

# A Practical Field Guide for ISO 9001:2000



## **A PRACTICAL FIELD GUIDE FOR ISO 9001:2000**

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*By submitting this paper, I affirm that this work is my own except for where the words or ideas of others are specifically acknowledged. I also affirm that this work, as it stands, did not exist before the beginning of the course for which it is submitted.*

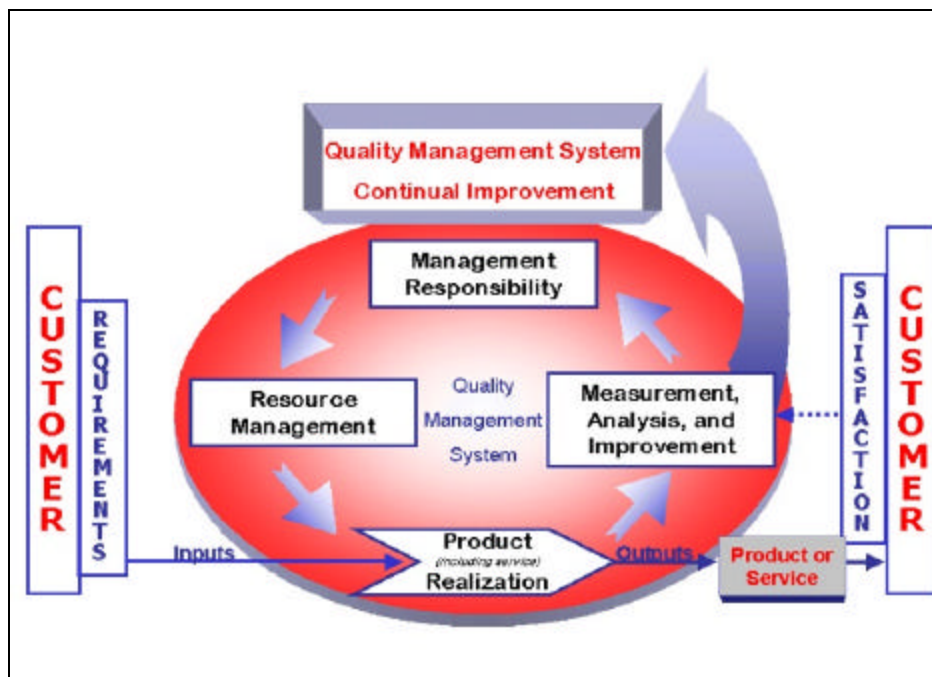
**Target audience:** practitioners of the standard, their clients and related professionals seeking an enhanced understanding of the standard.

**Purpose of this paper:** to present, and publish, a new body of knowledge regarding the international standard in a new and unique textual and graphical style.

**Executive summary:** regardless of the position within or outside of any organization, this field guide will provide the reader with a novel way to both read and look at the standard and its related requirements.

## A PRACTICAL FIELD GUIDE FOR ISO 9001:2000

- Management Guidance
- Implementation Support
- Documentation Assistance
  - Auditing Technique



By:

**Erik V. Myhrberg, IRCA Lead Auditor**

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# A Practical Field Guide for ISO 9001:2000



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## DEDICATION PAGE

*To my wonderful family:*

Marcena  
Brandon  
Heather

*To my fellow researchers:*

David Rigg  
Tamitha Smith  
Holly Wilson

*To my ISO mentors:*

Alan Griffin  
Keith Roberts  
Michael Burden

## PUBLICATIONS PAGE

*Also by Erik Myhrberg:*

The ISO 9001:2000 QMS “[Bluesheet](#)”, Copyright © 2003

The ISO 14001:1996 EMS “[Greensheet](#)”, Copyright © 2003

The ISO Core (C<sup>4</sup>) Four Pocket Guide, Copyright © 2002

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# A Practical Field Guide for ISO 9001:2000



## INTRODUCTION

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.

More than twelve years have passed (and over 115 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 has emerged.

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 21<sup>st</sup> century, companies are being pushed to the extreme limits 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.

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 9001:2000 series of standards is, both useful to the organization and, here to stay.

Best regards in your ongoing ISO efforts!

Erik V. Myhrberg

Erik V. Myhrberg, CEO  
Moorhill International Group, Inc.  
<http://www.moorhill.com>

# A Practical Field Guide for ISO 9001:2000



## 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 9001:2000, whether “from scratch” or by transitioning from ISO 9001/2:1994. In keeping with ISO 9000:2000’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 2-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 9001:2000’s requirements for implementation purposes
- Identify the documents/documentation required, along with recommendations on what to consider retaining/adding to a QMS during ISO 9001:2000 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 9001:2000’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 summarization of what a sub-clause of ISO 9001:2000 requires in easy-to-understand language, with references to information in ISO 9000:2000 and guidance in ISO 9004:2000 to enhance the user’s understanding of what ISO 9001:2000 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 9001:2000, along with a box providing guidance on use of the flow chart.
- ◆ *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 9001:1994.

# A Practical Field Guide for ISO 9001:2000



- ◆ These cross-evaluations are provided to assist the user if his/her organization is transitioning from ISO 9001/2:1994 and appear at the end of the field guide's coverage of each section of ISO 9001:2000 (Sections 4-8).

This field guide is designed to provide you with a consistent approach to implementing an ISO 9001:2000-conforming QMS, which is appropriate since ISO 9001:2000 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 9001:2000, which contain the requirements, with Characteristics 1-4 presented on the even page and Characteristic 5 presented on the facing odd page.

The example on the following pages presents Sub-clause 1.2, Scope—Application, which does not contain requirements but is critical to properly excluding any requirements of ISO 9001:2000 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.

What separates this field guide from most other books on ISO 9001:2000 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 9001:2000's requirements, but will 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 over time.

# A Practical Field Guide for ISO 9001:2000



## QUALITY MANAGEMENT SYSTEM SECTION 4

- 4.1 – General requirements
- 4.2 – Documentation requirements



# A Practical Field Guide for ISO 9001:2000



## 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:

#### Required:

- No specific documents, although this sub-clause relates to and affects other requirements in ISO 9001:2000 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.

### Internal Audit Questions:

- 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?

### Management Summary:

#### 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:

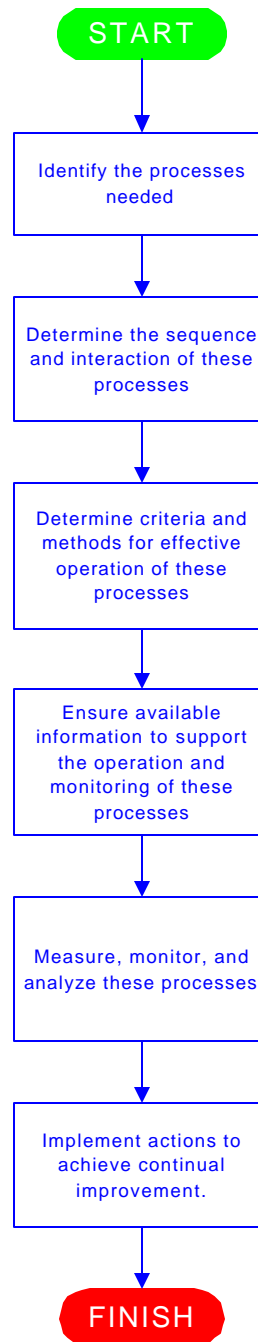
- Have a true customer focus
- Demonstrate leadership
- Involve people
- Use a process-oriented approach
- Use a systems approach to management
- Strive for continual improvement
- Base decisions on facts and data
- Cultivate mutually beneficial supplier relationships

## 4.1 The General Requirements of a Quality Management System

The organization shall:

- **Establish**
- **Document**
- **Implement**
- **Maintain**
- **Continually Improve**

a Quality Management System



# A Practical Field Guide for ISO 9001:2000



## 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:

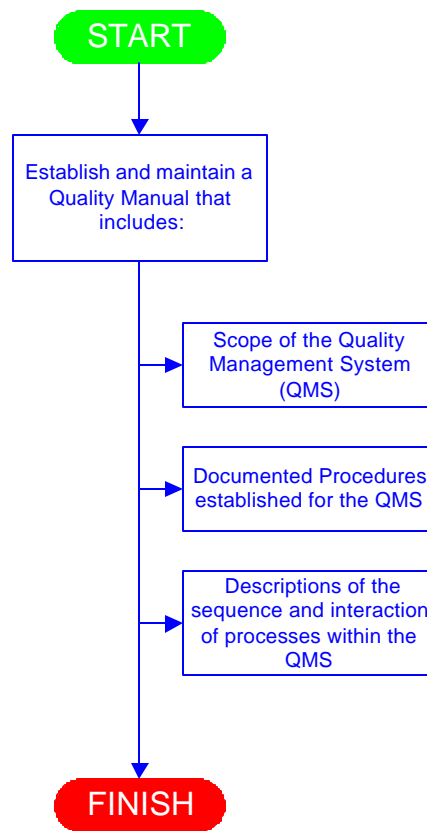
Management must define the documentation, including records, that:

- are required to establish, implement and maintain a QMS
- support an effective and efficient operation

## 4.2 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

# A Practical Field Guide for ISO 9001:2000



## 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?

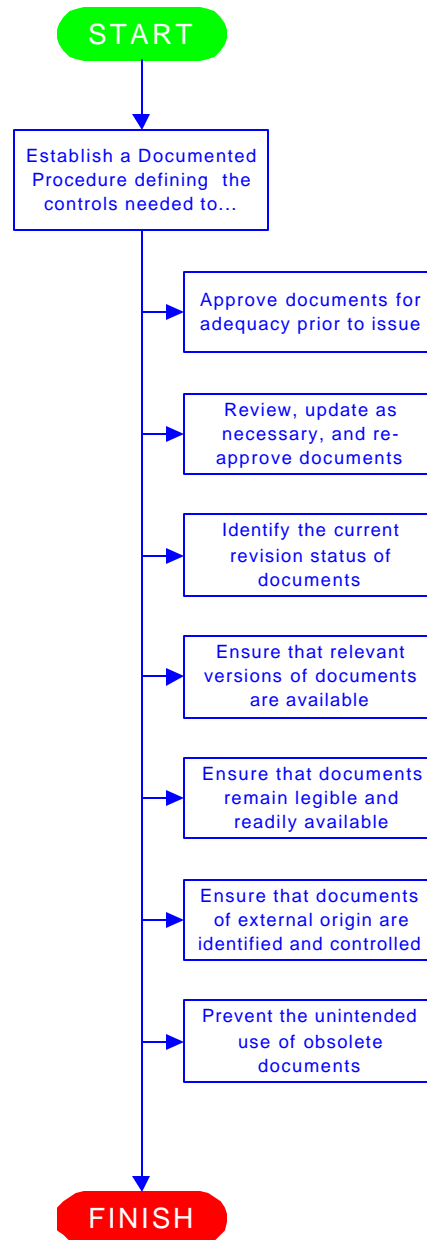
#### Management Summary:

##### 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



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 4.0 Quality management system*

### **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”.

### *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:*

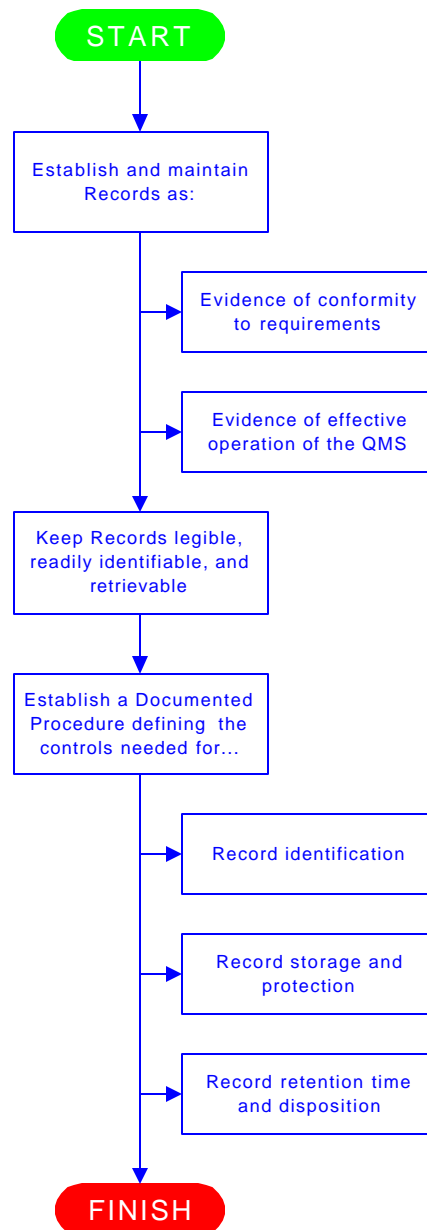
- Is there a documented procedure for control of records?
- Have the organization’s records been identified?
- Are protection requirements in place for all records?
- Have retention times and disposition requirements been established for all records?
- Are records disposed of as required by the established procedures?
- Have storage and retrieval requirements been determined and implemented for all records?

### *Management Summary:*

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



# A Practical Field Guide for ISO 9001:2000



## ISO 9001:2000 X ISO 9001:1994 CROSS EVALUATION

1994 Clauses ( <i>across</i> ) x 2000 Sections ( <i>down</i> )	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	4.15	4.16	4.17	4.18	4.19	4.20
<b>4</b> <b>Quality Management System</b>																				
4.1      General requirements		4.2.1																		
4.2      Documentation requirements																				
4.2.1    General		4.2.2																		
4.2.2    Quality manual		4.2.1																		
4.2.3    Control of documents					4.5.1\2\3															
4.2.4    Control of records																4.16				

## MANAGEMENT RESPONSIBILITY SECTION 5

- 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

# A Practical Field Guide for ISO 9001:2000



## The Standard: 5.0 Management responsibility

### 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:

#### 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 of the enhanced responsibilities and roles it has with ISO 9001:2000 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:

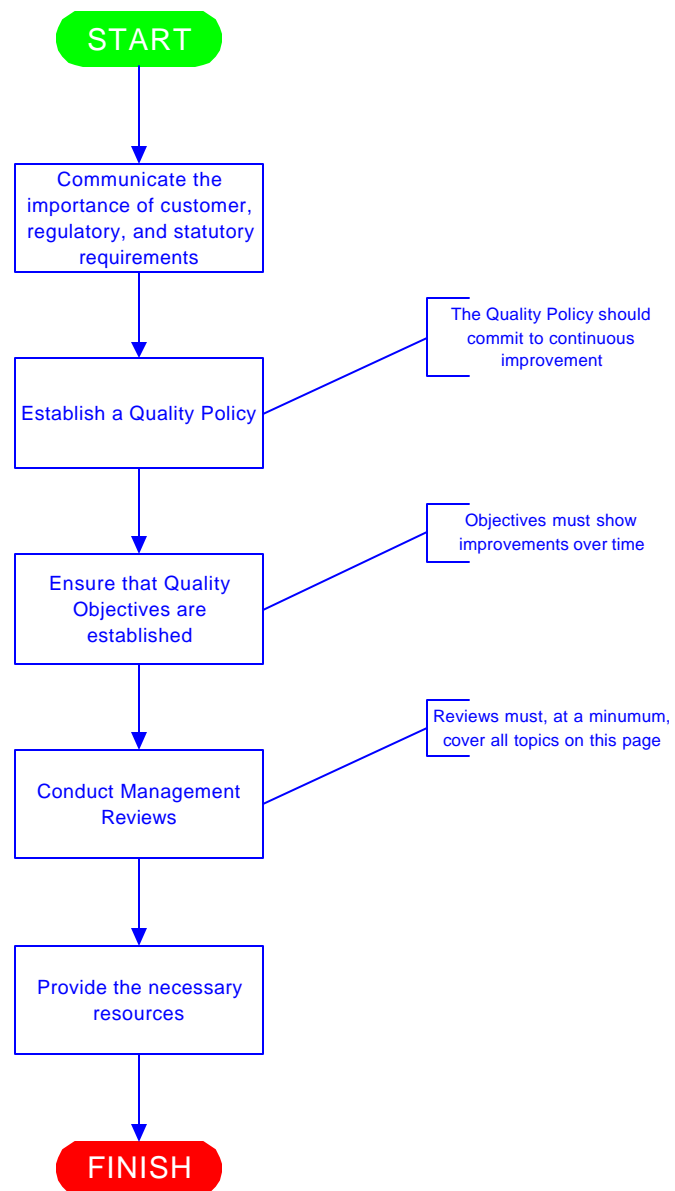
- Has management established Quality Objectives and developed a Quality Policy?
- Are management reviews performed?
- Does management provide and review the adequacy of resources?
- Is a process in place to ensure that all employees understand the importance of fulfilling customer, regulatory and legal 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 provide be 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 for section Clause 4.1.

## 5.1 Management Commitment

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



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 5.0 Management responsibility*

### **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 regards 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 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?

### *Management Summary:*

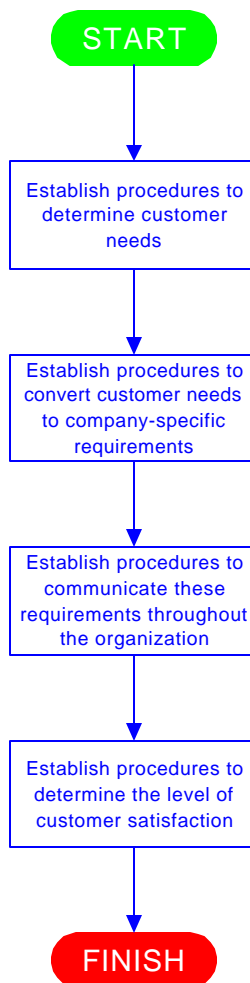
The organization should identify personnel needs and expectations for recognition, work satisfaction, and personal development in order to ensure the involvement and motivation of its people with relations to customer satisfaction.

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



# A Practical Field Guide for ISO 9001:2000



## 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, explain 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, regularly for continuing suitability, 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 if the personnel know what the policy means and their role in carrying out the policy fulfilling it?

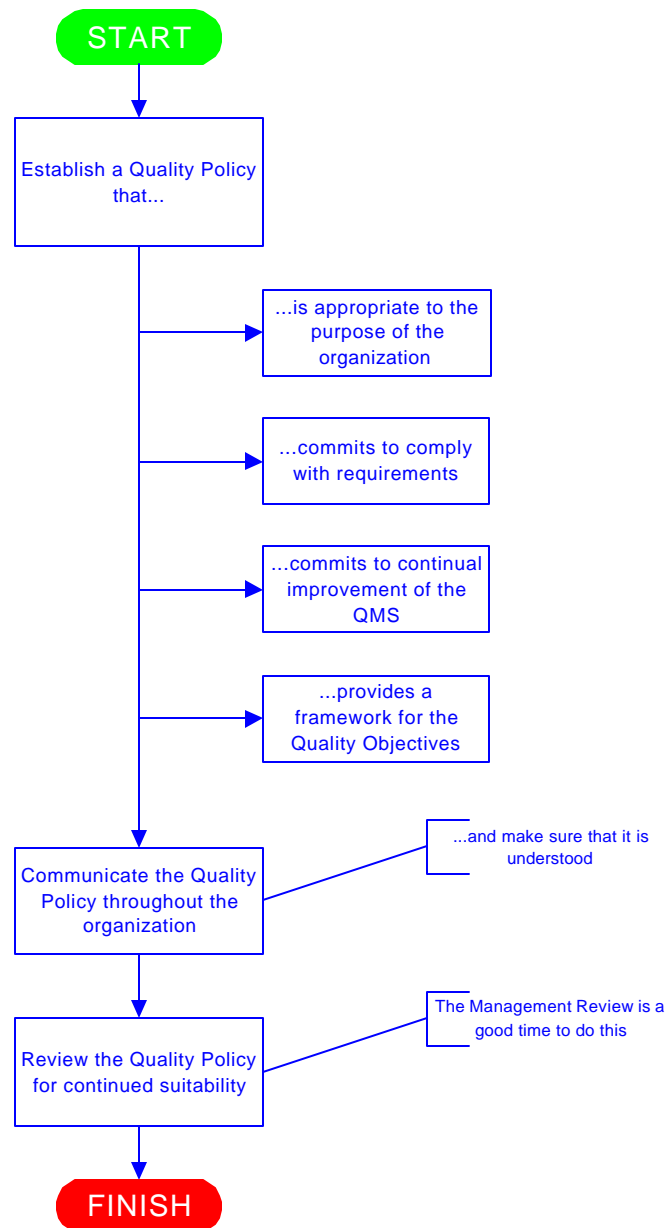
### Management Summary:

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



# A Practical Field Guide for ISO 9001:2000



## 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 9001:1994 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

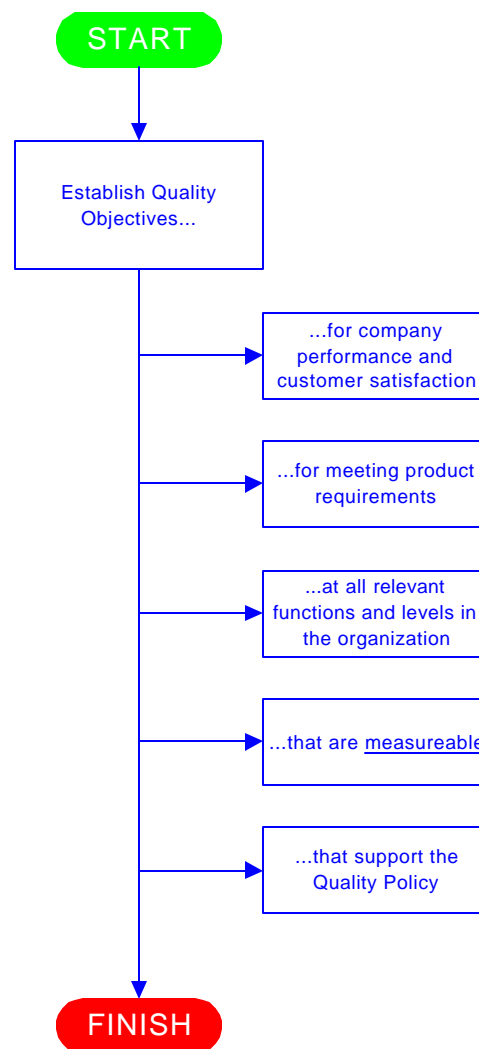
Quality Objectives must be measurable and communicated in such a way that all personnel can contribute to their achievement.

Quality Objectives must be regularly and systematically reviewed and revised.

## 5.4 Planning for Quality

### 5.4.1 Quality Objectives

TOP MANAGEMENT  
must ensure that meaningful  
Quality Objectives  
are established



# A Practical Field Guide for ISO 9001:2000



## 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 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 (i.e. program briefs, action item in a management review record or reference to an existing procedure)?

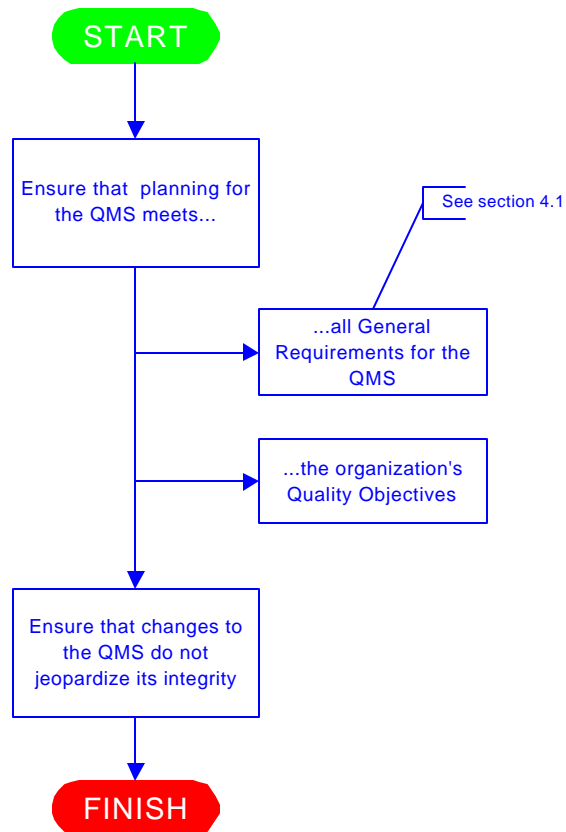
### Management Summary:

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



# A Practical Field Guide for ISO 9001:2000



## *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?

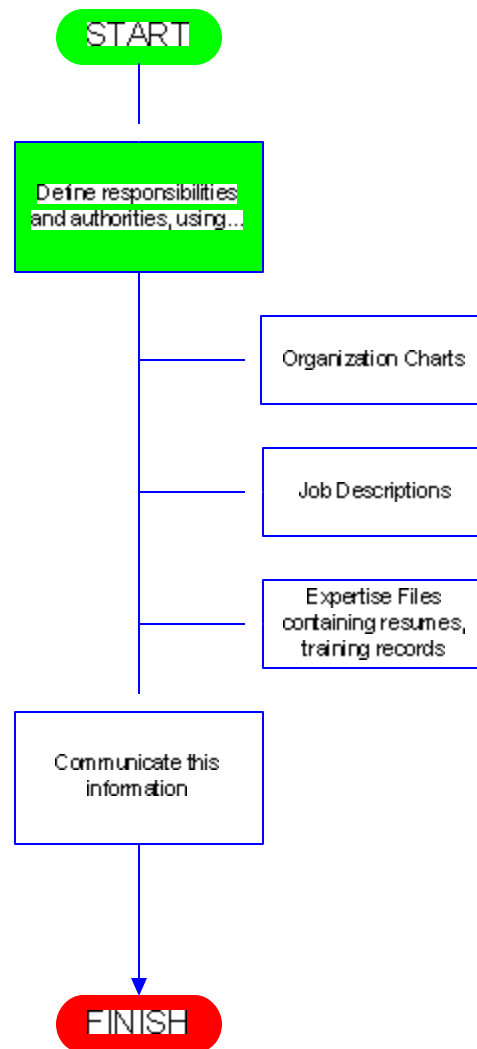
### *Management Summary:*

- 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.



# A Practical Field Guide for ISO 9001:2000



## 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 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, 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.

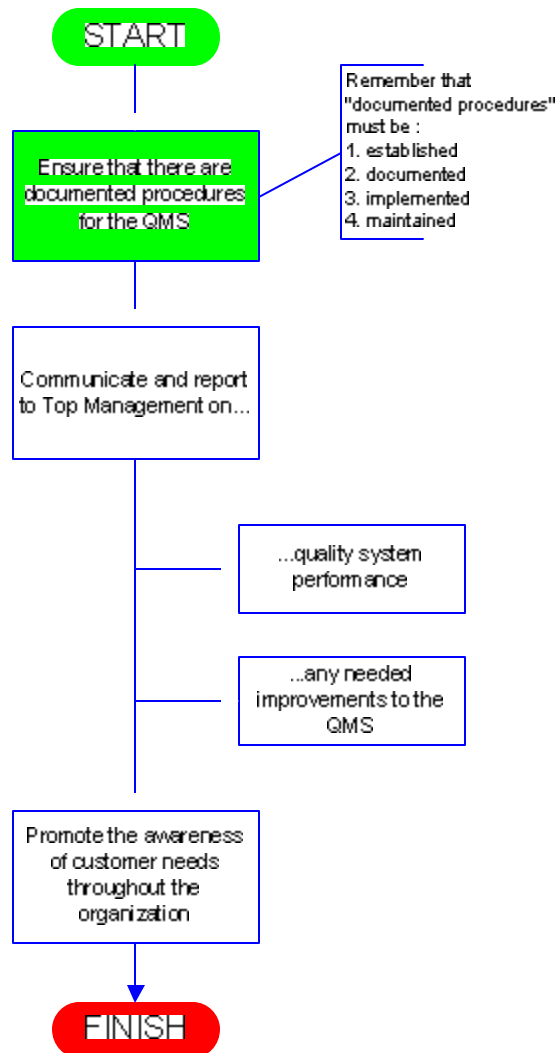
The management representative has additional responsibility to promote awareness of customer requirements.

Ensure that planning takes place to produce and update an ISO 9001:2000-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



# A Practical Field Guide for ISO 9001:2000



## 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:

- 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?

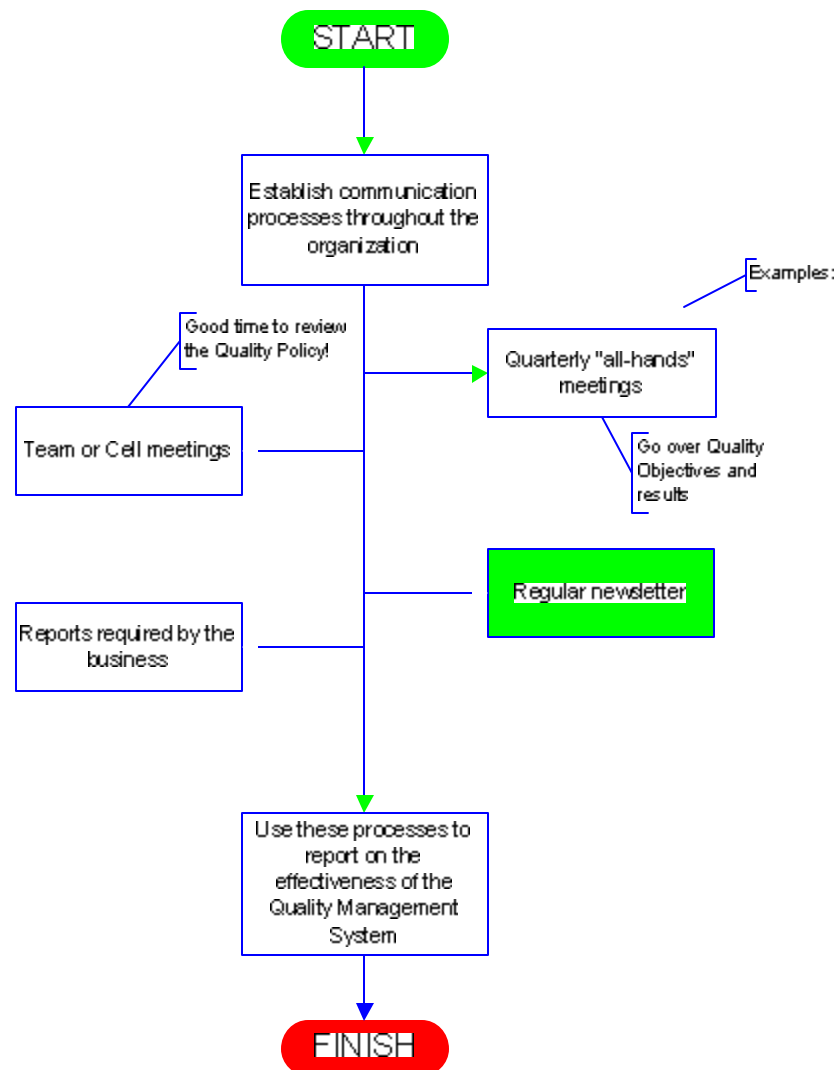
### Management Summary:

- 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 communication process.

## 5.5 Responsibility, Authority, and Communication

### 5.5.3 Internal Communication

TOP MANAGEMENT  
must ...



# A Practical Field Guide for ISO 9001:2000



## *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:***

- Top management has the management representative oversee creation, implementation and maintenance of the QMS processes required by ISO 9001:200?
- 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.

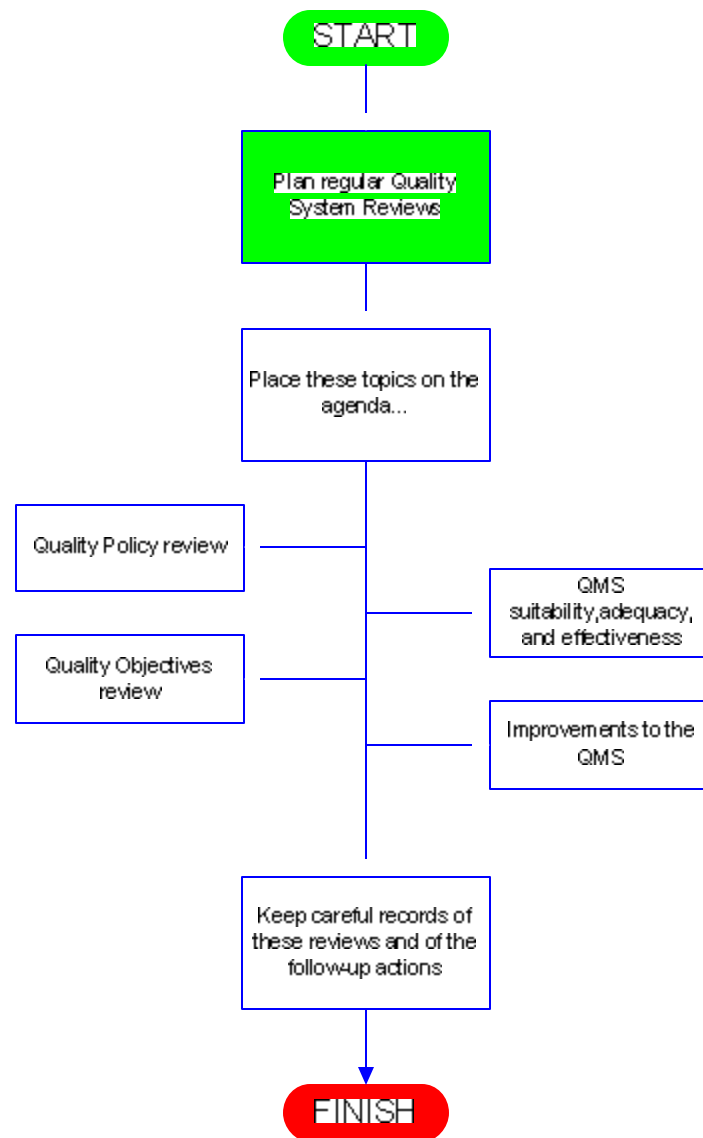
The frequency of management reviews should be determined by the needs of the organization.

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..



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 5.0 Management responsibility*

### **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.

### *Document Requirements:*

#### Remember:

There are specified. The organization 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 (e.g., 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, 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 Summary:*

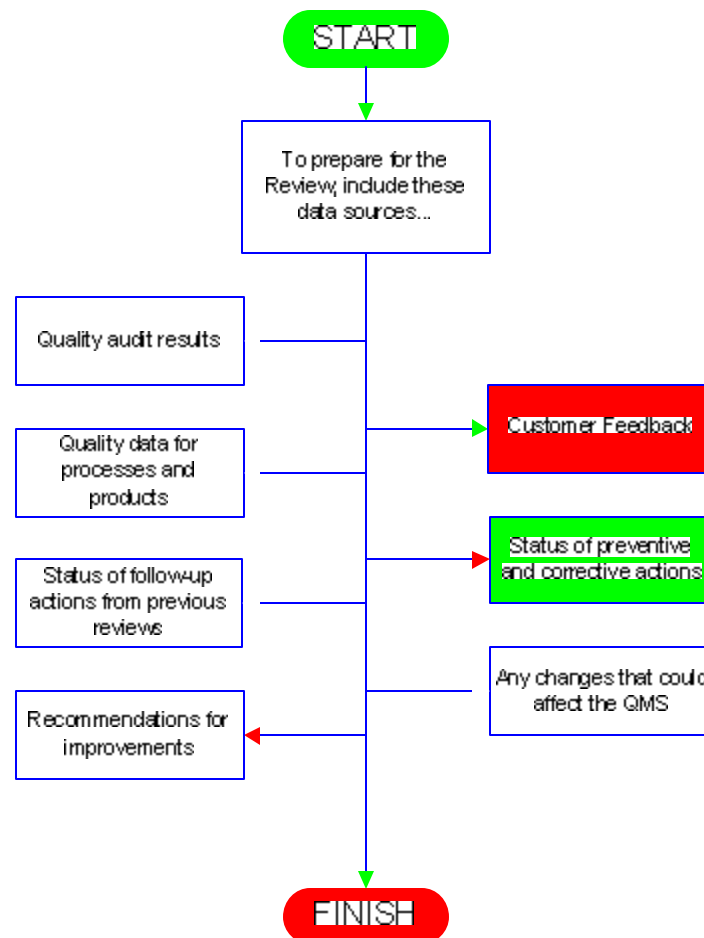
Management review inputs should include the status of relevant internal and external factors, as well as results of existing processes.

Inform the organization of and quality objectives QMS and resulting processes to be followed QMS Top management should seek verification that QMS effectiveness—and the need for improvements—are known and understood throughout the organization.

To foster employee 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.

## 5.6 Management Review

### 5.6.2 Review Input



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 5.0 Management responsibility*

### **5.6 Management review**

#### 5.6.3, Review Output

9001.....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.

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:*

#### Remember:

Management review meeting minutes will be required to address these improvement activities and the resources required to initiate these process actions.

### *Internal Audit Questions:*

- 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?

### *Management Summary:*

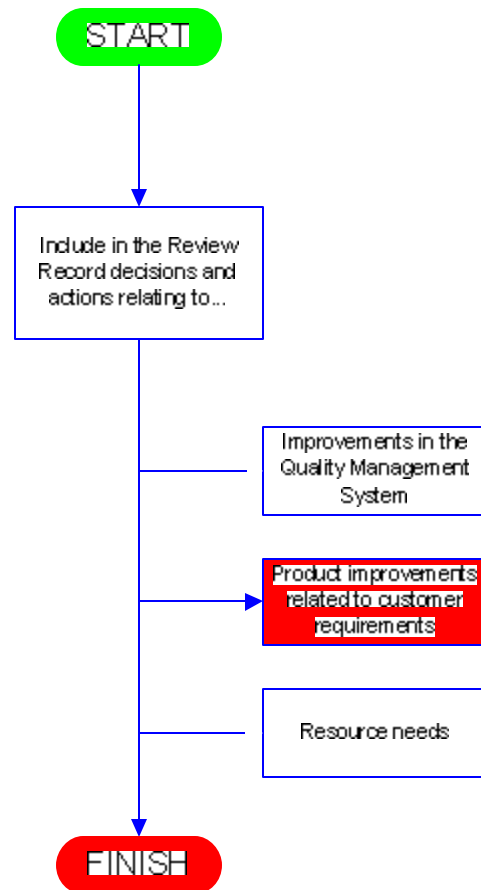
The strategic planning process should determine the frequency of management reviews should be determined by the needs of the organization.

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.

## 5.6 Management Review

### 5.6.3 Review Output



# A Practical Field Guide for ISO 9001:2000



## ISO 9001:2000 X ISO 9001:1994 CROSS EVALUATION

1994 Clauses ( <i>across</i> ) x 2000 Sections ( <i>down</i> )		4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	4.15	4.16	4.17	4.18	4.19	4.20	
5	Management responsibility																					
5.1	Management commitment	4.1.1																				
5.2	Customer focus			4.3.2																		
5.3	Quality Policy	4.1.1																				
5.4	Planning																					
5.4.1	Quality Objectives	4.1.1																				
5.4.2	Quality Management System planning		4.2.3																			
5.5	Responsibility, authority and communication																					
5.5.1	Responsibility and authority	4.1.2.1																				
5.5.2	Management representative	4.1.2.3																				
5.5.3	Internal communication																					
5.6	Management review																					
5.6.1	General	4.1.3																				
5.6.2	Review input																					
5.6.3	Review output																					

## RESOURCE MANAGEMENT SECTION 6

- 6.1 – Provision of resources
- 6.2 – Human resources
- 6.3 – Infrastructure
- 6.4 – Work environment

# A Practical Field Guide for ISO 9001:2000



## The Standard: 6.0 Resource management

### 6.1, Provision of Resources

9001.....The organization is to identify and make available the means for creation, continued operation and ongoing increases in the effectiveness of the QMS and improvement in the level of customer satisfaction.

9004.....Defines possible resources to be provided and recommends that top management provide the resources to pursue strategic goals and achieve objectives. Includes a list of possible resources and considerations to help improve organizational performance.

### Document Requirements:

#### Remember:

- Management will be required to formalize its resource planning process to ensure timely availability.

### Internal Audit Questions:

- Has the organization determined and provided the resources necessary to implement the processes of the Quality Management System?
- Has the organization determined and provided the resources necessary to improve the processes of the Quality Management System?
- Has the organization determined and provided the resources necessary to address customer satisfaction?
  - Are the resources provided in a timely manner? Internal and other QMS audit reports
  - Data derived from customer feedback processes
  - Process and product performance monitoring and measurement results
  - Reports on preventive and corrective actions undertaken and their status
  - The status of actions undertaken in response to earlier management reviews
  - Changes that could affect the Quality Management System

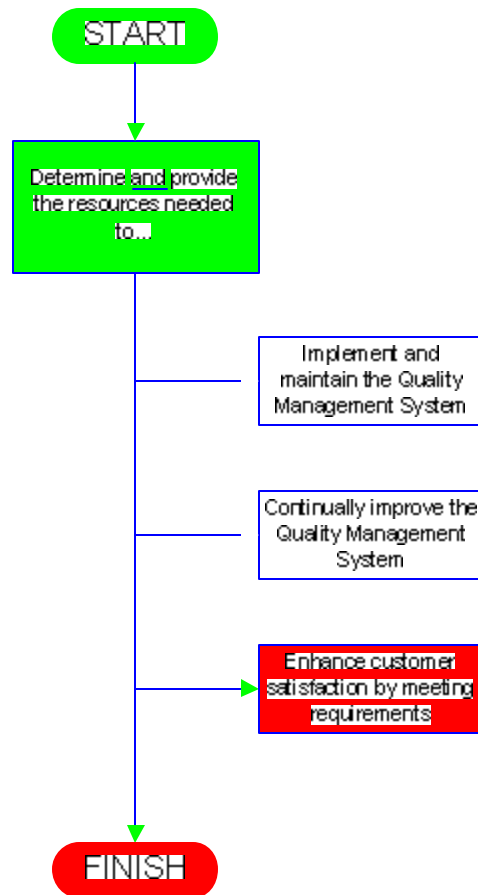
### Management Summary:

- *Top Management should provide adequate resources to implement the QMS and achieve its objectives.*
- Top management must direct those having responsibility and/or authority for the QMS and related organizational operations to provide specified inputs to be used in management reviews of the QMS, including the frequency of such inputs and the processes and forms in which the inputs are to be provided.
- Top management should consider the amount of inputs to be reviewed in allocating adequate time for the reviews to evaluating them (and any time prior to the meetings for participants to study the inputs).
- Top management should approach evaluating of the inputs with consideration of what the quality policy and quality objectives state and what the organization's business performance measurements indicate.

#### Resources may include:

- *People*
- *Infrastructure*
- *Work environment*
- *Information*
- *Suppliers and partners*
- *Natural and financial resources*

## 6.1 Provision of Resources



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 6.0 Resource management*

### **6.2 Human resources**

#### 6.2.1, General

9001.....Personnel whose actions impact on product quality must be competent to work on products based on “education, training, skills and experience”.

9004.....For an organization to achieve performance improvements, recommends 12 types of activities to pursue to “encourage the involvement and development of its people”.

### *Document Requirements:*

#### Remember:

- Records that are created by the activities to assure competency may need to be controlled per clause 4.2.4, Control of records.
- Records of the management reviews. While the need for documentation of any decisions reached and actions determined as outputs of the reviews is not specified, some form of documentation will be necessary in most cases to communicate the improvements that top management wants to the QMS and/or product.

### *Internal Audit Questions:*

- Do personnel with assigned responsibilities within the Quality Management System have competency in the appropriate education, training, skills, and experience?
- Decisions and/or effectiveness of the decisions and/or so as to better meet and enhance customer satisfaction.
- Has top management made changes to the quality policy and/or quality objectives as a result of management reviews?

### *Management Summary:*

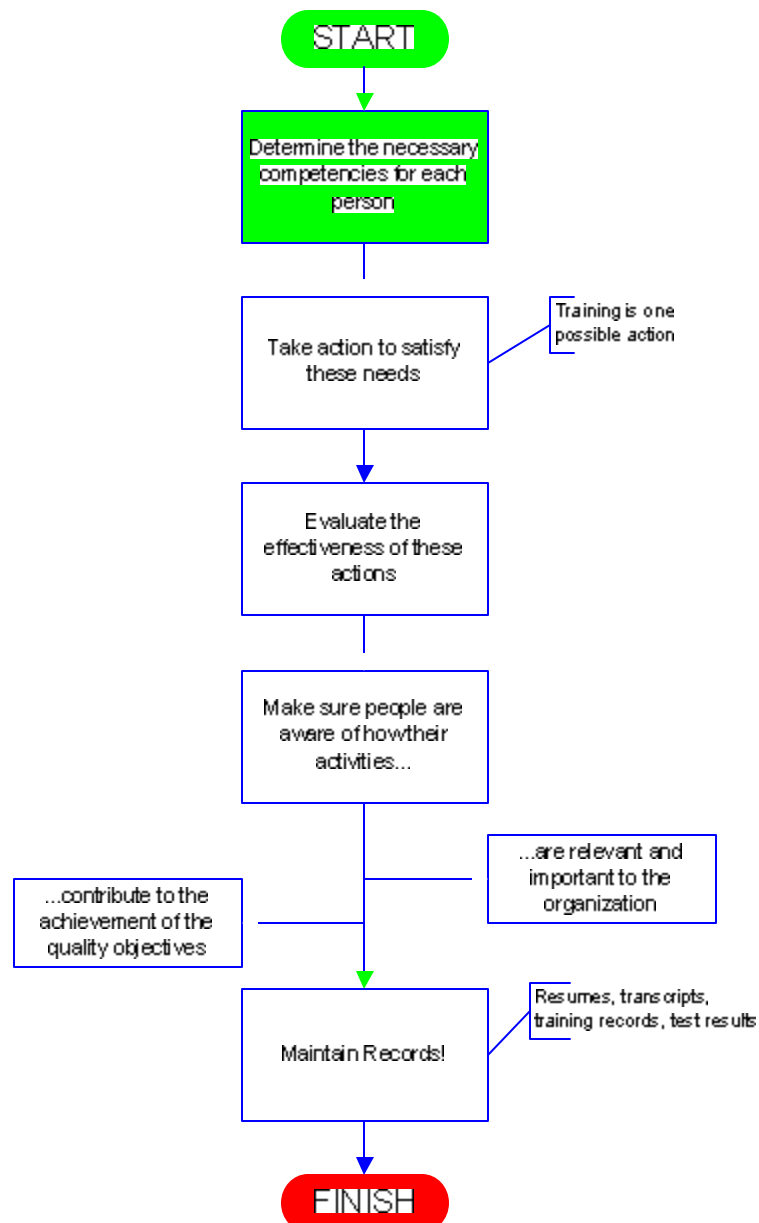
- Improvements to the effectiveness and efficiency of the organization should be accomplished through the involvement and support of the people within the organization.
- Top management must use management reviews as a forum in which to ensure that the QMS remains effective in meeting the needs of the organization and its customers and to determine what continual improvement efforts will be undertaken before the next review.
- It is expected that top management will reach decisions about improvements and direct the organization to take steps to achieve those improvements as outputs of management reviews.

## 6.2 Human Resources

### 6.2.1 General

Anyone who can affect product quality must be competent to do so.

### 6.2.2 Competence, Awareness, and Training



# A Practical Field Guide for ISO 9001:2000



## The Standard: 6.0 Resource management

### 6.2 Human resources

#### 6.2.2, Competence, Awareness and Training

*9001* .... The organization must identify qualifications required for each position affecting product quality, take appropriate actions to ensure personnel competency in those positions, assess the effectiveness of these efforts and make personnel aware of how they affect quality and what they can do to achieve quality objectives. The organization must document personnel competence and actions taken relative to competence and retain these documents as quality records.

*9004* .... Recommends that an organization analyze present and future needs and determine gaps between needs and existing personnel capabilities, with consideration of five sources for determining competency needs. Explores what to consider with education and training relative to meeting quality objectives and raising awareness. Defines possible subjects to include in education and training and to be addressed in training plans.

#### Document Requirements:

##### Required:

- Record (e)

#### Internal Audit Questions:

- Does the organization identify the competency needs of personnel performing activities affecting quality (including additional training needs)?
- Does the organization provide training to satisfy these needs?
- Does the organization evaluate the effectiveness of the training?
- Does the organization ensure that employees are aware of the importance of their activities and how they contribute to the achievement of the Quality Objectives?
- Does the organization maintain records of education, experience, training, and qualifications (i.e. banners, posters, bulletin boards or intranet sites)?

#### Management Summary:

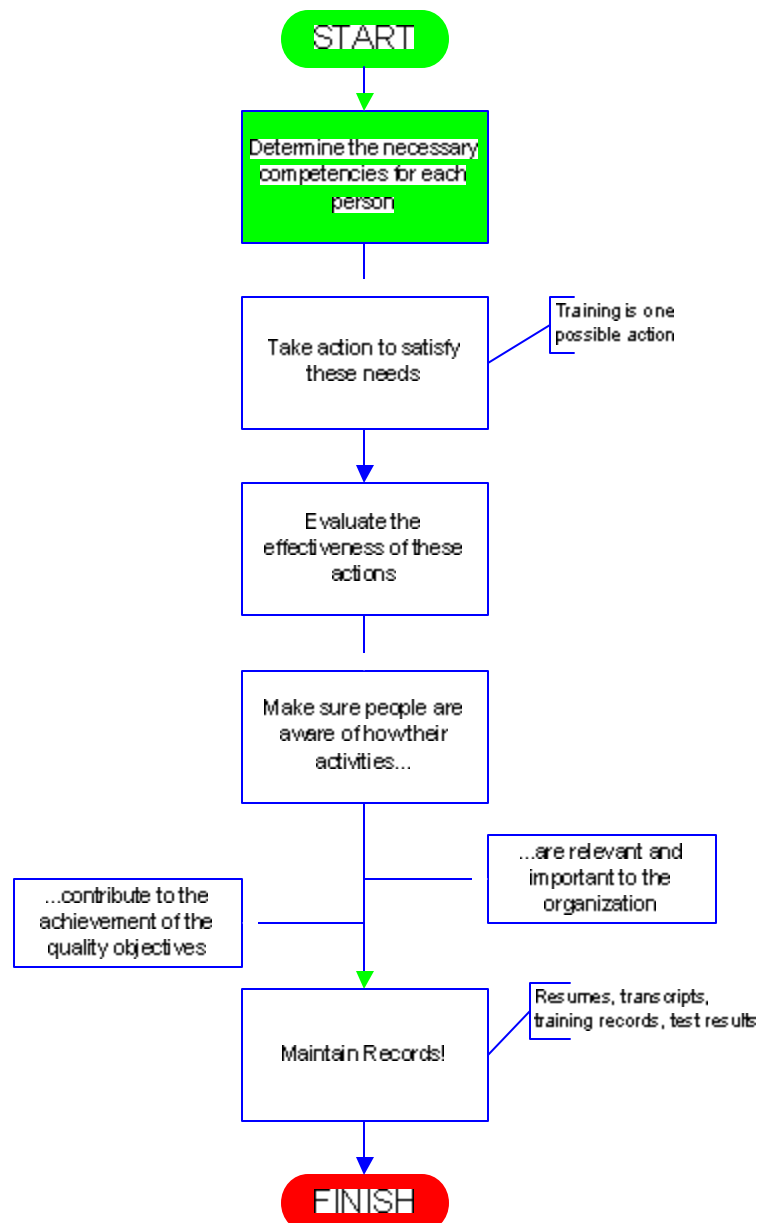
- *Management should analyze both the present and expected competence needs within the organization.*
- *Management should plan for education and training needs and take into account the organization's processes, stages of development and culture.*

## 6.2 Human Resources

### 6.2.1 General

Anyone who can affect product quality must be competent to do so.

### 6.2.2 Competence, Awareness, and Training



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 6.0 Resource management*

### **6.3, Infrastructure**

*9001* ....The organization is responsible for the establishment and upkeep of the “infrastructure” required to provide customers with products according to specifications, with examples of what is meant by infrastructure spelled out.

*9004* ....Recommends four factors that management should address in defining the required infrastructure and advises an organization to consider natural phenomena and the risks they pose to its operations in developing and keeping up the infrastructure.

*9000* ....Defines “infrastructure” in 3.3.3 as a “system of facilities, equipment and services needed for the operation of an organization”.

### *Document Requirements:*

#### Remember:

- The records that are created by the activities to fulfill the requirements of this clause may need to be controlled per clause 4.2.4, Control of records.

### *Internal Audit Questions:*

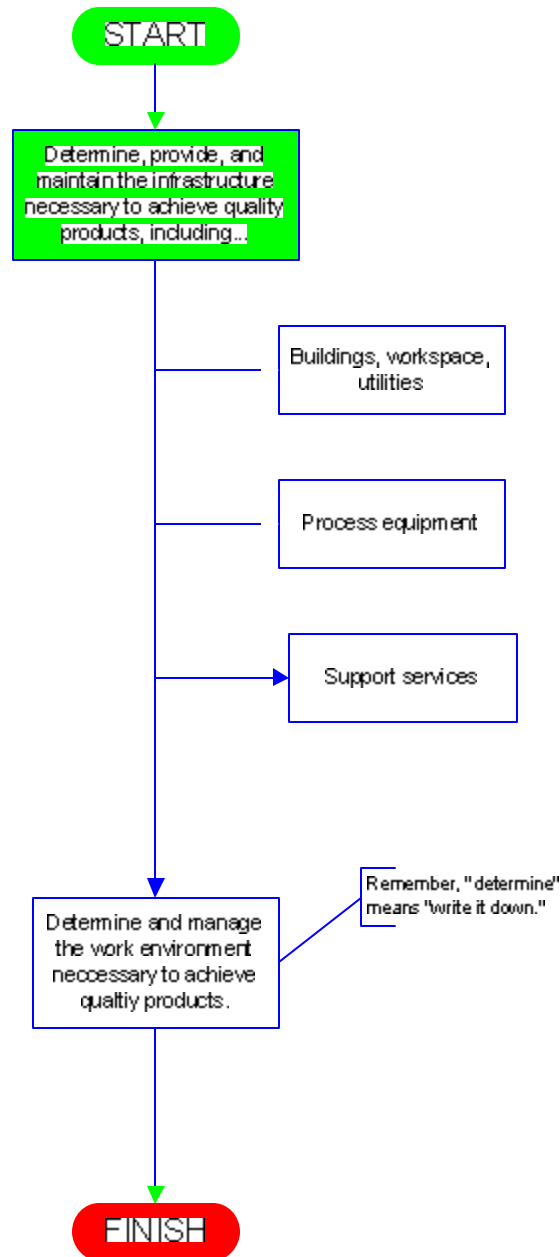
- Does the organization identify, provide, and maintain the workspace and associated facilities needed to achieve conformity of product?
- Does the organization identify, provide, and maintain the supporting services, equipment, hardware, and software it needs to achieve conformity of product?

### *Management Summary:*

- Infrastructure includes plant, workspace, tools, equipment, support services, information/communication technology, and transport facilities.

## 6.3 Infrastructure

## 6.4 Work Environment



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 6.0 Resource management*

### **6.4, Work Environment**

*9001* ....The organization is required to maintain the work environment in a state to permit product to satisfy requirements.

*9004* ....Encourages management to maintain the work environment so as to improve employee “motivation, satisfaction and performance” and thereby improve organizational performance. Identifies seven aspects of the work environment that should be evaluated in developing/revising the work environment.

*9000*.....Defines “work environment” in 3.3.4 as a “set of conditions under which work is performed”, with a list of conditions to be included in the scope of the work environment. Clarifies this as the conditions under which work is performed, not conditions under which people perform work.

### *Document Requirements:*

#### Remember:

- The records that are created by the activities to fulfill the requirements of this clause may need to be controlled per clause 4.2.4, Control of records.

### *Internal Audit Questions:*

- Does the organization identify and manage the human and physical factors of the work environment needed to achieve conformity of product?

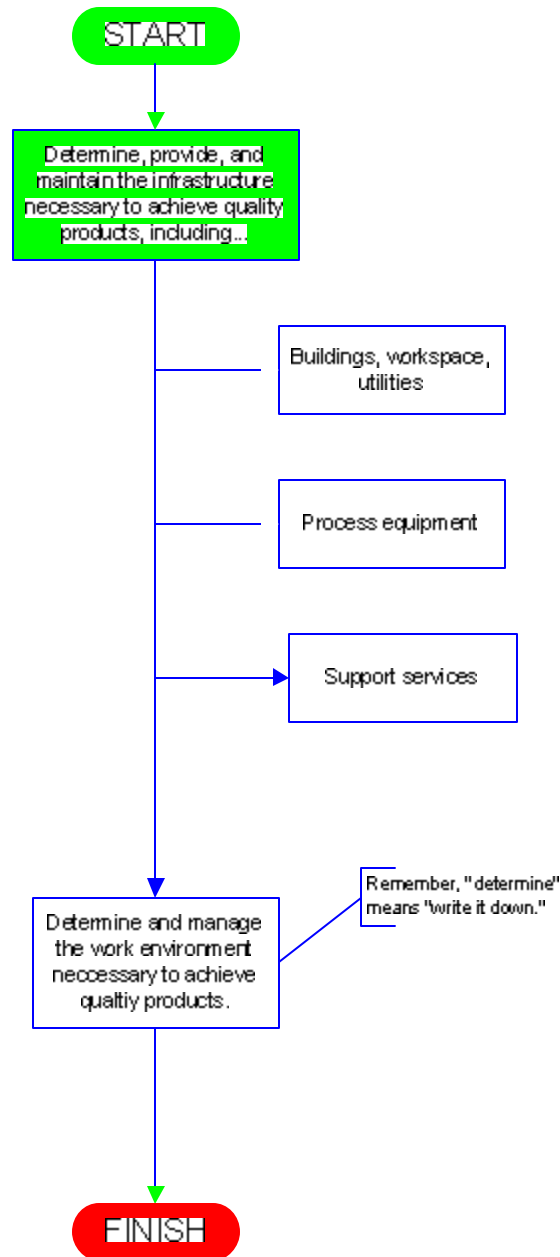
### *Management Summary:*

Using a combination of human and physical factors, Management should consider:

- Creative work methods and opportunities for greater involvement
- Ergonomics
- Heat, humidity, light airflow
- Hygiene, cleanliness, noise, vibration and pollution

## 6.3 Infrastructure

## 6.4 Work Environment



# A Practical Field Guide for ISO 9001:2000



## ISO 9001:2000 X ISO 9001:1994 CROSS EVALUATION

1994 Clauses ( <i>across</i> ) x 2000 Sections ( <i>down</i> )	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	4.15	4.16	4.17	4.18	4.19	4.20
<b>6 Resource management</b>																				
6.1 Provision of resources	4.1.2.2																			
6.2 Human resources																				
6.2.1 General	4.1.2.2																			
6.2.2 Competence, awareness and training																		4.18		
6.3 Infrastructure									4.9											
6.4 Work environment								4.9												

## PRODUCT REALIZATION SECTION 7

- 7.1 – Planning of product realization
- 7.2 – Customer-related processes
- 7.3 – Design and development
- 7.4 – Purchasing
- 7.5 – Production and service provision
- 7.6 – Control of monitoring and measuring devices

# A Practical Field Guide for ISO 9001:2000



## The Standard: 7.0 Product realization

### 7.1, Planning of Product Realization

**9001** .... The organization is to engage in planning to create processes to achieve “product realization”—the processes required to design, develop, produce, deliver and/or service a product—in conformance with other QMS requirements. Outcomes are to be identified as a result of the planning process, including: a product’s quality objectives; processes, documentation and resources for the product; procedures acceptable to the customer that will ensure the product meets specifications; records that prove the processes and product satisfy requirements. The outputs of the planning process must be appropriate for use by the organization based on how it functions.

**9004** .... Recommends that top management take steps to ensure the effectiveness and efficiency of all product realization and support processes and examines these processes as both inputs and outputs, with consideration of the roles of documentation, personnel and operating plans. Examples are provided of support processes, input issues and topics to be covered in process performance reviews.

**9000** .... Defines “inspection”, “test”, “verification” and “validation” in 3.8.2-3.8.5.

### Document Requirements:

#### Required:

- Record (d)

#### Remember:

- A documented procedure may be needed for describing how the planning is accomplished. See Note 1 above.

### Internal Audit Questions:

- Have documented quality plans for product realization processes and product validation been established (i.e. drawings, specifications, materials, process flow diagrams, process flowcharts, setup sheets, validation reports, etc.)?
- Is there evidence of planning of production processes?
- Does the planning encompass all product-realization processes?
- Is the planning consistent with other elements of the Quality Management System?
- Does documentation of product-realization exist?
- Are product-realization resources and facilities defined during the planning process? Are they adequate?
- Does the planning define the records that are prepared to show confidence of the conformity of the processes and final product?

### Management Summary:

- *For effective operation, Management should recognize that a process output might become the input to another process.*
- *Verification results and process validations should be considered as inputs to a process.*
- *Effective processes can only offer increased benefits, improved customer satisfaction and use of resources and waste reduction.*

*Process inputs can be internal or external to the organization such as:*

- *competence of people*
- *documentation*
- *equipment capability and monitoring*
- *health, safety and work environment.*

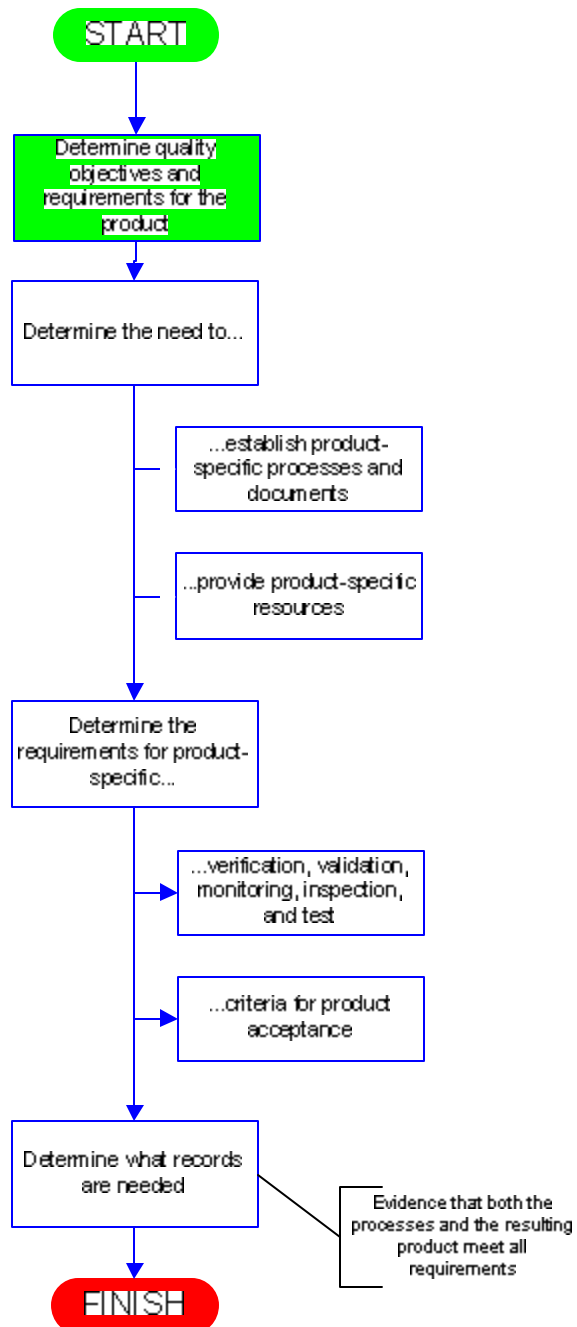
## Section 7

## Product Realization

### 7.1

#### Planning of Product Realization

The organization must define its own processes for product realization.



# A Practical Field Guide for ISO 9001:2000



## *The Standard 7.0 Product realization:*

### **7.2 Customer-related processes**

#### 7.2.1, Determination of Requirements Related to the Product

*9001* .... The organization must identify all requirements of a product, including those from customer specifications, unspecified but necessary for the product to work properly, imposed by legal and regulatory authorities and deemed necessary by the organization.

*9004* .... Recommends management consider the needs and expectations of all interested parties, including the customer, in determining other requirements for a product. (Note: This applies for 7.2.2 and 7.2.3 below.)

*9000* .... Defines “requirement” in 3.1.2 as a “need or expectation that is stated, generally implied or obligatory”, with four NOTES clarifying the definition.

## *Document Requirements:*

### Remember:

- Organization should consider having a documented procedure to determine customer requirements. They are a vital part in achieving customer requirements, needs, and expectations.

## *Internal Audit Questions:*

- Has the organization determined customer requirements?
- Have processes been established to determine both specified and unspecified customer requirements?
- Do records exist to provide evidence that customer requirements have been determined (i.e. contract review records, service records, customer feedback records, surveys, market testing reports, design input and design validation records, identified legal and regulatory requirements, etc.)?

## *Management Summary:*

*Management should consider the following to ensure that the customer’s needs and expectations are met:*

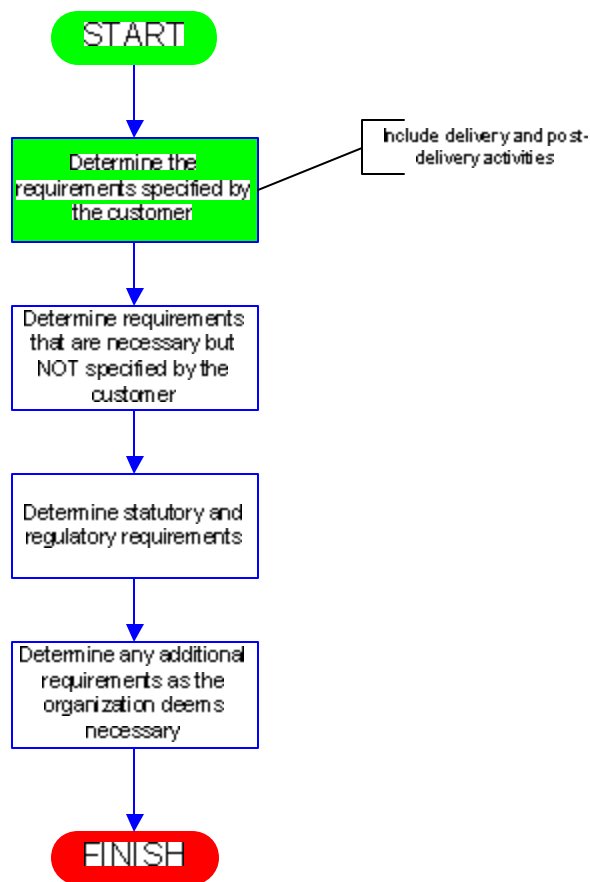
- *operating conditions for the product*
- *use or application of the product*
- *disposal of the product*
- *life cycle of the product*
- *environmental impact of the product*

Section 7

## Product Realization

### 7.2 Customer-related Processes

#### 7.2.1 Determination of product-specific requirements



# A Practical Field Guide for ISO 9001:2000



## The Standard: 7.0 Product realization

### 7.2 Customer-related processes

#### 7.2.2, Review of Requirements Related to the Product

*9001* ....Product requirements, whether involving a bid request, a new contract order or an amendment to an existing contract, must be reviewed by the organization to ensure the requirements and/or any changes are clearly understood and can be met, including in situations where the customer provides no written specifications. The review process results are to be treated as quality records, which must be updated whenever requirements change—with changes relayed to “relevant personnel” to ensure customer requirements are met effectively.

*9000* ....Defines “review” in 3.8.7 as “activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives”.

### Document Requirements:

#### Required:

- Record

#### Remember:

- Consider having a documented procedure for the review of customer requirements and how these requirements can be met.

### Internal Audit Questions:

- Is there a process that requires the review of identified customer requirements before commitment to supply a product to the customer?
- Is there a process that requires the review of quotes and orders for adequacy of the definition of requirements?
- Is there a process for handling review of verbal orders?
- Is there a process to handle resolution of differences between quotations and orders?
- Is there a process for handling changes to product requirements?
- Are records of quote, tender, contract, and order review available and maintained?

### Management Summary:

- *Product and process changes should be identified, recorded, evaluated, reviewed and controlled in order to understand the effect on other processes and the needs and expectations of customers.*
- *The organization should define the authority for initiating process changes in order to maintain control.*

Section 7

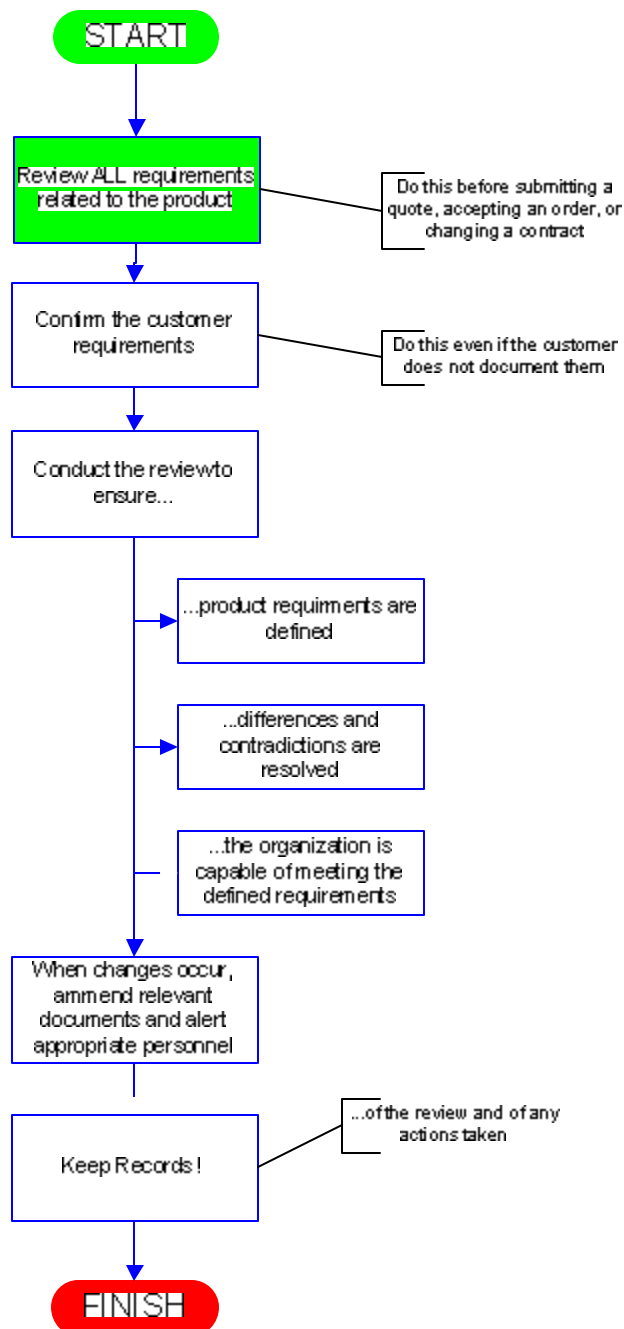
## Product Realization

### 7.2

#### Customer-related Processes

##### 7.2.2

#### Review of product-specific requirements



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 7.0 Product realization*

### **7.2 Customer-related processes**

#### 7.2.3, Customer Communication

*9001*The organization must establish procedures for effective communication with customers regarding product specifications and the receipt and handling of product orders and amendments and any questions regarding these and in obtaining customer feedback on products and related services.

#### *Document Requirements:*

N/A

#### *Internal Audit Questions:*

- Is there a process in place to communicate with customers regarding product information, enquiries, contracts, order handling (including amendments), and customer feedback including customer complaints?

#### *Management Summary:*

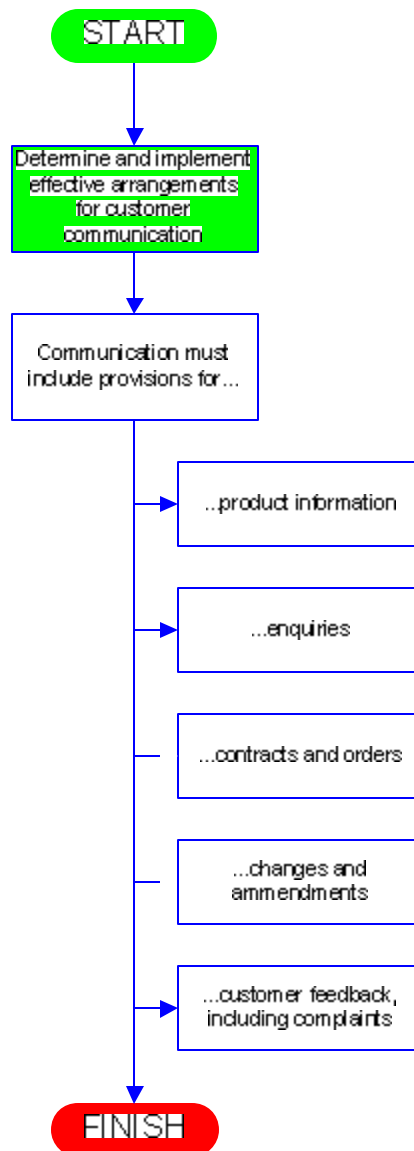
- *The organization should implement and maintain a process to translate customer needs and expectations into requirements for the organization.*
- *The organization should fully understand the customer requirements prior to acceptance.*

Section 7

## Product Realization

### 7.2 Customer-related Processes

#### 7.2.3 Customer communication



# A Practical Field Guide for ISO 9001:2000



## The Standard: 7.0 Product realization

### 7.3 Design and development

#### 7.3.1, Design and Development Planning

*9001* .... The processes involved in design and development of a product must be planned out and managed by the organization to ensure that each group involved with its design and development is engaged at all appropriate stages—and everyone involved understands who is responsible for which activities at what times—and that proper evaluations of prototypes, etc., are conducted at appropriate stages. The output from this planning must be revised to reflect the product’s progress through the design and development process.

*9004* .... Suggests that top management should consider a number of aspects and techniques not directly related to customer specifications for the product in planning its design and development, including the design of the organization’s processes. Recommends taking steps to “identify and mitigate potential risk” to product users and those affected by the organization’s processes, providing a list of six risk assessment tools that could be applied in planning design and development.

*9000* .... Defines “design and development” in 3.4.4 as a “set of processes that transforms requirements into specified characteristics or into the specification of a product, process or system”.

#### Document Requirements:

#### Internal Audit Questions:

- Are the design and/or development project stages defined? Where?
- Are verification and validation activities addressed and appropriate?
- Is it clear who is responsible for what?
- Are the communication channels defined?
- Does evidence exist to show that communications on projects is occurring and is effective?

#### Management Summary:

- *Risk assessment should be utilized to assess the potential for, and the effect of, possible failures or faults in products or processes.*

*Management should consider the following factors that contribute to meeting the product and process performance expected by customers:*

- *life cycle*
- *safety and health*
- *testability and usability*
- *user-friendliness*
- *dependability and durability*
- *ergonomics*
- *product disposal and the environment*

Section 7

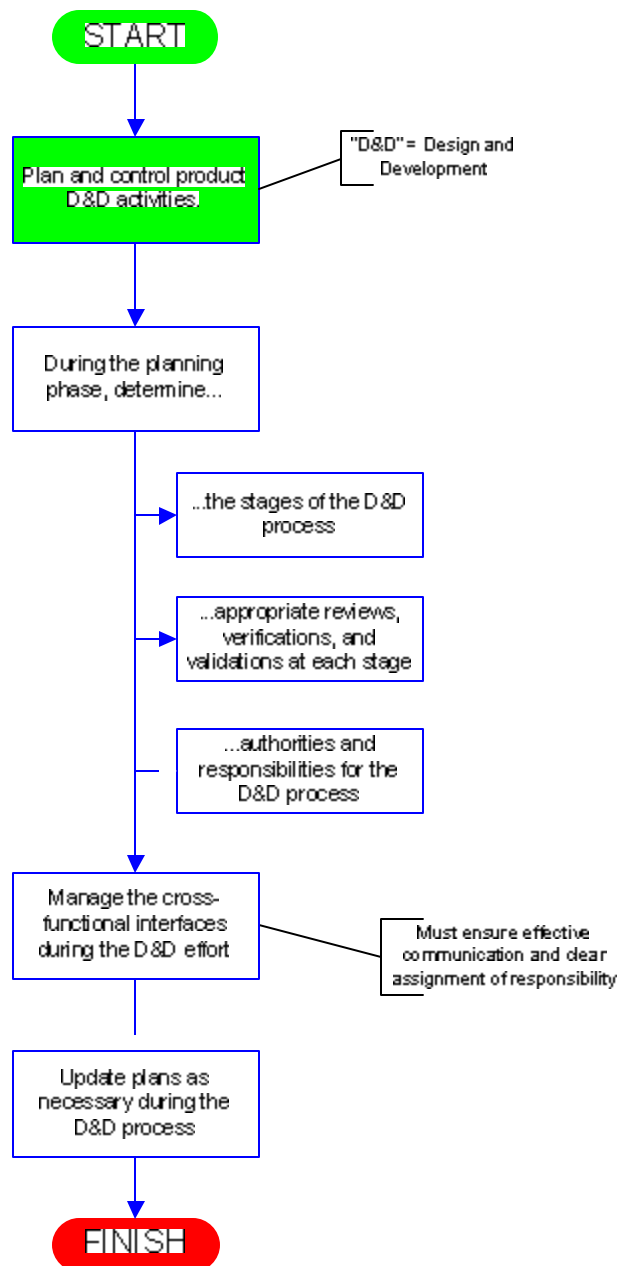
## Product Realization

### 7.3

#### Design and Development

##### 7.3.1

##### Design and Development Planning



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 7.0 Product realization*

### **7.3 Design and development**

#### 7.3.2, Design and Development Inputs

*9001* ....The organization is to identify all inputs required for the design and development process, evaluate their adequacy for determining product design and development and treat the identified inputs for a product as a quality record. Four specific types of inputs are required to be included, and the inputs identified must cover all requirements, be clearly defined and cannot create conflicting situations.

*9004* ....Recommends identification of process as well as product inputs and coupling of internal needs and expectations with external ones. Presents examples of external inputs, internal inputs and inputs that identify critical process and product characteristics.

#### *Document Requirements:*

- Record

#### *Internal Audit Questions:*

- Are new product requirements defined and documented?
- Are the requirements complete, unambiguous and without conflict?

#### *Management Summary:*

- *External and internal needs and expectations should be suitable for translation into input requirements for design and development processes.*

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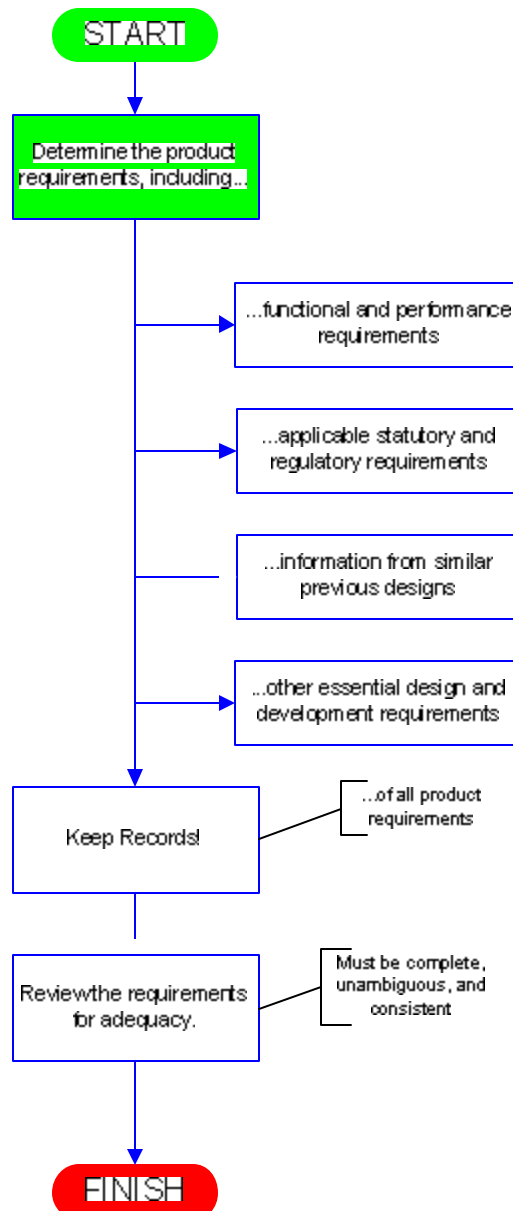
## Product Realization

### 7.3

#### Design and Development

##### 7.3.2

#### Design and Development Inputs



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 7.0 Product realization*

### **7.3 Design and development**

#### 7.3.3, Design and Development Outputs

*9001* ....The organization must capture and approve the outputs in a medium that permits verification against the inputs before their release. Design and development outputs must meet four criteria, including the ability to satisfy requirements identified as inputs, disseminate data to accomplish product-related processes within the organization and spell out product characteristics that are critical to its “safe and proper use”.

*9004* ....Provides examples of eight types of outputs.

#### *Document Requirements:*

#### *Internal Audit Questions:*

- Does a form with the output of design and/or development projects exist?
- Does it show how design and/or development outputs satisfy input requirements?
- Does output provide information for production operations?
- Are product acceptance criteria clearly stated?
- Is product safety and use characteristics identified?
- Does an approval process exist for the release of products from the design and/or development process?

#### *Management Summary:*

- *Design and development outputs should be reviewed against inputs to provide objective evidence that they have effectively met the process and product requirements.*

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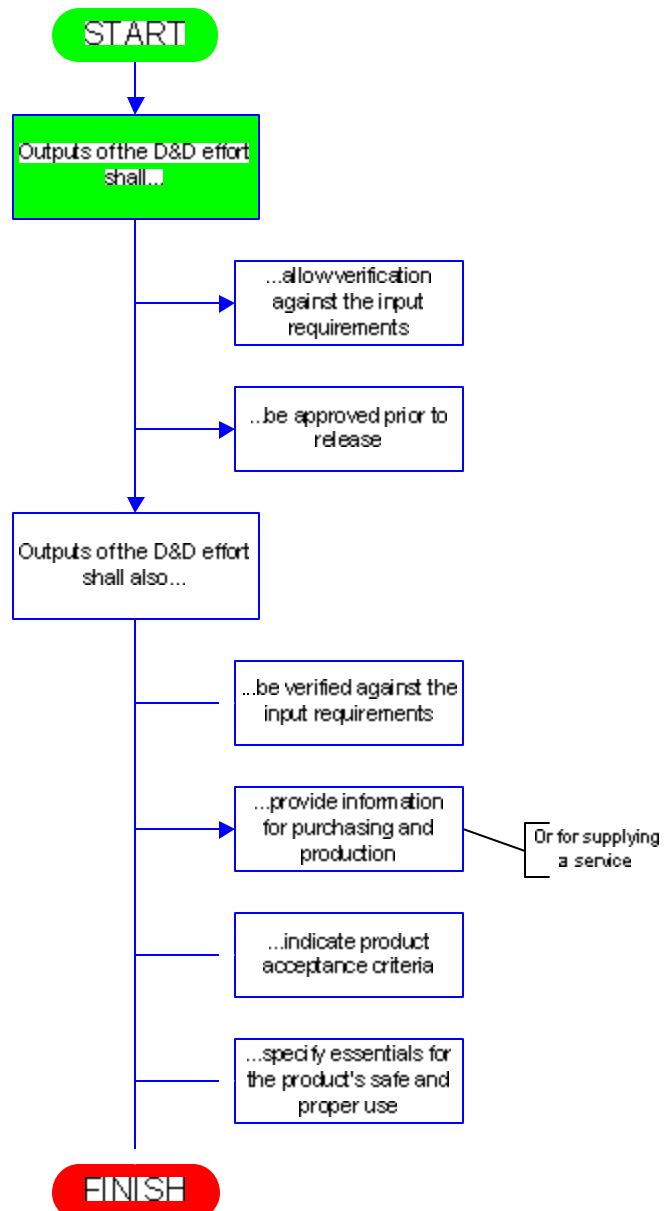
## Product Realization

### 7.3

#### Design and Development

##### 7.3.3

#### Design and Development Outputs



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 7.0 Product realization*

### **7.3 Design and development**

#### 7.3.4, Design and Development Review

*9001* ....The organization is to engage in “systematic reviews” of design and development activities at appropriate stages to ensure the results are meeting product and design and development requirements and to catch and correct problems before they impact on overall design and development. All groups involved in design and development should be represented in these reviews, and the review results are to be treated as quality records.

*9004* ....Provides examples of topics to be covered during the reviews.

#### *Document Requirements:*

- Record

#### *Internal Audit Questions:*

- Are reviews of design and/or development being performed? Are they indicated in the project-planning documents?
- Who attends these reviews? Is the attendance appropriate?
- Are results of the reviews documented? Are follow-up actions taken?

#### *Management Summary:*

- *Systematic reviews may be conducted at suitable stages in the design and development process as well as at completion.*

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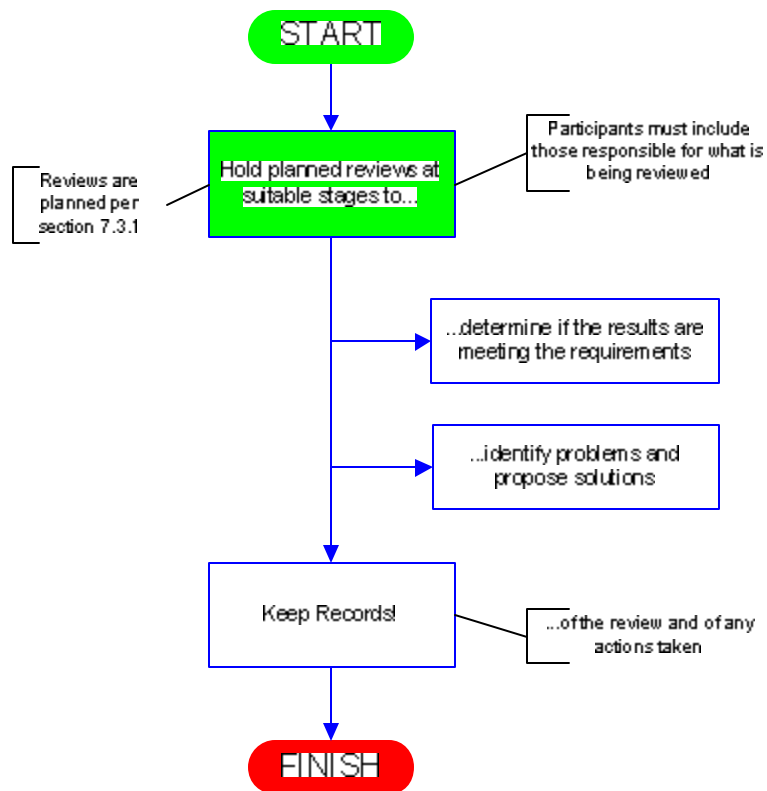
## Product Realization

### 7.3

#### Design and Development

### 7.3.4

#### Design and Development Review



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 7.0 Product realization*

### **7.3 Design and development**

#### 7.3.5, Design and Development Verification

*9001* .... The organization must verify that design and development outputs meet all input requirements and that the results of verification activity are treated as quality records.

*9004* .... Provides examples of verification and validation activities to be undertaken to ensure the end-product will be well-received by customers and others.

*9000* .... Defines “verification” in 3.8.4 as the “confirmation, through the provision of objective evidence, that specified requirements have been fulfilled”, with activities that constitute confirmation provided in a NOTE.

#### *Document Requirements:*

- Record

#### *Internal Audit Questions:*

- Is there a verification process in place?
- Is it effectively implemented?
- Are results of the verification documented?
- Are follow-up actions recorded?

#### *Management Summary:*

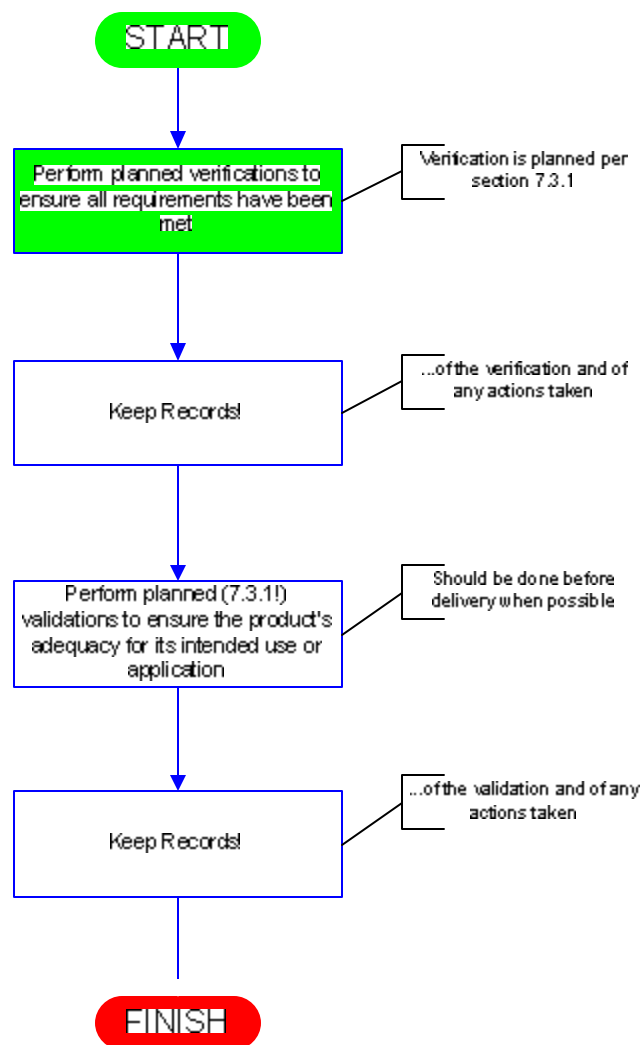
- *The organization should evaluate design and development outputs and the processes in order to prevent nonconformities and deficiencies.*

Section 7

## Product Realization

### 7.3 Design and Development

#### 7.3.5 and 7.3.6 Design and Development Verification and Validation



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## The Standard: 7.0 Product realization

### 7.3 Design and development

#### 7.3.6, Design and Development Validation

*9001* ....The organization must validate a product’s ability to meet customer specifications and “known intended use or application” at the conclusion of the design and development process. Validation is to be conducted before product delivery or its “implementation” whenever it is possible to do so after the product’s completion. Validation results and any necessary actions subsequent to the validation are to be treated as quality records.

*9000* ....Defines “validation” in 3.8.5 as “confirmation, through...objective evidence, that the requirements of a specific intended use or application have been fulfilled”.

#### Document Requirements:

- Record

#### Internal Audit Questions:

- Is design and/or development validation performed to confirm that the product is capable of meeting requirements for intended use?
- Is validation completed prior to delivery when applicable?
- Is partial validation provided when full validation cannot be performed prior to delivery?
- Are design validation results documented?
- Are follow-up actions recorded?

#### Management Summary:

*Customers, suppliers, people in the organization should be able to use and evaluate the validation output prior to:*

- *construction, installation or application of engineering designs;*
- *installation or use of software outputs;*
- *widespread introduction to services*

Section 7

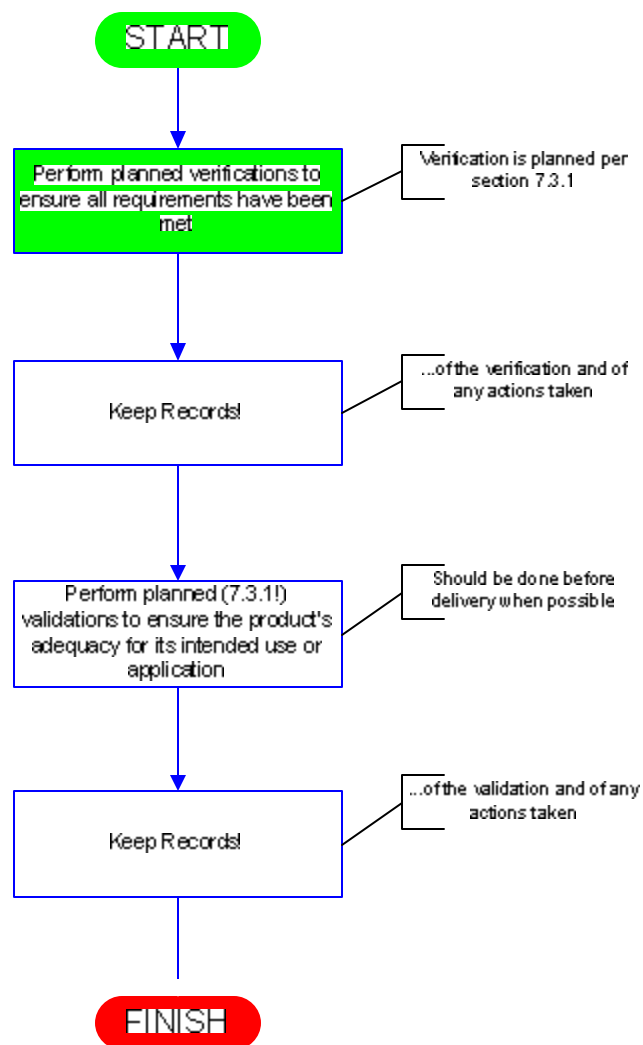
## Product Realization

### 7.3

### Design and Development

#### 7.3.5 and 7.3.6

#### Design and Development Verification and Validation



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## *The Standard: 7.0 Product realization*

### **7.3 Design and development**

#### 7.3.7, Control of Design and Development Changes

*9001* .... When a change to a product's design and/or development occurs, it must be noted, with the information to be treated as a quality record. The organization must examine each change to ensure the product will remain in conformance with customer and any other requirements before approving a change. The change's impact on both components and the product delivered to the customer must be covered in the examination.

#### *Document Requirements:*

- Record

#### *Internal Audit Questions:*

- Are all design and/or development project changes documented?
- Is there evidence to demonstrate that changes are authorized?
- Do records include the results of review of changes?
- Have changes been communicated to interested parties?
- Do records include follow-up actions related to the review of changes?

#### *Management Summary:*

*Verification and validation data should be reviewed by methods such as:*

- *process and product improvement*
- *output usability*
- *adequacy of process and review records*
- *investigation of failures*
- *future design and development process needs*

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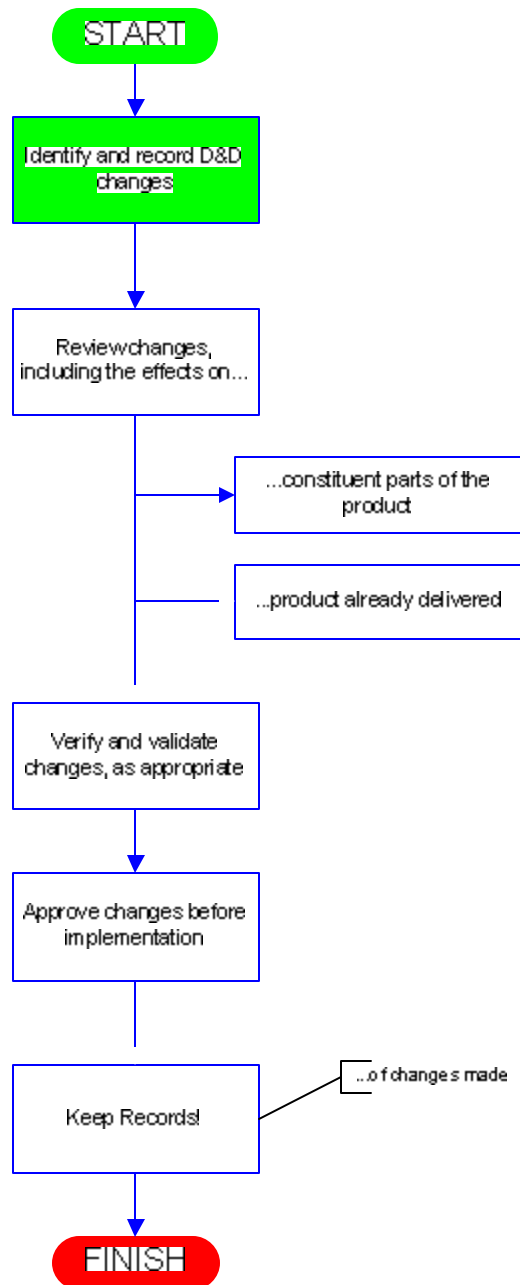
## Product Realization

### 7.3

### Design and Development

#### 7.3.7

#### Control of Design and Development Changes



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## The Standard: 7.0 Product realization

### 7.4 Purchasing

#### 7.4.1, Purchasing Process

*9001* .... The organization must make sure that materials, components and services purchased from suppliers satisfy customer specifications for the organization's product, with the degree of supplier oversight proportional to the impact a part or service has on the product or processes. Suppliers must be qualified and capable of supplying parts/services needed to satisfy product and organizational requirements based on criteria developed by the organization for choosing suppliers and engaging in ongoing verification of qualifications and capability. The organization must treat as quality records the results of its verification activities and actions taken in response to verification outcomes.

*9004* .... Recommends "electronic linkage" with suppliers to ensure communication of requirements and supplier participation in setting specifications for parts and services. Encourages consideration of 15 types of activity in the purchasing process. Provides 10 inputs organizations should use in managing supplier quality and advises organizations to assist suppliers in their development.

*9000* .... Notes in 3.3.6 that suppliers include providers of a service or information.

#### Document Requirements:

- Record

#### Internal Audit Questions:

- Have criteria for selection and periodic evaluation of suppliers been defined?
- Does a process exist for selecting and evaluating suppliers?
- Are evaluation results documented and retained as records?
- Are follow-up actions documented?

#### Management Summary:

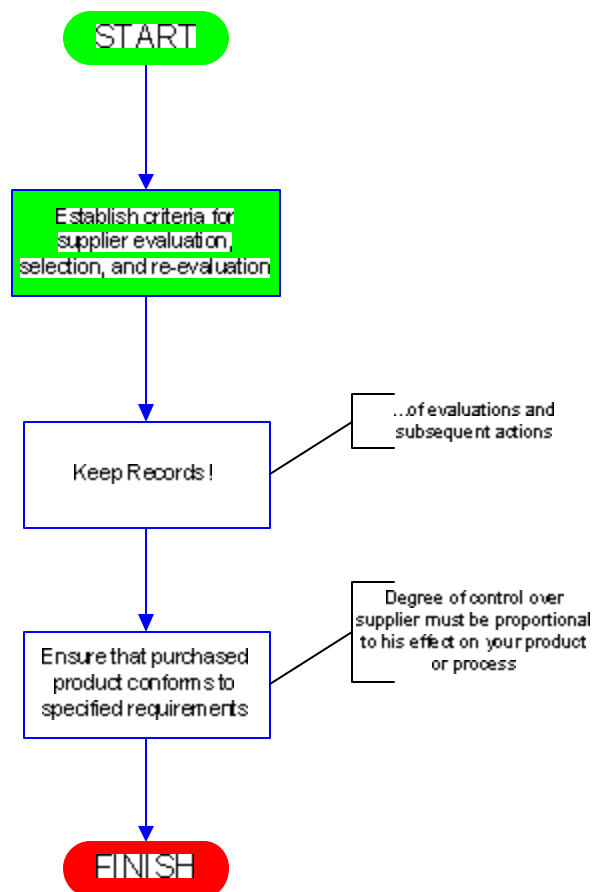
- *Management should consider electronic communication of requirements to suppliers.*
- *The organization should consider involving suppliers in the purchasing process to help the organization control inventory.*

Section 7

## Product Realization

### 7.4 Purchasing

#### 7.4.1 Purchasing Process



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## The Standard: 7.0 Product realization

### 7.4 Purchasing

#### 7.4.2, Purchasing Information

*9001* .... The specifications for a product being purchased from a supplier must be part of the purchasing information, which must include approval requirements for the product and related items and activities, competency requirements for employees working on the product and QMS requirements for the supplier's operations. The organization is required to make sure all requirements are identified and spelled out before transmitting the purchasing information to the supplier.

#### Document Requirements:

N/A

#### Internal Audit Questions:

- Does purchasing information adequately describe the products being ordered?
- Does purchasing information include (where appropriate) requirements for approval or qualification of product, procedures, processes, equipment, and personnel?
- Does purchasing information include (where applicable) Quality Management System requirements?
- Is purchasing information reviewed/approved to assure adequate descriptions of the specified requirements prior to release?

#### Management Summary:

*Management should consider the following activities when creating purchasing processes:*

- *unique supplier processes*
- *warranty replacement for nonconforming purchased products*
- *logistic requirements*
- *control of purchased product deviation from requirements*
- *access to supplier's premises*
- *mitigation of risks associated with purchased product*

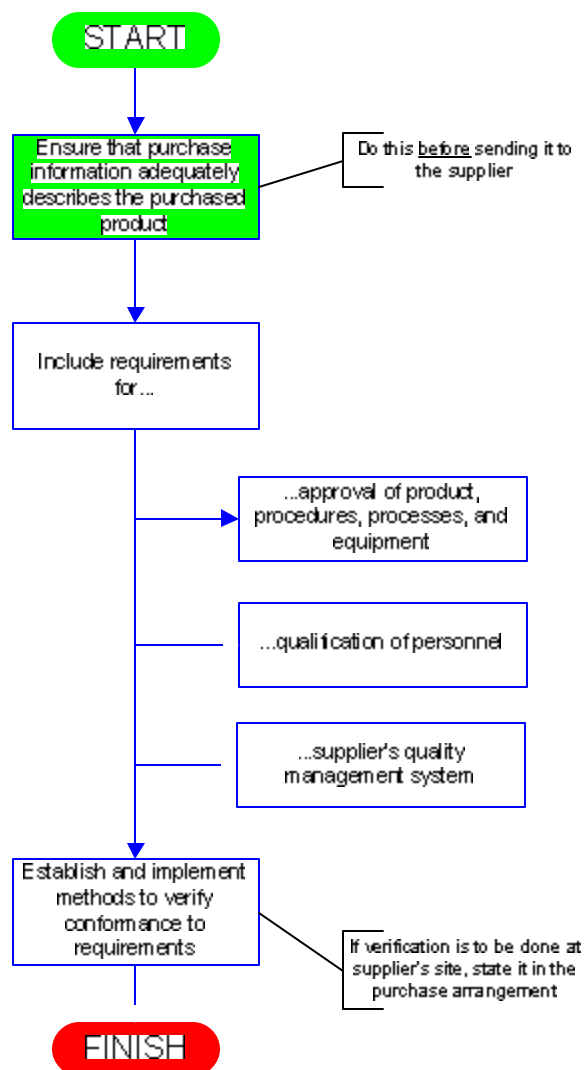
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## Product Realization

### 7.4 Purchasing

#### 7.4.2 Purchasing Information

#### 7.4.3 Verification of Purchased Product



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 7.0 Product realization*

### **7.4 Purchasing**

#### 7.4.3, Verification of Purchased Product

*9001* ....The organization is to create and use verification practices to confirm that purchased product conforms to the requirements conveyed to the supplier in the purchasing information. The purchasing information also must indicate whether the organization or its customer will conduct on-site inspections of the product, processes and/or supplier's facility and the related procedures for product release.

*9000* ....Defines "release" in 3.6.9 as "permission to proceed to the next stage of a process".

#### *Document Requirements:*

#### *Internal Audit Questions:*

- Has the organization defined a process for verifying that purchased product conforms to defined requirements?
- Is the process effectively implemented?
- Does objective evidence exist of product acceptance?
- Is verification of purchased product performed at the supplier's premises?
- If so, are the arrangements specified and does objective evidence exist to show effective implementation?

#### *Management Summary:*

- *In the event of supplier failure, Management should have actions in place to maintain the organization's performance.*

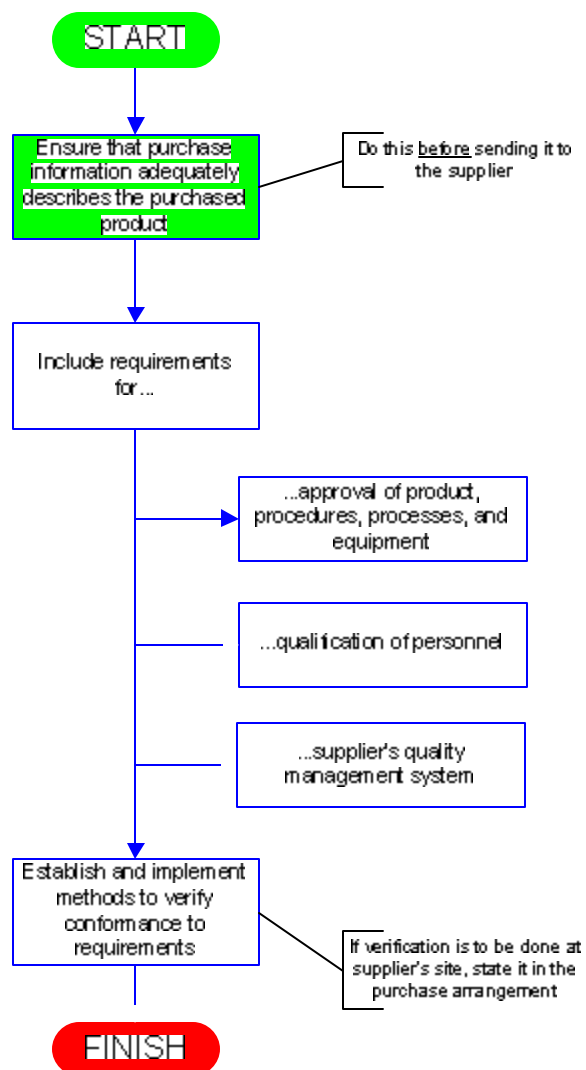
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## Product Realization

### 7.4 Purchasing

#### 7.4.2 Purchasing Information

#### 7.4.3 Verification of Purchased Product



# A Practical Field Guide for ISO 9001:2000



## The Standard: 7.0 Product realization

### 7.5 Production and service provision

#### 7.5.1, Control of Production and Service Provision

*9001* .... Production and service operations are to be conducted under planned procedures that control the activities involved, including production, monitoring and measuring, delivery and post-delivery servicing. To ensure processes and products conform to customer specifications and other requirements, the organization is required to control six items, including the availability and/or use of procedures, work instructions, information detailing product characteristics and proper equipment.

*9004* .... Provides guidance on going beyond control of production and service processes to increased effectiveness and efficiency and associated activities that support these processes, with examples of the support activities provided.

*9000* .... Defines “quality control” in 3.2.10 as “part of quality management, focused on fulfilling quality requirements”.

#### Document Requirements:

#### Internal Audit Questions:

- Are specifications available that define quality characteristic requirements of the product and/or service?
- Has the organization demonstrated the suitability of equipment for production and service operations to meet product and/or service specifications?
- Are all production and service operations that require control defined (including those that need ongoing monitoring, work instructions, and/or special controls)?
- Are work instructions available and adequate to permit control of the appropriate operations to ensure conformity of product and/or service?
- Have the work environment requirements been defined and are they being met to ensure conformity of the product and/or service?
- Is suitable measuring and monitoring equipment available when and where necessary to ensure conformity of the product and/or service?
- Have monitoring and verification activities been planned and are they carried out as required?
- Have suitable processes for hardware, processed material, and software been implemented for release of the product and for their delivery to the customer?
- Are suitable release mechanisms in place to ensure service conforms to requirements?

#### Management Summary:

*To improve the effectiveness and efficiency of the realization processes, Management should consider the following:*

- *reducing waste*
- *developing supplier capability*
- *improving infrastructure*
- *processing methods and process yield*
- *monitoring methods*

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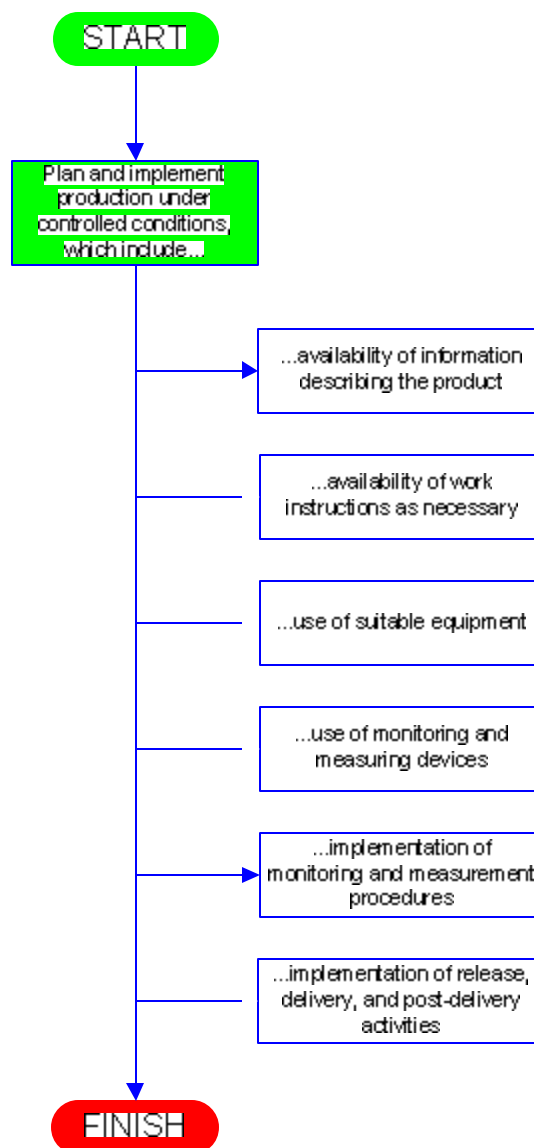
## Product Realization

7.5

Production and Service Provision

7.5.1

Control of Production and Service Provision



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 7.0 Product realization*

### **7.5 Production and service provision**

#### 7.5.2, Validation of Processes for Production and Service Provision

*9001*.....When a product or service cannot be tested during and/or after production and/or service delivery to verify its conformance to customer and other requirements, the organization must ensure that the processes involved are capable of producing a product or service that conforms to requirements, validating the processes. There are six items the organization must have in place to ensure processes are validated and remain in conformance, including criteria for process review and approval, employee and equipment approval procedures and defined production/service techniques and processes to be followed.

#### *Document Requirements:*

- Record (d)

#### *Internal Audit Questions:*

- Are there defined criteria for review and approval of the validation of processes?
- Is there a process in place to handle deficiencies with product that is in use or that has been delivered?
- Are there records of validation of processes for production and services provisions?

#### *Management Summary:*

- *The organization must also validate processes when product that is in use or has been delivered results in deficiencies.*

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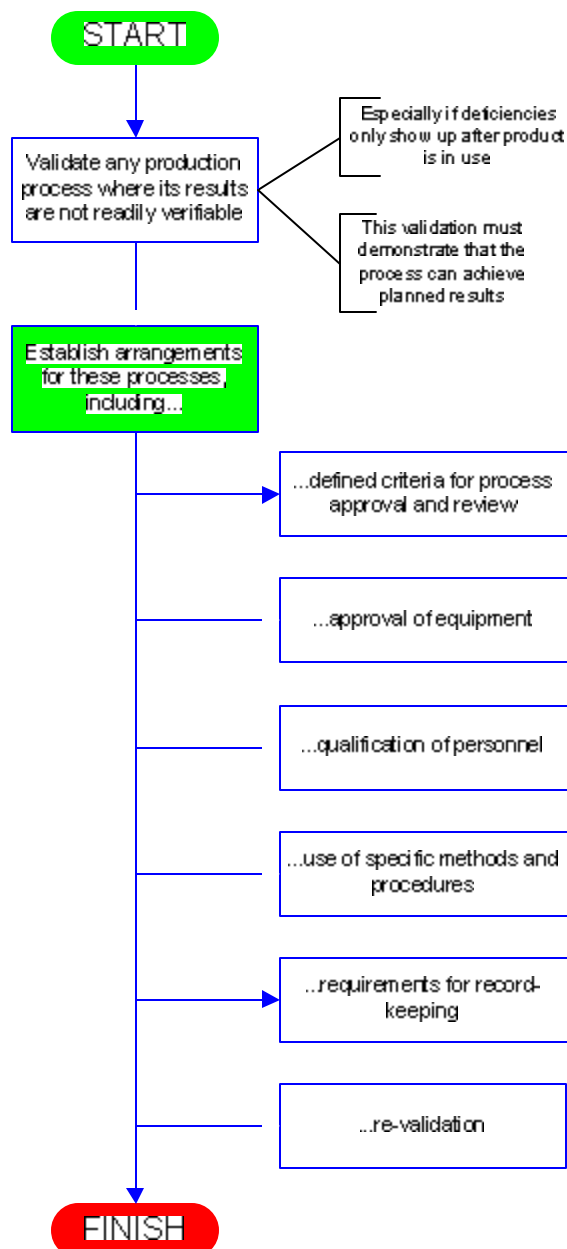
## Product Realization

### 7.5

### Production and Service Provision

#### 7.5.2

#### Validation of Processes for Production and Service Provision



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 7.0 Product realization*

### **7.5 Production and service provision**

#### 7.5.3, Identification and Traceability

*9001* ....The organization must have an effective system in place to maintain identification of a product throughout the production process, including its inspection and test status, whenever these are needed. When a product must be traceable, the organization must impose a “unique identification” on each product and record the identification information to permit traceability, with the record to be treated as a quality record.

*9004* ....Recommends collecting data during the identification and traceability processes to go beyond product requirements to improving the product and its processes.

*9000* ....Notes in 3.5.4 that traceability can relate to the origin of materials and parts, among other things.

#### *Document Requirements:*

- Record

#### *Internal Audit Questions:*

- Has the product been identified by suitable means throughout production and service operations?
- Has the status of the product been identified at suitable stages with respect to measurement and monitoring requirements?
- Is traceability a requirement? If so, is the unique identification of the product recorded and controlled?

#### *Management Summary:*

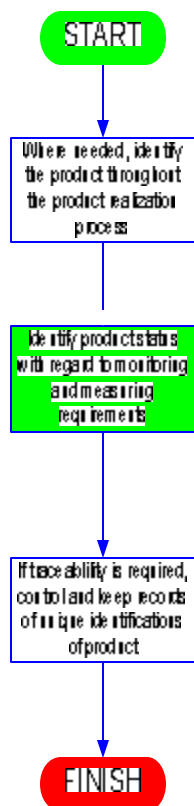
- *In order to collect data for improvement, the organization may establish a process for identification and traceability that goes beyond regular requirements.*

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## Product Realization

### 7.5 Production and Service Provision

#### 7.5.3 Identification and Traceability



# A Practical Field Guide for ISO 9001:2000



## The Standard: 7.0 Product realization

### 7.5 Production and service provision

#### 7.5.4, Customer Property

*9001* ....The organization is to have procedures to protect from damage, misuse or loss property supplied by the customer for use by the organization in its processes or as components in the product to be supplied to the customer, including intellectual property. The organization must alert the customer if its property is nonconforming and keep records of these incidences as quality records.

*9004* ....Provides examples of the types of property customers or other interested parties might entrust to an organization for use or in production/service activities.

#### Document Requirements:

- Record

#### Internal Audit Questions:

- Has the organization identified, verified, protected, and maintained customer property provided for incorporation into the final product?
- Does control of product extend to all customer property including intellectual property?
- Are there records that indicate when customer property has been lost, damaged, or otherwise found to be unsuitable?
- When customer property has been lost, damaged, or otherwise found to be unsuitable, is there evidence that the customer has been informed?

#### Management Summary:

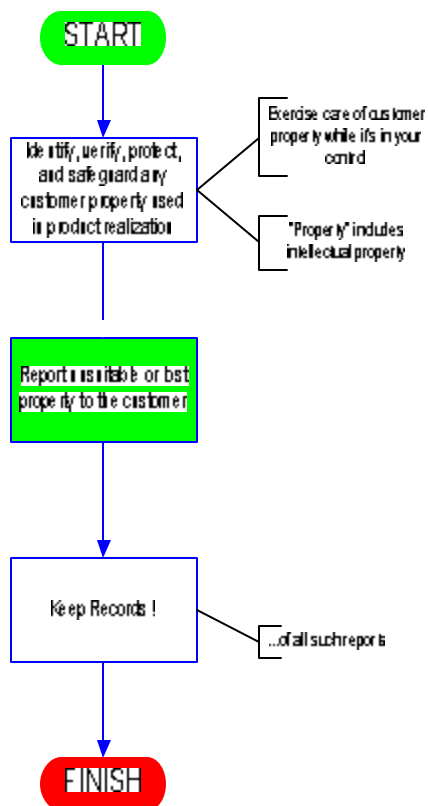
- Examples of customer property that the organization may be responsible for include:*
- *ingredients or components for inclusion in a product*
  - *product supplied for repair, maintenance or upgrading*
  - *packaging materials*
  - *transport of customer property to a third party*
  - *customer intellectual property*

Section 7

## Product Realization

### 7.5 Production and Service Provision

#### 7.5.4 Customer Property



# A Practical Field Guide for ISO 9001:2000



## The Standard: 7.0 Product realization

### 7.5 Production and service provision

#### 7.5.5, Preservation of Product

*9001* .... The organization must ensure that a product and its components continue to satisfy customer specifications and other requirements throughout the production process until delivery to the customer's intended operations.

*9004* .... Advises management to ensure resources are available to protect a product from destruction, deterioration or misuse while in the organization's possession and to inform the customer and others what is required to preserve the product during its life cycle.

#### Document Requirements:

#### Internal Audit Questions:

- Is product identified during internal processing and delivery?
- When handling product during internal processing and delivery, does the organization preserve conformity to customer requirements?
- When packaging product during internal processing and delivery, does the organization preserve conformity to customer requirements?
- When storing product during internal processing and delivery, does the organization preserve conformity to customer requirements?
- Does the organization protect the product during internal processing and delivery to preserve conformity to customer requirements?

#### Management Summary:

*To control handling, packaging, storage , preservation and delivery of product, Management should consider special requirements that may arise from the nature of the product such as:*

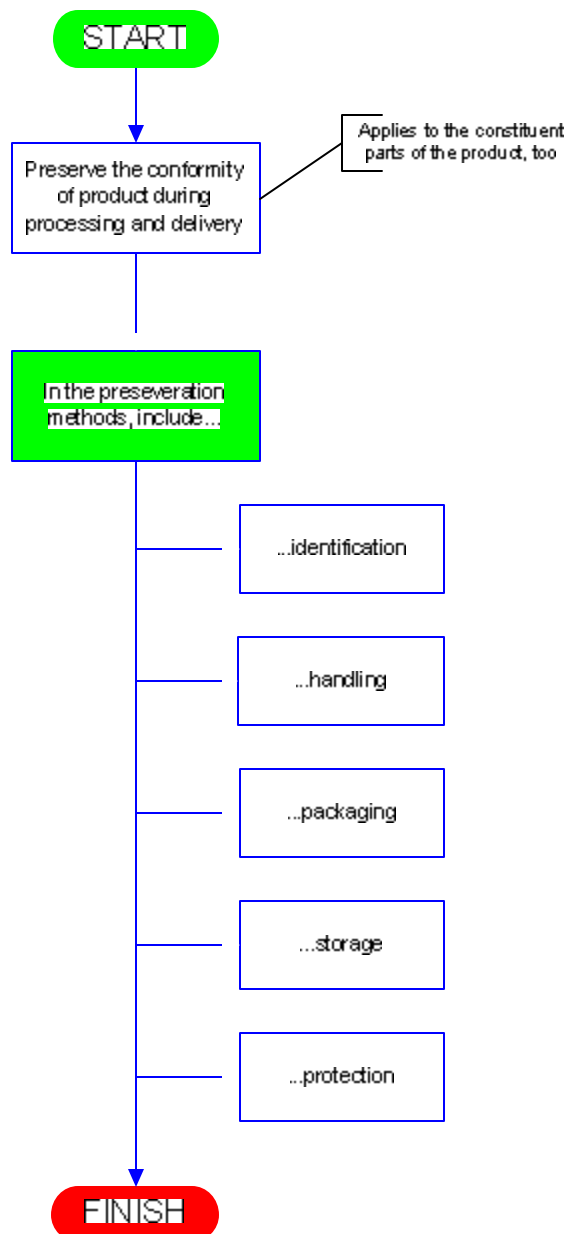
- *software*
- *electronic media*
- *hazardous materials*
- *products requiring special service people*
- *unique or irreplaceable products and materials*

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## Product Realization

### 7.5 Production and Service Provision

#### 7.5.5 Preservation of Product



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## The Standard: 7.0 Product realization

### 7.6, Control of Monitoring and Measuring Devices

*9001* ....The organization is to decide what types and frequency of monitoring and measuring are required to ensure a product satisfies customer and other requirements, identify the devices necessary for these activities and put in place procedures to ensure monitoring and measurement is conducted in accordance with the organization's specifications. The organization must maintain the devices in a condition to ensure accurate monitoring and measurements, including calibration, with the results, along with device maintenance records, to be treated as quality records. Specific requirements are spelled out for computer software used for monitoring and measurement purposes. When a device is out of conformity, previous measurements must be examined to ensure the nonconformity did not result in product nonconformities.

*9004* ....Expands on what monitoring and measurement processes could involve and achieve, with emphasis on the organization taking steps to eliminate potential problems within processes and thus reduce the need to rely on monitoring and measuring activities.

*9000* ....Provides related definitions in 3.8.2, Inspection, and Subsection 3.10, Terms Related to Quality Assurance for Measurement Processes.

#### Document Requirements:

- Record (a)
- Record
- Record

#### Internal Audit Questions:

- Has the organization identified the measurements to be made? Has the organization identified the measurement and monitoring devices required to assure conformity of product to specified requirements?
- Are measuring and monitoring devices used to ensure measurement capability? Are they calibrated and adjusted periodically or prior to use against devices traceable to international or national standards? Are those calibration results recorded?
- When traceability to international or national standards cannot be done since no standards exist, is the calibration recorded?
- Are measuring and monitoring devices safeguarded from adjustments that would invalidate the calibration? Are they protected from damage and deterioration during handling, maintenance, and storage?
- Does the organization have the validity of previous results from measuring and monitoring devices reassessed if they are subsequently found to be out of calibration? Is corrective action taken?
- Is software used for measuring and monitoring of specified requirements validated prior to use?

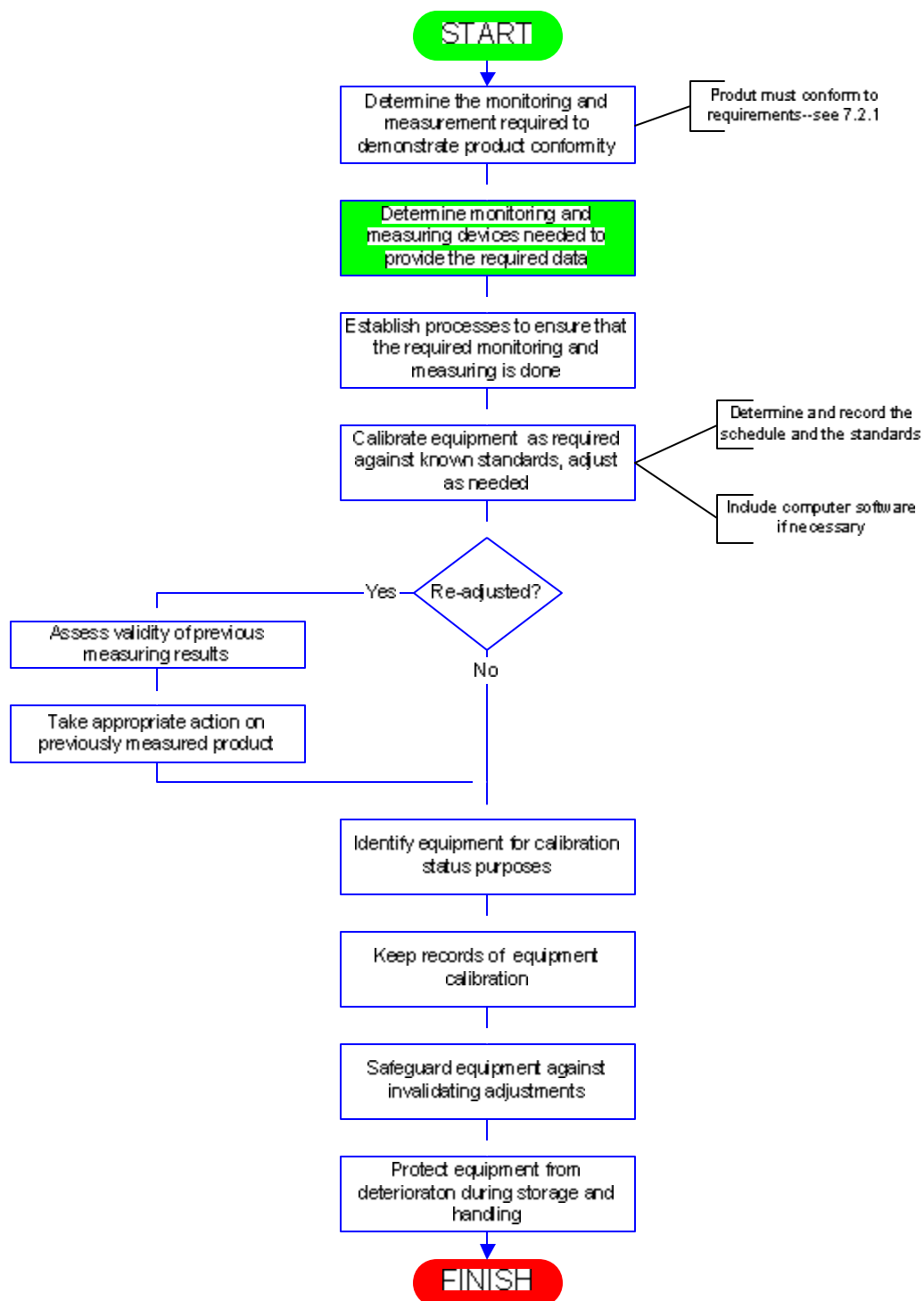
#### Management Summary:

- *For data confidence, measuring and monitoring processes should include confirmation that the device is fit for use, identifiable and maintained to suitable accuracy and accepted standards.*

Section 7

## Product Realization

### 7.6 Control of Monitoring and Measuring Devices



# A Practical Field Guide for ISO 9001:2000



## ISO 9001:2000 X ISO 9001:1994 CROSS EVALUATION

1994 Clauses ( <i>across</i> ) x 2000 Sections ( <i>down</i> )	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	4.15	4.16	4.17	4.18	4.19	4.20
<b>7 Product realization</b>																				
7.1 Planning of product realization		4.2.3								4.10.1										
7.2 Customer-related processes																				
7.2.1 Determination of requirements related to the product			4.3.2	4.4.4																
7.2.2 Review of requirements related to the product			4.3.2/3/4																	
7.2.3 Customer communication			4.3.2																	
7.3 Design and development																				
7.3.1 Design and development planning				4.4.2/3																
7.3.2 Design and development inputs				4.4.4																
7.3.3 Design and development outputs				4.4.5																
7.3.4 Design and development review				4.4.6																
7.3.5 Design and development verification				4.4.7																

# A Practical Field Guide for ISO 9001:2000



<b>1994 Clauses (across) x 2000 Sections (down)</b>	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	4.15	4.16	4.17	4.18	4.19	4.20
7.3.6 Design and development validation				4.4.8																
7.3.7 Control of design and development changes				4.4.9																
7.4 Purchasing																				
7.4.1 Purchasing process						4.6.2														
7.4.2 Purchasing information						4.6.3														
7.4.3 Verification of purchased product						4.6.4				4.10.2										
7.5 Production and service provision																				
7.5.1 Control of production and service provision									4.9						4.15.6				4.19	
7.5.2 Validation of processes for production and service provision									4.9											
7.5.3 Identification and traceability								4.8		4.10.5		4.12								
7.5.4 Customer property							4.7													
7.5.5 Preservation of product															4.15.2/3/4/5					
7.6 Control of monitoring and measuring devices											4.11.1/2									

# A Practical Field Guide for ISO 9001:2000



## MEASUREMENT, ANALYSIS AND IMPROVEMENT SECTION 8

- 8.1 – General
- 8.2 – Monitoring and measurement
- 8.3 – Control of nonconforming product
- 8.4 – Analysis of data
- 8.5 – Improvement

# A Practical Field Guide for ISO 9001:2000



## *The Standard: 8.0 Measurement, analysis and improvement*

### **8.1, General**

*9001* ....The organization is to plan for, establish and improve processes to monitor measure and analyze its QMS and procedures, which must provide evidence that its products meet customer and other requirements, verify the QMS's effectiveness and use and achieve continual improvement of the QMS. This will require identification of what statistical and other techniques are needed and how much they need to be used.

*9004* ....Provides 11 topics to be evaluated in establishing measurement, analysis and improvement processes. Offers guidance on applying measurement to improve the organization's performance into the future and to assess the value of the measurements in meeting its needs.

*9000* ....Explores in 2.10, Role of Statistical Techniques, their use in understanding variability to help "improve effectiveness and efficiency".

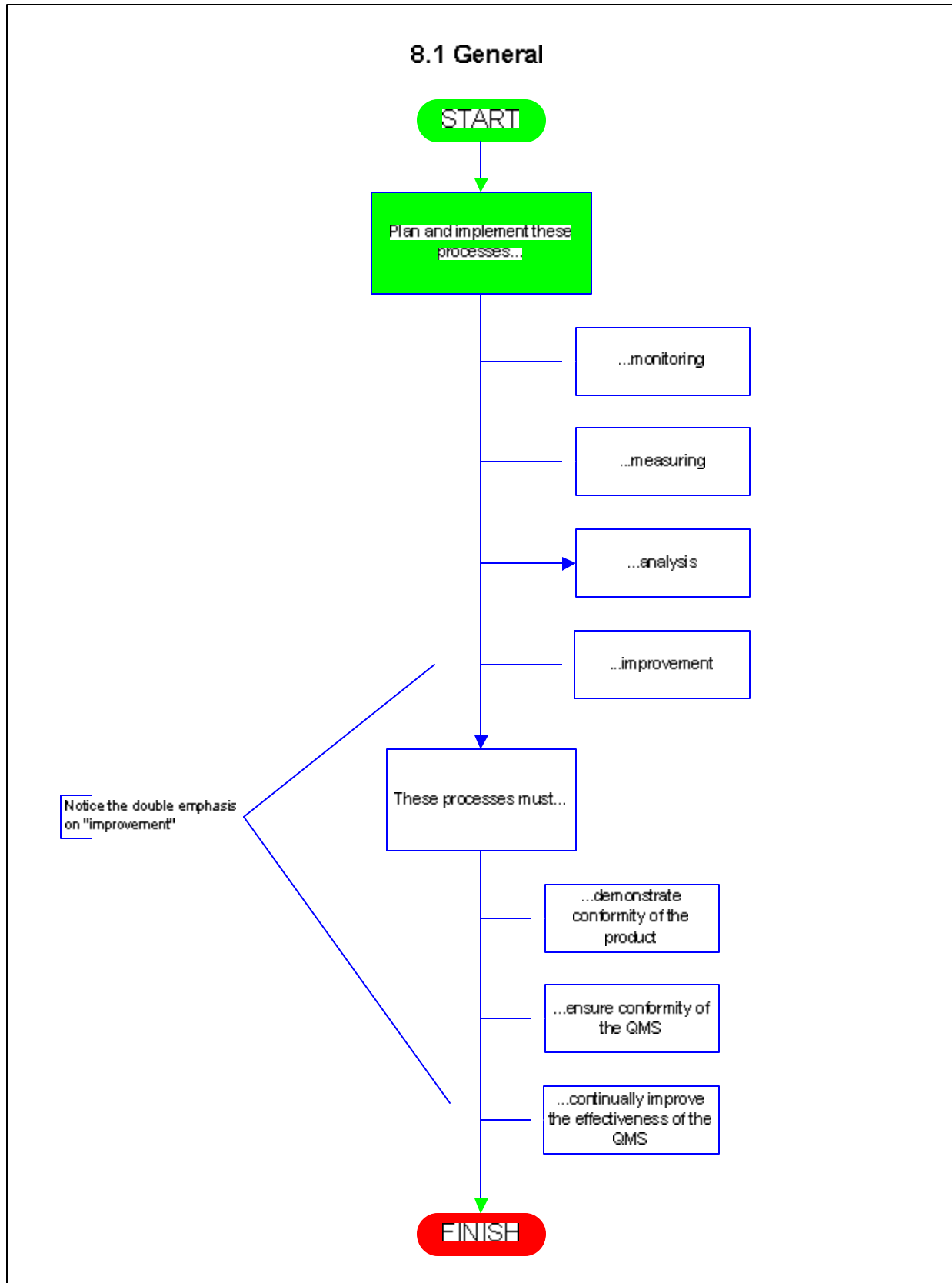
### *Document Requirements:*

### *Internal Audit Questions:*

- Is there objective evidence to demonstrate that the organization has defined, planned, and implemented the measurement and monitoring activities needed to assure conformity and to achieve improvement?
- Is there objective evidence to demonstrate that the organization has determined the need for and use of applicable methodologies including statistical techniques (i.e. specifications, procedures, work instructions, control plans, process sheets, etc.)?

### *Management Summary:*

- *Results of data analysis from improvement activities should be a management review input.*
- *Management should note that measurements of customer satisfaction are vital for evaluating the organization's performance.*



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 8.0 Measurement, analysis and improvement*

### **8.2 Monitoring and measurement**

#### 8.2.1, Customer Satisfaction

*9001* ....The organization must establish a program to collect, measure and take action on data regarding customer satisfaction.

*9004* ....Provides guidance on developing a system to measure customer satisfaction, including examples of available information relating to customers and their interaction with an organization and of sources of information on customer satisfaction.

*9000* ....Defines “customer satisfaction” in 3.1.4 as the customer’s perception of how well its “requirements have been fulfilled”.

### *Document Requirements:*

### *Internal Audit Questions:*

- Are customer satisfaction and/or customer dissatisfaction information monitored?
- Are methods for gathering and using customer information determined and deployed throughout the organization?
- Has the customer information been processed in a way to provide quantifiable data and trends?

### *Management Summary:*

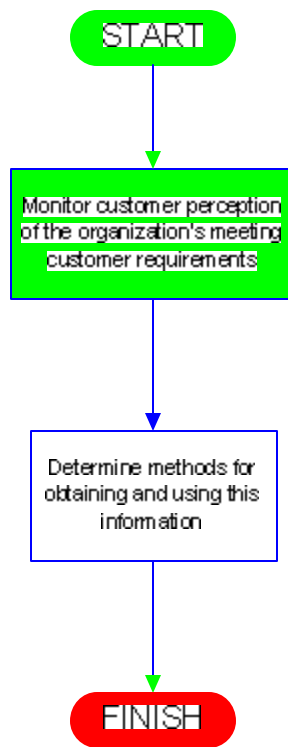
- *The organization should use customer feedback to plan processes that listen effectively and efficiently to the “voice of the customer.”*

*The organization should identify sources of customer and end-user information (from internal and external sources) such as:*

- *customer complaints*
- *direct communication with customers*
- *questionnaires and surveys*
- *focus groups*
- *consumer reports*
- *various media reports*
- *sector and industry studies*

## 8.2 Monitoring and Measurement

### 8.2.1 Customer Satisfaction



# A Practical Field Guide for ISO 9001:2000



## The Standard: 8.0 Measurement, analysis and improvement

### 8.2 Monitoring and measurement

#### 8.2.2, Internal Audit

**9001**.....A documented internal audit program must be established to assess the QMS's effectiveness in meeting the requirements of ISO 9001 and any other requirements the organization has specified for its QMS and that its QMS is functioning and is being conformed to by employees in the course of organizational activities. The organization must plan out and conduct audits of each process, procedure and area frequently and thoroughly enough to ensure the system's effective operation. Auditors must be capable of accurately assessing the areas they audit. Management for an area where nonconformity is identified is responsible for ensuring prompt and effective corrective action is taken, with the internal auditors responsible for verifying that the action eliminates the nonconformity and its causes.

**9004**.....Provides guidance on the purpose and management of internal audits and emphasizes the need for top management to take action to improve the QMS in response to internal audit findings. Offers 11 examples of topics to be examined in internal audits.

**9000**.....Defines 14 terms in 3.9, Terms Relating to Audit, although it is noted that most of these terms and definitions are subject to change when ISO 19011, which will provide a single QMS and EMS auditing guidelines standard, is published. Explores role and types of audits in 2.8.2, Auditing the Quality Management System.

#### Document Requirements:

- Documented procedure
- Record

#### Internal Audit Questions:

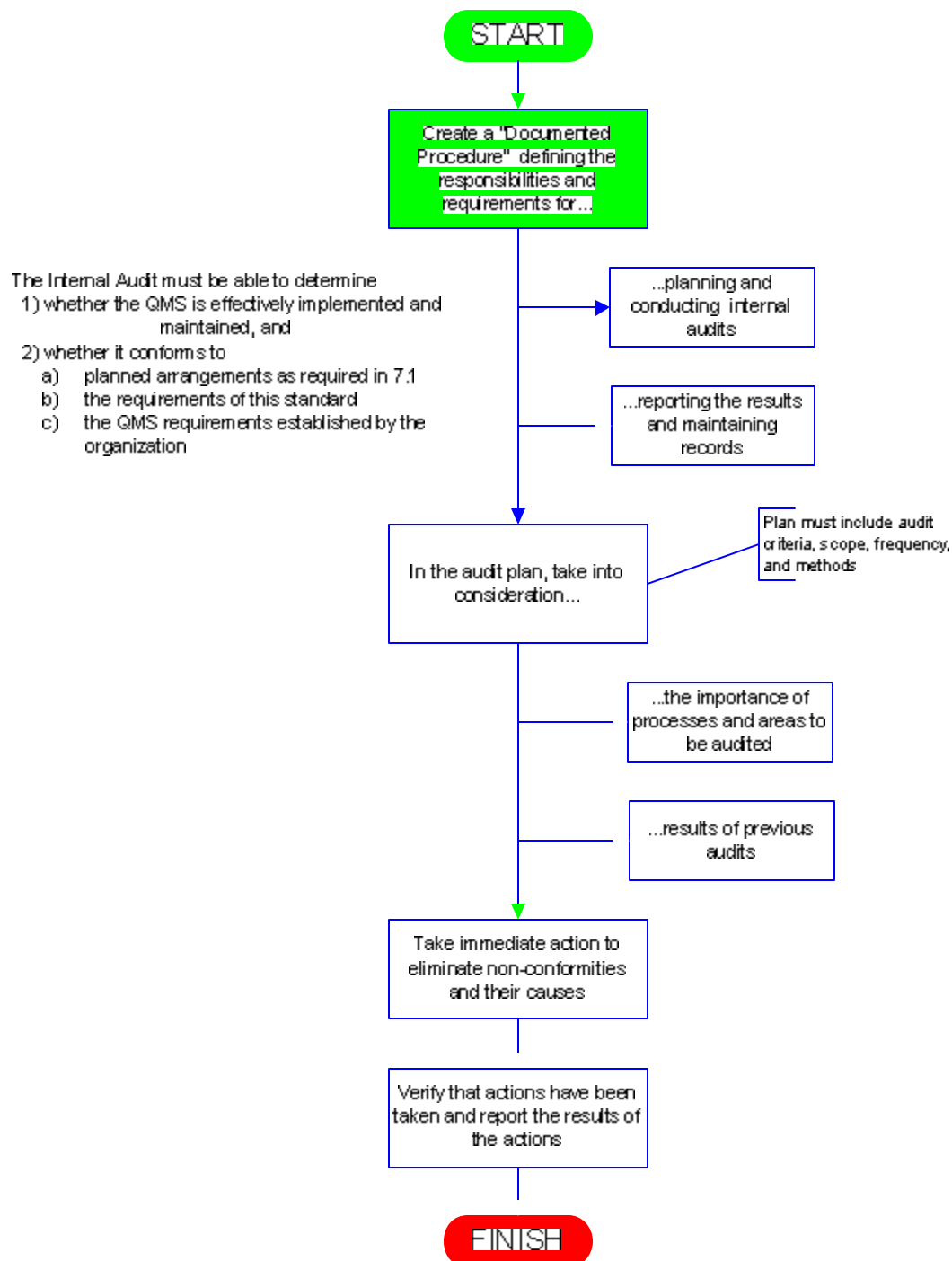
- Does the organization conduct periodic audits of the Quality Management System?
- Do the periodic audits evaluate the conformity of the Quality Management System to the requirements of ISO 9001:2000?
- Do the periodic audits evaluate the degree to which the Quality Management System has been effectively implemented and maintained?
- When planning the audit program, does the organization consider the status and importance of areas to be audited, and results of previous audits?
- Are the methodologies, audit scope, and frequency defined?
- Do personnel other than those who perform the activity being audited perform the audits?
- Is there a documented procedure that includes the responsibilities and requirements for conducting audits?
- Is there a documented procedure that describes how to ensure the independence of auditors?
- Is there a documented procedure for recording results and reporting to management?
- Does management take timely corrective action on deficiencies found during the audit?
- Do follow-up actions include the verification of the implementation of corrective action?
- Do follow-up actions include the reporting of verification results?

#### Management Summary:

- *The internal audit process is a management tool for independent assessment of a process or activity.*
- *Planning for internal audits should be flexible in order to allow changes in emphasis based on findings and objective evidence found during the audit.*
- *Management should provide opportunities for recognition of areas that achieve excellent performance during an internal audit.*

## 8.2 Monitoring and Measurement

### 8.2.2 Internal Audit



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 8.0 Measurement, analysis and improvement*

### **8.2 Monitoring and measurement**

#### 8.2.3, Monitoring and Measurement Processes

*9001* ....QMS processes must be monitored and measured to the degree necessary to ensure the processes produce conforming product and achieve expected outcomes, with corrective actions to be taken when the processes do not produce expected outcomes.

*9004* ....Provides guidance on the use and advantages of self-assessments (including Annex A, Guidelines for Self-Assessment) to improve performance and on the use of QMS information to measure financial performance. Recommends measuring process performance and includes examples of performance aspects that can be measured.

*9000* ....Explores in 2.8.1, Evaluating Processes Within the Quality Management System, the questions to be addressed in evaluating a QMS.

#### *Document Requirements:*

#### *Internal Audit Questions:*

- Has the organization identified the key realization processes necessary to meet customer requirements?
- Has the organization employed suitable methods to measure and monitor key realization processes?
- Are the intended purposes of the key realization processes quantified by process parameter specifications, by specifications for the product output of the process, or by some other means?
- Is the measurement and monitoring methods for realization processes adequate for confirming the continuing suitability of each process to satisfy its intended purpose?

#### *Management Summary:*

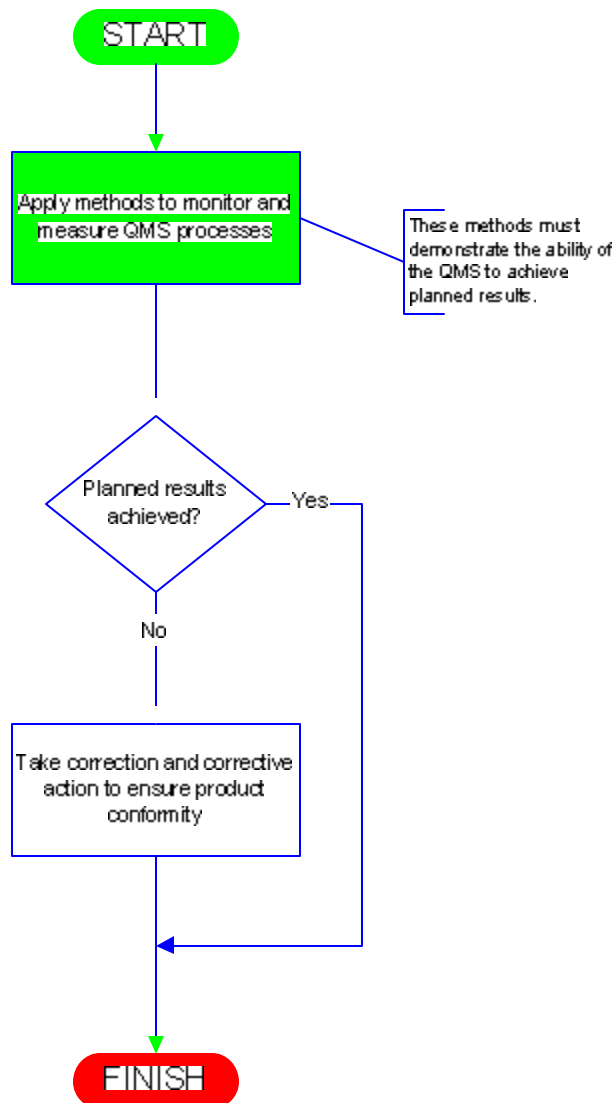
- *The organization should incorporate measurements of process performance into processes and use the measurements in process management.*

*Measurements of process performance include:*

- *cycle time or throughput*
- *dependability*
- *yield*
- *technology utilization*
- *waste reduction*
- *cost allocation and reduction*

## 8.2 Monitoring and Measurement

### 8.2.3 Monitoring and Measurement of Processes



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 8.0 Measurement, analysis and improvement*

### **8.2 Monitoring and measurement**

#### 8.2.4, Monitoring and Measurement of Product

*9001* ....The organization must engage in monitoring and measurement activities throughout its production processes to verify that product conforms to customer and other requirements, “maintain” its evidence of conformance and treat documentation identifying who is responsible for a product’s release as quality records. A product must not be released until monitoring and measurement indicate the product conforms to requirements unless the employee responsible for its release authorizes the release beforehand—and the action is acceptable to the customer. The same requirements apply to service delivery.

*9004* ....Recommends using product measurement to improve production processes. Offers 10 aspects and elements of the measurement process that should be considered in selecting measurement methods and 4 examples of measurement records to be kept.

*9000* ....Defines “release” in 3.6.9 as “permission to proceed to the next stage of a process”.

#### *Document Requirements:*

- Record

#### *Internal Audit Questions:*

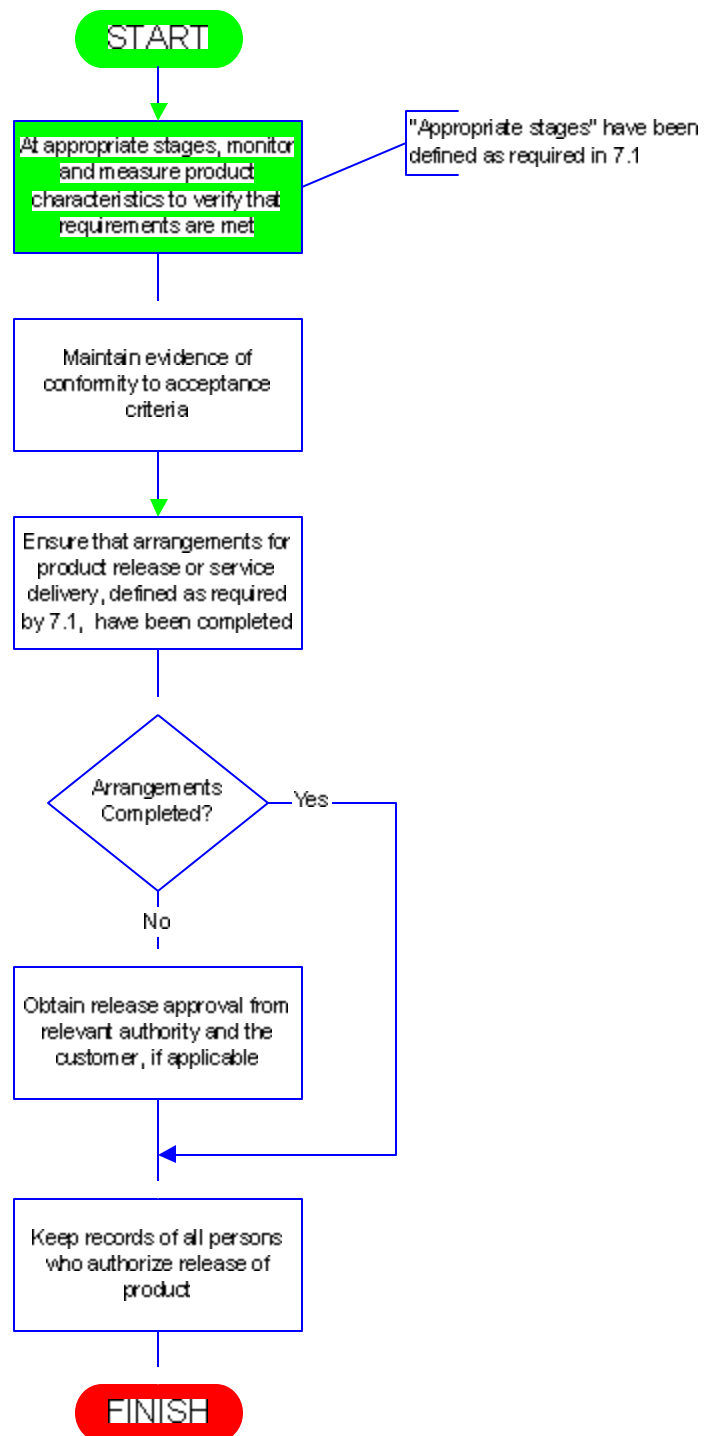
- Do the organization measure and monitor product characteristics to verify that product requirements are met?
- Do the organization measure and monitor product characteristics at appropriate stages of the product-realization process?
- Is there objective evidence that acceptance criteria for product have been met?
- Is there identification of the authority responsible for release of the product?
- Are all specified activities performed prior to product release and service delivery?
- When specified activities have not been performed prior to product release or service delivery, is the customer informed?
- Has the customer approved of the action?

#### *Management Summary:*

- *The organization should review the methods used for measuring products and verification records, to improve performance.*

## 8.2 Monitoring and Measurement

### 8.2.4 Monitoring and Measurement of Product



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 8.0 Measurement, analysis and improvement*

### **8.3, Control of Nonconforming Product**

*9001* ....The organization must prevent unintended delivery or use of nonconforming product, with documentation of the processes to be followed and the authorities responsible for identifying, controlling and disposing of nonconforming product. The organization must correct nonconformity, offer the product on an “as is” basis or scrap it, with information on the nonconformity and the product’s disposition to be treated as a quality record. Corrected product must be re-evaluated to ensure the nonconformity has been eliminated, and the organization is responsible for resolving known or potential nonconformities that arise after a product is delivered or in use.

*9004* ....Examines how top management can establish procedures to deal with nonconforming product that will not only prevent unintended use, but will provide feedback to the organization for quality planning and process improvement.

*9000* ....Defines terms relating to the disposition of nonconforming product in 3.6.8, Release, 3.6.10, Repair, 3.6.11, Rework, 3.6.12, Re-grade, and 3.6.13, Scrap.

#### *Document Requirements:*

- Documented procedure
- Record

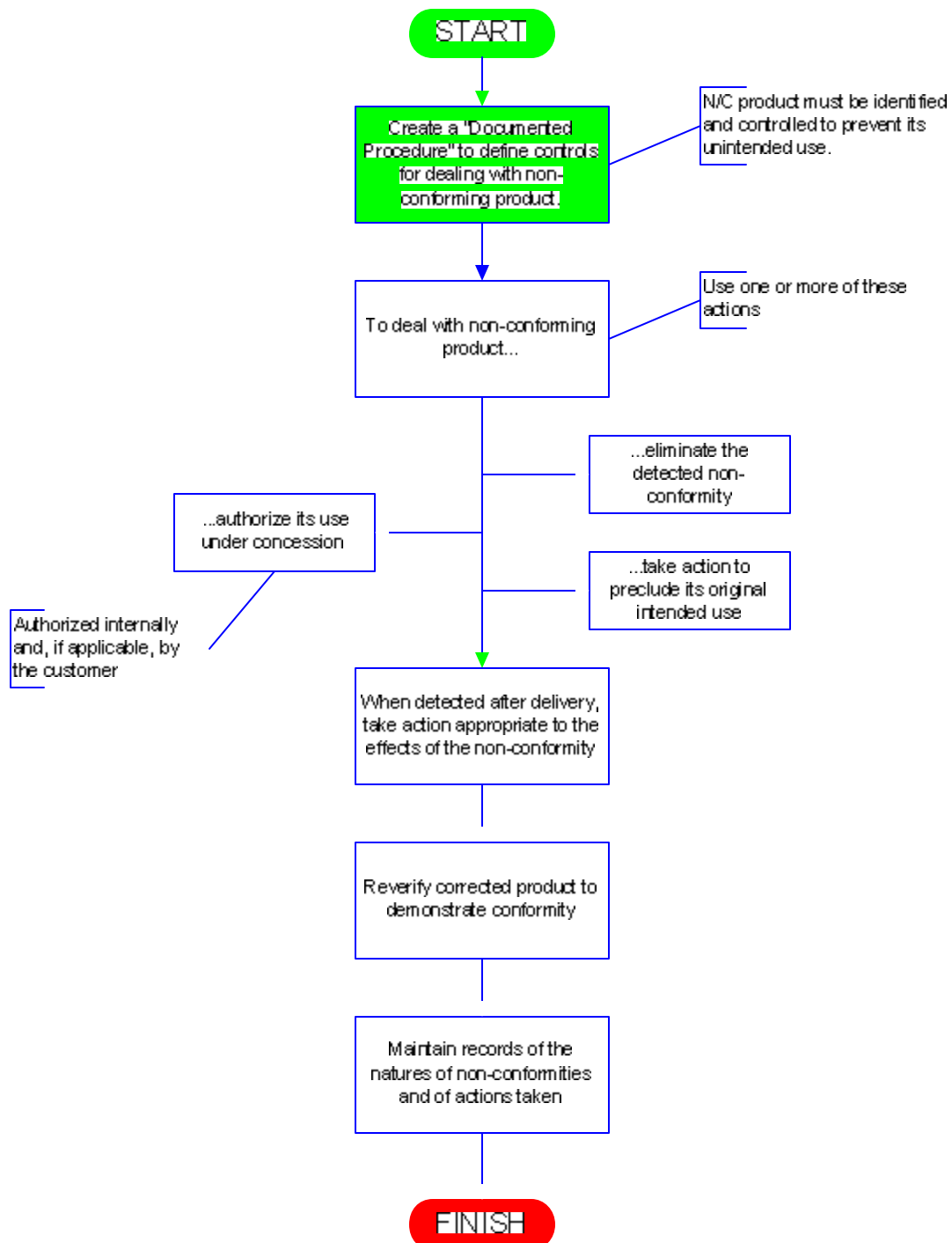
#### *Internal Audit Questions:*

- Is there a documented procedure to assure that product that does not conform to requirements is identified and controlled to prevent unintended use or delivery?
- Is there evidence of appropriate action being taken when nonconforming product has been detected after delivery or use has started?
- Is it required that any proposed rectification of nonconforming product be reported for concession to the customer, the end-user, or a regulatory body?
- Is there objective evidence of appropriate communication with a customer when the organization proposes rectification of nonconforming product?

#### *Management Summary:*

- *To provide analysis data and improvement activities, the organization should record nonconformities to both product realization and support processes.*
- *During reviews of nonconformities, negative trends should be considered for improvement as well as input to management review for consideration.*
- *Acceptance of nonconformity disposition may be a contractual requirement of the customer.*

## 8.3 Control of Non-Conforming Product



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 8.0 Measurement, analysis and improvement*

### **8.4, Analysis of Data**

*9001* ....The organization must use data from its monitoring and measuring activities and other sources to verify that the QMS is appropriate to the organization's needs and effectively conforms to ISO 9001 and other requirements and to identify opportunities for improvement of the QMS. It requires the resulting analysis to provide data on four subjects relating to the QMS and the organization's products.

*9004* ....Stresses the value of fact-based measurements and of identifying root causes of problems. Identifies nine purposes to which analysis can be put.

### *Document Requirements:*

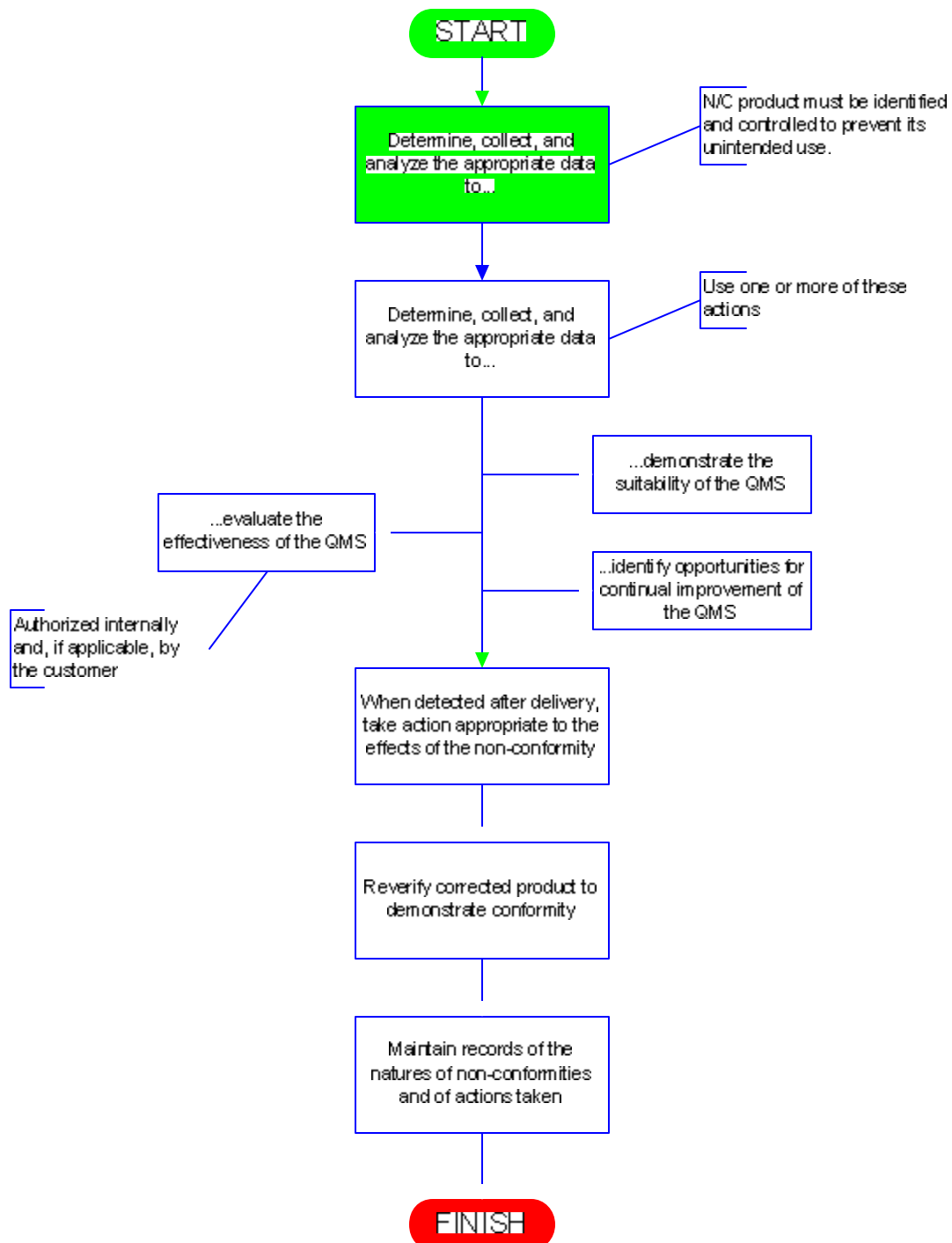
### *Internal Audit Questions:*

- Has the organization determined the appropriate data to be collected to determine the effectiveness of the Quality Management System and where improvements can be made?
- Does the organization analyze appropriate data to determine the suitability and effectiveness of the Quality Management System and improvements that can be made?
- Does the organization analyze appropriate data to provide information on customer satisfaction and/or dissatisfaction and conformance to customer requirements?
- Does the organization analyze appropriate data to provide information on characteristics of processes, product, and their trends?
- Does the organization analyze appropriate data to provide information on suppliers?

### *Management Summary:*

- *The organization should analyze data to assess performance against plans, objectives, and defined goals and to identify areas for improvement.*

## 8.4 Analysis of Data



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 8.0 Measurement, analysis and improvement*

### **8.5 Improvement**

#### 8.5.1, Continual Improvement

*9001* ....The organization is required to use seven specified QMS elements/processes, all required by ISO 9001, to “continually improve the effectiveness” of the QMS.

*9004* ....Explores the range of improvements management can pursue and encourages a proactive approach.

*9000* ....Defines “continual improvement” in 3.1.13 as “recurring activity to increase the ability to fulfill requirements” and explores in 2.9, Continual Improvement, the purpose of and actions that lead to continual improvement.

### *Document Requirements:*

### *Internal Audit Questions:*

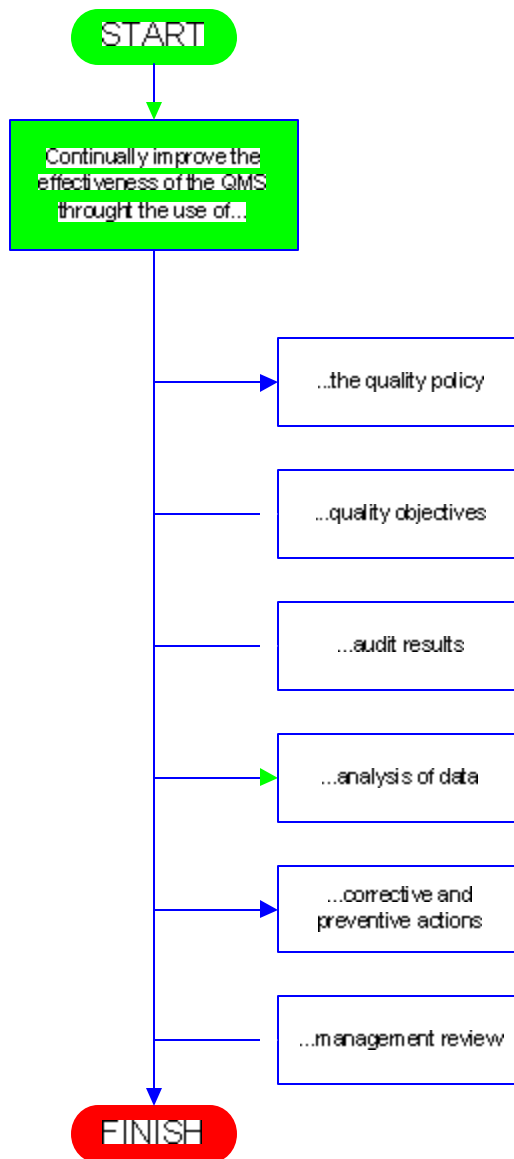
- Does the organization plan and manage processes necessary for continual improvement of the Quality Management System?
- Does the organization use the Quality Policy, Quality Objectives, and analysis of data to facilitate continual improvement of the Quality Management System?
- Does the organization use audit results, corrective action, and preventive action to facilitate continual improvement of the Quality Management System?
- Does the review of quality data result in action items designed to improve the Quality Management System (also see section 5.6.3)?

### *Management Summary:*

- *Top management should define and implement a process for continual improvement that can be applied to realization and support processes.*
- *Top management should create an environment that challenges people to seek opportunities for improvement of performance in processes, activities and products.*

## 8.5 Improvement

### 8.5.1 Continual Improvement



# A Practical Field Guide for ISO 9001:2000



## The Standard: 8.0 Measurement, analysis and improvement

### 8.5 Improvement

#### 8.5.2, Corrective Action

*9001* ....The organization must document the processes to be used to assess and correct nonconformities, eliminate their cause(s) to stop future nonconformities from the same cause and evaluate the effectiveness of the correction. Corrective action must be proportionate to the severity of the nonconformity, and documentation of corrective actions is to be treated as a quality record.

*9004* ....Provides guidance on planning for corrective actions and determining causes. Offers 10 examples of information resources that help define effective correction actions.

*9000* ....Defines “corrective action” in 3.6.5 as “action taken to eliminate the cause of a detected nonconformity or other undesirable situation” and notes that it is meant to prevent recurrence of nonconformity while preventive action is meant to avoid the possibility of a nonconformity ever occurring.

#### Document Requirements:

- Documented procedure
- Record (e)

#### Internal Audit Questions:

- Does the organization take corrective action to eliminate causes of nonconformities?
- Is corrective action taken appropriate to the impact of the problems encountered?
- Do corrective action procedures provide for identifying nonconformities, determining causes, evaluating need for actions to prevent recurrence, determining the corrective action needed, and implementation of the needed corrective action?
- Do corrective action procedures provide for recording the results of corrective actions taken?
- Do the preventive action documented procedures provide for reviewing the corrective action taken?

#### Management Summary:

- *Corrective action should be used as a tool for improvement.*
- *Corrective actions should be included in management review.*
- *The organization should incorporate root-cause analysis into the corrective-action process.*

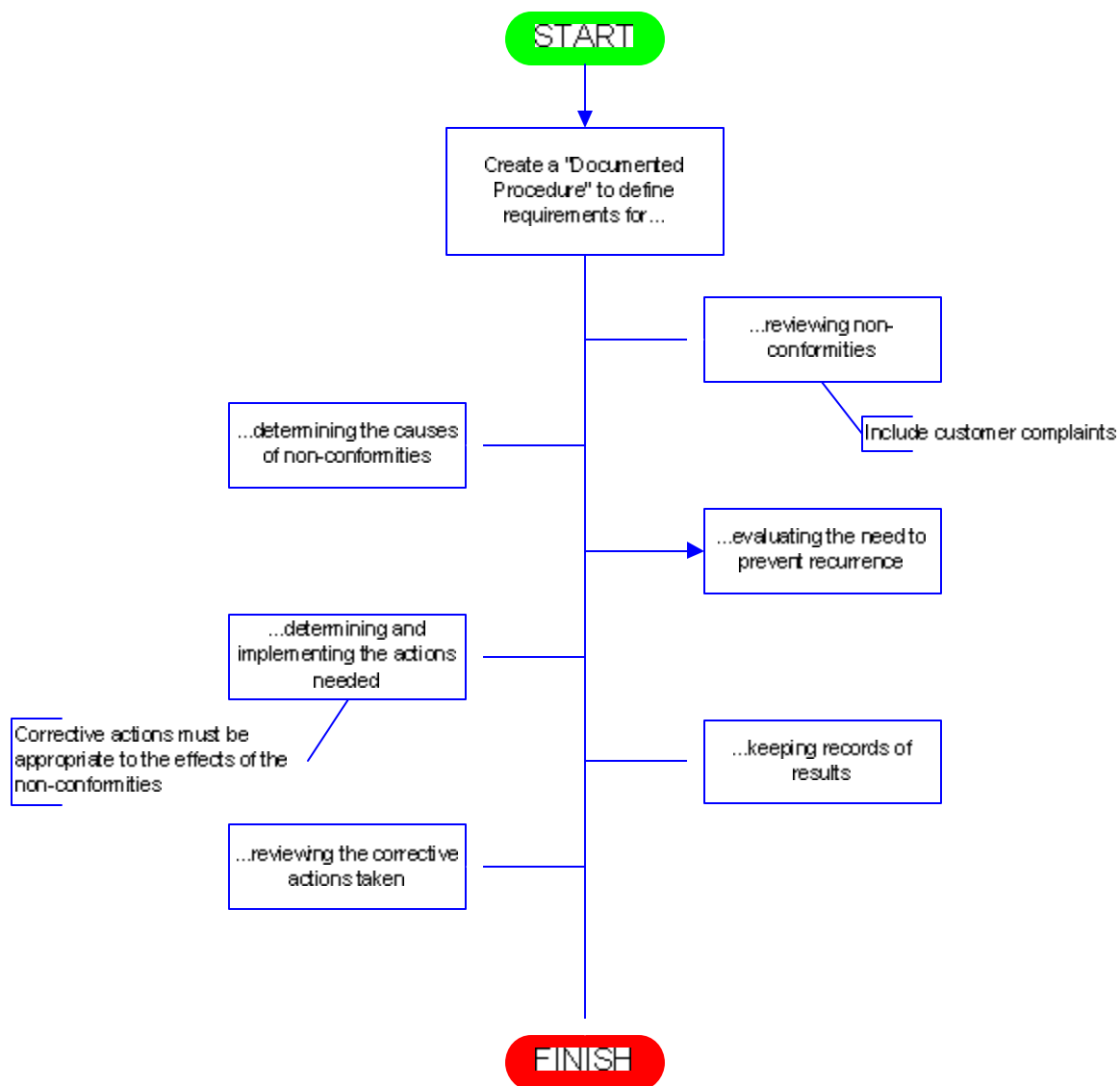
#### *Corrective action considerations include:*

- *customer complaints*
- *nonconformity reports*
- *internal audit reports*
- *management review outputs*

## 8.5 Improvement

### 8.5.2 Corrective Action

Corrective actions eliminate the causes of non-conformities to prevent recurrence



# A Practical Field Guide for ISO 9001:2000



## *The Standard: 8.0 Measurement, analysis and improvement*

### **8.5 Improvement**

#### 8.5.3, Preventive Action

*9001* ....The organization must document the processes to be used to prevent nonconformities from ever occurring by assessing and eliminating their potential causes, with action proportionate to the severity of a potential nonconformity, and evaluating the effectiveness of the actions. Documentation of preventive actions is to be treated as quality records.

*9004* ....Recommends “planning for loss prevention” and offers 12 sources for quantitative data to be used in the planning process.

#### *Document Requirements:*

- Documented procedure
- Record (d)

#### *Internal Audit Questions:*

- Does the organization identify preventive actions needed to eliminate the potential causes of possible nonconformities?
- Is preventive action taken appropriate to the impact of potential problems?
- Do the preventive action documented procedures provide for identifying potential nonconformities and their probable causes?
- Do the documented procedures for preventive action provide for determining the need for preventive action and implementation of the preventive action needed?
- Do the preventive action documented procedures provide for recording the results of the preventive actions taken?
- Do the documented procedures for preventive action provide for reviewing the preventive action taken?

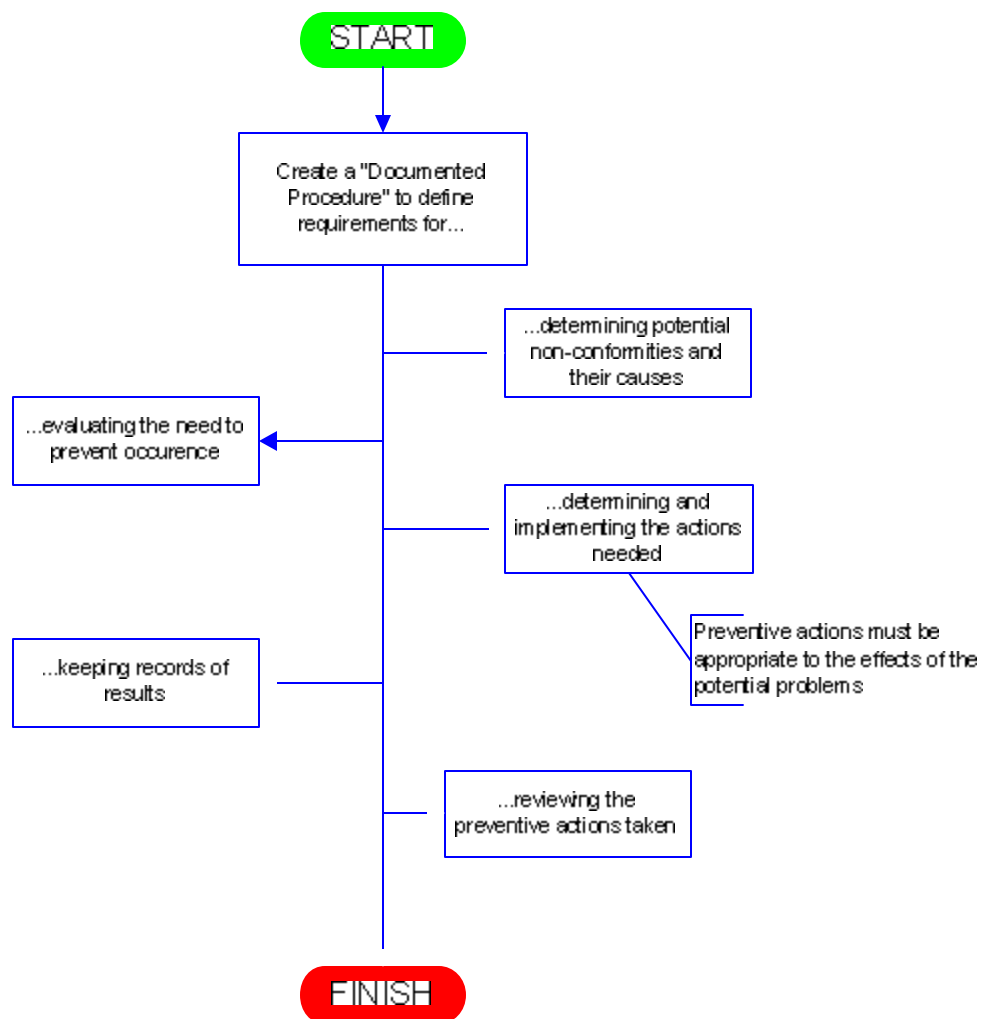
#### *Management Summary:*

- *The organization should develop a plan for loss prevention and apply it to realization and support processes, activities and products.*
- *Results of the evaluation of the loss prevention plan should be considered as an output for management review and should be used in the improvement processes.*

## 8.5 Improvement

### 8.5.3 Preventive Action

Preventive actions eliminate the causes of non-conformities before they occur



# A Practical Field Guide for ISO 9001:2000



## ISO 9001:2000 X ISO 9001:1994 CROSS EVALUATION

1994 Clauses ( <i>across</i> ) x 2000 Sections ( <i>down</i> )	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	4.10	4.11	4.12	4.13	4.14	4.15	4.16	4.17	4.18	4.19	4.20
<b>8 Measurement, analysis and improvement</b>																				
8.1 General										4.10.1										4.20.1/2
8.2 Monitoring and measurement																				
8.2.1 Customer satisfaction																				
8.2.2 Internal audit																	4.17			
8.2.3 Monitoring and measurement of processes																	4.17			4.20.1/2
8.2.4 Monitoring and measurement of product										4.10.2/3 /4/5										4.20.1/2
8.3 Control of nonconforming product													4.13.1/2							
8.4 Analysis of data																				4.20.1/2
8.5 Improvement																				
8.5.1 Continual improvement	4.1.3																			
8.5.2 Corrective action															4.14.1/2					
8.5.3 Preventive action														4.14.1/3						

# A Practical Field Guide for ISO 9001:2000



## ISO 9001:2000 DOCUMENTED REQUIREMENTS BY SECTION

<b>Sec</b>	<b>Title</b>	<b>Description</b>	<b>Type</b>
4.2.2	Quality manual	Quality manual	<b>M</b>
4.2.3	Control of documents	Documented procedure	<b>P</b>
4.2.4	Control of records	Documented procedure	<b>P</b>
8.2.2	Internal audit	Documented procedure	<b>P</b>
8.3	Control of nonconforming product	Documented procedure	<b>P</b>
8.5.2	Corrective action	Documented procedure	<b>P</b>
8.5.3	Preventive action	Documented procedure	<b>P</b>
5.6.1	General	Management reviews	<b>R</b>
6.2.2(e)	Competence, awareness, and training	Employee skills	<b>R</b>
7.1(d)	Planning of product realization	Product fulfillment	<b>R</b>
7.2.2	Review of requirements related to the product	Requirements review	<b>R</b>
7.3.2	Design and development inputs	Design inputs	<b>R</b>
7.3.4	Design and development review	Design reviews	<b>R</b>
7.3.5	Design and development verification	Design verification	<b>R</b>
7.3.6	Design and development validation	Design validation	<b>R</b>
7.3.7	Control of design and development changes	Design changes	<b>R</b>
7.4.1	Purchasing process	Supplier evaluation	<b>R</b>
7.5.2(d)	Validation of processes for production and service provision	Process validation	<b>R</b>
7.5.3	Identification and traceability	Product identification	<b>R</b>
7.5.4	Customer property	Customer product review	<b>R</b>
7.6 (a)	Control of monitoring and measuring devices	Calibration standards	<b>R</b>
7.6	Control of monitoring and measuring devices	Previous results	<b>R</b>
7.6	Control of monitoring and measuring devices	Results of calibration	<b>R</b>
8.2.2	Internal audit	Audit results	<b>R</b>
8.2.4	Monitoring and measurement of product	Product conformance	<b>R</b>
8.3	Control of nonconforming product	Nonconforming nature	<b>R</b>
8.5.2(e)	Corrective action	Corrective action results	<b>R</b>
8.5.3(d)	Preventive action	Preventive action taken	<b>R</b>

**Legend: M = manual / P = procedure / R = record**

# A Practical Field Guide for ISO 9001:2000



## SOURCES OF INFORMATION

- ISO 9000:2000
  - *Quality Management Systems — Fundamentals and vocabulary*
- ISO 9001:2000
  - *Quality Management Systems — Requirements*
- ISO 9004:2000
  - *Quality Management Systems — Guidelines for performance improvements*
- ISO/TC 176/SC 2/N525
  - *Guidance on the Documentation Requirements of ISO 9001:2000*
- ISO/TC 176/SC 2/N474
  - *Transition Planning Guidance for ISO/DIS 9001:2000*
- *ISO 9001:2000 Explained (2<sup>nd</sup> Edition)*
  - Cianfrani, Tsiakals, and West – ASQ Quality Press
- *ISO 9000: 2000 New Requirements (3<sup>rd</sup> Edition)*
  - Kanholm – AQA Co.
- *ISO 9000 at the Front Line*
  - Levinson – ASQ Quality Press
- *ISO 9000:2000 In a Nutshell (2<sup>nd</sup> Edition)*
  - Ketola and Roberts – Paton Press
- Informational Web sites –
  - <http://www.iso.ch>
  - <http://www.qualitydigest.com>
  - <http://www.informintl.com/home/>
  - <http://www.qsuonline.com/>
  - <http://www.asq.org>
  - <http://www.moorhill.com>

# A Practical Field Guide for ISO 9001:2000

