

ISO 9001:2008 Requirements Explained - An Adobe PDF File for Use on a Network System

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* Clauses that require written documentation

ISO 9001:2008 - List of all requirement clauses [Numbered clauses are links in the actual document.](#) [Scroll to next page.](#)

Contents page for ALL personnel: Shaded clauses contain requirements that should be known by all personnel.

You may need to know additional requirements depending on the type of work that you do. Summary statements below may not contain all requirements of the clause.

4	Quality management system (title only)	This page has a summary statement of the content of each clause.
4.1	General requirements	identify processes, their sequence and interaction, resources needed, how processes are controlled, and monitor, measure, analyze and improve processes
4.2	Documentation requirements (title only)	
4.2.1	General	defines what should be included in quality management system documentation
4.2.2	Quality manual	defines requirements for the Quality Manual and what should be included
4.2.3	Control of documents	requirements for documents, documents must be kept current, and how to request a document change
4.2.4	Control of records	requirements for identification, storage, protection, retrieval, retention time and disposal of records
5	Management responsibility (title only)	
5.1	Management commitment	evidence mgt. committed to quality system, customer / legal requirements, and continual improvement
5.2	Customer focus	Top management must ensure that customer requirements are determined and are met
5.3	Quality policy	requirements for the quality policy, must commit to meet requirements and continually improve QMS
5.4	Planning (title only)	
5.4.1	Quality objectives	Top mgt. must ensure measurable quality objectives are established at relevant levels in the organization
5.4.2	Quality management system planning	use 4.1 requirements to plan processes & quality objectives, plan system changes
5.5	Responsibility, authority and communication (title only)	
5.5.1	Responsibility and authority	who is responsible for activities and who has authority to take what action must be known
5.5.2	Management representative	a member of mgt. is Mgt. Rep respon. for QMS; reports to Top Mgt. on performance & needs of QMS
5.5.3	Internal communication	Top Mgt. ensures communication processes of the QMS are established and effective
5.6	Management review (title only)	
5.6.1	General	Top mgt. must review quality system to determine if changes are needed to improve system effectiveness
5.6.2	Review input	review must include audit results, customer feedback, conformance of product and processes, status of actions, etc.
5.6.3	Review output	determine actions needed to achieve objectives, improve product and processes; allocate resources for actions
6	Resource management (title only)	
6.1	Provision of resources	processes must have the resources required to perform the work
6.2	Human resources (title only)	
6.2.1	General	people must be competent to do work based on education, training, skills and experience
6.2.2	Competence, training and awareness	determining competency requirements, providing and evaluating training, people must know the importance of their work and how they contribute to meeting quality objectives
6.3	Infrastructure	identify, supply and maintain buildings, work areas, and services needed to meet conformity to requirements
6.4	Work environment	manage work environment so conditions allow workers to meet product requirements
7	Product realization (title only)	
7.1	Planning of product realization	what must be included when planning for a specific project, contract or order
7.2	Customer-related processes (title only)	
7.2.1	Determination of requirements related to the product	determine all customer requirements related to the order or contract
7.2.2	Review of requirements related to the product	review requirements, clarify differences, confirm requirements when no document
7.2.3	Customer communication	establish effective communication with customers about product, amendments, feedback, and complaints
7.3	Design and development (title only)	
7.3.1	Design and development planning	plan stages, reviews, verification, validation, responsibilities, authorities, info. flows, updates
7.3.2	Design and development inputs	what should be considered when defining design requirements for a product or service
7.3.3	Design and development outputs	must meet input req., provide info. for purchasing, prod. and servicing, acceptance criteria, etc.
7.3.4	Design and development review	hold design reviews to ensure requirements met and to i.d. problems (incl. reps. from all functions)
7.3.5	Design and development verification	verify outputs meet input requirements, keep records of verif. results and necessary actions
7.3.6	Design and development validation	validate product meets use requirements before product delivered; keep validation records
7.3.7	Control of design and development changes	review of design changes must include effect on other parts and delivered product
7.4	Purchasing (title only)	
7.4.1	Purchasing process	purchased items must meet requirements, requirements for selection, evaluation and re-evaluation of suppliers
7.4.2	Purchasing information	requirements for submitting a request for purchased products or services
7.4.3	Verification of purchased product	ensure purchased product meets specified purchase requirements
7.5	Production and service provision (title only)	
7.5.1	Control of production and service provision	work performed under controlled conditions - work instructions avail. where needed
7.5.2	Validation of processes for production and service provision	establish your requirements for validating special processes
7.5.3	Identification and traceability	product must be identifiable throughout product realization, and inspection and test status known
7.5.4	Customer property	identify, verify, protect and safeguard customer property; report any unsuitable lost or damaged property
7.5.5	Preservation of product	preserve product - considerations for identification, handling, packaging, storage, and protection
7.6	Control of monitoring and measuring equipment	determine measurements required; calibrate and verify measuring equipment
8	Measurement, analysis and improvement (title only)	
8.1	General	identify monitoring, meas., analysis and improvement processes needed to meet requirements, & control & improve the QMS
8.2	Monitoring and measurement (title only)	
8.2.1	Customer satisfaction	monitor information related to customer satisfaction
8.2.2	Internal audit	audit product/service plans and the organization's documentation; take corrective action on nonconformities
8.2.3	Monitoring and measurement of processes	monitor, and where appropriate, measure processes - take action and corrective action when planned results are not achieved
8.2.4	Monitoring and measurement of product	monitor and measure product at appropriate stages to verify requirements are met
8.3	Control of nonconforming product	identify, segregate and determine what will be done with nonconforming product
8.4	Analysis of data	collect and analyze data and information to demonstrate system effectiveness and where to improve system
8.5	Improvement (title only)	
8.5.1	Continual improvement	identify where improvements can be made to the quality management system
8.5.2	Corrective action	review/evaluate nonconformities, determine if action needed, plan action, implement, record results on CPAR form
8.5.3	Preventive action	determine action to eliminate potential nonconformities; actions must be appropriate to effects of potential problems

Best viewed at 87%

5.6 Management review	Comply	
	Y	N
<p>5.6.1 General</p> <p>Top management must review the quality management system, at planned intervals, to ensure it remains suitable, adequate and effective. The review must include evaluating opportunities for improvement and whether changes are needed to the quality management system, the quality policy, and quality objectives.</p> <p>Records from management reviews must be kept as described in clause 4.2.4.</p> <p>5.6.2 Review input</p> <p>The input to management review must include the following material:</p> <ul style="list-style-type: none"> a) results of audits, b) feedback from customers, c) information on conformity of product to requirements and process performance, d) status of preventative action and corrective action efforts, e) follow-up report on actions from any prior management reviews, f) changes that could have an affect on the quality management system, and g) recommendations for improvement. <p>5.6.3 Review output</p> <p>The output from the management review must include written records of any decisions and actions related to</p> <ul style="list-style-type: none"> a) improvement of the effectiveness of the quality management system and the processes that make up the system, b) improvement of the product and service related to customer requirements, and c) resource needs. 		

Text of ANSI/ISO/ASQ Q9001-2008 paraphrased with permission of the American Society for Quality.

[Next clause](#)

Guidance

Documents related to this clause

[Click on blue text](#) to view illustration documents. Other documents, forms and methods may be used.

Links to sample documents are not active here. You may view these samples from the product web page.

Action Number Form — This form is used to list items that are identified for possible action during the management review meeting.

This chart is located in **Directory:** Mgt review forms/ file: action number form.doc

Management Review Result Chart — All potential actions are listed on this Excel® chart as they are discussed during management review. A priority is assigned to each item. Items selected for action become improvement objectives for the organization.

This chart is located in **Directory:** Mgt review forms/ file: mgt review result chart.xls

Opportunities Log — Items not selected for action are placed in the Opportunities Log for future consideration when resources can be made available.

The Opportunities Log is located in **Directory:** Opportunities Log/ file: 1 opportunities log.xls

Instructions for the Opportunities Log are located in **Directory:** Opportunities Log/ file: 1 opportunities log instructions.xls

5.6 Management review

5.6.1 General

The standard requires that

top management review the quality management system, at planned intervals, to ensure it remains suitable, adequate and effective.

It is the ongoing responsibility of top management to review the quality management system to ensure the system continues to be suitable, adequate and effective.

The definitions on the following chart indicate the basis for evaluating the performance of the management system:

The system is	
Suitable	when results are achieved in the best way (using the best methods and most efficient use of resources)
Adequate	when output meets requirements, standards, and regulations
Effective	when planned results are achieved

Basis for evaluating management system performance

Planned intervals

The quality management system must be reviewed at planned intervals. Planned intervals means that the time period between management reviews should be determined in advance. This allows performance to be measured on a regular basis and enables comparisons to be made. A written statement in the quality manual or a procedure will meet this requirement. For example: The ISO Management Representative schedules the management review meeting at least annually during the last quarter of the year.

At a minimum, the review should be held once a year. An interval of every 6 months is more common as organizations find they must remain responsive to customers, changes in the marketplace, and changes within the organization itself. Reviews can be held more frequently if circumstances indicate that an entire system review is needed more frequently.

Organizations that want to focus on "rapid performance improvement" identify all items that require improvement, assign a priority to each of these items, and improvement projects are implemented (sometimes several at one time) until the system is established as effective. A program of rapid performance improvement is often carried out when the system is first implemented.

Improvement projects can take longer than a month to complete. The status of improvement projects can be monitored during monthly management meetings or at a defined interval. An improvement project status review is not considered "Management Review," which is intended to be a high level review of the entire system. A report on the status of improvement projects and the results of completed projects is included in the minutes (the record) of the next scheduled Management Review meeting.

A management review does not have to be conducted in a single meeting. Several meetings can be held, each covering a part of the quality management system, or a part of the organization. As the goal of management review is to obtain an overall view of the system, these meetings should be held within a several day to several week timeframe.

A management review must be held prior to the organization's initial registration audit. Records from this meeting provide evidence that management review is an established and implemented process.

How the review process works

The review process measures the current performance of the product and the processes used to make the product against:

1. the commitments the organization makes in its quality policy, and
2. the objectives top management has set for the management system.

Meeting commitments made in the quality policy

Management review evaluates if the current performance of the organization meets the commitments made in the quality policy.

When the ISO 9001 standard is used, the organization's **quality policy** makes a commitment (at a minimum):

1. to meet requirements (customer requirements, requirements for the product, and any legal or regulatory requirements), and
2. to continually improve the quality management system.

The quality policy may make additional commitments.

The objectives top management has set for the organization

When using the ISO 9001 Standard, top management defines objectives for the product and for the processes that comprise the quality management system. There are two types of objectives that are set for the organization. The first type relates to the "standard" that is set for products and for processes. The second type of objectives are called "quality objectives." These objectives relate to improving the current level of performance of the organization's products and processes and other goals that are set for the organization.

Objectives for products and processes - the standard

The first type of objectives are those that define the "standard" for acceptable performance. For products, the objectives are to meet (or exceed) the requirements stated in the specification for the product. For processes, the organization's objectives are stated as what the process is expected to achieve.

Collectively, the requirements for the product and requirements for processes are the objectives (and the "standard") that must be met by the organization. Thus, a major focus of management review is to determine if the basic standard set for the organization is being met.

Quality objectives

Top management also defines "quality objectives." These objectives relate to improving the current level of performance for both products and processes. See clause 5.4.1 Quality objectives for a more detailed explanation of quality objectives.

Quality objectives can relate to:

1. improving the performance of products and processes that are not meeting requirements
2. improving current products or the development of new products
3. goals to improve process performance

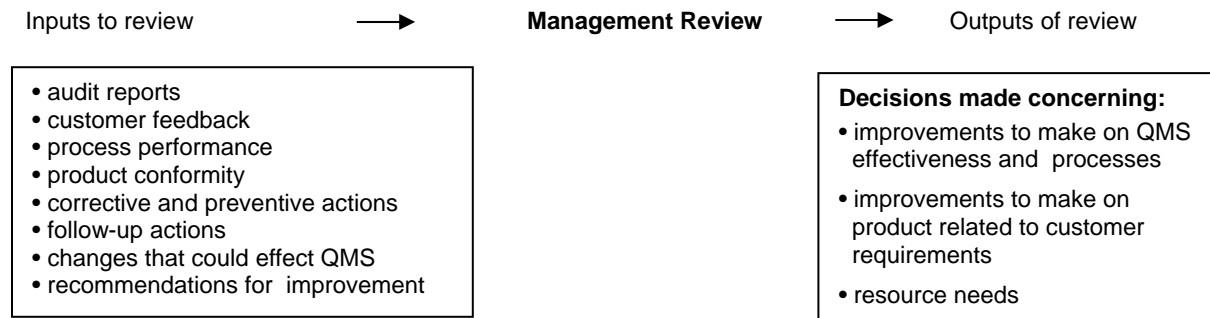
Where management review information comes from

Clause 8.4 of the Standard requires analysis of performance data. Management determines where and what methods to use to measure whether the requirements for the product are met, and whether processes are working effectively. Management determines who is responsible for the collection of performance data and who will analyze this data. Analysis results become the input for management review.

The review of current performance

Information on current performance and changes that could affect the organization are reviewed by members of top management. This provides an overall picture of the organization's present position that is based on factual information. It is likely that the overall picture has changed since the last review of the system. Based on the new "overall picture," top management determines what actions are needed to meet the commitments made in the quality policy and to meet the goals that management defines for the organization. Conditions in the marketplace are continually changing. Therefore, it is likely that new objectives are needed. These new objectives and the plans to achieve them are the output of the review.

The following graphic illustrates the management review process:



The ISO 9001:2008 Standard requires **review of the quality management system**. Though not required by the Standard, management review can be extended beyond verification of the processes that make up the quality management system and the requirements of the ISO standard. The review can be a review of the entire management system. A complete system review is of major significance because under-performance in any area of the system will be reflected in the financial performance of the organization. In addition, much of the data generated for the review of the quality management system also serves as input for 1) strategies and initiatives for marketing, 2) new product development, 3) loss prevention, 4) mitigation of identified risks, and 5) strategic planning for future needs of the organization.

Who participates in the management review process?

A review of the quality management system by top management typically includes the people who have the titles listed below. Those on this list may have more than one title. Your organization may also have a different name for the position.

Members of top management typically include:

Chief Executive Officer
 President
 Vice President(s)
 General Manager
 ISO Management Representative
 Quality Assurance Manager or Director
 Operations Manager or Director (or Manufacturing Manager)
 Human Resources Manager
 Sales/Marketing Manager

The Controller may be added to the attendee list. The Standard now requires that top management ensure that resources are provided for improvement activities, which involves financial considerations. Including the Controller in the review process also becomes more significant when the management review meeting is used for planning that relates to the entire management system and strategic planning for the organization.

Top management may include other managers in the review process.

The Management Representative prepares the agenda

It is the responsibility of the Management Representative to report to top management on the performance of the quality management system and any need for improvement. Thus, the Management Representative prepares the agenda for the review.

The agenda of topics to be discussed during a management review should be announced a week or more in advance so those contributing to the review will have time to prepare. Top management decides who will present the input to the review concerning each topic on the agenda.

Each process identified as part of the quality management system has a process owner who is responsible for managing the process and reporting on the performance of the process. Process owners who are not part of top management may be asked to attend the management review meeting to present analysis information related to the processes they own. Process owners may also be asked to submit a report to the member of top management to whom they report, or to the Management Representative.

The standard requires that the review

include evaluating opportunities for improvement and whether changes are needed to the quality management system, the quality policy, and quality objectives.

Evaluating opportunities for improvement

Management review is a review of the organization's current performance. A complete review of the system will find some situations where objectives are not being accomplished. These situations are opportunities for improvement.

Management review also includes reports about what the competition is doing, new marketing opportunities, reports about legislation, new standards, industry trends, new technology, and suggestions for improvement submitted by personnel. All of these may provide opportunities for improvement.

Rapid changes that occur in the marketplace and the changing needs of customers can result in a need to change the quality policy, the objectives of the organization and the processes designed to achieve them.

The standard requires that

records of management reviews must be kept as described in clause 4.2.4.

ISO 9000 defines a **record** as a document that provides evidence of activities performed or results achieved. The standard requires a written record of decisions and actions that are the results of the management review.

There should be a record of the results of management reviews for a number of reasons. A written record defines what actions were decided, who will carry them out, and the reasons the decisions were made. The record allows comparisons to be made to prior reviews to determine progress made on actions. The record also serves as evidence of system performance.

What should the record of a management review contain?

To be a complete record of the review, the review should contain:

1. The date of the review
2. The names and titles of those who attend the review
3. The organization's objectives. The effectiveness of the system is determined based on whether the organization's objectives are being achieved.
4. Evidence related to the current performance of the management system compared to objectives.
5. The criteria against which the management system is reviewed for continuing suitability—for example, possible future changes in customer requirements, legislation, standards, the organization, and markets
6. Evaluation of the management system—strengths, weaknesses, opportunities and possible threats

7. Conclusions - What changes should be made to improve system effectiveness?
8. Decisions that are made and actions that will be taken
9. Who will be responsible for actions, identification of resources required to implement actions, and the timeframe for when actions will be completed

5.6.2 Input to the review

The standard requires that the following input items must be included in the review:

a) Results of audits

Audit results should be used to determine if the system is performing properly and whether commitments made in the quality policy are being met. This can be determined by reviewing the results of all quality audits of the system, system processes, and products and comparing these results to the commitments made in the quality policy.

Audits can include all of the following types of audits that relate to the evaluation of the capability and performance of the quality management system:

1. internal audits of the quality management system
2. audits performed by an ISO 9001 registrar
3. audits performed by customers
4. audits by regulatory authorities
5. self-assessment audits performed by individual process owners

The organization may also perform audits of suppliers who provide products and services that affect the quality of the organization's products.

b) Feedback from customers

Feedback from customers should be used to establish if customer needs and expectations are being satisfied.

Feedback from customers can include customer survey data, customer complaints, product return rates, warranty claims, service defects, market share statistics, competitor statistics, lost customers and other possible types of feedback.

The results of customer feedback should be compared to the quality objectives that are set related to meeting customer needs and expectations.

c) Information on conformity of product to requirements and process performance

Information on conformity of product to requirements

Information related to **customer requirements for the product** (and customer expectations) may result from internal defect rate, customer complaints, customer reported safety concerns, product returns, and warranty repair rates.

Conformance of product to requirements

There are two types of product performance requirements—requirements for product characteristics, and requirements for the intended use or specified application for the product (i.e. what the product should achieve).

To determine if a specific product characteristic has been met, you compare performance data related to the product characteristic to how the characteristic is achieved in the design specification.

To determine if a use requirement has been met, you compare performance data related to the intended use requirement to how the requirement is achieved in the design specification.

Requirements for the product also include requirements for on-time delivery.

Information on process performance

You compare performance data on the current performance of processes to the objectives you have defined for the processes. A process meets its objectives when the overall objective for the process is achieved and the criteria for acceptable inputs and outputs have been achieved.

d) Status of corrective action and preventive action efforts

This relates to reviewing:

1. the amount of time required to close corrective and preventive actions,
2. the degree to which problems reoccur, and
3. determining whether the methods being used are effective in correcting and preventing problems.

e) Follow-up report on actions from any prior management reviews

The status and effectiveness of actions from prior reviews is reported during the management review. Actions that originate from management reviews are likely to fall into two categories — 1) corrective or preventive actions, and 2) projects.

The first category, **corrective or preventive actions**, uses the procedures established for corrective or preventive action. The person in charge of the audit program monitors actions for closure and effectiveness and reports on the status of these actions.

The second category of actions is **projects**. Some actions that result from management reviews are projects due to the scope of what is involved. Examples of projects include the development of a new product or service and the purchase and installation of new equipment or software. The person in charge of a project reports on the status of the project based on a schedule defined by the management team.

The report on actions from earlier management reviews should include:

1. Whether the action is open or closed
2. How effective the action was in achieving its objective

f) Changes that could have an affect on the quality management system

Changes that could affect the quality management system can include:

1. Planned changes in the organizational structure
2. New products and new processes
3. Planned changes in resources
4. Planned changes in infrastructure, including changes to the building, new equipment and its installation
5. New legislation and new standards
6. Customer requirements
7. Markets and what the competition is doing

g) Recommendations for improvement

Recommendations for improvement can relate to:

1. Improving the **effectiveness or the efficiency of processes**
2. Improvement by innovation (doing new things)
3. New marketing opportunities

5.6.3 Review output

The standard requires that

the output from the management review must include written records of any decisions and actions related to:

a) improvement of the effectiveness of the quality management system and the processes that make up the system

Clause 8.5.1 of the Standard requires continual improvement of the quality management system. A review of the system should result in determining where action should be taken to improve system processes. Actions to improve processes should improve the capability of the system to achieve the organization's objectives. Actions should focus on making beneficial changes that will result in a more effective and efficient organization.

b) improvement of the product or service related to customer requirements

Actions related to the improvement of products or services should relate to improving the extent to which the product conforms to customer requirements and expectations, and improvements to the product or service design.

It is important to note that there is no requirement to improve beyond the point where all customer requirements for the product are met. Clause 5.2 requires that top management "... ensure that customer requirements are determined and met with the aim of enhancing customer satisfaction" Thus, organizations will need to monitor the needs and expectations of customers to identify new customer requirements and take actions to meet them.

c) resource needs

Management ensures that resources are provided for the continual operation and improvement of the quality management system. The output of management review must identify the resources needed to carry out the actions that are identified for implementation. Resource allocation includes identifying who will be involved in implementing an action, the approximate time required for the tasks involved, and identifying any additional resources that are needed. No work should begin without adequate resources being available.

Few organizations have unlimited resources. Thus, it is often necessary to assign a priority to the items on a list of proposed actions and to initiate actions when resources are available to carry them out.

The output record should indicate changes that are needed to the quality management system, and if any changes are needed to the quality policy and to quality objectives.

System for conducting Management Review

This product contains a system for conducting the management review meeting and creating a review output record. An Action Number Form is completed for each identified potential action and opportunity for improvement as the meeting takes place. Each item is assigned a number, a priority and a Goal classification. An Excel® chart is used to list all the potential actions discussed (see chart below). Sorts are performed to assist in selecting items for action based on priority and the resources that can be made available to achieve the organization's objectives.

Items selected for action are assigned a CPAR# and are entered into the Corrective Preventive Action Request Log. The person identified as the Action Owner develops the plan to implement the action. All identified actions and items not selected for action are listed in the Opportunities Log to provide an overall record of the Management Review process. Items not selected for action may be selected at a future date when resources can be made available.

The following chart shows the headings that appear in the Opportunities Log database:

Review Result Chart: * This information is entered as the review takes place.

Column 1 Goal Key: \$ = more profit/ or reduce cost, CS = customer satisfaction,

Q = meet quality requirements, OT= On time delivery, CI = Continual improvement

Goal: \$ CS, Q, OT, CI	Priority 1-10	CPAR#/ Project	Op Log Action No.	Assigned to/ Last name	Due date	Action description <i>(Continue typing if more than 1 line is needed)</i>
*	*		*	*		*

Above: **Headings that appear on the Opportunities Log database.**

Audit: 5.6 Management review

Audit: 5.6.1 General

Verify that there is a management review procedure or process and that top management reviews the quality management system at planned intervals to determine if changes are needed to:

- the quality management system
- quality policy, and
- quality objectives.

Audit: 5.6.2 Review input

Do records indicate that management reviews include information concerning:

- a) results of audits
- b) feedback from customers
- c) information on conformity of product to requirements and process performance
- d) the status of preventive action and corrective action efforts
- e) a follow-up report on actions from any previous management reviews
- f) changes that could have an affect on the quality management system, and
- g) recommendations for improvement?

Audit: 5.6.3 Review output

- 1. Do management review records contain the decisions and actions that result from the review?
- 2. Does review output include actions related to the improvement of the quality management system and its processes?
- 3. Does review output include actions related to the improvement of the product or service related to customer requirements?
- 4. Does the output of management reviews include resource needs?

The written explanation of the standard is part of the "Auditor Training Course and Forms" available on this web site. It is also available as a separate purchase as an Adobe PDF file (for your network system) and in hard copy.

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