ISO 9001
QUALITY TIPS

HANDBOOK

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ISO 9001 QUALITY TIPS

For the planning, developing and implementing a quality management system

FOREWORD

The ISO 9001 Quality management systems standard provides an outline of what is to be considered when looking to plan, develop and implement a quality system. However, it doesn't tell the organization 'how' as this is up to each organization to determine and this is the stumbling block for Top Management and personnel who have been assigned to 'make it happen'.

The author of this Handbook has many years' experience as a quality consultant, auditor and trainer and has amassed many stories and examples of organizations' frustration and anxiety due to having little understanding of the ISO standard or its requirements or for supporting documentation.

A question often asked is "what will the auditor want to see?" It is really important that the organization documents and collects information that will benefit them and assist them in delivering products and services to the standard their customer requires and improves where it needs to rather than setting-up their system just to 'satisfy the auditor'.

The ISO 9001 Quality Tips Handbook will assist an organization in understanding what is required in the development of a quality management system and will address the following:

- Why it is necessary to have processes in place, which are controlled and documented where deemed necessary;
- The importance of keeping records providing evidence that activities have been performed;
- The importance of ensuring that monitoring, measurement and analysis is being conducted where ISO 9001 stipulates;
- Where the organization requires information for making decisions and improvements.

While this Handbook has a focus on quality management systems it can form the foundation of an eventual integrated management system where work, health & safety, environmental, food, finance, training and other systems can be added.

It is recommended that the ISO 9001 standard be read in conjunction with the information provided in ISO 9001 Quality Tips.

Christine Brown - Managing Director
Potential Unlocked

4. Quality management processes:

- Determining operational processes & sequence & interaction.
- Documentation process
  - Quality manual
  - Control of documents
  - Control of records

Overview of - Quality management systems

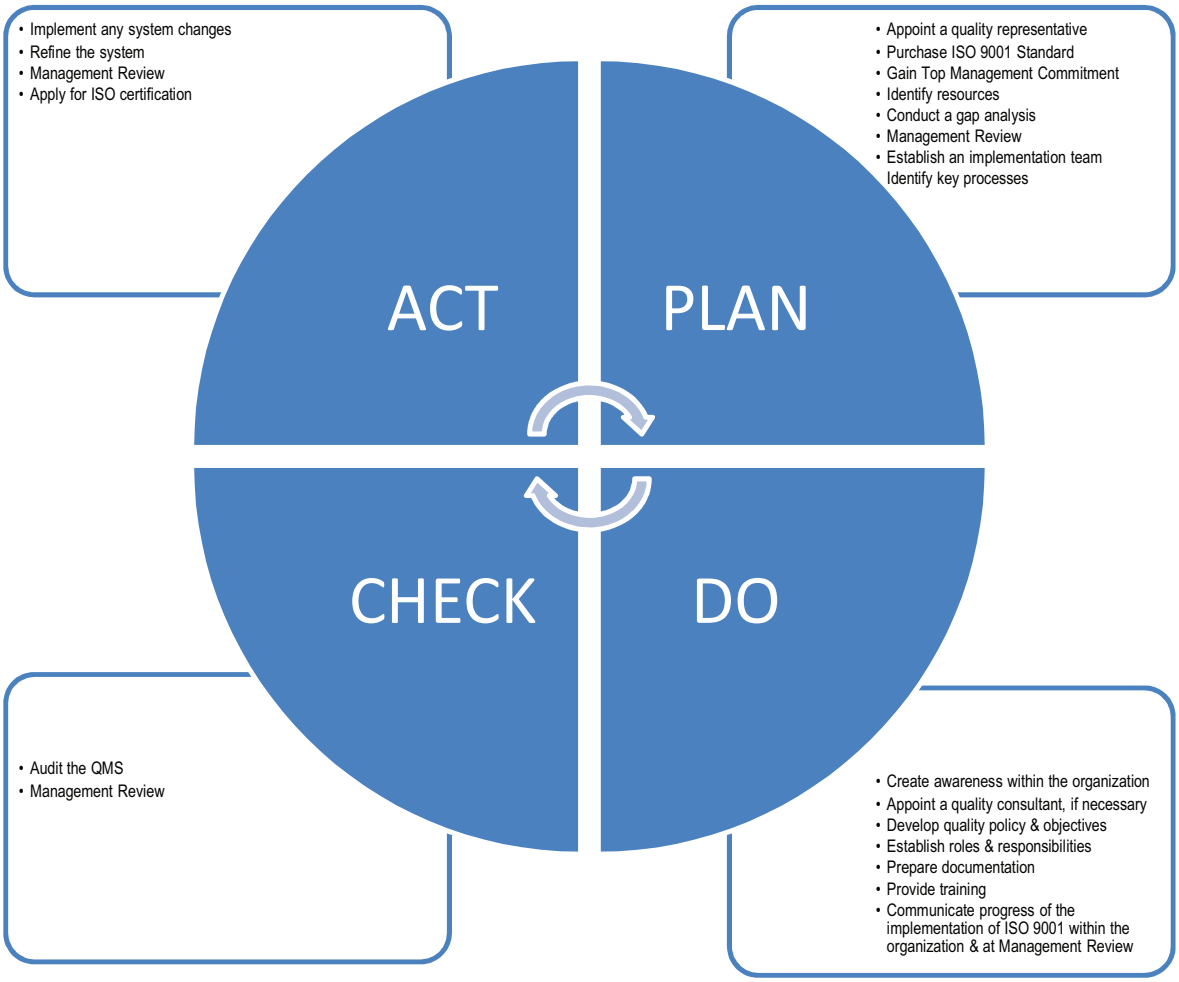
What needs to be in place?

Before you start your 'quality journey' or your organization has decided to review what is currently in place, it is a good idea to take a planned approach. The following model is a very useful tool and is called the **PDCA model**:

P – Plan
D – Do
C – Check
A - Act

Determining operational processes, sequence & interaction

The following is an example of steps to be thought through when planning, developing and implementing a quality management system.



General requirements

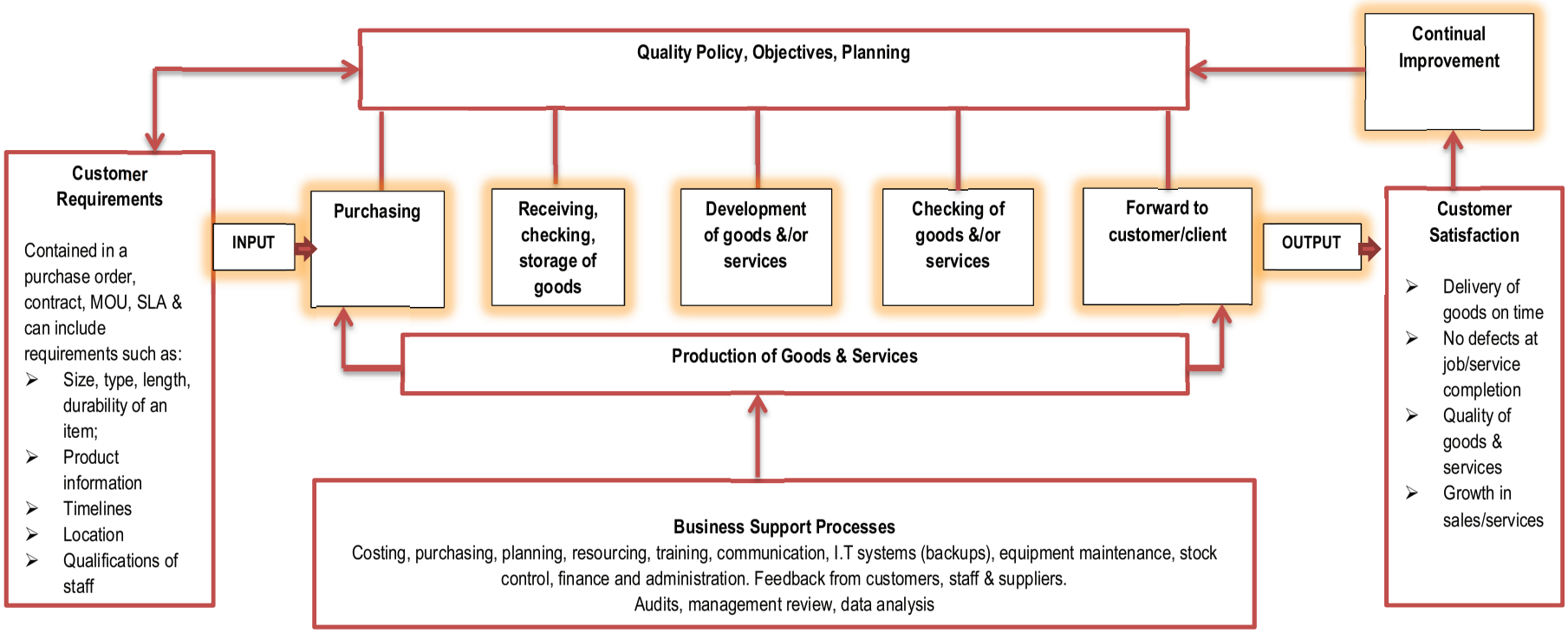
When thinking about the design of a Quality management System for your organization consider the following:

- Identify business processes and how they relate with each other to deliver high quality goods / services to the customer.
- Have controls in place to 'check things' during goods / services development and prior to release to the customer.
- Ensure suitable resources and information is available for staff to perform their job.
- Monitor, measure and analyse (where applicable) data to confirm that processes and resources are achieving planned results.

The following model shows the interrelationship of processes typical in an organization's quality management system, as described in ISO 9001.

Please note staff includes – full time / part time / casual employees, employers, owners, volunteers and contractors.

ORGANIZATION
QUALITY MANAGEMENT SYSTEM



Documentation process

Depending on the type of goods and / or services your organization provides (engineering/architectural services, welding, construction, piping, marketing, training, health services etc.) is dependent on the complexity and details of your documents. In general staff become discouraged if a system is overly complex or there is too much paperwork, so it is a good idea for an organization to consider *what* needs to be documented, *how* it will be documented and *where* these documents will be kept for easy access and use.

Why do we need to document?

Usually we generate policies, procedures, work instructions, specifications, guidelines, and drawings etc. to show staff what we want 'produced' and the standard to be achieved which meets organization, customer, legal, regulatory, and/or industry (etc.) requirements.
Processes documented by an organization can be used as:

- A training tool and during inductions.
- A means for sharing experiences and knowledge.
- Evidence that what was planned has actually been done (records)

Examples of documents an organization can develop

- Quality policy
- Quality objectives
- Strategic & Business plans
- Risk tools & registers
- Quality manual
- Procedure outlining how your organization controls its documents
- Procedure outlining how your organization controls its records
- Procedure outlining an organization's internal audit program
- Procedures describing how the organization handles non-conforming products and the processes in place for corrective and preventive action
- Procedures, work instructions/guidelines etc. outlining how an organization controls its internal business processes
- Quality plans
- Test and inspection plans
- Approved supplier lists
- Specifications
- Audit schedules
- Etc.

Quality Manual

It doesn't matter what an organization calls its 'Quality Manual' for example "Business Operations Manual", "Procedures Manual", "Operation Standards" but what is important is the information it holds.

Your 'Manual' is telling the reader what your quality management system is going to do and which parts of the organization are involved and identifies any areas of the organization / processes which will be excluded from its quality management system.

Basic information held in a 'Manual' is telling the reader:

- How it will control its documents and records
- Its approach to and frequency of internal audits, and
- How it will manage any potential non-conformance of product / service

These components are commonly referred to as 'the building blocks' of a quality management system. Small organizations may choose to include everything in its quality management system while large, geographically dispersed or multi-national organizations may need several manuals.

To assist the reader in understanding the organization and its quality management system a little better, organization charts and flow charts/process maps of key organizational processes and how they relate to each other can be included.

Exclusions/non-applicability can be claimed within section 7 "Product Realization" of ISO 9001 only. "Exclusion" should only be applied for clause 7.3 Design and Development and 7.6 Control of Monitoring and Measuring Equipment and must be fully justified in the quality manual.

Control of Documents

What is a document?

For further information on the section below ISO/TR 10013 Guidelines for quality management systems documentation and ISO 9001:2008 – 4.2.3) may assist you.

Below is a simple overview of what to consider when deciding which documents are to be controlled.

Primarily a document is for:

- Communicating information
- Evidence of conformity
- Knowledge sharing

Documentation contributes towards:

- Achievement of conformity to customer requirements
- Repeatability and traceability
- Provision of objective evidence
- Evaluation of the effectiveness and continuing suitability of the quality management system.

When planning how to control the documents developed by the organization and documents received from an external source the following issues need to be thought through:

- **Who approves and reviews** newly or updated written policies, procedures, work instructions, drawings etc.?

- **When changes are made** how do you let staff know, where is this documented?
  - In the actual document and/or in a document register?
  - Is there information in a document header / footer advising them of version number and date?

- **How Documents are made available to staff where they work?** For example electronically, hardcopy and accessible in the office, on-site, in a vehicle or vessel and are they protected from water damage, grease, soil, theft etc. so they are easy to read and understand.

- **Documents received from an external source**, distributed to appropriate staff within the organization; or transfer compliance obligations into policy, procedures & internal audits.

- **How obsolete documents are identified and labelled** as such and removed from general access. Electronic documents must also be removed for example from old websites, multiple content management systems.

Procedures required by ISO 9001 Standard

Control of Documents

What do auditors want to see?

- A mandatory procedure outlining the organization's process for controlling documents.

- Electronic structure for document management.

- Document version control.

- How and where organizational documents are stored including E-doc. back-up and information security protocols.

- Time-lines for reviewing currency of information.

- Evidence that a record of updates to policies, procedures, work instructions, forms etc. is in place. These updates can be placed in the actual policy, procedure or work instruction or kept in a register.

- Evidence that all staff has access to documented information at 'point of use' meaning at their place of work. However, at times it is not feasible for staff to have access to controlled information and an arrangement must be put in place whereby their supervisor or manager provides such information when requested.

Control of Records

Definition of a Record

ISO 9000:2005 – Fundamentals & Vocabulary

3.7.6 Record document - stating results achieved or providing evidence of activities performed.

Records can be used for:

- Traceability
- Verification
- Preventive action
- Corrective action.

Once key activities or tasks have been carried out, an organization should keep a record. Generally, organizations develop a 'procedure template' for staff to use so there is consistency in the format, a record generally doesn't.

Example of Records

- Purchase orders
- Dockets
- Inspections
- Feedback
- Personnel files
- Vehicle check sheets
- Meeting minutes
- Pre-start checks
- Test Inspection Plans
- Approved supplier lists
- Production schedules
- Organization chart

Each of the above examples is in a different format, however what needs to be uniform throughout the organization is:

- **How to identify records** - it can be through project identification, customer code or job number, a bar code, job number, drawing number, name of client or some other form of identifier.

- **Where records are stored** - by hardcopy and/or softcopy and through a central or de-centralised system.

- **Protection of records** - if stored electronically with only limited access, what steps are in place to ensure this? For example user passwords, virus/spam & firewalls, off-site secure back-up. Images - do they need light, humidity controls or a special storage facility?

- **Retrieval of records** – whether centrally stored or de-centralised throughout the organization, it can become extremely frustrating if records have not been identified at the beginning and there is not a clear 'storage' process in place with responsibilities identified.

- **Retention of records** – an organization must determine how long they need to keep records and this can be dependent on the life of a project, constructed item, legislative or customer requirements, business decision, insurance requirements etc.

- **Disposition of records** - depending on the type of record you want to dispose of and security/confidentiality requirements will determine how you dispose of records. At the low-medium risk end, shredding and/or placing the document in a bin with a padlock (to be removed by a company representative selected by the organization) is the option most commonly used.

Procedures required by ISO 9001 Standard

Control of records

What do auditors want to see?

- A mandatory procedure outlining the organization's process for handling records.

- A records matrix identifying the type of record, where it is stored (electronically and/or hardcopy), how long the record is kept and whether any archiving or disposing requirements are in place.

- Who has access to records and where they are kept e.g. central data base and/or within a department / business unit / site.

- How records are identified e.g. by job number, invoice number, location number or title etc.

Tips

- Keep your system simple.
- Decide what processes can be mapped or flow-charted as some people are very visual and prefer this to the written text procedure.
- Make sure staffs have access to the documents they require to do their job both in hard copy or softcopy and at their place of work, or have another agreed process in place if not feasible due to location etc.
- Develop procedures, work instructions, standard operating procedures, guidelines, etc. in a language that staff will understand and decide how much detail is needed in each document you write and ensure you take into consideration compliance requirements, skills, language difficulties, work or industry experience and any training that staff have.
- Information required in the header and footer of procedures and work instructions is document name and number, issue date, revision date (this can depend on legislation, regulation, standards, customer requirements, when changes are made to the process or at planned regular times e.g. annual, every 2, 3, 4, 5 years etc.)
- In-house YouTube channels, blog sites, photographs are used in many industries showing a step by step process while drawings are used by architects and engineers; Schedules, models and DVDs are other ways of informing staff what needs to be done, how it is to be done and when. You can be creative as you like when documenting your organizational processes.
- Determine who has the prime responsibility for document control and records. Ensure that management and all staff is aware of who occupies this position.
- If the organization restructures ensure all components of the system are associated to the new owner.