

A PRACTICAL FIELD GUIDE FOR AS9100C

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Erik Valdemar Myhrberg
with
Dawn Holly Crabtree and Rudolph “RE” Hacker

ASQ Quality Press
Milwaukee, Wisconsin

American Society for Quality, Quality Press, Milwaukee 53203

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Printed in the United States of America

16 15 14 13 12 11 10 5 4 3 2 1

Library of Congress Cataloging-in-Publication Data

Myhrberg, Erik V.

A practical field guide for AS9100C / Erik Valdemar Myhrberg ; with Dawn Holly Crabtree and Rudolph "RE" Hacker.

p. cm.

Includes bibliographical references.

ISBN 978-0-87389-793-8 (alk. paper)

1. Aerospace engineering—Quality control—Standards. 2. Aerospace industries—Management. 3. ISO 9000 Series Standards. I. Crabtree, Dawn Holly. II. Hacker, Rudolph. III. Title.

TL671.28.M94 2010

629.1068'4—dc22

2010021511

ISBN: 978-0-87389-793-8

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Publisher: William A. Tony

Acquisitions Editor: Matt T. Meinholz

Project Editor: Paul O'Mara

Production Administrator: Randall Benson

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To place orders or to request ASQ membership information, call 800-248-1946. Visit our Web site at <http://www.asq.org/quality-press>.

 Printed on acid-free paper



Quality Press
600 N. Plankinton Avenue
Milwaukee, Wisconsin 53203
Call toll free 800-248-1946
Fax 414-272-1734
www.asq.org
<http://www.asq.org/quality-press>
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*We dedicate this combined work
to our loving families.*

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PREFACE

With the dawning of the twenty-first century, companies are being pushed to the extremes of their limited 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.

Companies, teams, and individuals are still trying to meet customer expectations in an effective and efficient manner, worldwide competition still drives the need for innovation, and internal process pressures still demand continual improvement in order to remain functional. 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.

It is extremely challenging to stay competitive in the aerospace industry; the need for assurance of good material is paramount and has driven cost, sometimes unnecessarily due to the continued existence of outdated manufacturing and quality system thinking and practices. Cost is primarily due to small order quantities, product complexity, and special processes and materials. Yet, traditional production, over-inspection, and processing techniques are also extremely costly, as typically many redundant tests of the same feature occur to assure conformance.

When MIL-Q-9858 was retired, the aerospace industry started to feel the ill effects of the absence of aerospace-specific mandated criteria. Though many companies registered to ISO 9001, which provided a fantastic yet generic business quality management system, it did not address the needs of the aerospace industry. To those of us who could see the wastes in the traditional “product realization” system, the creation of AS9000, and subsequently AS9100 based on ISO 9001, was by divine providence. Here was a QMS that focused on process control that is efficient and effective, not redundant inspection, and communicated the industry-specific needs of aerospace—such as first inspection and product traceability. When ISO 9001 became a process-oriented standard in the year 2000 it better supported the process control structure of AS9100; hence, AS9100:2001 is the best QMS standard for aerospace—bar none!

From working with and within aerospace primes, medium-size suppliers, job shops, and software design, it has become apparent how little the concept of process control has caught on. Combining the

experience of over 150 QMS implementations with responsibilities covering internal and supplier quality engineering, and training and implementing of lean manufacturing and Six Sigma quality, we readily see how businesses could avoid long-term costs of redundant non-value-adding tasks like inspections, scrap, rework, and customer returns by following the requirements of AS9100 using proven quality tools. AS9100 is not prescriptive, but gives hints as to the use of these tools.

The purpose of this field guide is to assist the reader, step by step, in implementing a QMS in conformance with AS9100. This field guide has been created in order to facilitate 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.

In keeping with ISO 9000's definition of "quality" as the "degree to which a set of inherent characteristics fulfils requirements," we have identified the requirements and inherent characteristics (distinguishing features) of AS9100. Within this field guide, each subclause containing requirements is the focus of a two-page spread that consistently presents the features listed below.

Provisions (or What the Field Guide Will Do)

- Provide a user-friendly guide to AS9100's requirements for implementation purposes
- Identify the documents/documentation required, along with recommendations on what to consider retaining/adding to a QMS during AS9100 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 AS9100's enhanced requirements and responsibilities for top management
- Depict step by step what must occur to create an effective, conforming QMS

Direct Characteristics (or What the Field Guide Provides)

- *The standard*—A paraphrase of what a subclause of AS9100 requires in easy-to-understand language, with references to information in ISO 9000 and guidance in ISO 9004 to enhance the user's understanding of what AS9100 requires and what possible added steps the user can take to improve performance (per the ISO 9004 guidelines)
- *Document requirements*—A list of the documentation/documents required by the subclause, 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 subclause

- *Management summary*—A concise description of what management must do and/or is responsible for in order to achieve conformance to the subclause, along with some guidance on additional steps management can take to enhance the system
- *Process control tip*—Recommendations of method or tools to best infuse process control into the QMS, as AS9100 was intended to be used
- *Subclause flowchart*—A depiction of the steps that need to be undertaken during an implementation/transition effort to effectively and efficiently satisfy the requirements of the subclause of AS9100, along with a box providing guidance on use of the flowchart

This field guide is designed to provide you with a consistent approach to implementing an AS9100-conforming QMS, which is appropriate since AS9100 continues to view quality as the ability of an organization to consistently deliver product that meets customer specifications. The field guide examines each subclause of Sections 4–8 of AS9100, which contain the requirements.

Subclause 1.2, Scope—Application, does not contain requirements but is critical to properly excluding any requirements of AS9100 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.

Paragraphs and items in *bold italics* delineate AS9100 requirements above and beyond those of ISO 9001. This includes Clauses, Internal Audit Questions, Management Summary, Process Control Tips, and Flowcharts.

What separates this field guide from most other books on AS9100 and its implementation are the flowcharts showing the steps to be taken in implementing a QMS to meet a subclause’s requirements. But the flowcharts themselves can be overwhelming when you first look at them. For this reason, a box appears with each flowchart that explains pertinent facts and/or what the flowchart 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 AS9100’s requirements, but provide a set of processes that suits your organization and fosters improved use of the system and improvement in the processes of the organization over time. You may also use the ISO 9004 guidelines for further explanation. Please note that compliance to AS9100 may not ensure that your organization meets all contractual requirements.

A goal throughout this field guide is to provide clear concepts of how to ingrain process control into your business utilizing the AS9100 system. Your goal: for your processes to turn out aerospace conforming parts on time, every time, at a competitive cost. The companies that can compete now and in the future will need to do just that. Our hope is that our AS9100 field guide will help to get you there.

To your continued success,
Erik Myhrberg with Dawn Crabtree and Rudy Hacker

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SECTION 4: QUALITY MANAGEMENT SYSTEM

4.1—General Requirements

4.2—Documentation Requirements

4.0 Quality Management System

4.1 General Requirements

- AS9100** The organization must develop, document, set up, and maintain a QMS and continually improve its effectiveness through six activities, including (1) identification of needed processes, (2) making sure adequate resources and (3) information are available to support both the processes and their (4) monitoring, and (5) achieving expected results and (6) 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.
- ISO 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:

Required:

No specific documents, although this subclause relates to and affects other requirements in ISO 9001:2008 that concern specific QMS documents/documentation.

Remember:

- 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.

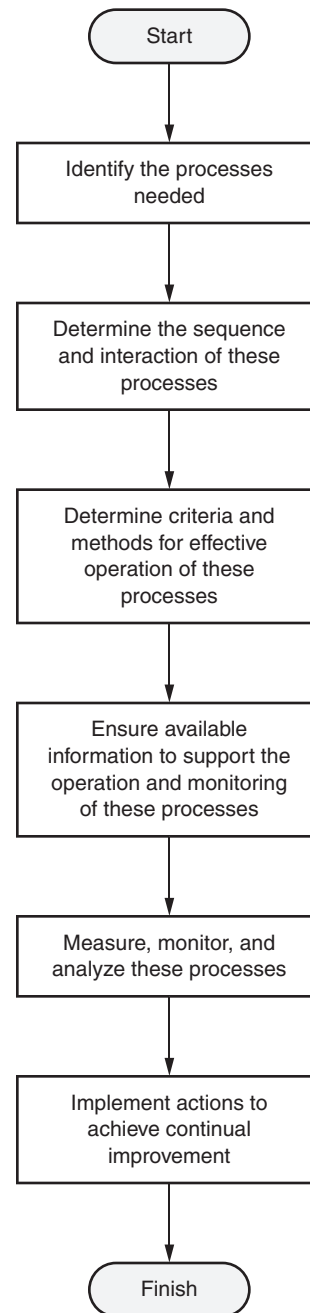
<i>Internal Audit Questions:</i>	<i>Management Summary:</i>
• Has the quality management system been established, documented, implemented, and maintained? • Have processes that are necessary for maintaining the quality management system been determined? • Has the organization demonstrated continual improvement? • Does the organization have control over processes that are outsourced?	Top management must: • Define systems and processes • Ensure that they are trained 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 Process Control Tip: <i>Process mapping the current state of your business will help to identify inconsistencies in operations and improvement opportunities. Involve employees that supply, perform, and are customers to the process to participate in creation of process maps. Since they define your business methods, these maps should be the main content in your procedures.</i> <i>Process maps provide a visual yet comprehensive view of the process and ease in changing procedures and in training new employees.</i>

4.1 General Requirements

To leverage your QMS for greater improvement you need to:

- Establish
- Document
- Implement
- Maintain
- Continually improve

your quality management system.



4.0 Quality Management System

4.2 Documentation Requirements

4.2.1 General

- AS9100** 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; quality records; ***all customer and regulatory requirements***. 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 (for example, flowchart, electronic file).
- ISO 9004** Suggests management should define the required QMS documentation for the organization, explains what the documentation should do, and provides factors management should consider in defining the QMS documentation.
- ISO 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

- AS9100** 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.
- ISO 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 subclause 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 on the size, type, complexity, and interaction of processes in the organization?
- Are the required records available?
- *Can you readily identify which requirement(s) are addressed in each procedure?*

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

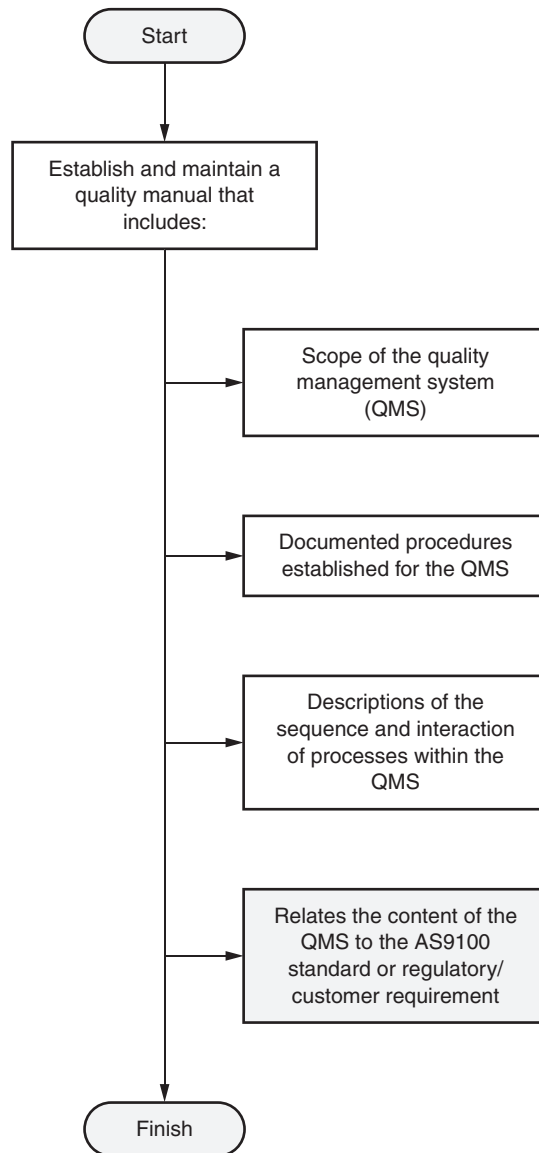
Process Control Tip:

Matrices of customer and regulatory requirements referenced to your QMS will assist in assuring compliance, during creation and change of processes, and greatly assists auditors.

4.2 Documentation Requirements of a Quality Management System

4.2.1 General

4.2.2 The Quality Manual



* "Documented Procedures" must be:

- Established
- Documented
- Implemented
- Maintained

4.0 Quality Management System

4.2 Documentation Requirements

4.2.3 Control of Documents

AS9100 The organization must develop and document a procedure that defines the necessary controls to ensure that eight document-related processes are established and provide the level of document control required by ISO 9001. These processes include document approval, review, updating and reapproval, revision status identification, availability of documents where they are needed, legibility, identification and control of external documents, prevention of unintended use of obsolete documents, and coordination of document changes with customer and/or regulatory authorities in accordance with contract or regulatory requirements.

ISO 9004 Advises that control of documentation should be evaluated to ensure that 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 reapproval 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 reapproved 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 latest versions of applicable documents available at points of use? Are relevant versions of 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
- Feed back proposed document changes to contract review to ensure compliance with contracts and notification to customer and/or regulatory authorities where required

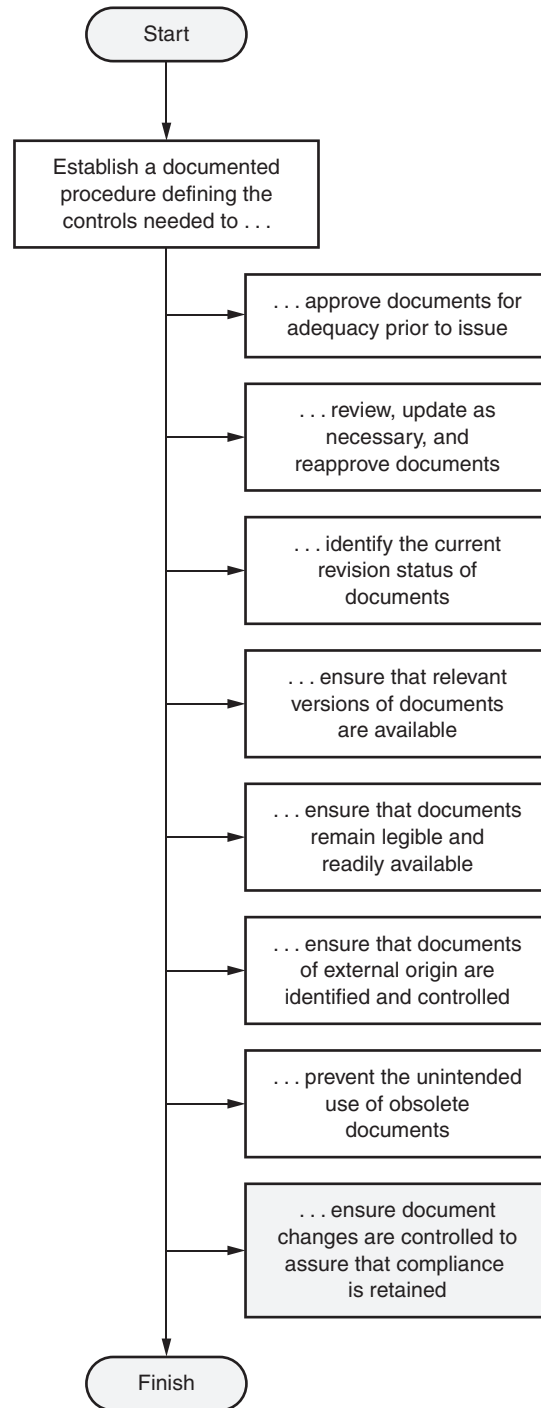
Process Control Tip:

A control plan for any process addresses change management and, where required, should list applicable contractual requirements. This ensures that during process changes customer and regulatory requirements are always adhered to.



4.2 Documentation Requirements

4.2.3 Control of Documents



4.0 Quality Management System

4.2 Documentation Requirements

4.2.4 Control of Records

AS9100 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; **this includes controlling quality records retained by your supplier.**

ISO 9000 Defines a “record” in 3.7.6 as a “document stating results achieved or providing evidence of activities performed.”

Document Requirements:

Required:

Documented procedure

Remember:

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.

Internal Audit Questions:

- Is there a documented procedure for control of records?
- Have the organization’s records been catalogued?
- 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?
- Is there a documented procedure addressing supplier control?
- Are you flowing down to suppliers the requirement to control documents where the organization has chosen for the supplier to control them?
- Have you verified that your suppliers are controlling applicable documentation?

Management Summary:

Management must establish and maintain records in order to provide objective evidence of conformance to the organization’s QMS.

Records retained by suppliers shall be controlled and made available on request; therefore, supplier contracts (purchase orders) must flow down this requirement (refer to Section 7.4).

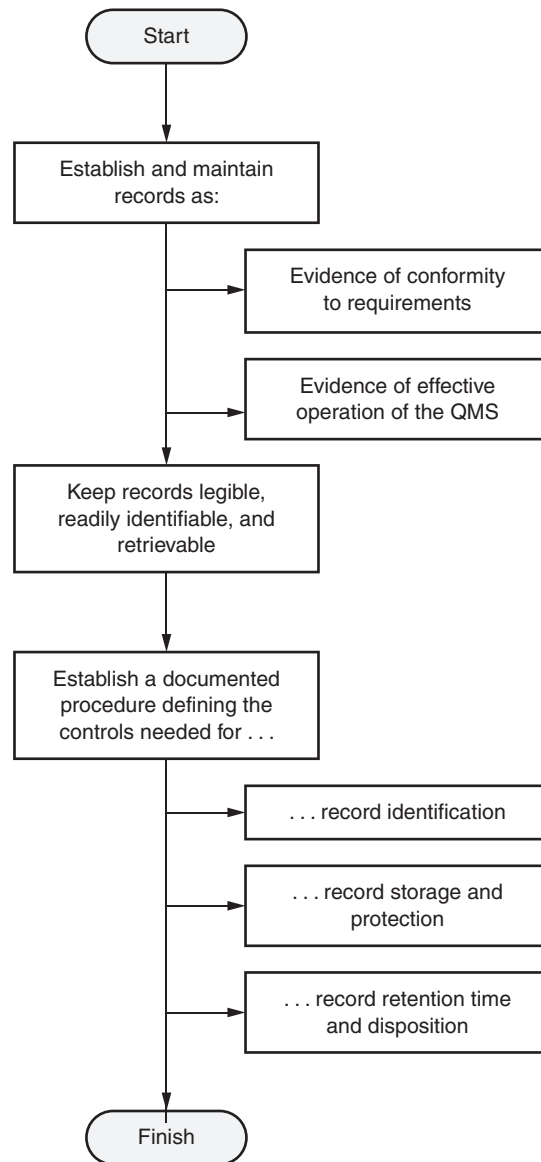
All quality records shall be made available to customer or regulatory authorities per contractual requirements.

Process Control Tip:

- 1. Implement a visual document system for simplification and easy retrieval.***
- 2. Create a document control plan that links to contact requirements; this ensures the proper availability of records that may be requested by customer/regulatory authorities (see Process Control Tip in element 4.2.1).***

4.2 Documentation Requirements

4.2.4 Control of Records



4.0 Quality Management System

4.3 Configuration Management

AS9100 A controlled process of configuration management for all product is required to assure best quality in design and control of the design.

ISO10007 Guide to Configuration Management

This document will simplify the design and implementation of a robust configuration management system.

Document Requirements:

Required:

Documented procedure

Remember:

- The procedure should simplify the configuration process.
- All design and contract reviews should feed into this process.

Internal Audit Questions:

- Is there a documented procedure for configuration management?
- Are configurations current?
- Is the configuration management process appropriate for the product?

Management Summary:

Process Control Tip:

Develop and map a robust process to ensure that all feedback from suppliers, customers, and internal processes that recommend design or modification to product are controlled and the best use of the change control process is utilized.



REVISIONS TO AS9100:2009 (REVISION C), CLAUSE 4

(Source: Larry Whittington)

4. Quality Management System

4.1 General Requirements

AS9100C inserts the following sentence to add customer and legal requirements to those of AS9100C. The rationale for this addition is to indicate that these requirements apply at the quality management system level, not just at the previously stated documentation level:

The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.

In 4.1, subclause (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 that 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 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.

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 subclauses 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 subclause (c) allowed subclause (e) to be dropped. Subclause (d) has been expanded to include the necessary records.

AS9100C removed subclause (f) because its new general requirement in clause 4.1 more broadly states that the system must address the applicable statutory and regulatory quality management system requirements:

~~f) quality system requirements imposed by the applicable regulatory authorities.~~

AS9100C reworded the first sentence of this paragraph and deleted the second sentence. It makes sense that personnel not just have access to, but be made aware of the documentation and changes:

The organization shall ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes. ~~are aware of relevant procedures. Customer and/or regulatory authorities' representatives shall have access to quality management system documentation.~~

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 to satisfy 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 to split the required procedure for the control of documents into two separate documented procedures.

4.2.2 Quality Manual

AS9100C deleted this entry under 4.2.2, subclause (b) regarding the relationship between requirements and documented procedures. It was too prescriptive and didn't really contribute to product quality:

~~when referencing the documented procedures, the relationship between the requirements of this International Standard and the documented procedures shall be clearly shown.~~

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 subclause (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.

AS9100C deleted this sentence because the 4.1 addition in General Requirements addresses customer and legal requirements for the entire system:

~~The organization shall coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.~~

4.2.4 Control of Records

The opening sentence of 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.

AS9100C deleted the following sentence from clause 4.2.4 because the 4.1 addition in General Requirements addresses customer and legal requirements for the entire system:

Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

The Configuration Management clause 4.3 in AS9100B has been moved to clause 7.1.3 in AS9100C:

4.3 Configuration Management

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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

5.0 Management Responsibility

5.1 Management Commitment

- AS9100** 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 organizationwide 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.
- ISO 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.
- ISO 9000** Discusses in 2.6 Role of Top Management within the Quality Management System.

Document Requirements:

Required:

No specific documents, although evidence of top management’s commitment to the QMS must be present

Remember:

- 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 has enhanced responsibilities in its role 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.

Internal Audit Questions:

- 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?

Management Summary:

Top management should strive to be a model of leadership, show commitment, and be actively involved in achieving customer satisfaction and regulatory and legal compliance.

Top management should 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.

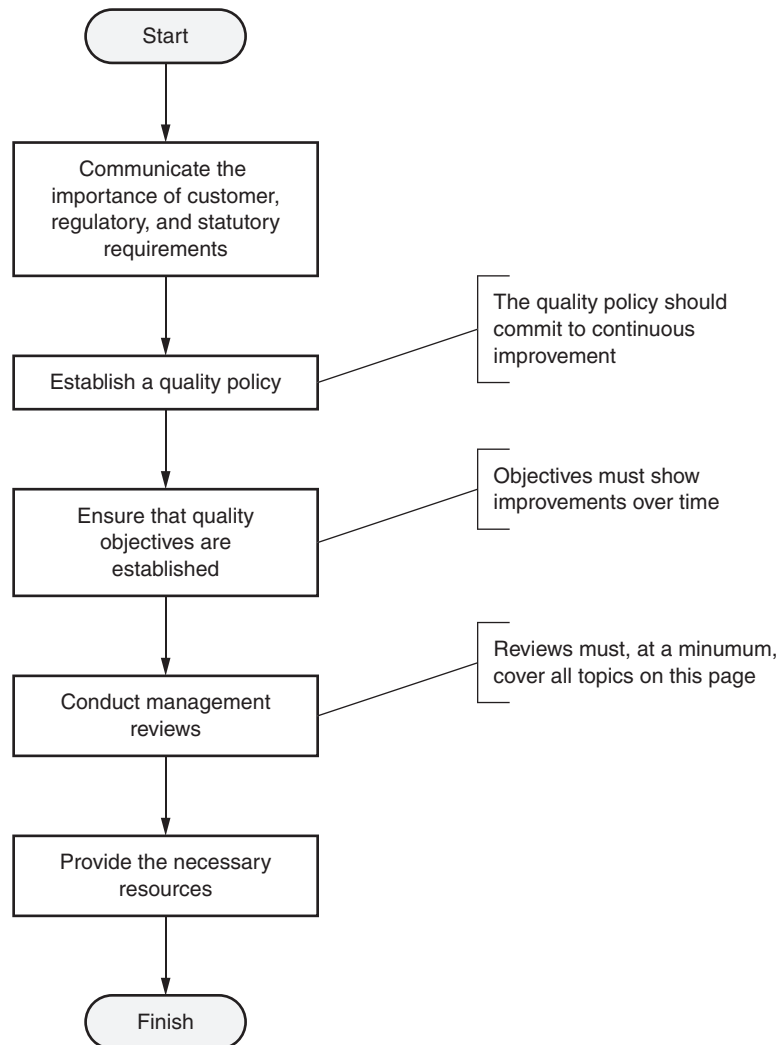
When developing, implementing, and managing the QMS, top management must be involved in the development of quality objectives, either by participating in their setting or by providing the framework and environment for their creation.

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 for clause 4.1.

5.1 Management Commitment

These are the actions
required of the organization's
top management.



5.0 Management Responsibility

5.2 Customer Focus

- AS9100* To increase customer satisfaction, top management must ensure that the organization understands and is capable of satisfying customer requirements (see 7.2.1 and 8.2.1).
- ISO 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.

Document Requirements:

Remember:

Top management must be able to demonstrate that they have put in place processes to make certain that these requirements are met.

Internal Audit Questions:

- 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 that these processes were used?
- How has top management led the organization in such a way that the organization's focus is on meeting the needs of the customers, not just making a product?

Management Summary:

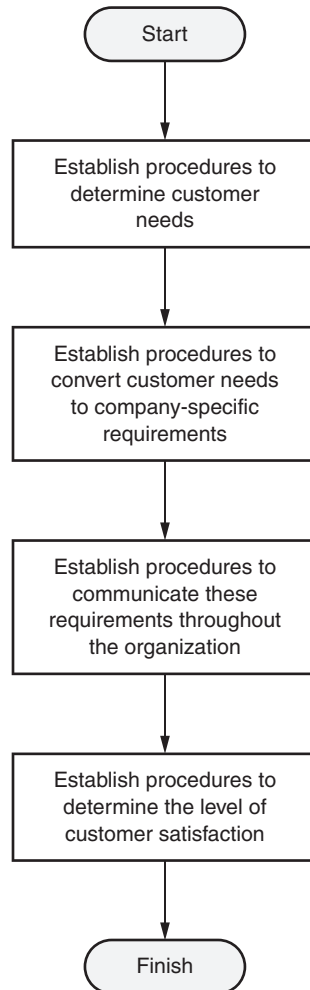
The organization should identify personnel needs and expectations for recognition, work satisfaction, and personal development in order to ensure the involvement and motivation of its people with relation to customer satisfaction.

In order to understand and satisfy the current and future needs of customers, the organization should:

- Identify, assess, 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



5.0 Management Responsibility

5.3 Quality Policy

- AS9100** 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.
- ISO 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.
- ISO 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 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 their stated quality policy?
- Are the members of the organization clear that the personnel know what the policy means and their role in carrying out the policy?

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.

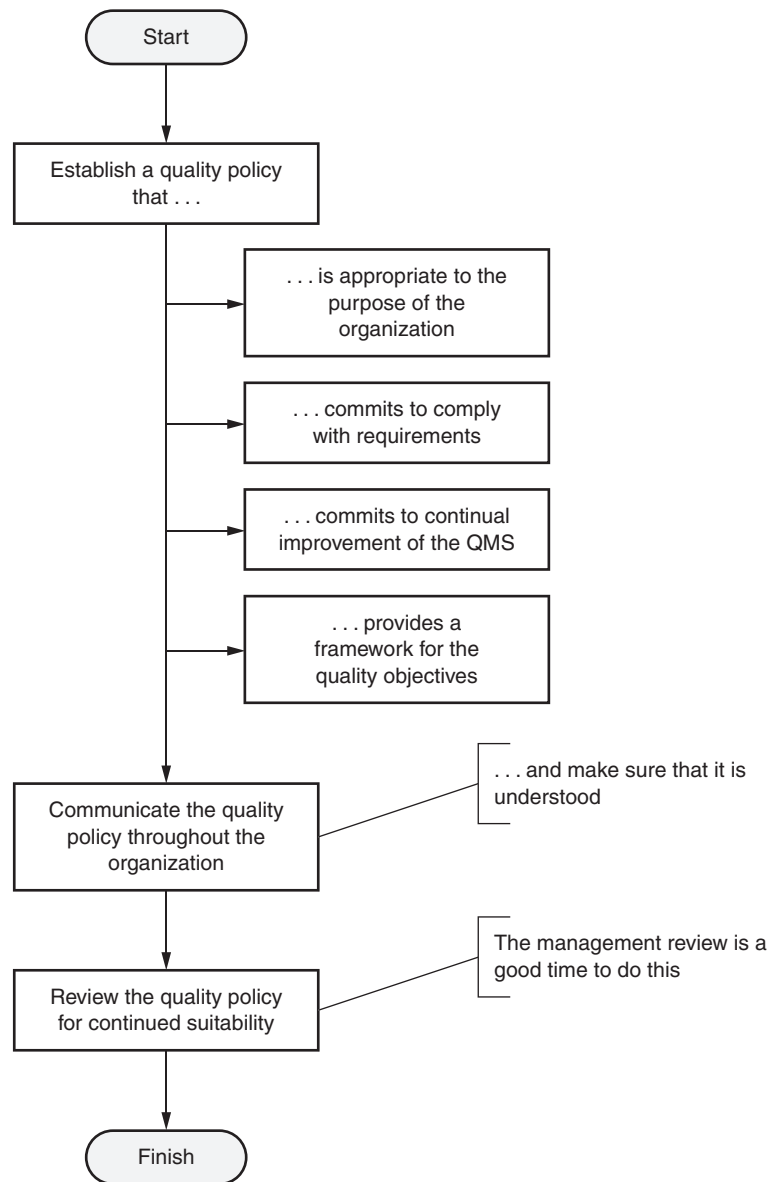
The policy must be ambitious but realistic and relevant to the organization.

Process Control Tip:

The best quality policies state not only how the company will focus its operations, but how the organization will measure those objectives to assure quality.

5.3 Quality Policy

Top management
must establish *and* maintain
a meaningful quality policy



5.0 Management Responsibility

5.4 Planning

5.4.1 Quality Objectives

- AS9100** 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.
- ISO 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.
- ISO 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 need for objectives to be quantifiable in form as actual input on QMS effectiveness, which was only implied in ISO 9001:1994, 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.

Process Control Tip:

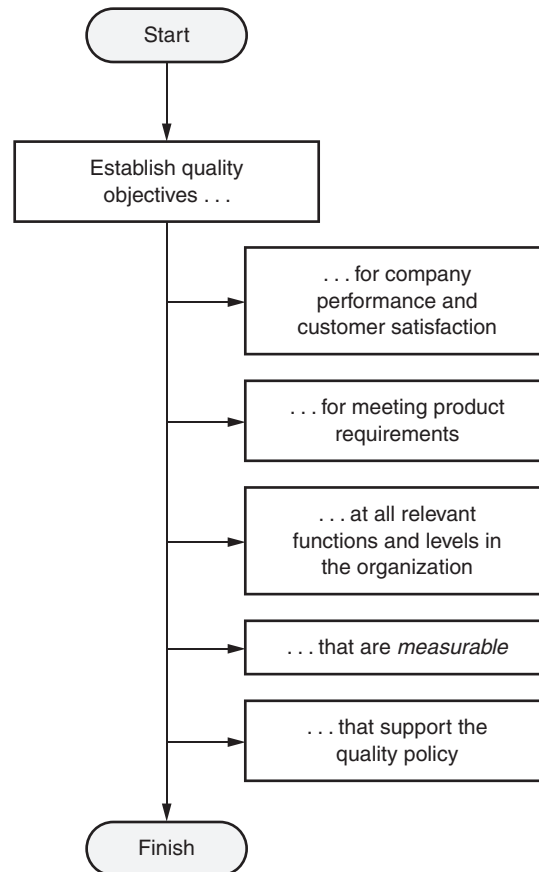
Ensure that the elements of the quality policy exist in the hoshin plan.



5.4 Planning

5.4.1 Quality Objectives

Top management
must ensure that meaningful
quality objectives
are established



5.0 Management Responsibility

5.4 Planning

5.4.2 Quality Management System Planning

- AS9100** Title is clarified from “Quality Planning” in the standard. Top management must ensure that 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 that QMS revisions do not compromise ISO 9001 conformance and effectiveness of the QMS.
- ISO 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.
- ISO 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 is required that identifies the resources needed to achieve quality objectives.
- 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 (for example, 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.

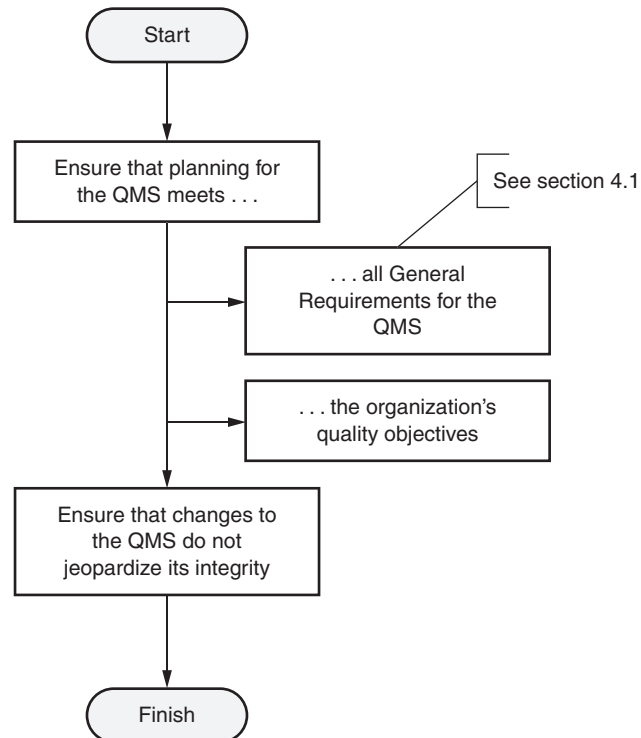
Process Control Tip:

Original versions of ISO 9001 and AS9100 were organized by requirement elements, whereas the latest versions address requirements based on business processes. The intent was to support organizations by simplifying the relationship between QMS requirements and processes for better process control.

5.4 Planning

5.4.2 QMS Planning

Top management
is responsible for both the
planning and the integrity of the
quality management system



5.0 Management Responsibility

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

AS9100 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.

ISO 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.

Process Control Tip:

Use hoshin methodology to cascade top-level objectives down into the organization, with employees being accountable for measures applicable to their job description. Personnel like to be aware of what is planned for in the company and how their efforts roll up to the major business objectives and the bottom line.

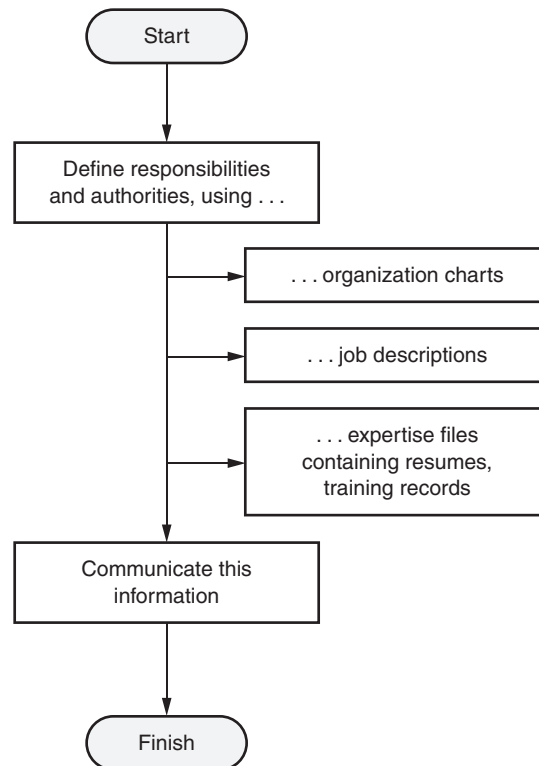
Following this method also eases linkage of project results to strategy.



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.



5.0 Management Responsibility

5.5 Responsibility, Authority, and Communication

5.5.2 Management Representative

AS9100 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 (that is, listening to the voice of the customer). **Organizationally, the representative must have the freedom to act on matters pertaining to quality.** The representative can serve as a liaison to external parties on QMS issues.

ISO 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 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 the organization, 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.

It is imperative that the representative have autonomy to act on matters of quality—their position should not be compromised by additional responsibilities that may conflict with achieving best quality.

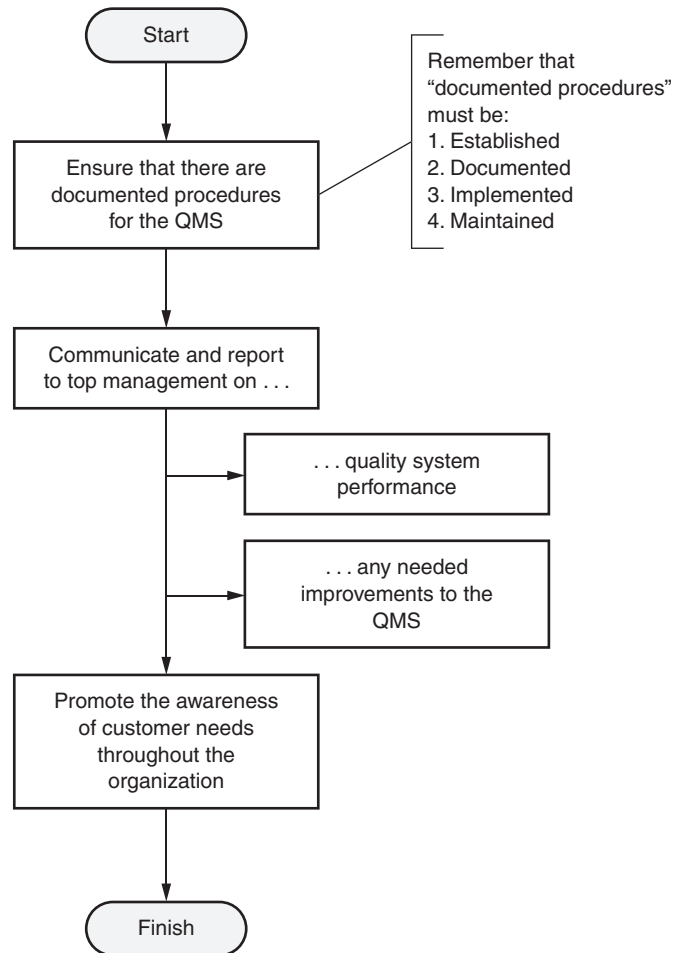
Process Control Tip:

Ensure that your organization is set up to support accountability of the overall value stream. Measure management across departments, where applicable, to assure overall system effectiveness.

5.5 Responsibility, Authority, and Communication

5.5.2 Management Representative

Top management
must appoint a manager
authorized to oversee the
quality management system



5.0 Management Responsibility

5.5 Responsibility, Authority, and Communication

5.5.3 Internal Communication

AS9100 Top management must ensure that the organization adopts communication processes that inform all within the organization about how effective the QMS is.

ISO 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:

- A functioning QMS within the organization will have defined responsibilities and authorities effectively known to, understood, and used by personnel throughout the organization. What objective evidence exists to document internal communication (document distribution lists and records, training records, minutes of management reviews, and so on)?
- Does the organization hold discussions with all employees to communicate processes of the quality management system and their effectiveness?

Management Summary:

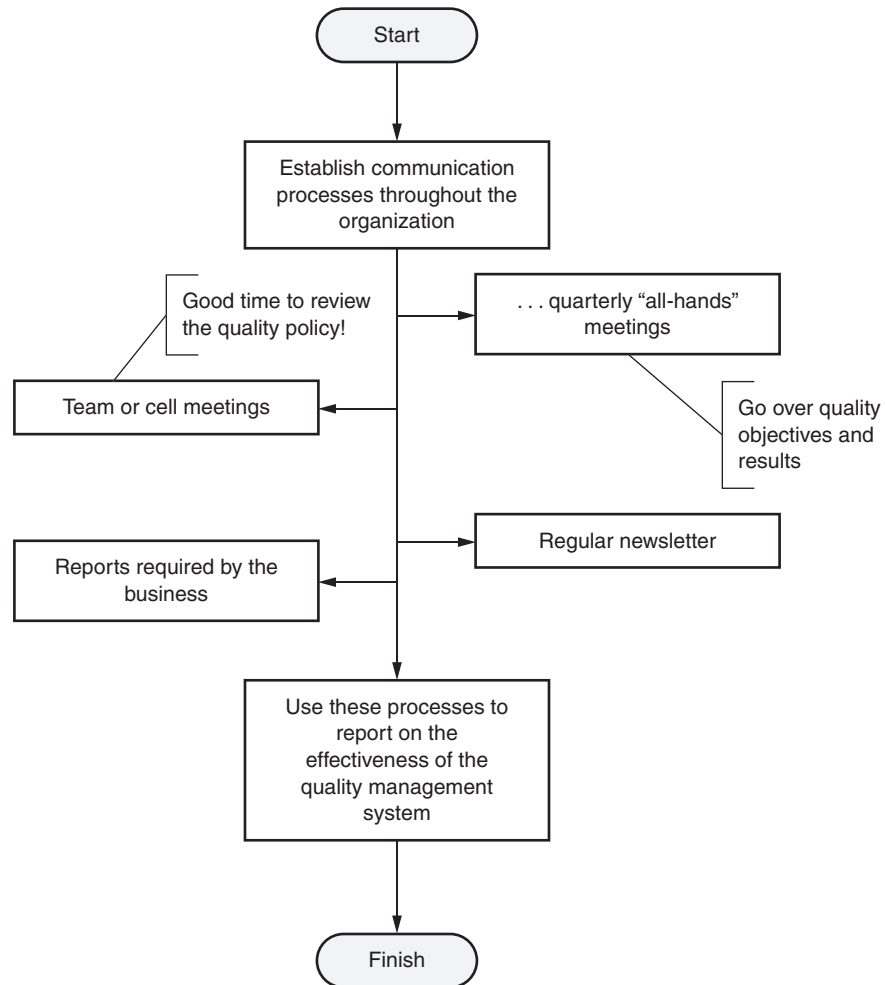
- It is top management's responsibility to provide the processes and directives so that QMS responsibilities and authorities can be delegated to the appropriate personnel within the organization (where management does not actually determine those roles) and communicated so that all personnel understand 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 the communication process.



5.5 Responsibility, Authority, and Communication

5.5.3 Internal Communication

Top management
must . . .



5.0 Management Responsibility

5.6 Management Review

5.6.1 General

AS9100 Top management is to review the QMS “at planned intervals” to verify that it 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.

ISO 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.

ISO 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:

Required:

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 management representative overseen creation, implementation, and maintenance of the QMS processes required by the standard?
- Has top management responded appropriately to defined 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.

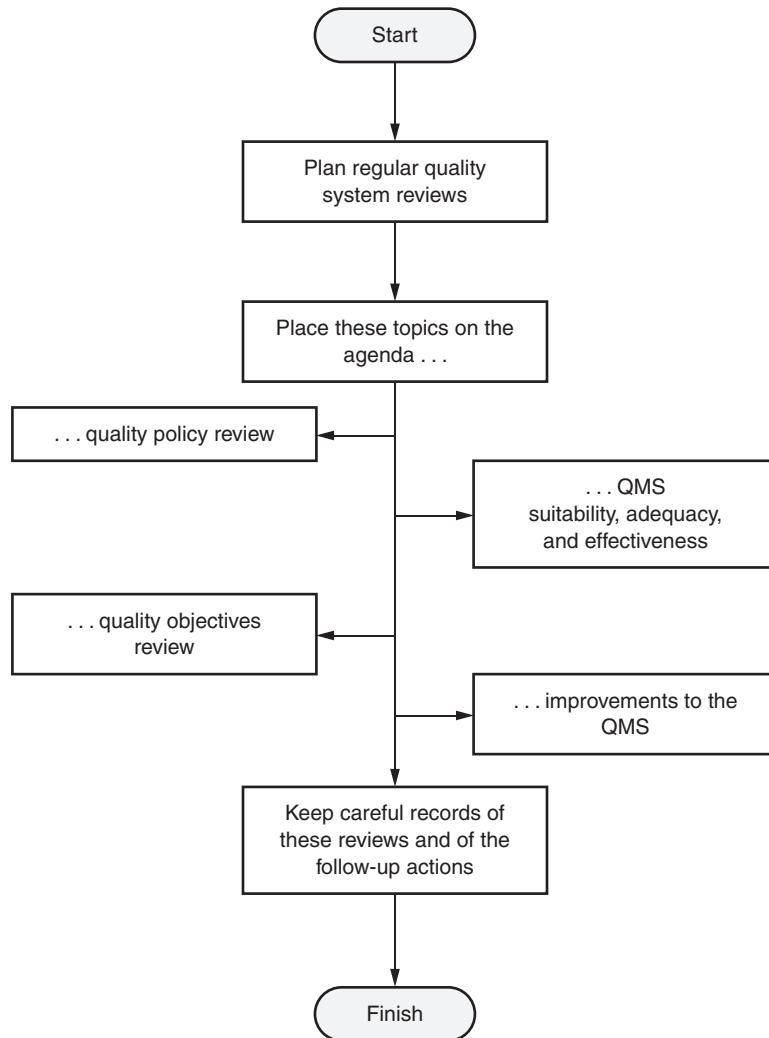
The frequency of management reviews should be determined by the needs of the organization.

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 . . .



5.0 Management Responsibility

5.6 Management Review

5.6.2 Review Input

AS9100 Management must include seven categories of data as mandatory review inputs:

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

ISO 9004 Includes as suggested inputs 13 categories of data, ranging from QMS results beyond the ISO 9001 requirements to non-quality business considerations.

Document Requirements:

Remember:

There are specified document requirements. The organization has now clearly defined items that must establish communications approaches that would best be documented and where included on the actual communications must take place through some form of documentation (for example, QMS effectiveness memos, reports, and/or intranet or Web-based communications). Records of these communications should be kept.

Internal Audit Questions:

- Does management review input include: audit results, customer feedback, process performance and product performance, 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 Summary:

Management review inputs should include the status of relevant internal and external factors, as well as results of existing processes.

Inform the organization of the quality policy objectives 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 management must ensure that communication processes are put into use.

Process Control Tip:

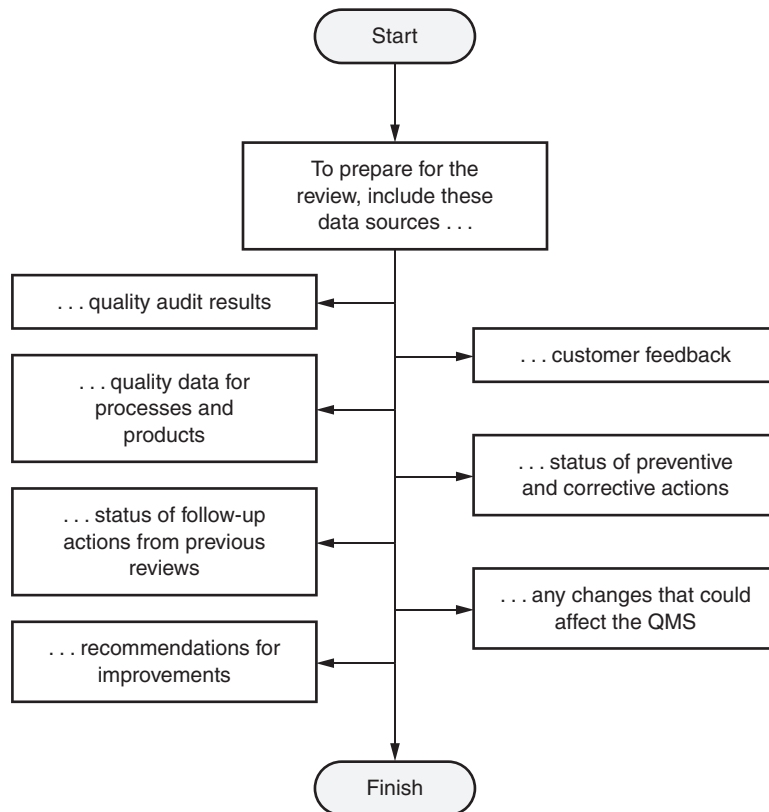
Many organizations perform management review as a separate quality meeting instead of infusing it into the overall strategic and operational meetings necessary for proper business functioning throughout the year.

Utilization of hoshin principles can help infuse AS9100 requirements into the major business objectives.



5.6 Management Review

5.6.2 Review Input



5.0 Management Responsibility	
5.6 Management Review	
5.6.3 Review Output	
AS9100	The output from management reviews must include any “decisions and actions” in three categories relating to the QMS and customer satisfaction, including product improvements linked to customer specifications.
ISO 9004	Provides guidance on how top management can use outputs from an “expanded management review” to identify potential performance improvements and to motivate employees by establishing new objectives. Suggests six categories of outputs linked to QMS efficiency that could be obtained.
Document Requirements:	
Required: Management review meeting minutes will be required to address these improvement activities and the resources required to initiate these process actions.	
Internal Audit Questions:	Management Summary:
• Do management review outputs include actions related to improving the quality management system and its processes? • Do management review outputs include actions related to improvement of product related to customer requirements?	The strategic planning process should determine the frequency of management reviews. Management reviews should result in changes to the organization’s processes so as to increase the existing efficiency and effectiveness of the QMS. Adequate records should be kept to provide traceability and facilitate the evaluation process in future management reviews.