

A PRACTICAL FIELD GUIDE FOR ISO 9001:2008



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A PRACTICAL FIELD GUIDE FOR ISO 9001:2008

Erik Valdemar Myhrberg

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To my blessed family:

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To my esteemed colleagues:

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INTRODUCTION

Almost 20 years have passed (and over 135 projects) since I first became aware of, and started using, the ISO 9000 standards. So much has changed and evolved during this time. The advent of the ISO 14000 series of environmental management standards, the addition and deletion of standards within the ISO 9000 series, and the creation of a host of industrial and sector-specific standards and “reports” based on ISO 9001 have emerged.

It is my hope that, through my years of extensive field and classroom experience, the readers and users of this field guide will benefit from it in their application of the ISO 9000 Quality Management System series standards.

Even with all this progress, the fundamental use of the ISO 9000 series has not changed. Companies, teams, and individuals are still trying to meet customer expectations; worldwide competition still drives the need for innovation; and internal process pressures still demand continual improvement in order to remain functional.

This field guide has been created in order to foster an inner reliance between senior management, middle management, functional teams, and the individual. Users of the field guide will find within it practical tools, tips, and techniques useful for not only implementing a Quality Management System but also for maintaining one.

With the dawning of the 21st century, companies are being pushed to the limits of their resources. At one time, it was sufficient to meet most of our customer’s requirements, but not now. On a global scale, we are all being asked to do more with less—and for less. At some point soon, the current internal systems will not be able to hold back the deluge, and companies will be faced with a stark decision—consistently improve or perish.

One of the best and most widely accepted ways in which companies can face these challenges is to implement an effective *and* efficient Quality Management System, which not only adds value to the organization but also satisfies the customer.

Indeed, this is already the century of international standards. The revised ISO 9001:2008 series of standards is both useful to the organization and here to stay.

Work diligently with regard to your ongoing ISO efforts!

Erik Valdemar Myhrberg

HOW TO USE THIS FIELD GUIDE

The purpose of this field guide is to assist organizations, step by step, in implementing a QMS in conformance with ISO 9001:2008, whether from scratch or by transitioning from ISO 9001:2000. In keeping with ISO 9000:2005's definition of "quality" as the "degree to which a set of inherent characteristics fulfils requirements," I have identified the requirements and inherent characteristics (distinguishing features) for this field guide. Within the guide, each sub-clause containing requirements is the focus of a two-page spread that consistently presents features that fulfill the requirements listed below.

Requirements (or what the field guide will do)

- Provide a user-friendly guide to ISO 9001:2008's requirements for implementation purposes
- Identify the documents/documentation required, along with recommendations on what to consider retaining or adding to a QMS during ISO 9001:2008 implementation
- Guide internal auditor(s) regarding what to ask to verify that a conforming and effective QMS exists
- Direct management on what it must do and should consider to satisfy ISO 9001:2008's enhanced requirements and responsibilities for top management
- Depict step by step what must occur to create an effective, conforming QMS.

Inherent Characteristics (or what the field guide provides)

- *The Standard*—A paraphrase of what a sub-clause of ISO 9001:2008 requires in easy-to-understand language, with references to information in ISO 9000:2008 and guidance in ISO 9004:2008 to enhance the user's understanding of what ISO 9001:2008 requires and what possible added steps the user can take to improve performance.
- *Document Requirements*—A list of the documentation/documents required by the sub-clause, with some ideas to consider in satisfying those requirements that will take the system beyond the requirements toward continual improvement.
- *Internal Audit Questions*—What every internal audit team needs to ask at a minimum when assessing the QMS for conformance with the sub-clause.
- *Management Summary*—A concise description of what management must do and/or is responsible for in order to achieve conformance to the sub-clause, along with some guidance on additional steps management can take to enhance the system.
- *Sub-clause Flow Chart*—A depiction of the steps that need to be undertaken during an implementation/transition effort to effectively and efficiently satisfy the requirements of the sub-clause of ISO 9001:2008, along with a box providing guidance on use of the flowchart.
- *A Sectional Cross-Evaluation*—A matrix that shows where the requirements in each sub-clause within a section of ISO 9001:2000 appear in ISO 9001:2008.
- These cross-evaluations are provided to assist the user if his/her organization is transitioning from ISO 9001:2000 and appear at the end of the field guide's coverage of each section of ISO 9001:2008 (Sections 4–8).

This field guide is designed to provide you with a consistent approach to implementing an ISO 9001:2008–conforming QMS, which is appropriate because ISO 9001:2008 continues to view quality as the ability of an organization to consistently deliver product that meets customer specifications. The field guide examines each sub-clause of Sections 4–8 of ISO 9001:2008, which contain the requirements with characteristics 1–4 listed above presented on the even page, and characteristic 5 presented on the facing odd page.

Sub-clause 1.2, Scope—Application, which does not contain requirements but is critical to properly excluding any requirements of ISO 9001:2008 that do not apply to your organization’s QMS, and should therefore be treated as an important part of the field guide, due to the importance of establishing the QMS’s scope and subsequent “permissible exclusions.”

What separates this field guide from most other books on ISO 9001:2008 and its implementation are the flow charts showing the steps to be taken in implementing a QMS to meet a sub-clause’s requirements. But the flow charts themselves can be overwhelming when you first look at them. For this reason, a box appears with each flow chart that explains pertinent facts and/or what the flow chart represents and how it is to be used.

Remember, the QMS your organization implements must meet the needs of its users—you and the rest of your organization’s employees, from senior management to the most junior employee. So the QMS you create using this field guide will not only satisfy ISO 9001:2008’s requirements, but will also provide a set of processes that suits your organization and will foster improved use of the system and improvement in the processes of the organization as it matures.



SECTION 4: QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

4.2 Documentation Requirements

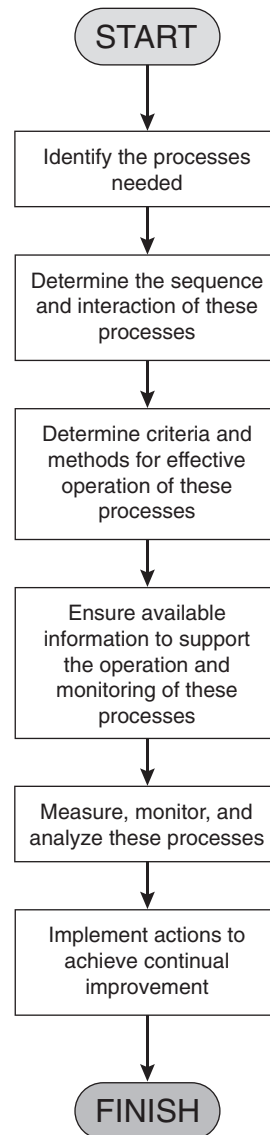
The Standard: 4.0 Quality Management System	
4.1 General Requirements 9001 The organization must develop, document, set up, and maintain a QMS and continually improve its effectiveness through six activities, including identification of needed processes, making sure adequate resources and information are available to support both the processes and their monitoring and achieving expected results and continual improvement of the processes through implemented actions. All related activities must conform to ISO 9001's requirements. When outsourcing related to product occurs, the QMS must contain provisions to ensure the organization controls the processes involved. A NOTE indicates processes that should be included in the QMS. 9004 Offers guidance on activities top management should pursue to create a customer-oriented organization and move it and its QMS toward continual improvement and improved performance. Annexes A and B provide guidance on self-assessment and process improvement.	
Document Requirements:	
<u>Required:</u> - No specific documents, although this sub-clause relates to and affects other requirements in ISO 9001:2008 that concern specific QMS documents/documentation <u>Remember:</u> - Processes need to be clearly defined, with the sequence and interactions between stages and with other processes defined. This will require documenting the organization's operations. - The defined processes must include all administration and management activities.	
Internal Audit Questions:	Management Summary:
- Has the Quality Management System been established, documented, implemented, and maintained? - Have processes that are necessary for maintaining the Quality Management System been determined? - Has the organization demonstrated continual improvement? - Does the organization have control over processes that are outsourced?	Top management must: - Define systems and processes - Ensure that they are understood and managed - Ensure effective control of processes - Utilize data to evaluate performance Top management must follow these Quality Management System principles: - Have a true customer focus. - Demonstrate leadership. - Involve people. - Use a process-oriented approach. - Use a systems approach to management. - Strive for continual improvement. - Base decisions on facts and data. - Cultivate mutually beneficial supplier relationships.

4.1 The General Requirements of a Quality Management System

The organization shall:

- Establish
- Document
- Implement
- Maintain
- Continually Improve

a Quality Management System



The Standard: 4.0 Quality Management System

4.2 Documentation Requirements

4.2.1 General

- 9001** Specifies what is to be included in the QMS documentation: quality policy, objectives and manual; procedures that must be documented to conform to ISO 9001; documents required for “effective planning, operation and control” of the organization’s processes; and quality records. Three NOTES define what is meant by “documented procedure,” clarify that the amount and level of QMS documentation will vary among organizations for three reasons, and explain that documentation can be in any form or medium (e.g., flow chart, electronic file).
- 9004** Suggests management should define the required QMS documentation for the organization, explains what the documentation should do, and provides six factors management should consider in defining the QMS documentation.
- 9000** Defines a “document” in 3.7.2 as “information and its supporting medium” and provides examples of types of documents. Explores in 2.7, Documentation, the value of documentation and the types of documents used in a QMS.

4.2.2 Quality Manual

- 9001** A quality manual is to be developed and maintained that includes the QMS’s scope—with full explanation for why any requirements are excluded—its documented procedures (or indications of where to find them) and a description of the process approach as it works in the QMS.
- 9000** Defines a “quality manual” in 3.7.4 as a “document specifying the [QMS] of an organization.”

Document Requirements:

Remember:

- A quality policy (statement *and* objectives), quality manual, the procedures specified, documents your organization needs to function and meet customer/regulatory requirements, and records conformance.
- The notes in this sub-clause section can have a significant bearing on the documentation when establishing the QMS.

Internal Audit Questions:

- Does the Quality Management System include documented statements of the Quality Policy and Quality Objectives?
- Is there a quality manual?
- Are the required documented procedures in place?
- Are there additional documented procedures where determined as needed by the organization?
- Is the Quality Management System documentation based upon the size, type, complexity, and interaction of processes in the organization?
- Are the required records available?

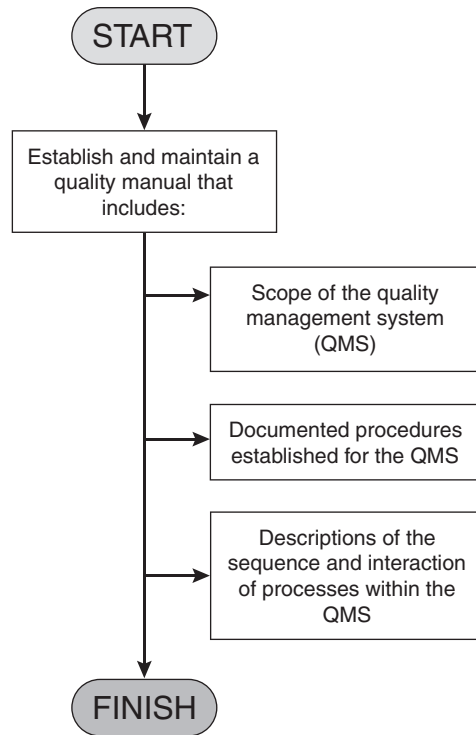
Management Summary:

- Management must define the documentation, including records, that:
- Are required to establish, implement, and maintain a QMS
 - Support an effective and efficient operation

4.2 Document Requirements of a Quality Management System

4.2.1 General

4.2.2 The Quality Manual



*“Documented Procedures” must be—

- Established
- Documented
- Implemented
- Maintained

*The Standard: 4.0 Quality Management System***4.2 Documentation Requirements****4.2.3 Control of Documents**

- 9001** The organization must develop and document a procedure that defines the necessary controls to ensure seven document-related processes are established and provide the level of document control required by ISO 9001. These processes include document approval, review, updating and re-approval, revision status identification, availability of documents where they are needed, legibility, identification and control of external documents, and prevention of unintended use of obsolete documents.
- 9004** Advises that control of documentation should be evaluated to ensure the procedures support the organization's effectiveness and efficiency when seven criteria are considered.

*Document Requirements:***Required:**

- Document control procedure

Remember:

- The review, updating, and re-approval process has always been a requirement; however, you must now add the concept that the documents themselves must be reviewed.

Internal Audit Questions:

- Is document control established in a documented procedure?
- Are documents reviewed, updated, and approved for adequacy prior to use? Are document changes re-approved to ensure adequacy prior to use? Is current document-revision status maintained?
- Are obsolete documents that are retained for any purpose suitably identified to prevent unintended use?
- Is there a process to ensure that documents remain legible, readily identifiable, and retrievable?
- Are versions of applicable documents available at points of use? Are external documents identified and controlled?

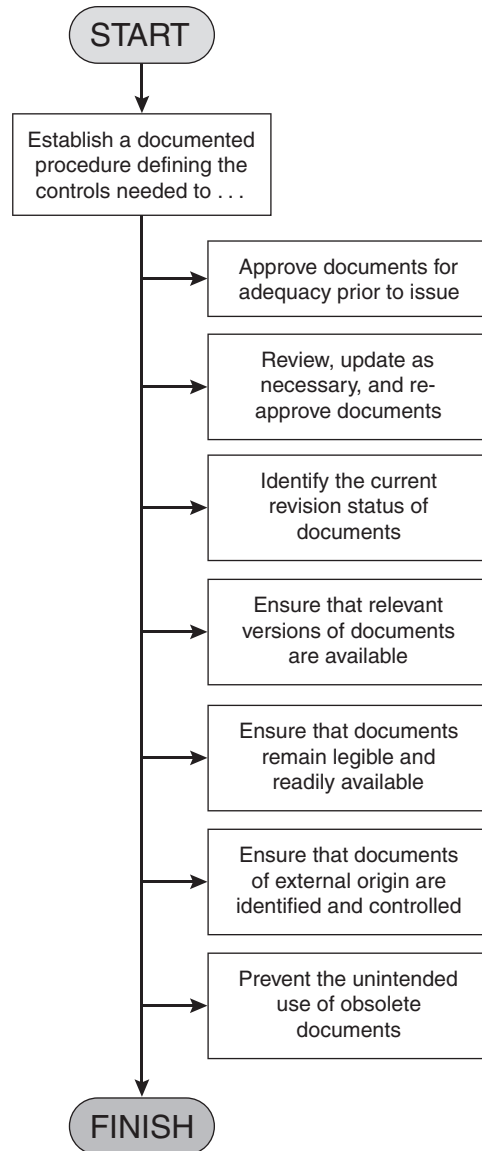
Management Summary:

Management should:

- Define the documentation required
- Give consideration to contractual requirements, acceptance of standards, regulatory requirements, organizational decisions, needs and expectations of interested parties
- Evaluate the generation, use, and control of documentation against criteria such as functionality, user friendliness, resources, policies and objectives, managing knowledge, benchmarking documentation, and interfaces used by outside sources

4.2 Documentation Requirements (continued)

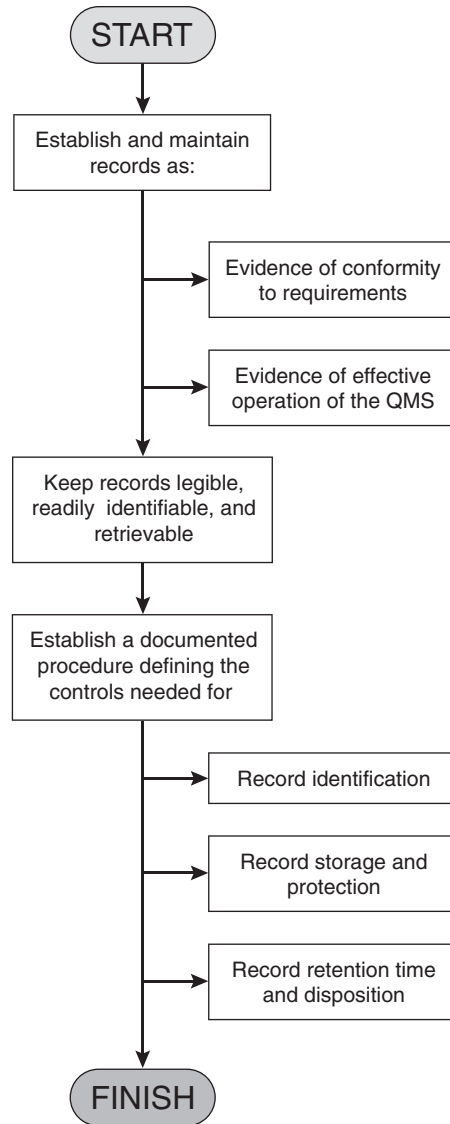
4.2.3 Control of Documents



<i>The Standard: 4.0 Quality Management System</i>	
4.2 Documentation Requirements 4.2.4 Control of Quality Records 9001 Quality records are to be “established and maintained” to prove that the QMS is operating as intended and is effective and satisfies the requirements of ISO 9001. The organization must establish a specific procedure in addition to those for 4.2.3 to define the controls that will apply to quality records and specify, among other things, their storage, retrieval, retention time, and disposition. 9000 Defines a “record” in 3.7.6 as a “document stating results achieved or providing evidence of activities performed.”	
<i>Document Requirements:</i>	
<u>Required:</u> • Documented procedure <u>Remember:</u> • The procedure must not only control records, but do so in a way that serves the organization’s needs without creating valueless paperwork and bureaucracy.	
<i>Internal Audit Questions:</i>	<i>Management Summary:</i>
• Is there a documented procedure for control of records? • Have the organization’s records been identified? • Are protection requirements in place for all records? • Have retention times and disposition requirements been established for all records? • Are records disposed of as required by the established procedures? • Have storage and retrieval requirements been determined and implemented for all records?	• Management must establish and maintain records in order to provide objective evidence of conformance to the organization’s QMS.

4.2 Documentation Requirements (continued)

4.2.4 Control of Records



REVISIONS TO ISO 9001:2000 IN ISO 9001:2008

(Source: Larry Whittington)

4 Quality Management System

4.1 General Requirements

In 4.1, General Requirements, sub-clause (a), the word “Identify” has been replaced with “Determine.”

a) ~~Identify~~ **Determine** the processes needed for the quality management system and their application throughout the organization (see 1.2),

Although similar, the words “Identify” and “Determine” have slightly different meanings. To identify is to recognize or establish something as being a particular thing. To determine is to apply reason and reach a decision. To determine the processes implies more analysis and judgment than merely identifying them.

e) monitor, measure where applicable, and analyze these processes, and . . .

Processes are monitored, but may not need to be measured. Therefore, the requirement change above indicates processes are only measured where applicable.

Later in clause 4.1, regarding outsourcing:

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

This addition clarifies that specific controls are to be defined and applied, not just identified. See the new Note 3 below for an explanation of the type and extent of controls for an outsourced process.

The current Note under clause 4.1 has been expanded and two new Notes have been added:

NOTE 1: Processes needed for the quality management system referred to above ~~should~~ include processes for management activities, provision of resources, product realization, ~~and~~ measurement, analysis, and improvement.

The text above expands from “measurement” to “measurement, analysis, and improvement” to match the title for clause 8. And, by deleting “should,” it clearly states that these processes are included.

The new Note below provides an explanation of what is considered an outsourced process.

NOTE 2: An outsourced process is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

The new Note below identifies the factors influencing the control of an outsourced process.

NOTE 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory, and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements.

b) the degree to which the control for the process is shared.

c) the capability of achieving the necessary control through the application of clause 7.4.

Outsourcing a process to another organization typically involves the purchase of those services. As a result, the requirements of clause 7.4, including the controls mentioned in 7.4.1, apply equally to the supplier selected to perform the outsourced process.

4.2 Documentation Requirements

4.2.1 General

The changes in this section are basically just a restructuring of the sub-clauses c), d), and e).

c) documented procedures and records required by this International Standard, and

d) documents, including records, ~~needed~~ determined by the organization to be necessary to ensure the effective planning, operation and control of its processes. ~~and~~

~~e) records required by this International Standard (see 4.2.4).~~

You can see that adding “records” to sub-clause (c) allowed sub-clause (e) to be dropped. Sub-clause (d) has been expanded to include the necessary records.

The first Note for clause 4.2.1 has added two more sentences:

A single document may include the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

An example for the first sentence would be satisfying the requirements for documented procedures in 8.5.2, Corrective Action, and 8.5.3, Preventive Action, through one combined Corrective and Preventive Action procedure. An example for the second sentence would be splitting the required procedure for the Control of Documents into two separate documented procedures.

4.2.2 Quality Manual

No changes in ISO 9001:2008.

4.2.3 Control of Documents

The opening sentence of this clause in ISO 9001:2008 still states that documents required by the quality management system are to be controlled. The only revision to clause 4.2.3 is shown below:

f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

The change in sub-clause (f) clarifies that not all external documents have to be identified and controlled; only those needed for the planning and operation of the quality management system.

4.2.4 Control of Records

The opening sentence for clause 4.2.4 has expanded from records being “maintained” to having them “controlled.” Maintaining records would simply keep them in good condition. Controlling the records means to regulate their use.

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

~~Records shall remain legible, readily identifiable and retrievable.~~

The organization shall establish a documented procedure ~~shall be established~~ to define the controls needed for the identification, storage, protection, retrieval, retention ~~time~~, and disposition of records.

Records shall remain legible, readily identifiable, and retrievable.

The requirement for a documented Record Control procedure has been rewritten, but the content is basically the same. It is now a separate paragraph for emphasis and moved up in the section.

Note that “retention time” has been reduced to “retention.” And, you can see that records must still remain legible, readily identifiable, and retrievable. This requirement is now a separate paragraph and moved to the end of clause 4.2.4.

SECTION 5: MANAGEMENT RESPONSIBILITY

5.1—Management Commitment

5.2—Customer Focus

5.3—Quality Policy

5.4—Planning

5.5—Responsibility, Authority, and Communication

5.6—Management Review

<i>The Standard: 5.0 Management Responsibility</i>	
5.1 Management Commitment	
9001	Top management must be committed to creation and implementation of a QMS and its continual improvement and will demonstrate its commitment through five types of activities. These activities include organization-wide communication of the criticality of meeting customer and other requirements, establishment of the quality policy and objectives, management reviews, and making sure QMS resources are available.
9004	Suggests actions top management should consider to maximize customer satisfaction and achieve benefits for all parties; recommends methods of performance measurement to help achieve objectives; explores activities relating to the quality management principles that top management should “demonstrate leadership in, and commitment to”; and notes activities that should be considered to optimize processes.
9000	Discusses what management can do in 2.6, Role of Top Management Within the Quality Management System.
Document Requirements:	
<u>Required:</u> No specific documents, although evidence of top management’s commitment to the QMS must be present	
<u>Remember:</u> - This clause is a reminder to top management that there must be a process not only to create awareness of the organization’s quality policy and quality objectives, but also to maintain this awareness. - In addition, top management is aware of the enhanced responsibilities and roles it has with ISO 9001:2008 and the need to demonstrate its commitment to the QMS in ways that can be not just audited by auditors but used by the rest of the organization to maintain and improve processes.	
<i>Internal Audit Questions:</i>	<i>Management Summary:</i>
- Has management established quality objectives and developed a quality policy? - Are management reviews performed? - Does management provide and review the adequacy of resources? - Is a process in place to ensure that all employees understand the importance of fulfilling customer, regulatory, and legal requirements? - Is a process in place to develop specific programs for communicating customer and regulatory requirements? - Is there objective evidence of conformance to these programs in management review records?	- Top management should provide a model of leadership, show commitment, and be actively involved in achieving active involvement to achieve customer satisfaction and regulatory and legal compliance. - Establish the quality policy as a sign of its commitment, and the policy should drive continual improvement of the QMS’s effectiveness. - Top management must define measurement methods to determine if planned objectives have been achieved. - When developing, implementing, and managing the QMS, top management must be involved in the development of quality objectives, either by participating in their setting or by providing the framework and environment for their creation. - Top management must evaluate the QMS regularly. - When developing, implementing and managing the QMS, top management must consider the principles listed in the Management Summary in clause 4.1.

5.1 Management Commitment

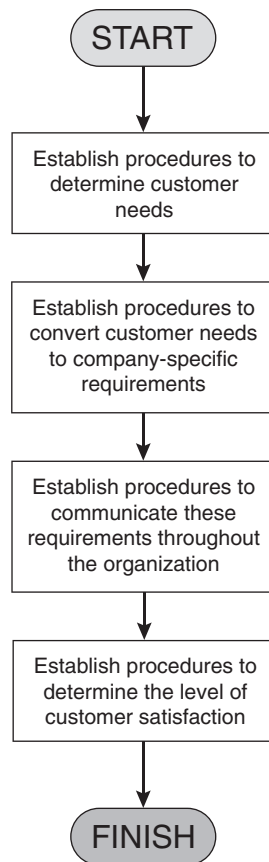
These are the actions required
of the organization's
TOP MANAGEMENT.



<i>The Standard: 5.0 Management Responsibility</i>	
5.2 Customer Focus 9001 To increase customer satisfaction, top management must ensure the organization understands and is capable of satisfying customer requirements (see 7.2.1 and 8.2.1). 9004 Provides examples of customer/end-user needs and guidance on what an organization should do to understand and satisfy the needs of all interested parties. Explores the value of partnerships and what an organization should undertake in regard to its relationship with society.	
<i>Document Requirements:</i>	
Remember: Top management must be able to demonstrate that they have put in place processes to make certain that these requirements are met.	
<i>Internal Audit Questions:</i>	<i>Management Summary:</i>
- Is there a process in place that precisely determines customer needs and expectations? - Is there a process in place to convert customer needs and expectations into company-specific requirements? - What objective evidence is available to confirm these processes were used? - How has top management lead the organization in such a way that the organization's focus is on meeting the needs of the customers, not just making a product?	The organization should identify personnel needs and expectations for recognition, work satisfaction, and personal development in order to ensure the involvement and motivation of its people with relation to customer satisfaction. In order to understand and satisfy the current and future needs of customers, the organization should: - Identify, understand, and respond to customer needs and expectations - Translate customer needs and expectations into requirements - Communicate the requirements throughout the organization - Focus on process improvements to ensure satisfaction

5.2 Customer Focus

TOP MANAGEMENT
must demonstrate a strong
commitment to customer
satisfaction.



*The Standard: 5.0 Management Responsibility***5.3 Quality Policy**

- 9001** Top management is responsible for guaranteeing that the quality policy is appropriate, commits the organization to conformance with all requirements and to continual improvement of the QMS, is a suitable basis for quality objectives, is disseminated and understandable to the entire organization, and is reviewed for ongoing appropriateness to the organization.
- 9004** Lists what top management should consider in establishing the quality policy and spells out conditions that will allow it to be used for QMS improvement.
- 9000** Defines a “quality policy” in 3.2.4 as a formal expression of the “overall intentions and direction of an organization related to quality.” 2.5, Quality Policy and Quality Objectives, explains the policy’s purpose and role and its relationship with the objectives.

*Document Requirements:***Required:**

- Quality policy statement

Remember:

- The quality policy will now need to include commitment to continuous improvement and to measurable objectives.

Internal Audit Questions:

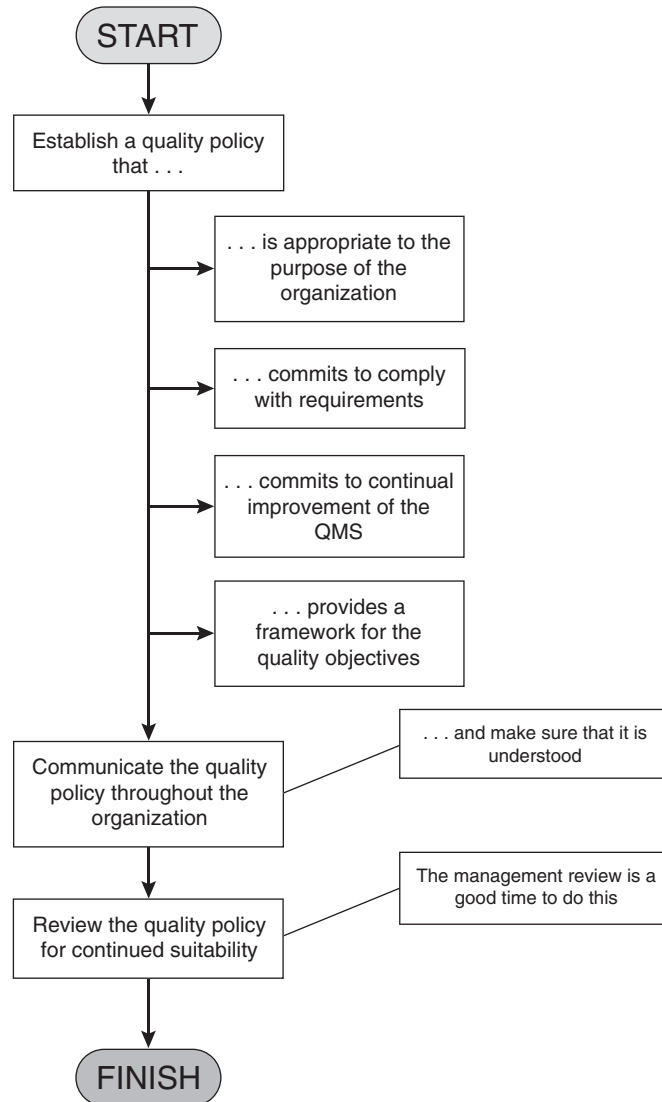
- Is the quality policy documented?
- Does the quality policy provide a framework for establishing and reviewing the Quality Objectives?
- Does the quality policy demonstrate a commitment to meeting requirements and include provisions for continual improvement?
- Does the management review the quality policy regularly for continuing suitability? Do the management review records indicate that the quality policy has been reviewed regularly for suitability?
- Do the quality objectives provide measurable evidence that the organization is achieving its stated quality policy?
- Are the members of the organization clear if the personnel know what the policy means and their role in carrying out the policy and fulfilling it?

Management Summary:

- Top management is responsible for setting this overarching vision for the QMS, from which the objectives will cascade, and must utilize the quality policy as a means of leading the organization toward improvement of its performance.
- The policy must be ambitious but realistic and relevant to the organization.

5.3 Quality Policy

TOP MANAGEMENT
must establish and maintain
a meaningful Quality Policy.



*The Standard: 5.0 Management Responsibility***5.4 Planning****5.4.1 Quality Objectives**

- 9001* Consistent, measurable quality objectives must be set under top management's auspices wherever they are required within the organization to satisfy product requirements and based on the foundation provided in the quality policy.
- 9004* Indicates that quality objectives lead to improved organizational performance and recommends that top management establish them based on the organization's strategic planning and quality policy. Suggests factors worth considering in setting objectives and then communicating the objectives so everyone contributes to their achievement.
- 9000* Defines "quality objective" in 3.2.5 and explains in 2.5, Quality Policy and Quality Objectives, their purpose/role with the policy and the benefits of achieving objectives.

*Document Requirements:***Required:**

- Quality policy objectives

Remember:

- The quantification of need for objectives to be quantifiable in form as actual input on QMS effectiveness, which was only implied in ISO 9001:2000 is now a specific requirement.

Internal Audit Questions:

- Have measurable quality objectives been established at relevant functions and levels within the organization? How are these documented?
- Do quality objectives include meeting requirements for the organization's products and/or services?
- Has the organization identified the activities and processes required to meet the quality objectives (Quality Management System, product and/or service-realization, verification processes)?

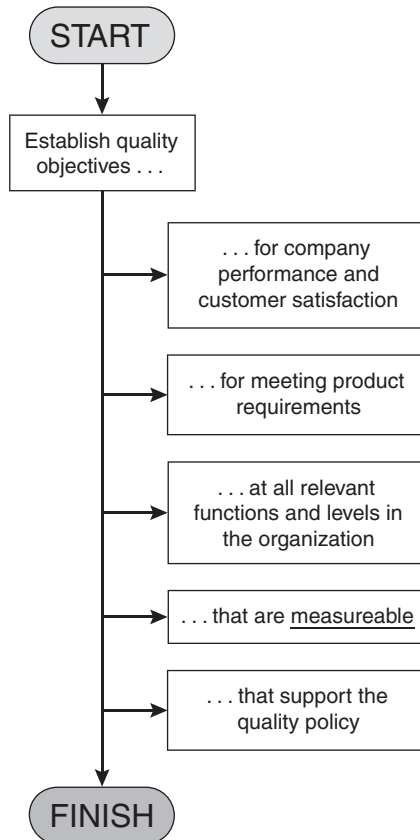
Management Summary:

- The organization should use its strategic planning process and quality policy as a framework for setting quality objectives.
- Top management sets quality objectives as a method for leading continual improvement within the organization
- Quality objectives must be measurable and communicated in such a way that all personnel can contribute to their achievement.
- Quality objectives must be regularly and systematically reviewed and revised.

5.4 Planning for Quality

5.4.1 Quality Objectives

TOP MANAGEMENT
must ensure that meaningful
Quality Objectives
are established.



*The Standard: 5.0 Management Responsibility***5.4 Planning****5.4.2 Quality Management System Planning**

- 9001** Title is clarified from “Quality Planning” in the DIS. Top management must ensure planning relative to the QMS is conducted so as to conform with the requirements of 4.1, Quality Management System—General Requirements, and achieve the organization’s quality objectives. This includes ensuring QMS revisions do not compromise ISO 9001 conformance and effectiveness of the QMS.
- 9004** Discusses the broader concept of “quality planning” and the inputs and outputs that could make the QMS and quality planning effective and efficient in meeting an organization’s quality objectives and strategic requirements.
- 9000** Defines “quality planning” in 3.2.9 as management activities “focused on setting quality objectives and specifying necessary operational processes and related resources to fulfill the quality objectives.”

*Document Requirements:***Remember:**

- A documented plan that identifies the resources needed to achieve quality objectives is required.
- Changes are to be introduced without failures of the Quality Management System.

Internal Audit Questions:

- Has the organization identified and planned processes and resources for the quality system?
- Do the processes provide for the control of changes to the Quality Management System?
- As organizational changes occur, does quality planning take into account the needs of the organization?
- What objective evidence exists to demonstrate that quality planning contributes to continual improvement (i.e., program briefs, action item in a management review record, or reference to an existing procedure)?

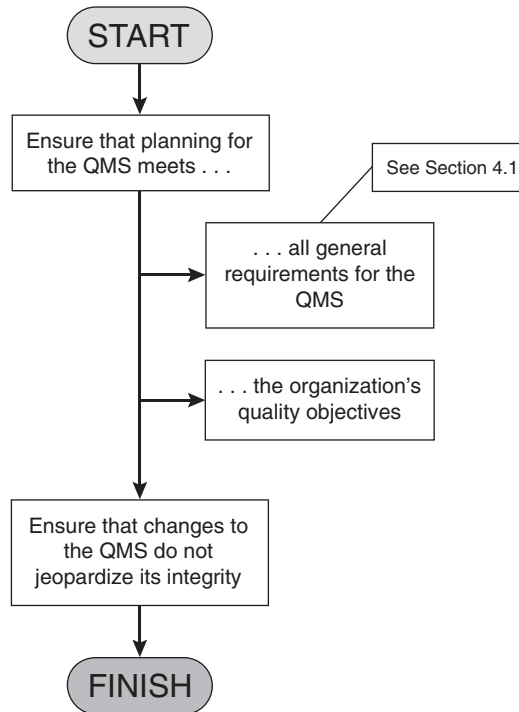
Management Summary:

- Top management must establish quality plans for the organization.
- Top management should plan processes effectively and efficiently to fulfill the organization’s quality objectives.

5.4 Planning (continued)

5.4.2 QMS Planning

TOP MANAGEMENT
is responsible for both the
planning and the integrity of the
Quality Management System.



*The Standard: 5.0 Management Responsibility***5.5 Responsibility, Authority, and Communication****5.5.1 Responsibility and Authority**

9001 The responsibilities and authorities for management of an organization's QMS and the interrelationships are to be "defined and communicated" throughout the organization, with top management responsible for guaranteeing this is accomplished.

9004 Recommends that top management should "define and communicate" the responsibilities and authorities, with a range of employees empowered to gain their contributions to quality objective fulfillment and their buy-in to the QMS.

*Document Requirements:***Remember:**

- Organizational chart
- Job descriptions
- Other documents defining the authority and responsibility of each job function

Internal Audit Questions:

- Are responsibilities and authorities defined and communicated to facilitate effective quality management?
- Are the quality objectives consistent with the stated quality policy, and do they provide measurable evidence that the organization is achieving that policy?
- Are responsibilities and authorities defined and communicated to facilitate effective quality management?

Management Summary:

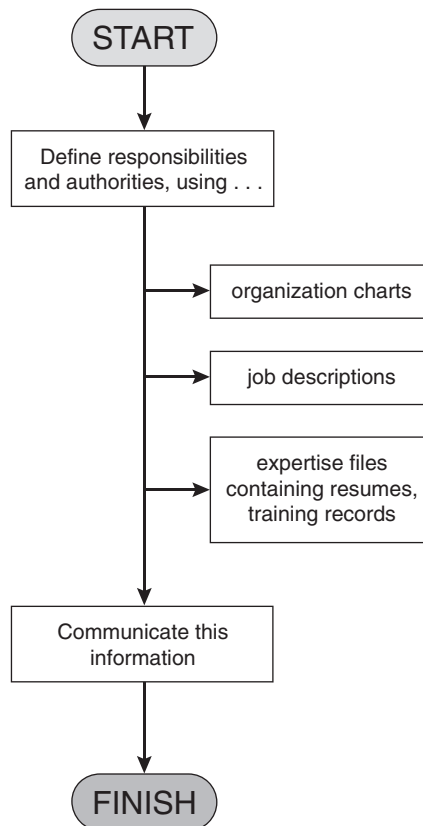
- The processes within the organization must enable people to contribute to the achievement of the quality objectives, thus better aligning the business system with the management system.
- Not all quality objectives will be suitable to and attainable by all operations or personnel, so top management must provide the direction and processes by which objectives can be set for each area and group of personnel.



5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

TOP MANAGEMENT
must see that responsibilities
and authorities are defined and
are communicated throughout
the organization.



*The Standard: 5.0 Management Responsibility***5.5 Responsibility, Authority, and Communication****5.5.2 Management Representative**

- 9001** Top management must appoint a management-level representative who is to: ensure a QMS is put in place and kept in operation; report to top management on how well the QMS is functioning and actions required to correct/improve the QMS; and ensure customer requirements are communicated and understood by all affected employees (i.e., listening to the voice of the customer). The representative can serve as a liaison to external parties on QMS issues.
- 9004** Advocates having the representative play the most active role in managing and overseeing the QMS and communicating with customers and others about the QMS.

*Document Requirements:***Remember:**

- No documents/documentation is required, although a documented QMS planning process and/or records of planning activities are recommended.
- Though not for creation, implementation, and revision of the QMS, a documented process for QMS planning will assist those involved in those planning activities and will help them, making a documented procedure and records of the QMS planning process useful.

Internal Audit Questions:

- Has the organization appointed one or more management representatives? Are the responsibilities and authorities of the management representative defined?
- As organizational changes occur, does QMS planning take into account the needs of the organization?
- Has the organization appointed one or more management representatives? Are the responsibilities and authorities of the management representative defined?
- Has the management representative implemented a system/program for communicating customer requirements to the organization?
- Is there objective evidence to demonstrate that this communication has taken place?
- Does the management representative report to top management on the performance of the Quality Management System?
- Does the management representative promote awareness of customer requirements throughout the organization?

Management Summary:

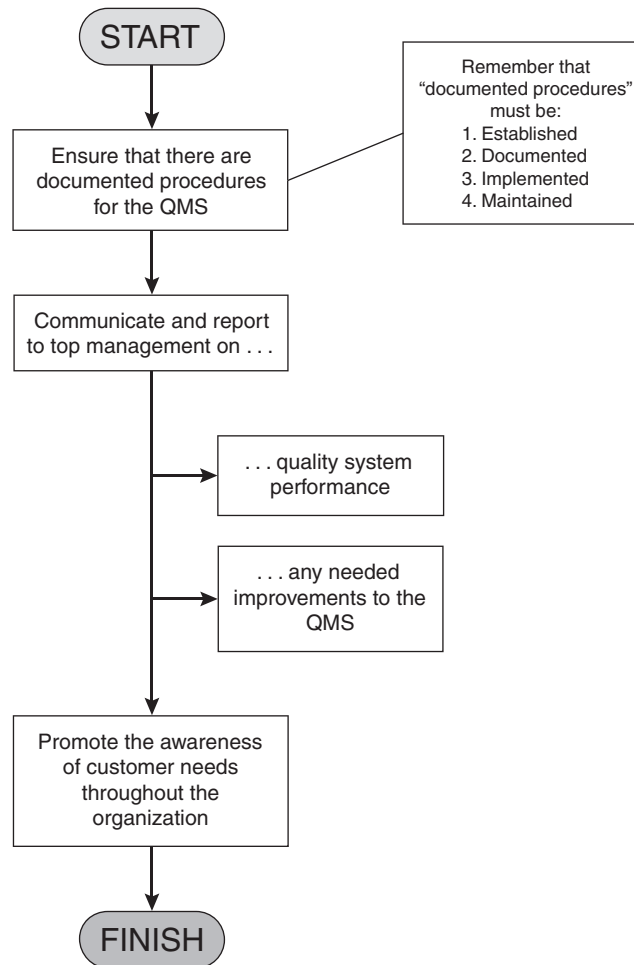
- The role of the management representative is to enhance effective and efficient operation and improvement of the QMS.
- The management representative has additional responsibility to promote awareness of customer requirements.
- Ensure that planning takes place to produce and update an ISO 9001:2008–conforming QMS that meets the needs of the organization.



5.5 Responsibility, Authority, and Communication

5.5.2 Management Representative

TOP MANAGEMENT
must appoint a manager
authorized to oversee the
Quality Management System.



*The Standard: 5.0 Management Responsibility***5.5 Responsibility, Authority, and Communication****5.5.3 Internal Communication**

9001 Top management must ensure the organization adopts communications processes that inform all within the organization about how effective the QMS is.

9004 Recommends management take direct responsibility for installing communication processes and including information on certain QMS elements and accomplishments to encourage employee participation in performance improvements, achievement of quality objectives, and providing QMS feedback. Lists ways to communicate with employees.

*Document Requirements:***Remember:**

- No documents/documentation is specified, although documentation is the most effective means of defining and communicating QMS responsibilities and authorities. The following types of documentation can be used to define and communicate: Documented Procedures and Records.

Internal Audit Questions:

- With regard to QMS functioning within the organization, are those defined responsibilities and authorities effectively known to, understood, and used by personnel throughout the organization? What objective evidence exists to document internal communication (i.e., document distribution lists and records, training records, minutes of management reviews, etc.)?
- Does the organization hold discussions with all employees to communicate processes of the Quality Management System and their effectiveness?

Management Summary:

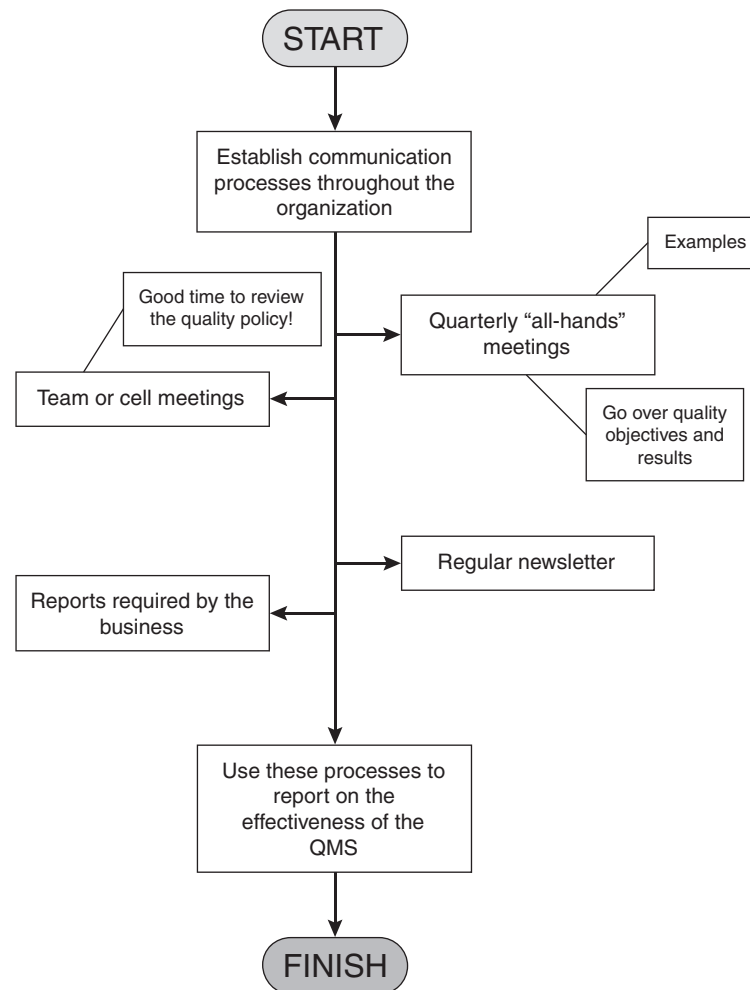
- It is top management's responsibility to provide the processes and directives so that QMS responsibilities and authorities can be delegated to the appropriate personnel within the organization (where management does not actually determine those roles) and communicated so that all personnel understand who to contact for approvals and information and to whom to give feedback.
- Management must communicate the quality policy, requirements, objectives, and accomplishments to the organization.
- Management should actively encourage feedback and communication from people in the organization as a means of involvement.
- It is a new requirement for management to define and implement a communication process.



5.5 Responsibility, Authority, and Communication

5.5.3 Internal Communication

TOP MANAGEMENT
must . . .



*The Standard: 5.0 Management Responsibility***5.6 Management Review****5.6.1 General**

- 9001** Top management is to review the QMS “at planned intervals” to verify the QMS is appropriate to the organization’s needs, satisfies ISO 9001 requirements and effectively meets customer requirements and employee needs. Meeting minutes of each review must be retained as quality records. During these reviews, management must evaluate potential QMS improvements and changes in response to nonconformities as well as achievements.
- 9004** Provides guidance on expanding management review to assess QMS efficiency and include review of all activities within the organization. The quality management principles should serve as the basis for “systematic control,” with the planning of performance improvements for the whole organization as an end-result.
- 9000** In 2.8.3, Reviewing the Quality Management System, explores what top management’s role is intended to be in the reviews.

*Document Requirements:***Requirement:**

- Records of reviews

Remember:

- Management may wish to hold more frequent reviews to address additional items and to demonstrate commitment to continual improvements.

Internal Audit Questions:

- Has the top management representative overseen creation, implementation, and maintenance of the QMS processes required by ISO 9001:2000?
- Has top management responded appropriately to those reports? Has the management representative implemented a system/program for communicating customer requirements to the organization that ensures awareness?
- Does management review the Quality Management System at planned intervals to ensure its continuing suitability, adequacy, and effectiveness?
- Do management reviews include evaluation of the need for changes to the organization’s Quality Management System, quality policy, and quality objectives?
- Are results of management reviews recorded and maintained as records?

Management Summary:

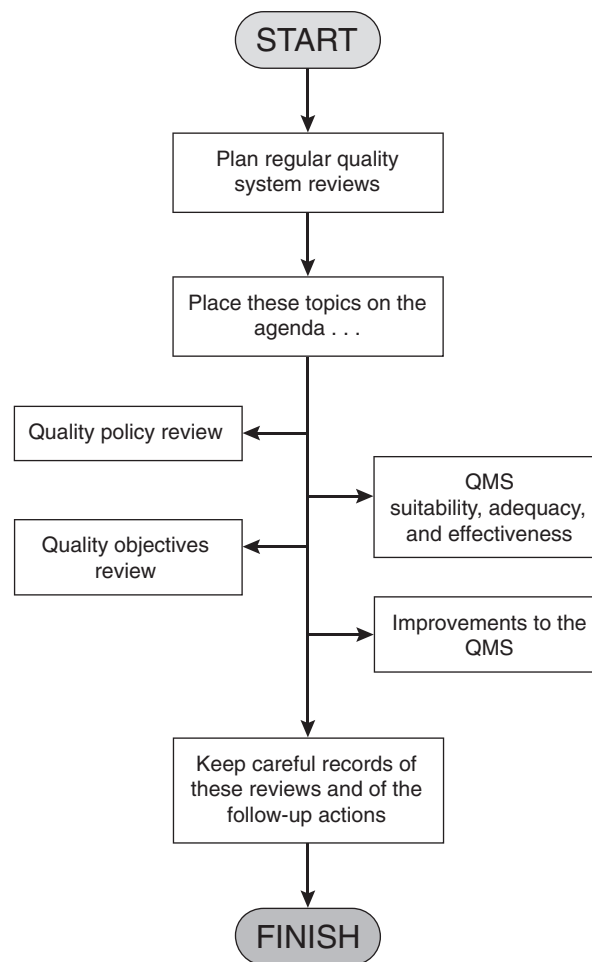
- Top management must select one of its members based on the ability to fulfill the obligations of the management representative.
- Top management must work with the management representative to establish a regularly scheduled report from the representative and must be committed to act in response to those reports.
- Top management should develop an expanded management review process that extends to the entire organization.
- Management review should be a platform to exchange new ideas with open discussion.
- The frequency of management reviews should be determined by the needs of the organization.
- Management review inputs should result in changes to the process that will increase the existing efficiency and effectiveness of the QMS.



5.6 Management Review

5.6.1 General

TOP MANAGEMENT
must . . .



<i>The Standard: 5.0 Management Responsibility</i>	
5.6 Management Review 5.6.2 Review Input 9001 Management must include seven categories of data as mandatory review inputs. 9004 Includes as suggested inputs 13 categories of data, ranging from QMS results beyond the ISO 9001 requirements to non-quality business considerations.	
<i>Document Requirements:</i>	
Remember: These are specified. The organization now clearly defines items that must establish communication approaches that would best be documented and where included on the actual communications must take place through some form of documentation (e.g., QMS effectiveness memos, reports, and/or intranet or Web-based communications). Records of these communications should be kept.	
<i>Internal Audit Questions:</i>	<i>Management Summary:</i>
- Does management review input include audit results, customer feedback, process performance, and product performance, and preventive and corrective action status, follow-up actions from earlier management reviews, and changes that could affect the Quality Management System? - Is top management involved within the QMS structure?	- Management review inputs should include the status of relevant internal and external factors, as well as results of existing processes. - Inform the organization of and quality objectives QMS and resulting processes to be followed. Top management should seek verification that QMS effectiveness—and the need for improvements—are known and understood throughout the organization. - To foster employees in the maintenance and improvement of the QMS top ensure that communication processes are put into use Management review inputs should include the status of relevant internal and external factors, as well as results of existing processes.