ISO AUDIT PREPARATION KIT 2016

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ISO

1 What is the ISO Audit?

"ISO 9001 specifies requirements for a quality management system that can be used for internal application by organisations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements" (p vi AS/NZS ISO 9001: 2008 Quality management systems – Requirements).

An audit is a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine whether audit criteria such as policies, procedures, processes and other requirements in the Institute's Quality Management System have been fulfilled.

A key feature of the ISO audits is to review previously issued findings from Institute external and internal audits.

2 What are the advantages of ISO certification?

The key function of ISO is to monitor and ensure improvements to operations and systems. The key outcomes of ISO certification is to increase customer satisfaction and retention through a more efficient and effective organisation. The purpose of an ISO audit is to monitor our performance against the ISO standards and to identify any areas of improvement.

3 ISO Audit

During the Institute's audit, the auditors assess the level of conformance of the Institute's quality management system to AS/NZS ISO 9001:2008. The Institute receives certification from this audit for a period of three (3) years. During these three (3) years, SAI Global will conduct annual surveillance audits.

4 Audit – Why me?

The ISO auditor identifies which college and business area will be the focus of the audit in a given year. A section or unit is audited to ensure that systems across the Institute are working and everyone is aware of key business processes.

The stages of the audit will consist of:

- ▲ Auditors asking questions
- ▲ The detection and observation of objective evidence
- ▲ The recording of objective evidence details

5 Entry meeting

An audit normally commences with a brief discussion between the auditors and key stakeholders. This discussion is referred to formally as the ‘opening meeting’ and has the following objectives:

- ▲ Introductions
- ▲ Confirm the purpose and scope of the audit
- ▲ Confidentiality
- ▲ Advice of the audit methods to be used during the audit
- ▲ Confirm access to objective evidence
- ▲ Sampling of documents and records
- ▲ Position on recommendations: observations, non-conformances, Improvement Requests
- ▲ Confirm the time for the exit meeting
- ▲ Confirm if any guides are required and their function
- ▲ Any special points the auditor should be aware of, e.g. safety, restricted areas

6 Audit Findings

Audit findings are documented and supported by evidence.

Audit findings consist of:

- ▲ Non Compliance Request (NCR)
- ▲ Area of Concern
- ▲ Opportunity for Improvement.

Non Compliance means the current practice does not comply with an Institute or Department policy or procedure.

An **Area of Concern** is an area the client is required to investigate potential nonconformity. Lack of client attention to such issues implies that a preventative action system is not working effectively, and could result in an NCR being raised at a later date.

An **Opportunity for Improvement** is a finding that may identify areas for improvement however shall not make specific recommendations. Systems and processes solutions may be developed and implemented in order to add value to operations and management systems.

7 Audit Report

It reflects both the tone and content of the audit. It should contain the following items, as applicable:

- ▲ Scope and objectives of the audit
- ▲ Audit findings against Standards
- ▲ Observations
- ▲ Improvement requests
- ▲ Summary and recommendation

8 Closing meeting

The main purpose of the closing meeting is for the auditors to present and discuss the audit findings with managers from the organisation.

The following activities occur in the closing meeting:

- ▲ Present audit findings, observations, areas of concern and improvement requests
- ▲ Quote the evidence
- ▲ Present conclusions regarding the quality management system’s effectiveness
- ▲ Follow-up – Annual Reviews

Annual Reviews occur between the three (3) yearly Certification audits.

It is possible for Certification to be suspended at any time should there be a major non-conformance finding.

ISO 9001:2008 Fact Sheet

Questions	Answers
What….	The International Organisation for Standardisation (ISO) is a worldwide federation of national standards' bodies. ISO 9001:2008 is a comprehensive set of internationally recognised standards that apply uniformly to any type and/or size of organisation. Organisations achieve Certification to this Standard by developing a quality management system focused on meeting customer requirements and continuous improvement. Regular audits by an external certification body provide an opportunity to validate the system and offer advice on opportunities for improvement. The institute's quality management system and extensive business systems support its operations. Compliance with ISO 9001:2008 expands our international business credibility.
Why….	The benefits of ISO Certification include: ▲ Increased focus on how our day-to-day business is managed; ▲ Identification of areas where our systems are inconsistent; ▲ Greater staff sharing and learning through involvement in systematic internal audits; ▲ Better customer service, through the continuous improvement of systems; and ▲ International recognition of the Institute's commitment to quality.
Where….	▲ The institute Quality Manual illustrates how the institute applies the standards to its business ▲ A PaCK search using the keywords *ISO* will retrieve ISO related documents
Business Rules….	To maintain ISO certification the Institute must: ▲ Monitor customer satisfaction and drive quality improvement initiatives to achieve further gains ▲ Integrate quality principles into our decision making groups and planning processes ▲ Monitor and action improvement opportunities. This is managed through the online Improvements Request System. ▲ Implement an annual internal audit program of Institute processes and procedures ▲ Identify and correct non-conformances. These are tracked through the online Internal Quality Audits System.

Further Information…

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- Go to ISO Online

Preparing for the ISO 9001:2008 Audit - 2016

Resources	Description		
1 Audit Guide	Each SAI Global auditor will be accompanied around each college by a college guide, who will ensure the auditor arrives at your section on the day at the correct time. They will also ensure the auditors have access to amenities on site.		
2 Areas of interest during the interview	The auditors are interested in the jobs that you do and will ask for examples of the documentation you use in undertaking your normal duties. They will want to see job related records, any resources you may use and your version control of these. They will want to know where they are kept and how they are maintained. At an individual level, they will be interested in how staff continually improve their knowledge, awareness and training within their job. They may seek evidence of staff development, personal development and the pursuit of continuous improvement. They may also seek evidence of business/section/unit planning and reporting. Auditors will want to know that staff have access to necessary applications such as PaCK (Policies and Corporate Knowledge), and how they access information to help them in their work. They may discuss internal communication, how the Institute's objectives are identified and incorporated into local level plans as well as the objectives in each section area.		
3 How to prepare your section	The first step is to ensure that all your staff are skilled in accessing information from the Intranet and PaCK. They should also know how to use the Improvement Request procedure and should be aware of internal quality audit reports. Training is available through the Strategic Planning and Performance Unit Documents to have at hand for the audit interview will be your business plans, business plan reports, projects, Strategic Plan, Annual Plan and other relevant documents for your business. All commonly used forms are on PaCK.		
4 ISO Compulsory Procedures	*4.2.3 Control of documents* Documents required by the quality management system shall be controlled.	PaCK User Guide PaCK - Publishing and Maintaining Items Developing Institute Policies and Procedures - Procedure	This procedure indicates how to publish or update documents on PaCK and meet quality assurance guidelines. This procedure applies to all staff, in particular managers, who are responsible for currency and quality assurance. This procedure applies when a change to, a review or removal of, a document from the PaCK is identified. This procedure assists the Institute in building business literacy and contributes to the

Resources	Description		
			pool of knowledge in the Institute.
	4.2.4 Control of records Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, legibility, storage, protection, retrieval, retention time and disposition of records.	Sydney Institute Records Management Program	This procedure identifies how to create and manage TRIM files. It is relevant to managers, section heads and administrative staff and applies when commencing a new project, new initiative, new regulation etc. Accountability, corporate knowledge, FOI, legal requirements.
	8.2.2 Internal Audit The organisation shall plan and implement the monitoring, measurement, analysis and improvement processed needed: a) to demonstrate conformity of the product; b) to ensure conformity of the quality management system and; c) to continually improve the effectiveness of the quality management system.	Internal Quality Audit Procedure	This procedure provides information on the process for conducting internal audits within the Institute to assess compliance with the Institute's management system and against ISO 9001:2008. It is relevant to Internal auditors and the Strategic Planning & Performance Unit as well as stakeholders. Through a deployment flow chart, it identifies key roles and responsibilities for all stages associated with internal audit.
	8.3 Control of Non-conforming Product The organisation shall ensure that product	Internal Quality Audit Procedure	These procedures determine the process for correcting errors in practices, processes and products associated with

Resources	Description		
	which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming products shall be defined in a documented procedure.	Improvement Request Procedure Complaints Handling Flowchart Complaints Handling Policy Complaints Handling Policy Guidelines	teaching and learning. The procedure assists the Institute in increasing customer satisfaction and ensuring optimum service delivery and outcomes for students and other customers.
	8.5.2 Corrective Action The organisation shall take action to eliminate the cause of non-conformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	Corrective Action Procedure	This procedure determines the processes to be followed for ensuring the continuing quality of Sydney Institute products and services. It identifies how to address a non-conformance identified through internal audit. It is particularly relevant to Directors, managers and section heads participating in internal audits. Its aim is to ensure local practice is consistent with Institute procedures.
	8.5.3 Preventive Action The organisation shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventing actions shall be appropriate to the effects of the potential problems.	Preventive Action Procedure	This procedure identifies the process for analysing information and data to determine areas of risk and to initiate preventive action. They are particularly relevant to the Strategic Planning & Performance Unit and Senior Management. The procedures allow the Institute to prevent non-conformities, maintain standards and foster continuous improvement.
5 Quality Manual	For copyright reasons, the ISO 9001:2008 Standards are not available on PaCK. The ISO standards can be downloaded from the Library and Information services page in our business on SYDNET. However, the Sydney Institute Quality Manual is on PaCK.		
6 Support from	The Strategic Planning and Performance (SPP) Unit have prepared		

Resources	Description
staff in SPP	documents for staff participating in the external audit. The Business Performance and Improvement Officer will also liaise with CEOS and managers at each location to assist in preparing for the audit.

ISO 9001:2008 Definitions

Quality Management Systems	The Institute Quality Management System refers to the systems, policies, procedures, practices, personnel and decision-making structures that manage and control the Institute's core business processes of delivering teaching and learning products and services.
Supplier	TAFE Institutes
Product	Institute activities focussed on the provision of expertise, resources and knowledge to meet the educational requirements of the customer. It is desirable that the purpose of the provision is incorporated into the product definition. Without that sense of purpose, it could be perceived that the organisation emphasises input and process rather than outcome, and its product will not necessarily have a clear defined customer focus. Therefore, options for product definition could include the following: ▲ Enhancement skills/knowledge/understanding/attitude/values ▲ Provision of: ▲ An educational environment ▲ A curriculum and other resources ▲ A community service ▲ Research outputs
Customer	A customer is: ▲ A student ▲ A student's parent(s) / guardian or employer ▲ A company or organisation with whom a research contract, a consultancy agreement or a training contract is entered into ▲ Industry ▲ An internal customer (i.e. staff member) ▲ A government, regulatory body, accreditation body or similar ▲ A relevant society group
Process	Defined as a set of interrelated or interacting activities which transforms inputs into outputs
Non-conformity	Non-fulfilment of a requirement.
Preventative Action	Action to eliminate the cause of a **potential** non-conformity or other undesirable situation.
Corrective Action	Action to eliminate the cause of a **detected** non-conformity or other undesirable situation.
Verification	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.
Validation	Confirmation, through the provision of objective evidence, that the requirements for a specific intended use of application have been fulfilled.
Audit	Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
Continual Improvement	Recurring activity to increase the ability to fulfil requirements (e.g. Management Review).

ISO Audit Preparation - 2016

Examples of evidence for Generic sections

Element reviewed	Related Evidence
4 Quality Management System **4.1-General requirements**	/ Intranet PaCK / Policies and procedures / Organisational information / Core business process maps / Support services / Quality Manual
4.2 Documentation	/ Reporting structure defined in Organisational Chart / Responsibilities defined in recruitment criteria used in advertising for new positions / Induction checklist for new staff / Policies and procedures / Audit findings and corrective actions / Actions from Sydney Institute Executive meetings
4.2.2 Control of records **4.2.3 Control of documents**	/ TRIM files / Version control – local / Gazettes / DEC site / Business plans
5.1 Management responsibility and commitment	/ Institute Director's Minutes / College communication and meetings / Communication of legislative requirements / Training requirements are included in the business plan and within budget allocations
5.2 Customer focus	/ Information sheet. / Course information is advertised in local media. / Flyers / Course hand books / Verbal communication by staff / Materials customised to meet the needs of various groups e.g. multi language, culturally adapted.
5.3 Quality policy	/ Quality improvements embedded in plans / TAFE NSW Quality Policy / Complaint handling via the TAFE Complaint Handling process. / Customer surveys / Stakeholder meetings / Quality Manual
5.4 Planning and Objectives	/ Quarterly staff meetings – meeting minutes show discussion items and actions. / Quarterly reports showing progress against priorities and objectives. / Reports to external stakeholders / Course completion reports showing statistics and success rate for target groups/clients / Core process business maps / Institute Annual Plan 2015 or successor and Performance

	measures
5.5 Responsibility, authority and communication	/ Organisation charts / Delegations manual / Sydney Executive, College Team, / Internal communication staff meeting minutes showing review of objectives and unit operational items. / Business plans identifying areas for continuous improvement / Internal audits / External audits conducted on various programs
5.6 Management review	/ Actions from Sydney Institute Executive meetings / Outcomes from internal and external audits / Institute quarterly performance reviews / Information on the Intranet / Institute Director's Minutes / Improvement request procedure / Quality improvement projects / Innovation projects
6 Resource management	/ Budget preparation and planning (I Plan) / Human resources i. Competence of staff ii. Recruitment and induction iii. Review iv. Staff training and development v. Technical update / IT and other equipment / Infrastructure and work environment / Scope process / Work, Health &Safety (WH&S) / Resource allocation process / Institute Annual Plan 2015 or successor
7.5 Process Control/ Validation/ Identification/ Traceability	/ Panel assessment sheets / Regular staff meetings / Calibration of measuring equipment / Internal control checklists / Institute/college quarterly performance review
7 Product realisation	/ Educational planning (I Plan) / Quality assurance / Assessment results and records
7.2 Customer requirements	/ Attendance at industry forums / Annual visit to employer base / Suppliers providing new technologies / Industry presentation night / Annual employer visits / Customer surveys / Curriculum documentation / Training packages and Training.gov.au documentation
7.2.3 Customer Communication and Feedback	/ Course information / School careers days / Enrolment day/ student questionnaire to assess needs. / Course information sheets / Handbook / Customer complaints process and results

7.3 Design and development	/	Evidence of industry demand and involvement in training plans, courses and assessments
7.4 Purchasing	/ / / / / /	Processes Suppliers Contracts Policies and procedures Internal control checklists Furniture, Equipment and Plant (FEAP)
7.5 Production and service provision	/ / / /	Course/program information Equipment work instructions, Standard Operating Procedures (SOPs) – Work Health & Safety (WH&S) Monitoring and measuring devices Customer satisfaction surveys
8. Measurement, analysis and improvement	/ / / / / /	Budget reports Informal student feedback Module/unit Completion rate Budget reports Section meetings Faculty meetings
8.1-8.4 Measurement, analysis and improvement	/ / / / / / / / /	Customer satisfaction and feedback Internal and external audit results and improvement actions Unit/Module Completion Rate Re-assessments Performance data Curriculum reviews Version control of curriculum documents Performance updates Internal control checklists
8.5 Continuous Improvement	/ / / / / /	Improvement requests Internal and external audit results and improvement actions Quality Improvement projects Complaints resolution Preventive action – staff meetings, Sydney Institute Executive minutes Innovation projects

ISO Audit Preparation- 2016

Examples of evidence for teaching units

Element Reviewed	Related Evidence
4 Quality Management System **4.1-General requirements**	/ Intranet PaCK / Policies and procedures / Organisational information / Core process maps
4.2 Documentation	/ Induction checklist for new staff / Roll books / Course Information books / Syllabus (Train.gov.au) / Guideline for roll books / ebs / Student Resource Package / Student Work Evidence Books
4.2.2 Control of records **4.2.3 Control of documents**	/ TRIM files / Version control – local / Gazettes / DEC site / Train.gov.au
5.1 Management responsibility and commitment	/ Institute Director's Minutes / College communication and meetings / Communication of legislative requirements / Training requirements are included in the business plan and within budget allocations
5.2 Customer focus	/ Education and Training Plans / Training and Assessment Strategy
5.3 Quality policy	/ Quality improvements embedded in plans / TAFE NSW Quality Policy
5.4 Planning and Objectives	/ I Plan / Timetable / Profile meeting / Course planning sessions / Timetable preparation / Section Business Plan / Learning and Assessment Strategy / Core process business maps / Institute Annual Plan & reporting / Strategic Directions 2015 or successor
5.5 Responsibility, authority and communication	/ Organisation charts / Delegations manual / Sydney Executive, College /Faculty Team, meetings and outcomes / Internal communication
5.6 Management review	/ Actions from SIE meetings / Outcomes from internal and external audits / Institute quarterly performance reviews / Information on the Intranet / Institute Director's Minutes

Element Reviewed	Related Evidence
	/ Improvement request procedure / Quality improvement projects / Innovation projects
6.0 Resource management	/ Budget preparation and course planning / Human resources i. Competence of staff ii. Recruitment and induction iii. Review iv. Staff training and development v. Technical update / IT and other equipment, infrastructure, work environment / Scope / WH&S
7.5 Process Control/ Validation/ Identification/ Traceability	/ Roll books / ebs completed showing attendance and assessment records. / Roll books / ebs (signed / approved) by head teacher / Assessment record summaries/ completed module planning sheet / Student acknowledgement of assessment guide / Panel assessment sheets / Roll books containing attendance sheets, assessment guideline and course brief. / Weekly staff meetings / Panel assessment used to validate assessment tools against learning outcomes / Syllabus printouts / Lesson Plans / Course program / Roll Books / ebs student records completed according to requirements and audited by Head Teacher. / Assessment validation in progress (mapping new TP requirements) / Calibration of measuring equipment every 6 months. / Internal control checklists
7 Product realisation	/ Curriculum / Educational planning / Teaching and Assessment strategy / Quality assurance / Assessment results and records
7.2 Customer requirements	/ Attendance at industry forums / Annual visit to employer base / Employer feedback to teachers during term / Suppliers providing new technologies / Student feedback during class / Industry presentation night / Annual employer visits / Teacher contact with employers.
7.2 Customer requirements	/ Reasonable adjustment / ABE / Learner support / Access and equity

Element Reviewed	Related Evidence
	/ RPL / Customer communication / Customer feedback and complaints / Course information and enquiries / Training and assessment strategy
7.2.3 Customer Communication and Feedback	/ Course information / internet / School careers days / Enrolment day/ student questionnaire to assess need / Handbook / Assessment of student portfolio and interview prior to enrolment. / Student feedback during class and attendance / Student survey forms used to collect formal feedback. / Student feedback and employer feedback.
7.3 Design and development	/ Evidence of industry demand and involvement in training plans, courses and assessments
7.4 Purchasing	/ Processes / Suppliers / On contract / Procurement policies and procedures / FEAPs
7.5 Production and service provision	/ Course information / Equipment work instructions/SOPs – WH&S / Monitoring and measuring devices / Customer satisfaction surveys / Assessment validation
8 Measurement, analysis and improvement	/ Budget reports / Student assessment results / Student contact with Head Teacher / Lesson Plans vetted by Head Teacher/supervision of staff / Informal student feedback / Completion rates / Ebs student monitoring & results / Section meetings / Faculty meetings
8.1-8.4 Measurement, analysis and improvement	/ Customer satisfaction and feedback / Internal audit / Unit/Module completion rates / Re-assessments / Performance data / Curriculum reviews / Version control of curriculum / Performance updates / Internal control checklists
8.5 Continuous Improvement	/ Undergoing assessment validation / Collating validated assessment tools / Improvement requests / Internal/external audit findings / Improvement projects

Element Reviewed	Related Evidence
	/ Complaints processes and resolution / Preventive – staff meetings, Sydney Institute Executive / Innovation projects

2016 Information Related to ISO External Surveillance Audit for Directors and Managers

The ISO auditors will be looking at planning, monitoring, feedback and improvement in the Institute's management system. The auditor will visit Institute and College / Faculty Directors and Managers in order to contextualise the way teaching sections and functional unit work is conducted. The auditors will then look at whether teaching sections and functional units are managing their areas according to established Institute policy and procedures.

The audit may reflect the following:

1 Planning and Quality Assurance

This segment looks at the business planning process (planning, monitoring, feedback, improvement)

- ▲ Overview of business planning process to see how activities and tasks are planned, defined and documented and that measurable quality objectives have been determined and set.
  - / *Evidence*: Annual Plan, Institute, Directorate, College and Faculty and Sectional Plans, Educational Planning (I Plan), Key Performance Indicator\s set out in business plans
- ▲ The responsibilities and authorities and interrelationships with respect to the process are defined and communicated.
  - / *Evidence*: SydNet processes, sub-processes and their management, organisational charts, senior staff meetings
- ▲ Customer requirements are determined, analysed, reviewed and communicated.
  - / *Evidence*: TGA, Customer Surveys, Senior Staff Meetings, Student Training Plans
- ▲ Product requirements have been defined.
  - / *Evidence*: Training packages and Curriculum Documentation
- ▲ The resources necessary to support the operation have been planned and made available. (i.e. personnel allocation and numbers, competence, infrastructure, work environment)
  - / *Evidence*: resource allocation model used in the Institute
  - / Scope process
  - / Institute Annual Plan or successor
  - / Workforce Development Plan
  - / Asset Plan

2 Faculty Level Audit Process

Faculty Directors (i.e. Faculty Executive Committee)

Business Planning Process

- Overview of Faculty – Size, diversity
- Quality objectives as in Key Performance Indicators and relationship to business planning and the process used to create Annual plan.
- College Business plan and quarterly review – Links with the Institute Annual Plan and section level planning
- Planning for Course Delivery - Review of consolidated educational planning and budgets against targets. (I Plan)
- This segment looks at the Faculty's ability to capture and act on corrective and preventative actions. (Continuous improvement)

Evidence may include:

- Faculty Annual plan – Development and monitoring process
- Minutes to senior staff meeting for items concerning- Customer satisfaction, complaints, audit actions etc.,
- ebs records
- Staff satisfaction
- Version control of curriculum documentation
- Complaints – handling and monitoring of complaints data

▲ Faculty Operations

The auditor will be gaining an understanding of the overall operation process. The consistency of the information given during this session will be tested by the auditor at a section level.

Overview of process (Planning, monitoring, feedback, improvement)

- What planning/research occurs in relation to this process?
- Is there an Annual Plan?
- How do you analyse progress with the plan?
- How do you assess system improvements? Have any been made?
- How is feedback sought?
- What support is offered to sections?
- What policies govern operations?
- What procedures govern operation?
-

Evidence: Surveys, emails, minutes of meetings, documents, Improvement requests

ISO Standards AS/NZS ISO 9001:2008

4. Quality Management System

4.1 General Requirements

The organisation shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.
The organisation shall:

a) Determine the processes needed for the quality management system and their application throughout the organisation
b) Determine the sequence and interaction of these processes
c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective
d) Determine the availability of resources and information necessary to support the operation and monitoring of these processes
e) Monitor, measure where applicable and analyse these processes and
f) Implement actions necessary to achieve planned results and continual improvement of these processes

These processes shall be managed by the organisation in accordance with the requirements of this International Standard.

Where an organisation chooses to outsource any process that affects product conformity to requirements, the organisation shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

4.2 Documentation Requirements

4.2.1 General

The quality management system documentation shall include

a) Documented statements of a quality policy and quality objectives
b) A quality manual
c) Documented procedures and records required by this International Standard, and
d) Documents, including records, determined by the organisation to be necessary to ensure the effective planning, operation and control of its processes

4.2.2 Quality Manual

The organisation shall establish and maintain a quality manual that includes

a) The scope of the quality management system, including details of and justification for any exclusions
b) The documented procedures established for the quality management system, or reference to them, and
c) A description of the interaction between the processes of the quality management system

4.2.3 Control of Documents

Documents required by the quality management system shall be controlled.

A documented procedure shall be established to define the controls needed

a) To approve documents for adequacy prior to issue
b) To review and update as necessary and re-approve documents,
c) To ensure that changes and the current revision status of documents are identified,
d) To ensure that relevant versions of applicable documents are available at points of use,
e) To ensure that documents remain legible and readily identifiable
f) To ensure that documents of external origin determined by the organisation to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose

4.2.4 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

The organisation shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

5. Management Responsibility

5.1 Management Commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving effectiveness by

a) Communicating to the organisation the importance of meeting customer as well as statutory requirements
b) Establishing the quality policy
c) Ensuring that quality objectives are established
d) Conducting management reviews, and
e) Ensuring the availability of resources

5.2 Customer Focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

5.3 Quality Policy

Top management shall ensure that the quality policy

a) Is appropriate to the purpose of the organisation
b) Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system
c) Provides a framework for establishing and reviewing quality objectives
d) Is communicated and understood within the organisation, and
e) Is reviewed for continuing suitability

5.4 Planning

5.4.1 Quality Objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product are established at relevant functions and levels within the organisation. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality Management System Planning

Top management shall ensure that
a) The planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organisation.

5.5.2 Management Representative

Top management shall appoint a member of the organisation's management who, irrespective of other responsibilities, shall have responsibility and authority that includes
a) Ensuring that processes needed for the quality management system are established, implemented and maintained
b) Reporting to top management on the performance of the quality management system and any need for improvement, and
c) Ensuring the promotion of awareness of customer requirements throughout the organisation.

5.5.3 Internal Communication

Top management shall ensure that appropriate communication processes are established within the organisation and that communication takes place regarding the effectiveness of the quality management system

5.6 Management Review

5.6.1 General

Top management shall review the organisation's quality management system, at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.
Records from management reviews shall be maintained.

5.6.2 Review Input

The input to management review shall include information on

a) Results of audits
b) Customer feedback
c) Process performance and product conformity
d) Status of preventive and corrective actions
e) Follow – up actions from previous management reviews
f) Changes that could affect the quality management system, and
g) Recommendations for improvement.

5.6.3 Review Output

The output from the management review shall include any decisions and actions related to

a) Improvement of the effectiveness of the quality management system and its processes
b) Improvement of product related to customer requirements, and
c) Resource needs.

6. Resource Management

6.1 Provision of Resources

The organisation shall determine and provide the resources needed

a) To implement and maintain the quality management system and continually improve its effectiveness, and
b) To enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, training and awareness

The organisation shall

a) Determine the necessary competence for personnel performing work affecting conformity to product requirements
b) Where applicable, provide training or take other actions to achieve the necessary competence
c) Evaluate the effectiveness of the actions taken
d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
e) Maintain appropriate records of education, training, skills and experience.

6.3 Infrastructure

The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

a) Buildings, workspace and associated utilities
b) Process equipment (both hardware and software), and
c) Supporting services (such as transport, communication or information systems).

6.4 Work Environment

The organisation shall determine and manage the work environment needed to achieve conformity to product requirements.

7. Product Realization

7.1 Planning of Product Realization

The organisation shall plan and develop the processes needed for product realisation. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.
In planning product realisation, the organisation shall determine the following, as appropriate,

a) Quality objectives and requirements for the product
b) The need to establish processes and document, and to provide resources specific to the product
c) Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance
d) Records needed to provide evidence that the realisation processes and resulting product meet requirements.

The output of this planning shall be in a form suitable for the organisation’s method of operations.

7.2 Customer – Related Processes

7.2.1 Determination of Requirements Related to the Product

The organisation shall determine,

a) Requirements specified by the customer, including the requirements for delivery and post – delivery activities,
b) Requirements not stated by the customer but necessary for specified or intended use, where known
c) Statutory and regulatory requirements applicable to the product, and
d) Any additional requirements considered necessary by the organisation.

7.2.2 Review of Requirements Related to the Product

The organisation shall review the requirements related to the product. This review shall be conducted prior to the organisation's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that,

a) Product requirements are defined
b) Contract or order requirements differing from those previously expressed are resolved, and
c) The organisation has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organisation before acceptance.

Where product requirements are changed, the organisation shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer Communication

The organisation shall determine and implement effective arrangements for communicating with customers in relation to,

a) Product information
b) Enquiries, contracts or order handling, including amendments, and
c) Customer feedback, including customer complaints.

7.3 Design and Development

7.3.1 Design and Development Planning

The organisation shall plan and control the design and development of product.
During the design and development planning, the organisation shall determine,

a) The design and development stages
b) The review, verification and validation that are appropriate to each design and development stage, and
c) The responsibilities and authorities for design and development.

The organisation shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 Design and Development Inputs

Inputs relating to product requirements shall be determined and records maintained. These inputs shall include,

a) Functional and performance requirements
b) Applicable statutory and regulatory requirements
c) Where applicable, information derived from previous similar designs, and
d) Other requirements essential for design and development.

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and Development Outputs

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall,

a) Meet the input requirements for design and development
b) Provide appropriate information for purchasing, production and service provision
c) Contain or reference product acceptance criteria, and
d) Specify the characteristics of the product that are essential for its safe and proper use

7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements,

a) To evaluate the ability of the results of design and development to meet requirements, and
b) To identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stages being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.

7.3.5 Design and Development Verification

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.

7.3.6 Design and Development Validation

Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained.

7.3.7 Control of Design and Development Changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained.

7.4 Purchasing

7.4.1 Purchasing Process

The organisation shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realisation or the final product.
The organisation shall evaluate and select suppliers based on their ability to supply product in accordance with the organisation's requirements. Criteria for selection, evaluation and re – evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

7.4.2 Purchasing Information

Purchasing information shall describe the product to be purchased, including, where appropriate,

a) Requirements for approval of product, procedures, processes and equipment
b) Requirements for qualification of personnel, and
c) Quality management system requirements

The organisation shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of Purchased Product

The organisation shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.
Where the organisation or its customer intends to perform verification at the supplier's premises, the organisation shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Product and Service Provision

7.5.1 Control of Production and Service Provision

The organisation shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable,

a) The availability of information that describes the characteristics of the product
b) The availability of work instructions, as necessary
c) The use of suitable equipment
d) The availability and use of monitoring and measuring equipment
e) The implementation of monitoring and measurement, and
f) The implementation of product release, delivery and post – delivery activities

7.5.2 Validation of Processes for Production and Service Provision

The organisation shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.
Validation shall demonstrate the ability of these processes to achieve planned results.
The organisation shall establish arrangements for these processes including, as applicable,

a) Defined criteria for review and approval of the processes
b) Approval of equipment and qualification of personnel
c) Use of specific methods and procedures
d) Requirements for records, and
e) Revalidation

7.5.3 Identification and Traceability

Where appropriate, the organisation shall identify the product by suitable means throughout product realisation.
The organisation shall identify the product status with respect to monitoring and measurement requirements throughout product realisation.
Where traceability is a requirement, the organisation shall control the unique identification of the product and maintain records.

7.5.4 Customer Property

The organisation shall exercise care with customer property while it is under the organisation’s control or being used by the organisation. The organisation shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organisation shall report this to the customer and maintain records.

7.5.5 Preservation of Product

The organisation shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.6 Control of Monitoring and Measuring Equipment

The organisation shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.
The organisation shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.
Where necessary to ensure valid results, measuring equipment shall,

a) Be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded
b) Be adjusted or re – adjusted as necessary
c) Have identification in order to determine its calibration status
d) Be safeguarded from adjustments that would invalidate the measurement result
e) Be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organisation shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organisation shall take appropriate action on the equipment and any product affected.
Records of the results of calibration and verification shall be maintained.
When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

8. Measurement, Analysis and Improvement

8.1 General

The organisation shall plan and implement the monitoring, measurement, analysis and improvement processes needed,

a) To demonstrate conformity to product requirements
b) To ensure conformity of the quality management system, and
c) To continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques and the extent of their use.

8.2 Monitoring and Measurement

8.21 Customer Satisfaction

As one of the measurements of the performance of the quality management system, the organisation shall monitor information relating to customer perception as to whether the

organisation has met customer requirements. The methods for obtaining and using this information shall be determined.

8.2.2. Internal Audit

The organisation shall conduct internal audits at planned intervals to determine whether the quality management system,

a) Conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by the organisation, and
b) Is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.
A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.
Records of the audits and their results shall be maintained.
The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.
Follow – up activities shall include the verification of the actions taken and the reporting of verification results.

8.2.3 Monitoring and Measurement of Processes

The organisation shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

8.2.4 Monitoring and Measurement of Product

The organisation shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realisation process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria shall be maintained.
Records shall indicate the persons authorising release of product for delivery of customer.
The release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of Nonconforming Product

The organisation shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, the organisation shall deal with nonconforming product by one or more of the following ways:

a) By taking action to eliminate the detected nonconformity
b) By authorising its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
c) By taking action to preclude its original intended use or application
d) By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re – verification to demonstrate conformity to the requirements.
Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.

8.4 Analysis of Data

The organisation shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.
The analysis of data shall provide information relating to,

a) Customer satisfaction
b) Conformity to product requirements
c) Characteristics and trends of processes and products, including opportunities for preventive action
d) Suppliers.

8.5 Improvement

8.5.1 Continual Improvement

The organisation shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective Action

The organisation shall take action to eliminate the causes of nonconformities in order to prevent recurrence.
Corrective actions shall be appropriate to the effects of the nonconformities encountered.
A documented procedure shall be established to define requirements for,

a) Reviewing nonconformities (including customer complaints)
b) Determining the causes of nonconformities
c) Evaluating the need for action to ensure that nonconformities do not recur
d) Determining and implementing action needed
e) Records of the results of actions taken
f) Reviewing the effectiveness of the corrective action taken.

8.5.3 Preventive Action

The organisation shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.
A documented procedure shall be established to define requirements for,

a) Determining potential nonconformities and their causes
b) Evaluating the need for action to prevent occurrence of nonconformities
c) Determining and implementing action needed
d) Records of results of action taken, and
e) Reviewing the effectiveness of the preventive action taken.