

Quality Management Systems

8440 version 4

Comply with laboratory quality management systems

Level: 5 Credits: 4

Entry information: Open.

Special notes

- 1 Candidates' health and safety practices must comply with AS/NZS 2243.1 (1997) *Safety in Laboratories – General* and subsequent additions and amendments. Practices must also comply with: the Hazardous Substances and New Organisms Act 1996, the Health and Safety in Employment Act 1992, and their subsequent amendments, codes of practice, and regulations. Obligations relating to the Health and Safety in Employment Act are not limited to the laboratory but extend to the workplace in general.
- 2 *Industry standard* refers to the NZS ISO/IEC 17025: 1999 *General requirements for the competence of testing and calibration laboratories*. Reference should be made to *OECD Principles on Good Laboratory Practice* (Available at the OECD website at www.oecd.org/ehs). This includes the detail that is required to comply with this unit standard.
- 3 Assessment against this unit standard must be related to a working laboratory in which laboratory quality management systems are followed and documented. This laboratory would be an accredited one conforming to NZS ISO/IEC 17025:1999.

Judgment statement

- Verifier: The trainee has shown ability to meet the standard stated within this unit in accordance with company specifications, procedures and where appropriate manufacturer's instructions.
- Assessor: Based on the evidence of the verifier and demonstrated skills and knowledge the candidate has met the criteria as specified within this unit including all range statements.
- Focus: Throughout this area of assessment the candidate will need to consistently apply knowledge learned relating to: sound businesses practices, organisational business rules and legislative requirements relating to acts, codes and legislation listed above.

Element 1		
Comply with laboratory equipment management systems.		
Performance Criteria	Candidate	Verifier/Assessor
1.1 Processes for checking laboratory accommodation and environment are followed in accordance with the documented laboratory quality management system.		
1.2 Processes for the control, maintenance and calibration of test equipment are followed in accordance with the documented laboratory quality management system.		

Element 2		
Comply with laboratory test methods and systems.		
Performance Criteria	Candidate	Assessor
2.1 Methods for carrying out tests are followed in accordance with the documented laboratory quality management system.		
2.2 Processes for controlling test items are followed in accordance with the documented laboratory quality management system.		
2.3 Processes for controlling nonconforming testing services are followed in accordance with the documented laboratory quality management system.		
2.4 Processes for statistical process control are followed in accordance with the documented laboratory quality management system.		

Element 3

Comply with laboratory recording systems.

Range: manual, computerised.

Performance Criteria	Candidate	Assessor
3.1 Procedures for reporting are followed in accordance with the documented laboratory quality management system.		
3.2 Procedures for administering raw data, test records, and certificates are followed in accordance with the documented laboratory quality management system.		
3.3 Procedures for measurement traceability are followed in accordance with the documented laboratory quality management system.		

Element 4

Comply with laboratory procurement systems.

Performance Criteria	Candidate	Assessor
4.1 Procedures for the purchase of equipment and consumable items are followed in accordance with the documented laboratory quality management system.		
4.2 Procedures for selecting sub-contracted services are followed in accordance with the documented laboratory quality management system.		

Element 5		
Comply with laboratory quality assurance systems.		
Performance Criteria	Candidate	Assessor
5.1 Procedures for monitoring levels of service provided are followed in accordance with the documented laboratory quality management system.		
5.2 Procedures for standardisation and continuous improvement activities are followed in accordance with the documented laboratory quality management system.		

Describe laboratory quality systems

Level: 5 Credits: 4

Entry information: Open.

Special notes

- 1 Glossary of terms
Accredited laboratory refers to a laboratory accredited according to the Australian/New Zealand Standard 17025: 1999 (NZS ISO/IEC) *General requirements for the competence of testing and calibration laboratories*.
- 2 To meet the requirements of this unit standard, any description of procedures must include interpretation of Australian/New Zealand Standard 17025: 1999 (NZS ISO/IEC) *General requirements for the competence of testing and calibration laboratories*. Reference should be made to OECD *Principles on Good Laboratory Practice* (Available at the OECD website at www.oecd.org/ehs). The requirements of the Health and Safety in Employment Act 1992 must also be considered.
- 3 The following guidelines are recommended to assessors as a resource for in-house validation: *Harmonized guidelines for single-laboratory validation of methods of analysis* (IUPAC Technical Report)(V) in Pure and Applied Chemistry, Volume 74(5) pp.835-855 (Available at the IUPAC website at <http://www.iupac.org/reports/2002/index.htm>).

Judgment statement

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- Assessor: Based on the evidence of the verifier and demonstrated skills and knowledge the candidate has met the criteria as specified within this unit including all range statements.
- Focus: Throughout this area of assessment the candidate will need to consistently apply knowledge learned relating to: sound businesses practices, organisational business rules and legislative requirements relating to acts, codes and legislation listed above.

Element 1		
Describe the aims of laboratory quality systems.		
Performance Criteria	Candidate	Verifier/Assessor
1.1 The description relates concepts of quality, fitness for purpose, and continuous improvement to laboratory quality systems.		
1.2 The description outlines client expectations relating to the reliability of laboratory results.		

Element 2		
Describe the components of quality systems found in accredited laboratories.		
Performance Criteria	Candidate	Assessor
2.1 The description outlines the technical requirements of the quality system found in any accredited laboratory. Range: may include but is not limited to - human factors, accommodation and environmental conditions, test methods and method validation, equipment, measurement traceability, sampling, calibration testing.		
2.2 The description outlines the areas requiring documentation. Range: policies, systems, programmes, procedures, instructions.		
2.3 The description outlines internal and external audit procedures.		

Element 3

Describe laboratory management systems in accredited laboratories.

Performance Criteria	Candidate	Assessor
3.1 The description outlines procedures for maintaining the laboratory environment.		
3.2 The description outlines procedures for ensuring the fitness of laboratory equipment.		
Range: may include but is not limited to - maintenance plan, calibration documentation, equipment modification documentation, instruction documents.		
3.3 The description outlines procedures for ensuring the competence of laboratory personnel.		
Range: may include but is not limited to - qualifications, training procedures, approval of and responsibility for reports.		
3.4 The description outlines laboratory procurement procedures.		
Range: equipment, consumable items.		

Element 4		
Describe the selection, validation and maintenance of test methods in accredited laboratories.		
Performance Criteria	Candidate	Assessor
4.1 The description outlines selection of test methods.		
4.2 The description outlines validation procedures for test methods.		
Range: may include but is not limited to - certified reference materials, inter-laboratory comparisons, in-house validation.		
4.3 The description outlines document control procedures relating to updating test methods.		
4.4 The description outlines the use of quality control procedures for test methods.		
Range: may include but is not limited to - reference materials, quality control blanks, analysis of known samples, duplicates, spikes, quality control charts.		

Element 5		
Describe calibration procedures in accredited laboratories.		
Performance Criteria	Candidate	Assessor
5.1 The description outlines traceability.		
5.2 The description outlines calibration protocols, and use and control of calibration standards.		

Element 6		
Describe the concept of uncertainty in measurement methods in accredited laboratories.		
Performance Criteria	Candidate	Assessor
6.1 The description outlines the concept of uncertainty in measurement.		
6.2 The description outlines the sources of uncertainty in measurements.		
Range: may include but is not limited to - sources of uncertainty in quantitative physical, chemical and microbiological analysis.		
6.3 The description outlines the differences between the concepts of uncertainty and bias.		

Element 7		
Describe laboratory reporting procedures in accredited laboratories.		
Performance Criteria	Candidate	Assessor
7.1 The description outlines sample handling systems.		
Range: analysis request forms, assignment of laboratory identifiers.		
7.2 The description outlines procedures for releasing results, including appropriate authorisation.		
7.3 The description outlines procedures for archiving results.		

Develop, implement and review quality management system

Level: 7 Credits: 10

Entry information: Recommended: Unit 8085, *Demonstrate knowledge of quality and its management*, or demonstrate equivalent knowledge and skills.

Special notes

1 Definitions

Organisation refers to a specific business entity which may be – profit or non-profit; in private, public, or voluntary sectors; a business unit, iwi, or other special-purpose body.

Customer refers to a person or organisation who receives products or services supplied by the organisation. Customers may be external or internal to the organisation. The term “customer” may be translated according to the user’s context as “client”, “consumer”, “member”, “patient”, or other title.

Customer requirements is the expression of features of products, services, production and delivery processes, including both essential features or needs (both stated and implied), and desirable features.

Quality is the totality of the characteristics of products and services that bear on their ability to satisfy stated and implied needs of customers and other stakeholders.

Quality management is a philosophy of management that encompasses quality management systems, customer focus, a consultation culture, and continuous improvement, for the purpose of improving the value of goods and services to internal and external customers, with the outcomes being improved business results and greater effectiveness and efficiency in day-to-day activities.

Stakeholders are individuals and groups, which have some direct interest in the organisation and its products or services. Stakeholders typically include customers, providers, owners, shareholders, managers, employees, employee organisations, and regulatory bodies.

2 This unit standard recognises the need for organisations to develop their own philosophy of “quality” which fits their context and culture; candidates should be able to demonstrate knowledge and understanding of quality concepts and philosophy and to explain the strategic and operational implications of quality objectives.

3 This unit standard will be assessed on the basis of evidence of demonstrated performance in the workplace. In practice this will call for a variety of modes of assessment and forms of evidence. Evidence is required to show consistency of performance across a range of situations and to demonstrate knowledge, understanding, and skill in the principles and practices directly relating to the competent performance of elements and performance criteria.

Judgment statement

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Assessor: Based on the evidence of the verifier and demonstrated skills and knowledge the candidate has met the criteria as specified within this unit including all range statements.

Focus: Throughout this area of assessment the candidate will need to consistently apply knowledge learned relating to: sound businesses practices, organisational business rules and legislative requirements relating to acts, codes and legislation listed above.

Element 1		
Develop and implement quality management system.		
Performance Criteria	Candidate	Verifier/Assessor
1.1 A quality management system established for the organisation sets forth a distinctive management philosophy, gives quality assurance to customers of its products and services, and expresses its commitment to quality goals and objectives.		
1.2 The quality management system provides evidence of a coherent integrated system, within which all activities and procedures are understood, controlled, and documented, with proof that they are followed.		
1.3 Consultation and feedback with key interest groups and stakeholders in the development of the quality management system ensure their commitment to meet the quality requirements of customers.		
1.4 Responsibilities and authorities, with lines of accountability for quality performance, control, and improvement, are defined and documented for all persons whose activities can affect the quality of the products and services offered.		
1.5 System information detailing all quality responsibilities, policies, and procedures is maintained in an updated, reliable and readily accessible form to meet user needs.		

Element 2

Review quality management system for conformance to requirements and improvement of quality.

Performance Criteria	Candidate	Assessor
2.1 Review demonstrates that operational procedures are in place for detecting causes of nonconformities, for initiating preventive and corrective actions, for following up, and verifying their effectiveness.		
2.2 Review validates quality of inputs, processes, and outputs against standards.		
Range standards include but are not limited to – customer requirements, technical standards, organisational objectives.		
2.3 Review demonstrates effectiveness of internal audit system in providing auditable criteria and an audit trail, ensuring identification of success and deficiencies, and enabling improvements in performance to be implemented.		
2.4 Review verifies that quality improvement opportunities, goals and plans are established, agreed and implemented.		
2.5 Review ensures that the quality management system continues to meet the requirements of customers and the organisation, and identifies opportunities for continuing improvement.		
2.6 Review demonstrates effectiveness of communication of the quality message throughout the organisation, showing commitment to the quality management system at all levels, and understanding of the contribution each person can make to the control and improvement of quality.		

Audit quality management systems for compliance with quality standards

Level: 6 Credits: 14

Entry information: Open.

Special notes

- 1 Although not prerequisites, Unit 8086, *Demonstrate knowledge required for quality auditing*, and Unit 8085, *Demonstrate knowledge of quality and its management* contain useful underpinning knowledge for this unit standard.

- 2 Definitions

Quality is the degree to which a set of inherent characteristics of products and services fulfils the stated and implied requirements of customers and other stakeholders.

Quality management is a philosophy of management that encompasses quality management systems, customer focus, and a consultative culture. The purpose is to continuously improve the value of goods and services to internal and external customers, with outcomes of improved business results and greater effectiveness and efficiency in day-to-day activities.

Quality management systems refers to a formal management system that establishes policy and objectives (and ways of achieving them) in order to direct and control an organisation with regard to quality.

Quality audit is a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Auditee is the organisation, or part thereof, that is to be audited.

Client is the person or organisation requesting the audit. The client can also be the auditee.

Quality standards are the criteria against which the auditee's performance will be audited. Examples of such standards may include but are not limited to:

Quality Health New Zealand Standards, available at <http://www.qualityhealth.org.nz/>;

AS/NZS 4801:2001: *Occupational Health and Safety Management standards – Specification with guidance for use*;

ACC Partnership Programme: *Audit standards* (Wellington: Accident Compensation Corporation, 2002), available at <http://www.acc.co.nz/index.htm>;

ISO 9000:2005 *Quality Management Systems* series;

ISO 22000:2005 – *Food Safety Management Systems*;

ISO 19011:2001 – *Guidelines for Quality and/or Environmental Management Systems Auditing*;

codes of practice;

any other criteria that have been agreed in the supplied scope of the audit. These can include auditee's plans, procedures, and quality objectives.

- 3 All activities must comply with: any policies, procedures, business protocols, and requirements of the organisation(s) involved; ethical codes and standards of relevant professional bodies; the cultural requirements of the organisation(s) and individuals involved; and any relevant legislative and/or regulatory requirements. Activities must also comply with any guidelines for quality management systems auditing, and any other special conditions pertaining to the industry being audited.
- 4 Legislation relevant to this unit standard can include but is not limited to: Health and Safety in Employment Act 1992, Resource Management Act 1991, Official Information Act 1982, Privacy Act 1993, State Sector Act 1988, Employment Relations Act 2000, Fair Trading Act 1986, Consumer Guarantees Act 1993, and subsequent amendments.
- 5 This unit standard can be applied to both internal and external audits, and to both compliance audits and audits conducted for the purpose of identifying opportunities for improvements.
- 6 The unit standard focuses on the process, not the scope. Candidates must complete at least one full workplace audit, (either internal or external) that includes all processes for each element of this unit standard. They will work from a supplied audit scope and plan. The audit may be completed individually or as part of a team.

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Element 1

Prepare to carry out a quality audit.

Performance Criteria	Candidate	Verifier/Assessor
1.1 Review of auditee's previous audits establishes possible impacts on the conduct of the current audit.		
1.2 Auditor's individual plan of activities matches the requirements of the supplied audit plan and enables the objectives of the audit to be met.		
1.3 Assembly and production of working papers ensure collection of the required evidence.		
Range working papers may include but are not limited to – checklists, quality standards, organisation charts, previous audit reports, quality system documentation.		

Element 2

Carry out technical aspects of a quality audit.

Performance Criteria	Candidate	Assessor
2.1 Audit objectives, audit process, and availability of resources are confirmed with the auditee before the auditing activities begin.		
2.2 Comparison of the quality standards with the auditee's plans for meeting the standards ensures that variances can be recognised.		
2.3 The auditing of auditee's performance against plans for these activities ensures that variations can be recognised.		
2.4 Audit observations are recorded in sufficient detail to ensure that the subsequent analysis can be carried out to the requirements of the supplied audit scope and plan.		
2.5 Comparisons of observations against auditee's plans and procedures, and against the quality standards, enable compliance or non-compliance to be determined.		
2.6 Evaluative decisions are made on the basis of sufficient and verifiable evidence so that the extent of compliance and opportunities for improvement can be identified.		
2.7 Any contingencies that occur during audit are managed to ensure that the integrity of the audit is not compromised.		
Range contingencies may include but are not limited to – dangerous and critical situations, incapacity of auditor to continue, significant failure of auditee's systems and/or equipment.		
2.8 Any actions taken as a result of the auditee's responses to findings while the audit is in process do not compromise the integrity of the audit.		

Element 3

Carry out interpersonal aspects of a quality audit.

Performance Criteria	Candidate	Assessor
3.1 Audit activities facilitate the co-operation of the auditee, the resolution of conflict, and the communication of all information required to meet the audit objectives.		
3.2 Communication with the auditee and (if applicable) client ensures that all parties remain informed of the progress of the audit and of any circumstances that could alter planned arrangements.		
3.3 Communication with any other participating auditors ensures the coordination of audit activities, the consistency of audit performance, and the completion of the audit plan.		
3.4 All communications with auditees and (if applicable) other auditors demonstrate respect, courtesy and cultural sensitivity.		

Element 4

Report on a quality audit.

Performance Criteria	Candidate	Assessor
4.1 Reports identify the extent of compliance with quality standards and areas requiring corrective action to ensure compliance, and include recommendations for improvement where such advice does not compromise the independence of the auditor.		
Range preliminary report presented at exit interview, final report.		
4.2 The presentation of the preliminary report covers the required scope, reflects all conclusions, findings, and observations, and ensures that the results of the audit are clearly understood by the auditee.		
4.3 Negotiation at exit interview establishes auditee's agreement regarding how, when, and by whom corrective actions are to be carried out to achieve compliance with quality standards.		
4.4 Final audit report is consistent with the preliminary report and negotiated outcomes of the exit interview.		
4.5 Reports are distributed in accordance with the requirements of the audit plan.		

Element 5

Verify corrective actions.

Performance Criteria	Candidate	Assessor
5.1 The evidence gathered is sufficient for an assessment of whether corrective actions have been completed.		
5.2 Status of corrective actions is reported to client in accordance with negotiated requirements.		
5.3 Where compliance is not achieved, renegotiation with auditee establishes additional corrective action required to achieve compliance.		