Implementing an ISO 9001 Quality Management System

ETI Group

This guide to implementing an ISO 9001 Quality Management System (QMS) was prepared by ETI Group. The guide is based on our experiences assisting more than 650 small, medium and large companies through the complete implementation process from start to successful registration.

Thought for Today

Quality management succeeds when the cost of the system is less than the cost of defects and poor service which would otherwise result.

PROFIT = INCOME - EXPENSES

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Introduction

For more and more companies, implementing a Quality Management System (QMS) based on ISO 9001 or one of the related standards such as AS9100, ISO 13485 or ISO/TS 16949 is becoming a necessity! It can help win new customers as well as retain existing ones. While the goal is to achieve registration to one of these standards, it is not the only goal. The internal benefits of implementing an effective QMS are significant.

This e-book is intended to be a guide to implementing an ISO 9001 Quality Management System in any organization. As the size and nature of organizations vary, we may not cover all of the circumstances unique to your company. We do however detail the typical process that ETI Group consultants use when assisting a company to implement an ISO 9001 Quality Management System (QMS).

Introduction

Implementing a QMS may seem daunting, especially for the smaller business, fortunately the standards are flexible, they mandate requirements for an organization to follow but allow you to fulfill the requirements in a way that makes sense for your business. This allows a wide range of companies, both large and small, manufacturing and service to create a QMS that meets the specific needs of their business as well as the requirements of the appropriate standard.

The ISO 9001 framework also provides an excellent and practical model from which to implement the additional requirements for an AS9100, ISO 13485 or ISO/TS 16949 Quality Management System.

Introduction

Every organization has management procedures and instructions for creating and delivering their products and services to customers. Most have evolved over the years, and are generally adequate – if they weren't, organizations would quickly go out of business.

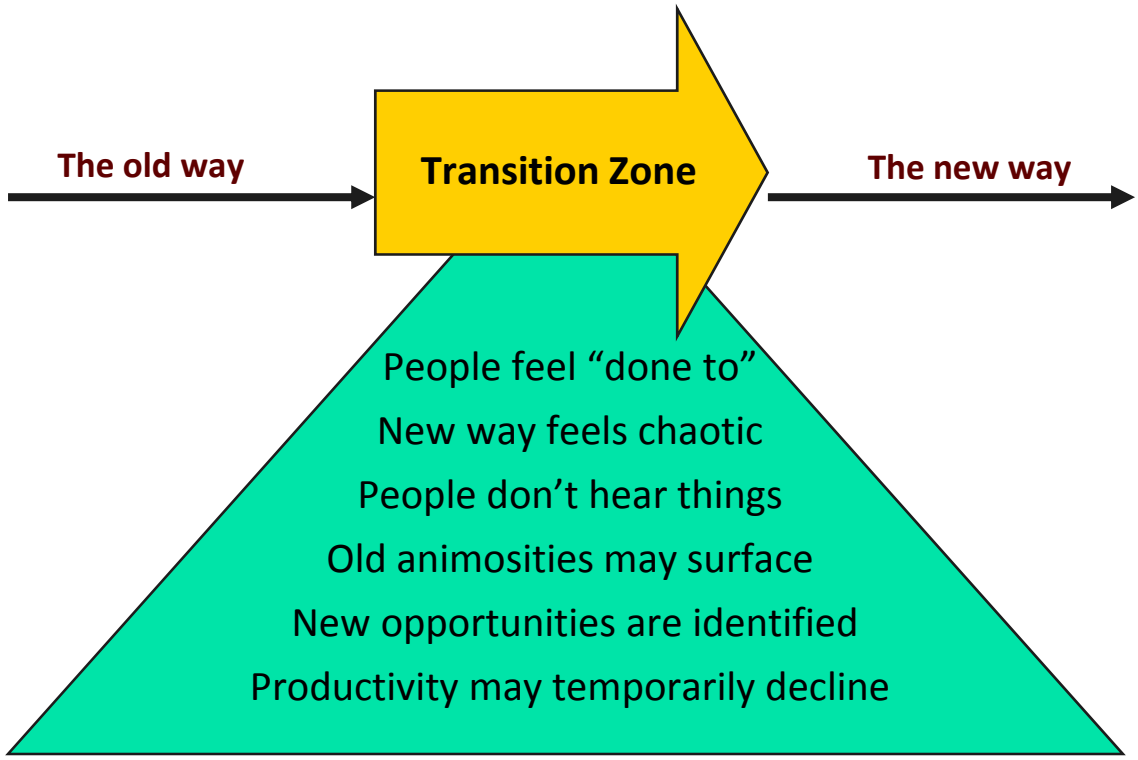
However poor management systems can lead to wasteful processes, poor products and services, and dissatisfied customers. An efficient organization can typically be characterized by:

- Explicit awareness of, and concern for, the needs of customers and other stakeholders (suppliers, employees, society, etc.),
- Senior and middle managers who understand and focus on business needs,
- A commitment to improve products and services,
- Employee development and training programs that meet the needs of the organization,
- Processes designed to identify and reduce wasted resources,
- Complete, current, clear and relevant documentation.

Organizations are increasingly introducing formal Quality Management Systems (QMS) to gain these and other benefits.

Managing Change

The greatest resource a company has is its people, inevitably there will be resistance to changes when implementing and maintaining your Quality Management System (QMS).



Resistance has many faces including denial, lack of motivation and questioning of the motivation behind the decision to implement a QMS. Strategies for managing change should be addressed during implementation planning.

Managing Change

The journey from a pre-QMS organization to one that operates with the quality and controls necessary for certification is not a casual task and is unlikely to succeed without the commitment and dedicated support of top management.

For Management change is…	For the people affected change is…
❖ Planned	❖ Out of their control
❖ Gradual	❖ Sudden
❖ A Solution	❖ Problematic
❖ Logical	❖ Arbitrary
❖ Opportunistic	❖ Disruptive
Intentional	**Disruptive**

Some common forms of resistance and suggested solutions are detailed on the following page.

Managing Change

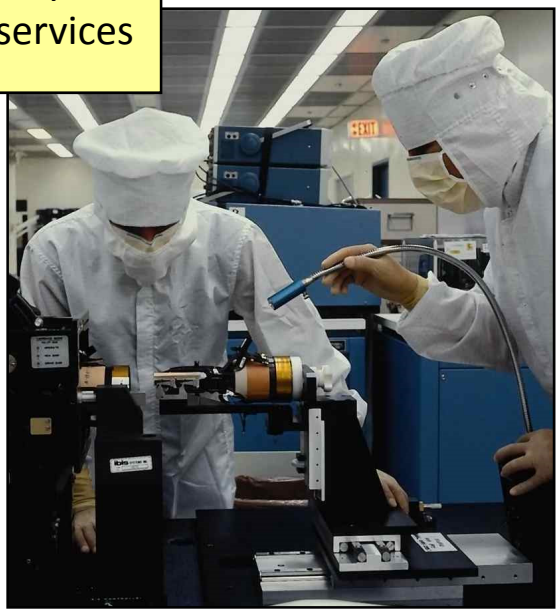
Common Forms of Resistance

Common Complaint	Root Cause	Proven Solution
"This is just another 'flavor of the month.'"	Past initiatives have been launched with high fanfare and little results	• Demonstrate leadership belief • Select best people as trainers • Minimize fanfare
"I don't have time…cannot free up resources."	Too many projects/ activities in process	• Stop other initiatives not related to current priorities or that only make a minor contribution.
"This can't work in my area of the business."	Misconception about how a Quality Management System works or lack of information about how it applies	• ISO 9001 has been successfully implemented in every business sector. • Show examples from other similar companies that are ISO 9001 registered.
"How is this different from past improvement initiatives?"	Fatigue from many improvement initiatives	• Explain/show key differences.
"Is this incremental to my existing business plan?"	Don't want to add to existing workload	• Align ISO 9001 implementation work to directly support the existing business plan
"Does management really believe/support it?"	Lack of confidence that everyone is on board	• Genuine leadership commitment to implementation is required – not just talk.

What is a Quality Management System?

Developed by the International Organization for Standardization, ISO 9001 comprises a set of requirements that reflect time-proven, universally accepted good business practices, the majority of which are mandatory. AS9100, ISO 13485 and ISO/TS 16949 standards utilize the ISO 9001 framework and have additional industry specific requirements.

A common sense way of
ORGANIZING THE BUSINESS PROCESSES
that affect the quality
of your products and services



The aim of a QMS is to assure that an organization consistently meets customer needs by controlling the core processes that affect them such as sales orders, design, production, inspection, delivery, etc.

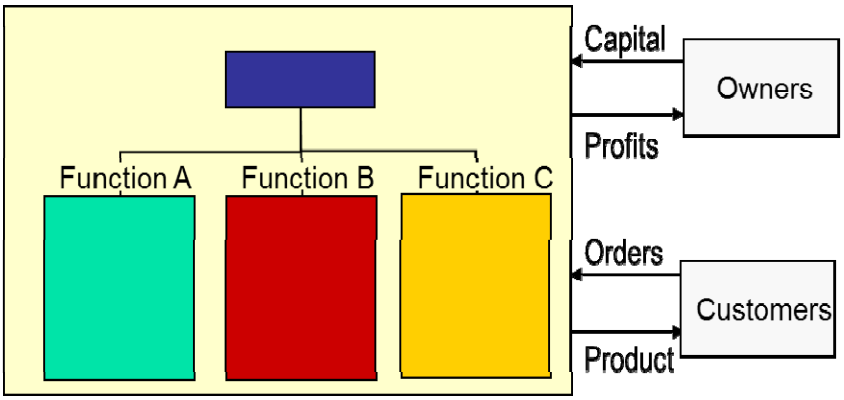
The requirements also go beyond these "core" processes to address support processes like purchasing, training, calibration, maintenance, and performance metrics.

What is a Quality Management System?

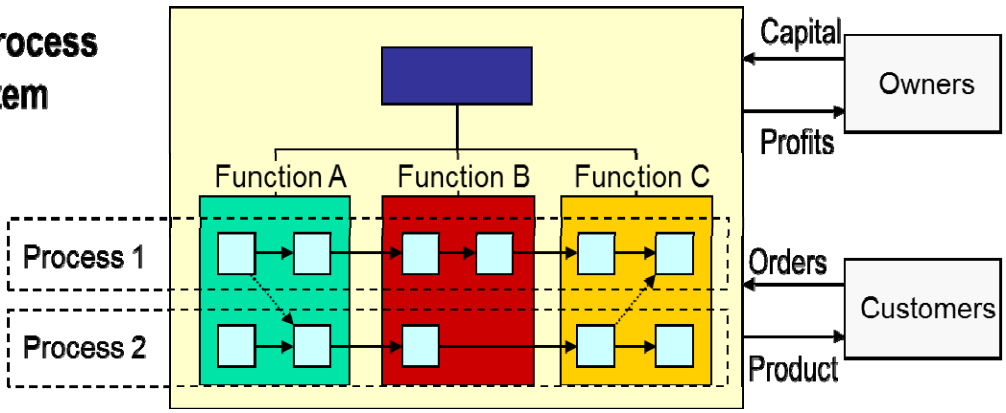
A Process Approach

An important aspect of a QMS is its process-oriented approach. Instead of looking at departments and individual processes, it requires an organization to look at how processes interact and integrate with each other.

Traditional/Functional View of System



Performance/Process View of System



Bottom line: A QMS is much more than a comprehensive set of rules. It will help you manage your business more effectively and improve the performance of your organization on an ongoing basis.

What is a Quality Management System?

A QMS will help you manage your business more effectively and improve the performance of your organization on an ongoing basis.

Say what you'll do!

Do what you say!

Prove It!

Improve It!

Basically, ISO 9001 requirements fall under four major categories:

- Requirements that help assure that the organization's products and/or services meet customer specifications.
- Requirements that assure the QMS is consistently implemented and verifiable.
- Requirements for measuring the effectiveness of the various components of the system.
- Requirements that support the continual improvement of the company's ability to meet customer needs.

What is a Quality Management System?

The general components of a Quality Management System (QMS), as defined by ISO Technical Committee, TC176, are as follows:

Customer Focus: Customer's needs and expectations need to be identified and achieved.

Leadership: Top Management must show their commitment to the QMS by leading, communicating and uniting everyone in the organization to achieve the company's desired goals and by providing the resources necessary to accomplish them.

Involvement of people: Irrespective of their position in the company everyone is involved in the QMS.

Process Approach: All activities in the company are treated as a process. This will provide for a systematic definition of activities in order to meet the stated goals and identify the resources required to meet those goals.

Systems Approach to Management: Requires identifying all of the processes in the company and their interdependence and then managing these processes as a complete system.

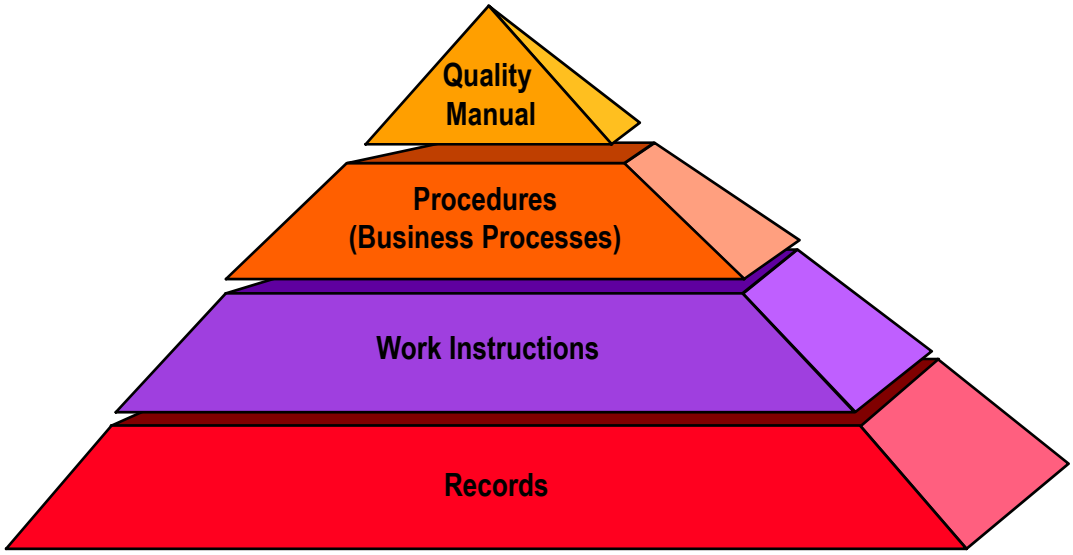
Continual Improvement: Continual Improvement of the company is a never ending process involving establishing goals and measuring progress towards achieving those goals.

Factual Approach to Decision Making: This is the method of collecting and analyzing data and then using it to make sound decisions on what path to take.

What is a Quality Management System?

Quality Management System Requirements

To achieve ISO 9001 certification your company must establish, document and implement a QMS and maintain its effectiveness in accordance with the standard. Controlled documents are typically organized and written according to a hierarchy shown below.



ISO 9001 Documentation Pyramid

Quality Manual addresses each area of the standard with a statement explaining how the organization maintains compliance to requirements.

Procedures are "high-level" documents that detail how the organization's processes are designed and controlled.

Work Instructions are very specific and detail all necessary instructions required for performing a specific task.

Records must be maintained to show compliance to quality system requirements.

What is a Quality Management System?

Documents

Quality System documents should detail processes and procedures to ensure they meet the requirements of the standard. This will ensure that:

- Employees perform the same task, the same way, every time
- Information is recorded in the same way, every time
- New employees are trained to a consistent standard.

Everyone!

Everywhere!

Every Time!

Controlled Documents

Documents must be controlled to ensure only the current version is available to employees while performing their duties. A procedure is required to detail the management of all controlled documents.

Why Implement a Quality Management System?

Internal Benefits…

Quality Management System registration will help you win new customers and retain existing ones. While the goal is to achieve registration, it is not the only goal. The internal benefits of an effective system are significant:

- An understanding that quality is not just the responsibility of the quality department, it's everyone's responsibility.
- Documented procedures and work instructions form the basis for repetition and become "the way we do business."
- Less dependency on key individuals, responsibility and accountability for key tasks are distributed across the work force.
- Monitoring and measuring of key quality performance indicators improves management oversight.
- Internal Audits help identify problems that could impact customer satisfaction and/or operational efficiency.
- A formal Corrective and Preventative Action system ensures permanent solutions to problems are developed and implemented.
- Operations transformed from detection mode to a prevention mode. Prevention takes a lot less work and is far less expensive than detection.
- Increased profitability as productivity improves and rework costs are reduced.

Why Implement a Quality Management System?

Results of a survey of ISO 9001 Registered Companies, Quality Systems Update Magazine

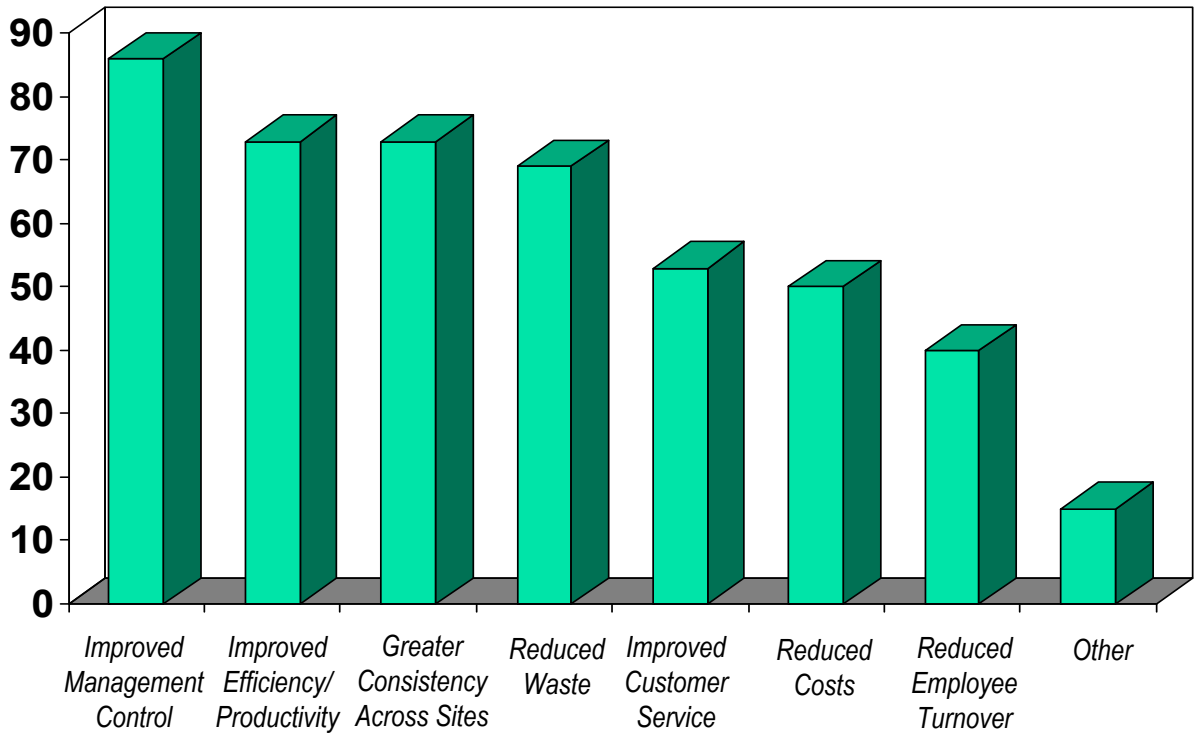
Customer Satisfaction

- On-time delivery increased 20%

Improved Operations

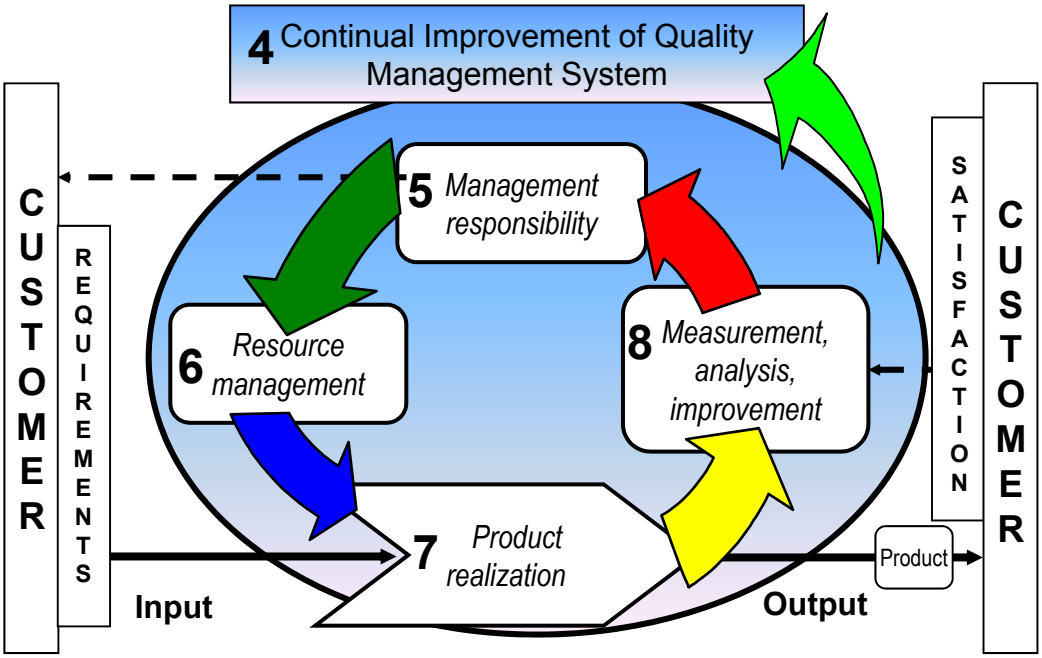
- 89% report greater operational efficiency
- 48% report increased profitability
- 76% report marketing benefits
- 26% report improved export sales

Results of a survey of ISO 9001 Registered Companies in The United Kingdom conducted by Lloyds Register Quality Assurance



The ISO 9001 Standard

Goal = Develop Consistent, Reliable Processes



Model of a process-based Quality Management System

A reliable process produces a consistent, predictable outcome, and is:

- **Consciously developed:** Facts and data are collected, the method is thought about by participants, debated, and agreed to, before the method is implemented.
- **Explicitly established:** The method is carefully documented in sufficient detail for the purposes needed. Every attempt is made to make the method error-proof.
- **Consistently followed:** Everyone follows the method as documented!
- **Currently believed to be best way:** The method is used until someone thinks of a better way.

The ISO 9001 Standard

4 – Quality Management System

4.1 General Requirements

- Describes how your QMS is to be established
- Provides "rules" for all processes in the QMS

4.2 Documentation Requirements

- Describes information structure of your QMS
- Should think in terms of "information" management and control rather than "document" management

5 – Management Responsibility

5.1 Management Commitment

5.2 Customer Focus

5.3 Quality Policy

5.4 Planning

5.5 Responsibility, Authority & Communication

5.6 Management Review

Implication

This system belongs to **management**!

Strong emphasis on **responsibilities** of management!

The ISO 9001 Standard

6 – Resource Management

6.1 Provision of Resources

Determine & provide resources needed

- Implement & maintain & …
- Continually improve QMS
- Enhance customer satisfaction

Provide & Manage Resources Needed to Meet Customers' Requirements

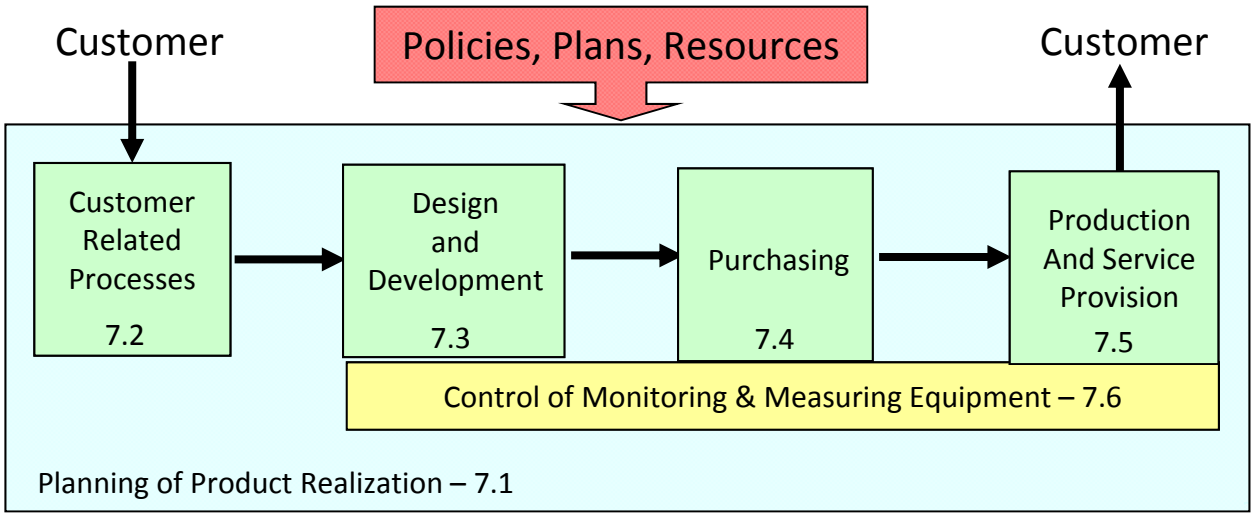
6.2 Human Resources

- Assignment of personnel
- Competence, training, and awareness

6.3 Infrastructure – buildings, utilities, equipment, transport, IT

6.4 Work Environment – temperature, humidity, lighting, cleanliness, ESD protection, etc.

7 – Product Realization



Sequence of processes & sub-processes needed to produce the product
Strong emphasis on sequence of processes & interactions

The ISO 9001 Standard

7.1 Planning of Product Realization

Documented in a 'suitable' form (Quality Plan or use of established QMS)

Determine:

- Quality objectives for product, project or contract
- Specific resource & process needs for product
- Verification, validation, monitoring, measurement, inspection and test activities needed (including acceptance criteria)
- Record requirements

Planning for each product, project or contract must be done

7.2 Customer Related Processes

7.2.1 Determination of requirements related to the product – What is it?

7.2.2 Review of requirements – Can we do it? Is there a change?

7.2.3 Customer Communication – questions, orders and changes, feedback, complaints

The ISO 9001 Standard

7.3 Design and Development

7.3.1 Planning – project plan with design stages, tasks, responsibilities

7.3.2 Inputs –the design requirements

7.3.3 Outputs – the documented design, the product specification

7.3.4 Review – checking output against input for each stage

7.3.5 Verification – making sure the design will meet requirements

7.3.6 Validation – making sure the product will meet requirements

7.3.7 Control of Changes – ensure changes are identified, evaluated, controlled and recorded

7.4 Purchasing

7.4.1 Purchasing Process – Select & manage suppliers

7.4.2 Purchasing Information – Specify requirements for what you want to buy

7.4.3 Verification of Purchased Product – To inspect or not to inspect?

The ISO 9001 Standard

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

- Info that describes the product
- Work Instructions as needed
- Suitable equipment
- Availability and use of monitoring & measuring equipment
- Inspections and tests
- Release, delivery and post-delivery activities

7.5.2 Validation of Processes for Production and Service Provision – "special processes"

7.5.3 Identification and Traceability – ID, pass/fail status, unique ID as required

7.5.4 Customer Property – safeguard customer supplied product, equipment, software, intellectual property, personal data

7.5.5 Preservation of Product – protect product from start to finish

The ISO 9001 Standard

7.6 Control of Monitoring and Measurement Equipment

- A.K.A. Calibration
- Calibrated or verified at specified intervals, or prior to use, against traceable measurement standards
- Identified to enable status to be determined
- Record calibration/verification results
- Assess & record validity of prior results if devices are found to not conform to requirements – take corrective action on equipment and affected product

8 - Measurement, Analysis and Improvement

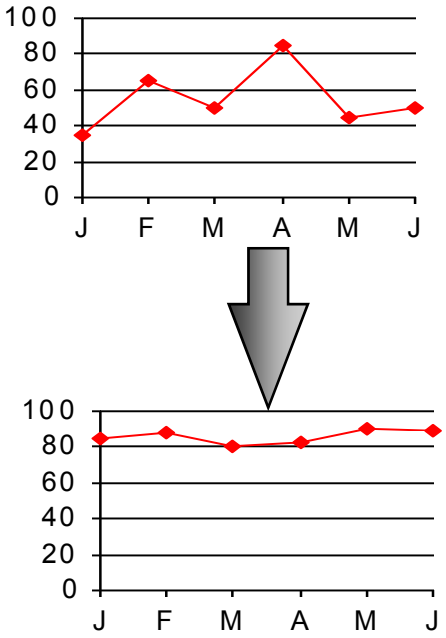
8.1 General – Plan & determine methods (statistical techniques) and extent of use

8.2 Monitoring & Measurement

8.3 Control of Nonconforming Product

8.4 Analysis of Data

8.5 Improvement



The ISO 9001 Standard

8.2 Monitoring & Measurement

8.2.1 Customer Satisfaction – monitor perception of quality

8.2.2 Internal Audit – a *tool* for evaluating internal compliance

- Audits must be planned and recorded,
- objective and impartial, with
- timely Corrective Action taken by Management and follow-up to verify actions taken.
- Results must be reported.

8.2.3 Monitoring & Measurement of Processes

- Ability to meet performance objectives
- Maintain capability and improve if needed

8.2.4 Monitoring & Measurement of Product

- Verify requirements are met
- Results recorded
- Record authority responsible for release to customer

The ISO 9001 Standard

8.3 Control of nonconforming Product

- Identification and control of any defective material/product to prevent its use
- Determination of actions to take
- Re-verification after rework/repair
- Evaluation of need for recall of shipped product

8.4 Analysis of Data

Determine, collect and *analyze* appropriate data, Purpose:

- Demonstrate suitability and effectiveness of QMS
- Evaluate improvement opportunities

Include data generated by monitoring/measuring activities & other relevant sources

Analyze data for information on:

- Customer satisfaction
- Conformity to product requirements
- Characteristics & trends of processes and products

Look for Preventive Action opportunities

- Supplier performance

The ISO 9001 Standard

8.5 Improvement

8.5.1 Continual Improvement

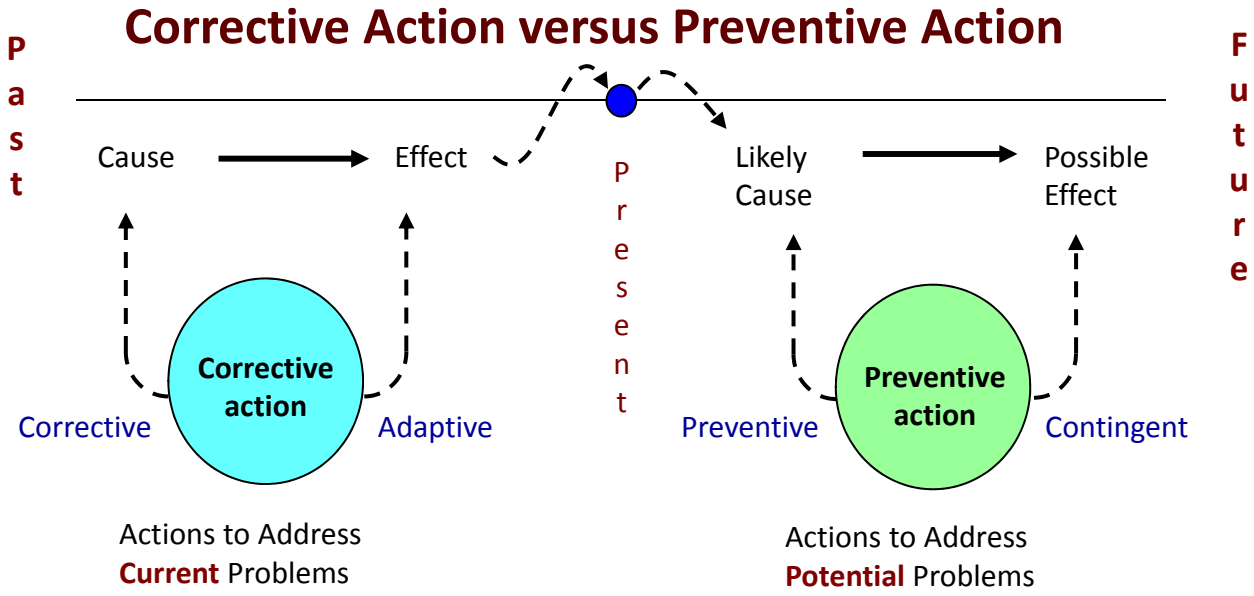
- **Continually improve** organization's performance
- **Use** Policy, objectives, audits, data, CAPA and Management Review to facilitate improvement

8.5.2 Corrective Action

- Defined, documented process; comprehensive
- Eliminate cause(s) to prevent recurrence
- Appropriate to the impact

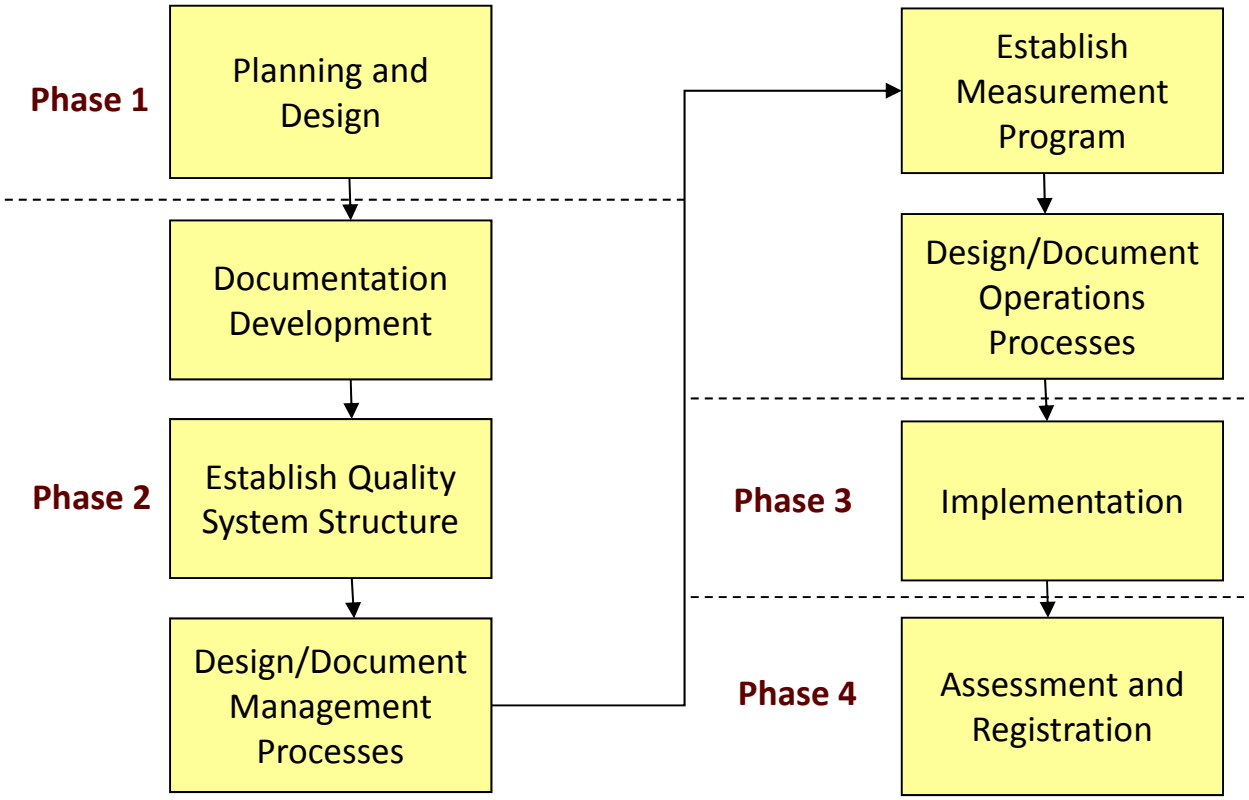
8.5.3 Preventive Action

- Basically same process as Corrective Action but use data proactively
- Detect — Analyze — Eliminate causes of **potential** problems



15 Steps to Implement ISO 9001

Designing, documenting and implementing an ISO 9000-based Quality Management System is a significant undertaking. Typically, ETI Group recommends and uses a four phase approach to assist clients in implementing a system that meets the specific needs of their business.



This approach has been used successfully by ETI Group in more than 650 organizations, both large and small. A task by task overview of this approach is provided on the following pages.

15 Steps to Implement ISO 9001

PHASE 1: PLANNING AND DESIGN

Step 1 — Decision Making and Commitment

The first task is for top management to decide if the company should pursue ISO 9001 (or one of the associated standards – ISO 13485, AS9100C or ISO/TS 16949) registration.

To make an informed decision, top management should have a good understanding of ISO 9001 from a business point of view, the concepts behind ISO 9001, the general process for implementation and the requirements of the standard as they apply to your company.

Top management must also demonstrate its commitment and determination to implement an ISO 9001 Quality System in the organization. Without top management commitment, no quality initiative can succeed.

15 Steps to Implement ISO 9001

1.1 Top Management Commitment

To provide evidence of commitment to the development and implementation of a QMS and continually improve its effectiveness, top management can achieve this by:

- Communicating to the organization the importance of meeting customer, statutory and regulatory requirements,
- Defining the organization's quality policy and making this known to every employee,
- Ensuring that quality objectives are established at all levels and functions,
- Ensuring the availability of resources required for the development and implementation of the quality management system, and
- Conducting the required management review meetings.

Top management should also consider actions such as:

- Leading the organization by example,
- Participating in improvement projects,
- Encouraging the involvement of all employees.

15 Steps to Implement ISO 9001

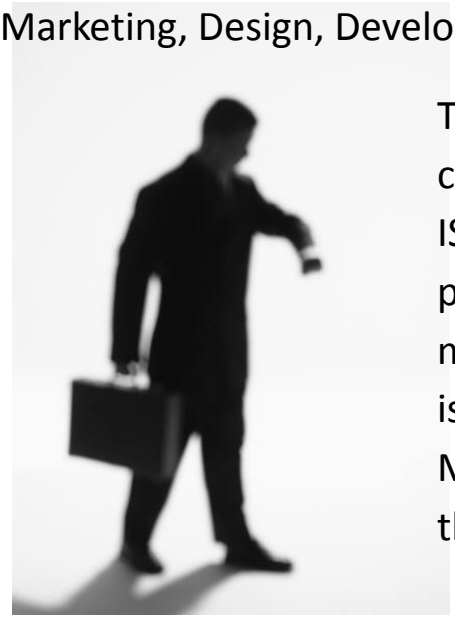
1.2 Top Management Commitment

Top management should identify the goals to be achieved through the Quality System. Typical goals may be:

- To become more efficient and profitable
- To produce products and services that consistently meet customers' needs and expectations
- Improve customers satisfaction
- Increase market share
- Reduce costs and liabilities

Step 2 — Implementation Team & Management Representative

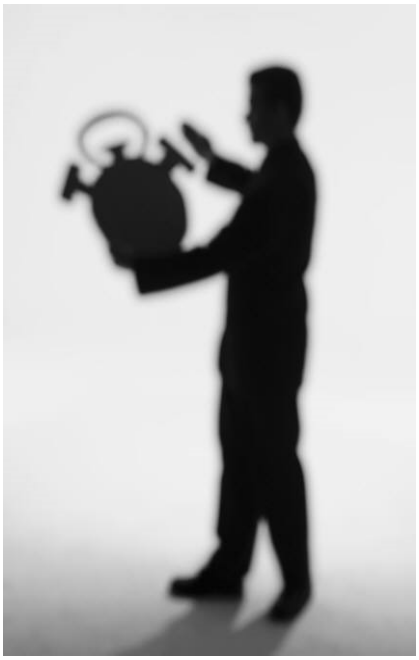
ISO 9001 is implemented by people. The next step is to establish an implementation team and appoint a Management Representative (MR) as its coordinator to plan and oversee implementation. Implementation team members should include representatives of all organizational functions - Marketing, Design, Development, Planning, Production, Quality control, etc.



The “Management Representative” is your company's point-person and soon to be expert on ISO 9001. In the context of the standard, this person acts as the interface between your top management and the ISO 9001 registrar. This role is, in fact, much broader than that. The Management Representative should also act as the organization’s “Quality System Champion."

15 Steps to Implement ISO 9001

2.1 Management Representative (MR) Responsibilities



The MR must be a person with:

- The total backing of the CEO,
- A genuine and passionate commitment to quality in general and the ISO 9001 quality management systems in particular,
- The respect resulting from rank and/or seniority to influence people at all levels and functions of the organization, and
- A good knowledge of quality methods in general and ISO 9001 in particular.

The standard makes it very clear that the Management Representative takes on the three responsibilities described below.

1. Quality System Maintenance. Ensuring that Quality Management System processes are established, implemented and maintained.

2. Reporting on Quality System performance. Reporting to top management on how well, or poorly, the QMS is performing, including identifying any needs for improvement.

3. Promoting customer requirements. Ensuring all employees are aware of customer requirements. It is essential that all employees understand what the customer needs, and how they can affect how well the company satisfies these needs.

Steps to Implementing ISO 9001

Step 3 — Employee Awareness Training

It is important to inform employees as early as possible of your plan to become ISO 9001 registered. You will need to explain the concept of ISO 9001 and how it will affect employees in order to gain buy-in and support. Don't delay this simple step, if negative rumors and gossip develop, your implementation efforts will become much more difficult!

Since the ISO 9000 Quality System affects all the areas and all personnel in the organization, training programs should be structured for different categories of employees - senior managers, middle-level managers, supervisors and workers. This training should cover:

- The basic concepts of quality systems and the standard,
- The overall impact on the company's strategic goals
- The changed work processes, and the likely work culture implications of the quality system.

In addition, initial training may also be necessary on writing quality manuals, procedures and work instructions. When the in-house ability to provide this training is not available, it may be necessary to participate in external training courses run by a professional training organizations or an external training organization could provide this training in-house

15 Steps to Implement ISO 9001

Step 4 — Perform a Gap Assessment

The next step in the implementation process is to compare your existing quality system with the requirements of the ISO 9001 standard. This is often referred to as " gap assessment'‘ with the goal of determining:

- What existing company processes and procedures already meet ISO 9001 requirements
- What existing procedures and processes need to be modified to meet ISO 9001 requirements
- What additional procedures and processes need to be created to meet ISO 9001 requirements

In general, the steps to perform a gap assessment are:

1. What is the present operation/process? What already exists?,
2. Analyze the relevant sections of the ISO 9001 standard to determine what is actually required?
3. Document the “gaps.”

The gap assessment can be performed internally, if the required knowledge exists, or an experienced ISO 9000 consulting firm can provide this service for you.

15 Steps to Implement ISO 9001

Step 5 — Implementation Planning

After the gap assessment, you should have a clear picture of how your existing Quality System compares with the ISO 9001 standard.

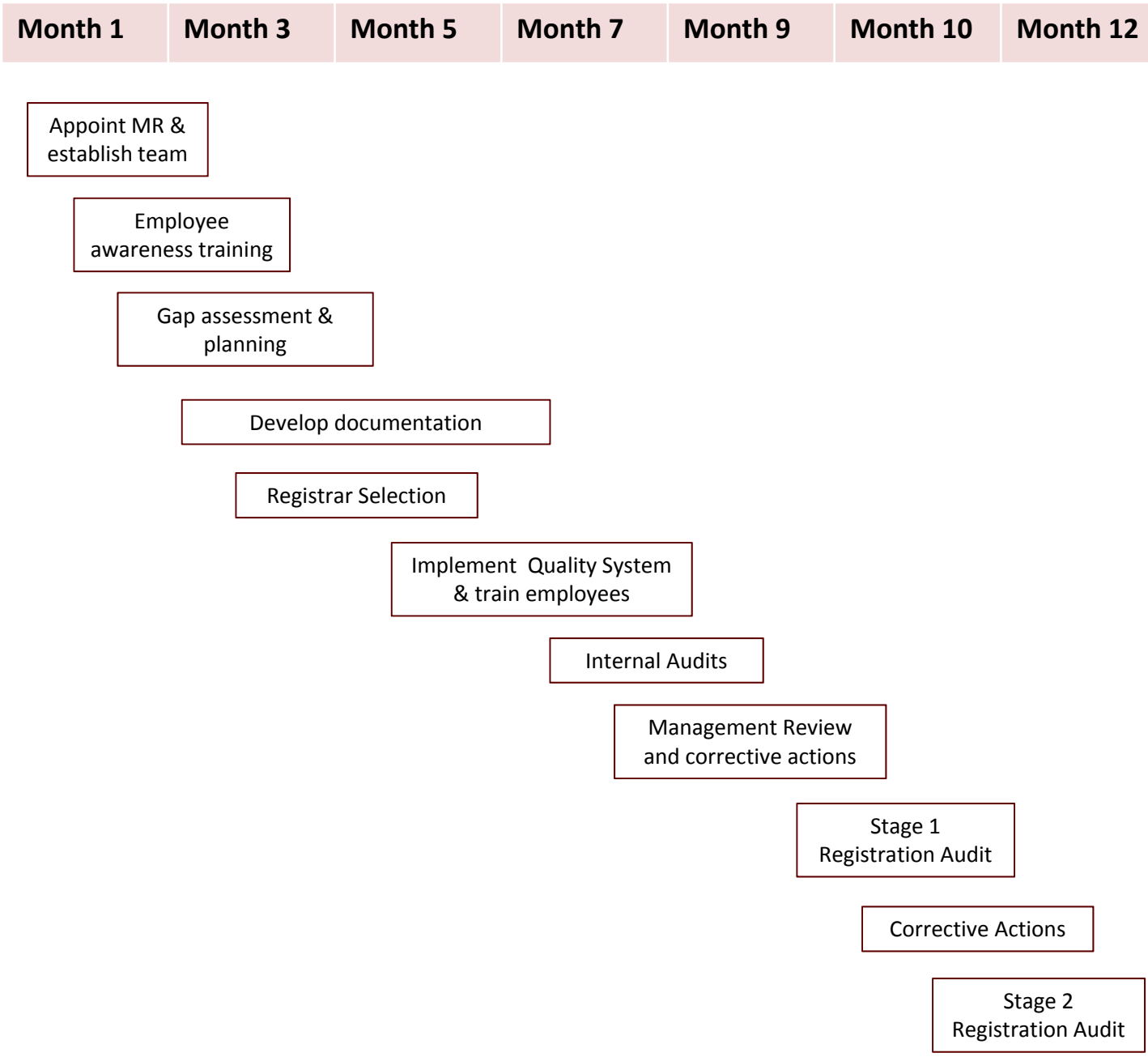
A detailed implementation plan should be developed that identifies and describes task required to make your Quality System fully compliant with the standard. This plan should be thorough and specific, detailing:

- Quality documentation to be developed
- The relevant ISO 9001 standard section
- Person or team responsible
- Approvals required
- Training required
- Resources required
- Estimated completion date

These elements should be organized into a detailed chart, to be reviewed and approved by top management. The plan should define responsibilities of different departments and personnel and set target dates for the completion of tasks. Once approved, the Management Representative should control, review and update the plan as documentation and the implementation process proceeds.

A typical implementation action plan is shown on the following page.

15 Steps to Implement ISO 9001



'High-level" 12 month implementation plan

15 Steps to Implementing ISO 9001

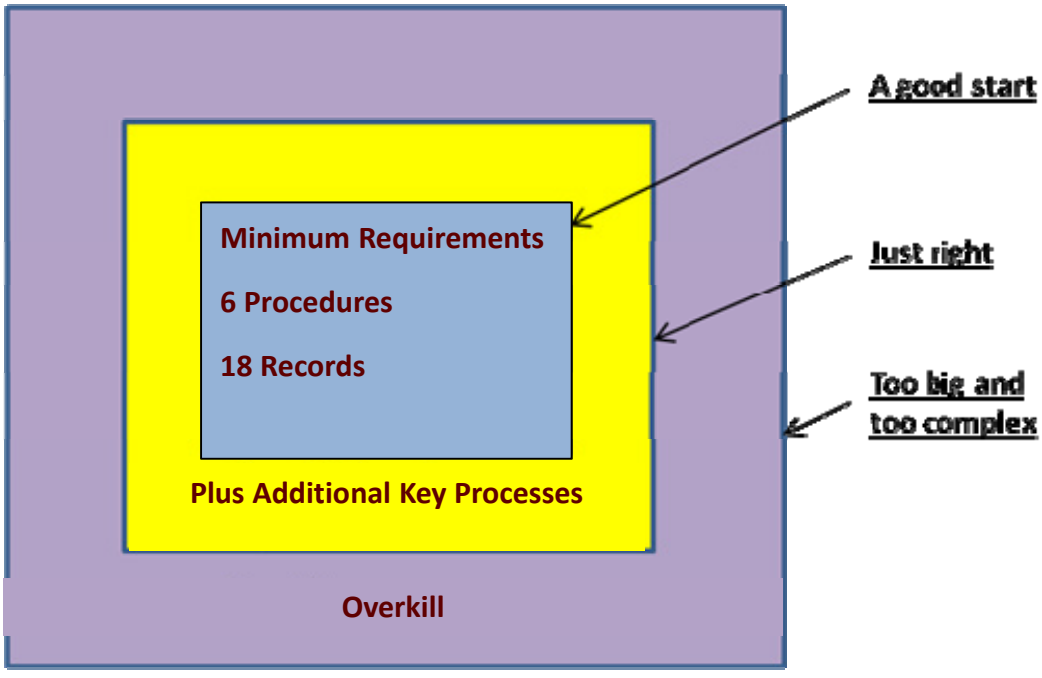
PHASE 2: DOCUMENTATION DEVELOPMENT

Step 6 — Documentation Development

There is no right or wrong way to document your QMS. We believe that your company should start with the minimum requirements. Currently there are six documented procedures required to create an ISO 9001 QMS: Document Control; Control of Records; Internal Audit; Non-Conforming Product; Corrective Action and Preventive Action.

There will be some additional documented procedures that will be helpful for your staff to follow while working on your company's various processes. These can be determined during the planning stage and should be included in your implementation project plan.

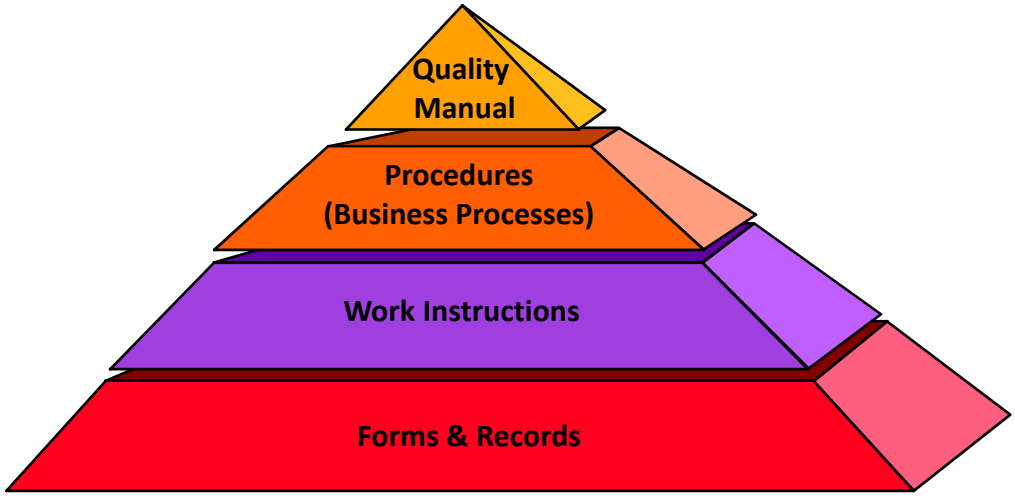
The "Right-Size" Quality Management System



15 Steps to Implementing ISO 9001

6.1 Organizing and Documenting Your Quality System

Documentation is typically organized and written according to a hierarchy shown below. A list of the documents to be prepared should have been drawn up and the responsibility for writing documents assigned to the persons responsible for each of the quality system processes in your company during implementation planning.



The Quality Manual – A high-level document that typically includes:

- A statement explaining the scope of the Quality Management System, including exclusions and details for their justification
- A description of the Quality System processes and their interactions
- The company's quality policy and quality objectives
- An company profile showing the relationships and responsibilities of persons whose work affects quality
- An overview of the system level procedures

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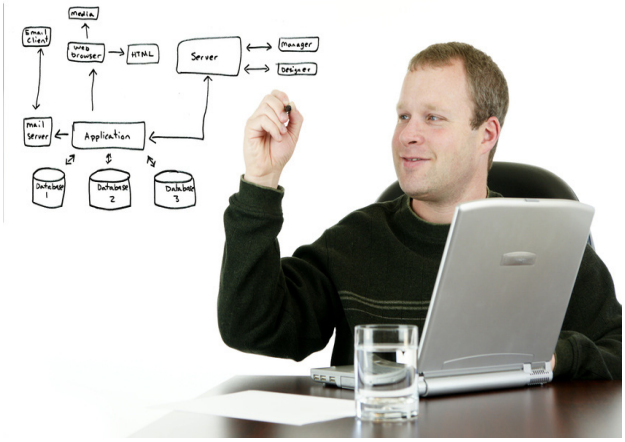
Quality Manual (Continued)

The Quality Manual is usually written early on in your QMS implementation. Processes and procedures may change as your organization works through the documentation process. It will be necessary to go back and revise the Quality Manual to bring it back up to date and ensure that the correct process interfaces are defined and responsibilities and authorities documented.

Procedures are "high-level" documents that detail how the organization's processes are designed and controlled and the checks that are carried out.



Work Instructions are very specific, and detail all necessary instructions required for performing a specific task.

Lists provide information. They can also be incorporated into the back of a procedure as additional information (Appendix, Attachments, etc.).

Forms capture records for data/information required to support or confirm processes. Forms can be separately controlled documents and/or included within the appropriate procedure.

Records must be maintained to show compliance to quality system requirements.

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6.2 Record Keeping - Quality records provide objective evidence of your compliance to many of the ISO 9001 requirements. You must keep your records up to date to prove compliance during your registration or subsequent surveillance audits. Minimum required records include:

- Evidence that metrics are used to monitor and improve processes (Quality Objectives)
- Management Review Meetings
- Employee Competence, Awareness, and Training
- Product planning meets customer requirements
- Contract review and actions arising from the review
- Design and development planning, inputs, reviews, verification, validation (including changes to designs)
- Supplier evaluation and re-evaluation
- Results of monitoring and measuring
- Internal Audits
- Approval to release product for delivery
- Action taken on non-conforming product
- Corrective Action
- Preventive Action

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6. 3 Documentation – Getting Started

Your company probably already has some documented policies and/or procedures. Although they may be incomplete, lacking specific detail, be out of date, or are not integrated with other business processes as required by the ISO 9001 standard.

Make a list of all these documents, including procedures, work instructions, forms and lists and include their current status… incomplete, lacking detail, out of date, inaccurate, not integrated with other business processes, etc.

There may also be some areas of the business which you choose not to include within the scope of your QMS, such as finance or business strategy documents.

Areas deemed out of scope must not have an impact on product quality and should not be included in your QMD documentation, although these areas should be listed in the exclusions documented in your Quality Manual.

Consider the primary audience for the document and use language and vocabulary that is appropriate for the company and for the users.

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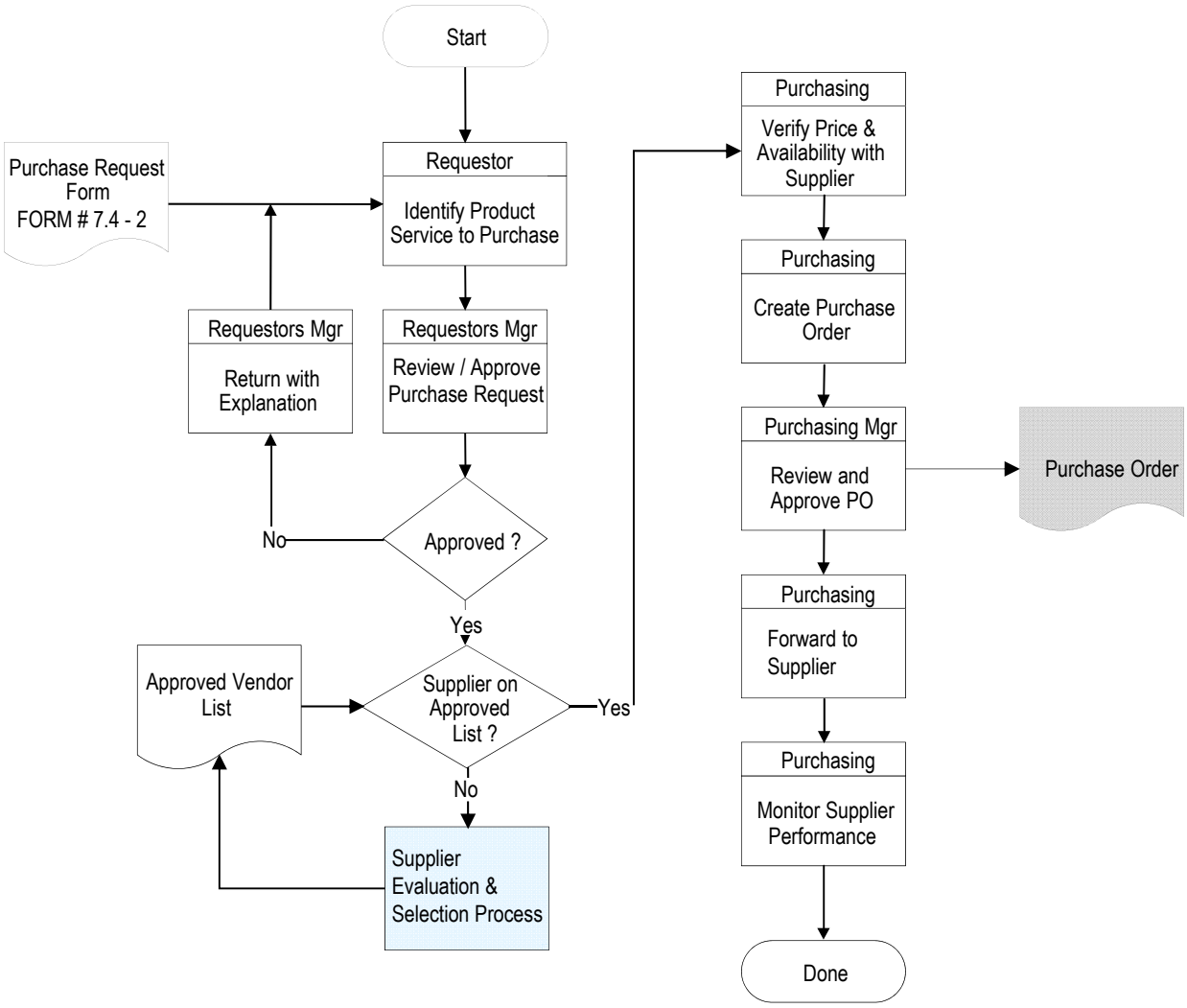
6. 4 Documentation – Map Current Processes

Map the processes used to manage the quality framework, including their sequence and interaction with each other. Ensure that all stakeholders are included in the mapping process and gaps are noted where documents are missing or where a process needs to be updated to meet a requirement of the ISO 9001 standard.



Typical Process Map

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6.5 Templates for Controlled Documents

Templates should be developed for all of the controlled document types you intend to use. Templates should have consistent styles and formats so that documents are easy to read and navigate.

Each template must meet controlled document requirements. Procedures and Work Instructions should have Purpose, Scope and Responsibilities sections. A company logo can also be included with the document header.

Documenting your Quality System is challenging and time-consuming but can be simplified with good pre-designed templates or the help of an experienced consulting firm. If you choose to purchase templates they should be chosen carefully as they will have a significant impact on the effort you spend on implementation, and even more importantly, on how efficient and business-friendly your company's Quality System will be.

6.6 Create a Company Quality Policy

We have all read an organization's posted "Mission Statement" when entering their establishment. A Quality Policy is similar but addresses the specific requirements of ISO 9001. This is the foundation of your QMS and establishes top management's commitment to Quality. It should also be communicated throughout your organization.

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6.7 Top Level Quality Objectives

The framework for determining your Quality Objectives is established in your organization's Quality Policy, these objectives are present at all levels of the organization, they establish measureable processes to assure your product or service meets stated requirements.

6.8 Determining Interactions

One of the many benefits in creating your QMS is improved communications between departmental functions.

Accomplishing this requires that you clearly define these departmental functions and identify their interactions. You can use the Quality Manual, Documented Procedures, or a Process Flow Chart to do this.

6.9 Determine Authorities

Another benefit of your QMS is the requirement to clearly define and document authorities. It is not uncommon in many organizations to make staff responsible for something without giving them a clearly defined authority to see the task through. This often leads to stress and low morale.

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6.10 Document Control

A Documentation Control System must be created to manage the creation, approval, distribution, revision, storage, and disposal of the various types of documentation that your company develops. Your document control systems should be as simple and as easy to operate as possible but sufficient to meet ISO 9001 requirements. It should include:

- A unique identification, usually a letter code for the type of document (e.g. SOP, WI, LST) and a sequential number.
- Revision control where each update to the document must result in an incremental increase in the revision number.
- A change history summarizing changes made to a document
- Signatures of the person preparing and the person approving the document. A verification signature is also usually required to confirm that the contents of the document are accurate.
- The date of the version or revision

The principle of ISO 9001 document control is that employees should have access to the documentation and records needed to fulfil their responsibilities.

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Step 7 — Review and Release Documents

Management should review all of the documentation to ensure it meets the operational needs of the business as well as ISO 9001 requirements. Following the reviews, subsequent revisions, and final management approval, documentation is released for use

PHASE 3: IMPLEMENTATION

Step 8 — Implementation and Employee Training

The newly documented Quality System is put into practice throughout the company. Management and employees are trained on the new or revised work processes, procedures and work instructions as formalized in your documentation.

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Step 9 — Quality System Registrar Selection

It is advisable to select a Registration Body that is suited to your organization early in your implementation project. The registration body is an independent organization that is officially accredited to issue Quality System certifications. The registrar will audit your company's Quality System and if the audit is successful – issue the Quality System certificate.

When choosing a certification body to carry out your ISO 9001 registration audit, some selection criteria should be taken into account:

- Is the certification body accredited and, if so, by whom? Accreditation means that the certification body has been officially approved as competent to carry out certification by a national accreditation body.
- Is the certification body recognized by your company's customers?
- Does the certification body auditor(s) have experience in your organization's business sector?
- Is you organization comfortable working with your auditor(s) as both sides have to work together for a long period of time?
- Last but not least, we consider it important that your actual auditor is based geographically close to you, otherwise travel expenses for your auditor's visit to your facility could be very high?

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Step 10 — Internal Auditor Training & Commence Internal Audits

ISO 9001 and related standards require that your company periodically perform an internal audit to evaluate the effectiveness of your Quality System and check that it complies with ISO 9001 requirements as well as your organization's own documented work practices.

A quality audit is a: "Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled."
—ISO 9000:2005

Internal audits are also a great help implementing your Quality System and **a complete internal audit of your Quality System is required before you can pass your registration audit.**

Your internal audit program should be planned, taking into consideration the status and importance of the different processes that are running in your organization.

At least two of your employees will need to be trained as internal auditors.

The criteria for the audit, scopes, frequencies and methods should also be defined. The person(s) responsible for the audit, should be objective and impartial, the only restriction is that they cannot audit their own work.

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Step 11. Management Review

When your Quality System has been operating for three to six months and an internal audit of your Quality System has been completed a Management Review should be conducted and corrective actions implemented as necessary.

Management reviews are conducted to ensure the continuing suitability, adequacy and effectiveness of your Quality System. The review should include assessing opportunities for improvement and the need for changes to the Quality System, including the quality policy and quality objectives. The input to management review should include:

- Results of audits,
- Customer feed back
- Process performance and product conformity
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews

- Changes that could affect the Quality System, and recommendations for improvements
- Management Reviews should also address **pitfalls** to effective Quality System implementation

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PHASE 4: ASSESSMENT AND REGISTRATION

Step 12 — Stage 1 Registration Audit

When you Quality System has been in operation for a few months and has stabilized, it is normally time to schedule your stage 1 registration audit.

Your selected registration body will first carry out an audit of your documentation and then, if your documents meet the requirements of the standard , the registrar will visit your facility and perform a stage 1 Audit to ensure all applicable ISO 9001 or related standard requirements have been met.

Step 13 – Corrective Actions

Following your stage 1 audit, management will review the results and make corrective actions to fix any non-conformances (activities that are not in compliance with the requirements of the standard and/or your own documented work practices) found during the stage 1 registration audit

15 Steps to Implementing ISO 9001

Task 14 — Stage 2 Registration Audit

Your selected Registrar will perform a stage 2 Registration Audit to ensure all applicable ISO 9001 or related standard requirements have been met and that you have corrected any non-conformances found during the stage 1 audit.

Following the successful completion of the stage 2 audit your company will be awarded an ISO 9001 certificate, generally for a period of three years. During this three-year period, your registration body will carry out periodic surveillance audits to ensure that the system is continuing to operate satisfactorily.

Task 15 — Continual Improvement

Certification to ISO 9000 should not be an end. You should continually seek to improve the effectiveness and suitability of your Quality System through the use of your:

- Quality policy
- Quality objectives
- Audit results
- Analysis of data
- Corrective and preventive actions
- Management review

ETI Group:

To date, ETI Group has assisted more 650 companies to achieve Quality Management System (QMS) Certification…all passed their registration audits at the first attempt. Our services include. Our Quality Management System services cover the full range of ISO 9001 and related standards:

ISO 9001 - AS9100 - ISO/TS 16949 - ISO 13485

Implementing a QMS can be expensive, challenging and time consuming. It can also distract key people from their regular day-to-day tasks. To minimize disruptions to your business, ETI Group offers a broad range of practical solutions to assist you in implementing a QMS that meets the specific needs of your business as well as the requirements of the appropriate standard(s).

For more information on how we can help you implement an effective Quality Management System please contact ETI Group at:

Tel: 360-681-2188 or 503-484-5979
Email: info@etigroupusa.com

or

visit our website at www.etigroupusa.com