current safety operations and facilities that are acceptable within the framework of the current premises with those of a modern building. The audit will monitor equipment,

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storage facilities and current methodologies in order to determine the necessary infrastructure changes that might be incorporated into the plan, or changes in methodologies that would bypass the need for the building changes through a change in equipment.

Biomedical

There have been a few problems in the sample reception area. Not all tests specified in requests have been allocated and, on a few occasions, a test was deleted because a technical assistant decided that there was insufficient sample provided. The supervisor has decided that the processing system should be reviewed and the reasons for the mistakes and omissions identified. After tracking the sample arrival, processing, labelling and distribution, the supervisor noted that the technical assistants often could not identify the sample test code. Despite the instruction to seek assistance, they did not contact a supervisor if they could not be approached immediately. Sometimes they put the sample aside for the supervisor's attention and it was forgotten over the shift change. On other occasions, they assigned a test code in good faith. As a result of the audit, a database of the test codes, sample requirements, distribution destination and conditions for storage was established at sample reception. The technical assistants were shown how to access information that they might require if the supervisor was not available. This action reduced the number of mistakes and the frequency of test omissions, and improved throughput of samples.

Food processing

Following an internal audit, a major non-conformance was identified which had resulted in a beverage label listing an ingredient that was not present. A corrective action had been made requiring that a new form be generated for release of label details from the purchasing department. The laboratory supervisor was given the responsibility as part of the audit team to follow up three weeks later and confirm that the corrective action had been completed. The laboratory supervisor gathered the data and a copy of the corrective action report and organised a meeting with staff from the purchasing department. During the meeting, the laboratory supervisor checked the revised quality form that now included the signature of the authorising officer from the

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purchasing department. The laboratory supervisor also reviewed the quality procedures to ensure that the new form's code was updated and that all old copies were removed. The report was then presented to the audit team for final approval and signing off.

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
 - BS 5750 Quality systems
- Australia New Zealand Food Standards (ANZFS) Code
- Australian code of good manufacturing practice for medicinal products (GMP)
- customer specific requirements/standards
- HACCP principles
- National Association of Testing Authorities (NATA) Accreditation programs requirements
- National Health and Medical Research Council (NHMRC) Guidelines

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	• national measurement regulations and guidelines • principles of good laboratory practice (GLP) • occupational health and safety (OHS) national standards and codes of practice • quality manuals and procedures • Therapeutic Goods Regulations 1009
Elements of a quality system	Elements of a quality system may include: • responsibilities of personnel within quality system • contract review • inspection and test status • control of non-conforming product • design control • document and data control • purchasing • control of customer-supplied product • product identification and traceability • process control • inspection and testing • statistical analysis • corrective and preventative action • handling, storage, packaging, preservation and delivery • control of quality records • internal quality audits • training • servicing • control of inspection, measuring and test equipment
Information sources	Information sources may include: • enterprise quality manual • documentation related to the quality elements being audited • customer complaints • training records • data records • certification documentation from clients/suppliers • material/equipment specifications

RANGE STATEMENT	
Quality improvement tools and techniques	Quality improvement tools and techniques may include: • run charts, control charts, histograms and scattergrams to present quality control data • plan, do, check, act (PDCA) • Ishikawa fishbone diagrams and cause and effect diagrams • logic tree • similarity/difference analysis • Pareto charts and analysis • force field/strengths, weaknesses, opportunities, threats (SWOT) analysis • process capability
Communication	Communication may involve: • managers • customers and suppliers • laboratory and production personnel • other personnel with quality assurance responsibilities
Reporting	Reporting may include: • verbal responses, • judgement and recommendations • written reports and presentations • data entry into laboratory or enterprise databases
Documentation	Documentation may include: • audit documents • enterprise quality manual and HACCP plans • safety procedures, standard operating procedures (SOPs), work instructions • quality (certification or registration) requirements
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

RANGE STATEMENT

	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		