

SELF ASSESSMENT GUIDE

Standard based		
Self Assessment date and duration:		
Company Name:		
Street / P.O. box:		
Zip code / city:		
Self Assessment Performed By:		
Site / branch office/division		actual number of employees

Remarks on how to use

the self assessment question list / topic list:

1. There are no basic changes as far as the handling of the audit question list is concerned.
 - In the column with the heading "**Requirement / topic**" the relevant requirements of the standard are reproduced in the form of key words rather than in fully formulated questions.
 - Relevant documentation (Quality Manual section no., Procedure no. and section, etc.) is entered in the "**Documentation**" column; evaluation is effected in the adjacent column, "E".
 - In the column with the heading "**Documents reviewed**" you find potential documents or records that might be presented by the company. Only documents that have really been submitted by the company or evidence of which has been provided in another way (e.g. database) are to be ticked. If evidence is provided by means of other documents, these other documents or records shall be recorded either in the "Documents reviewed" or "Audit notes" columns. In general, additional information such as date, order no. customer, design and development project, product, identification no. of inspection, measuring and test equipment etc. is to be provided in as far as applicable and expedient in connection with evidence of reviewed documentation.
 - The "**Audit notes**," column is to be used as hitherto. (short description of the performance) Evaluations are entered in the adjacent column "E". If all sub-points of a question block have been complied with, an overall evaluation of "1" will suffice. If sub-points have not been complied with or are only complied with to some extent, they must be identified separately by an evaluation score of "2" or "3" in the column "E".
2. The audit question list must be completed **separately for each audit**, i.e. a new list must be used for surveillance and repeat audits. Each relevant element and question must be scored and filled out completely.
3. As a rule, a **separate question list** for pertinent process elements must be kept for **each site** of multi-site companies.

E: Evaluation: 1 = conformance 2 = observation 3 = nonconformance n.a.: not applicable
4. **Evaluation** is as hitherto, with 1 = conformance, 2 = observation (minor issue for which the relevant corrective action will be verified in the next audit), 3 = nonconformity
5. The "**Documentation**" column must only be completed in cases involving initial evaluation; in subsequent audits, this column must only be completed in cases involving amendments/additions.
6. Column headings are only quoted on the first page.

7. The numbers in brackets shows the elements of ISO 9001:1994
8. Text marked with “~” shows the additional requirements of the ISO 9001:2000 against the requirements of the ISO 9001:1994. Therefore the self-assessment question list (topic list) also can be used for self-assessments acc. to ISO 9001:1994. The relevant standard must be marked on the cover sheet.

Document Review:

The need for documentation still exists ! As before, there is a column to include document references and notes made during the formal documentation review process. Include the rating number of 1, 2, or 3 for each sub-clause of ISO 9001:2000 in the appropriate column. However, a lack of a procedure may not be a deficiency. In the Document Review Report use wording that indicates what is not clear. For example, *“It is not clear that the organization ensures that discrepancies between quotations and customer orders are resolved”*.

The level and/or type of documentation can vary. However, all major processes must be described in some manner. Assessors need to verify that inputs, outputs, activities, and responsibilities are addressed for all major processes. For example, the Quality Manual may state:

The Sales Administration group receives all customer purchase orders. The administrator compares price to the current price list and verifies that stock is on hand to meet requested delivery date. If acceptable, the order is entered into the MRP computer system. Entry into the MRP system is the record of review. The customer file will contain a note explaining how any discrepancies were resolved.

The above example may be the complete documentation for confirming customer requirements in a company selling only catalog parts. It identifies inputs (customer purchase orders), responsibilities (Sales Administration), process activities (comparing price and delivery) and outputs (enter into MRP system).

The notes after Clause 4.2 make it clear that where the standard specifically requires a “documented procedure”, the procedure has to be established, documented, implemented and maintained. It also emphasizes that the extent of the QMS documentation may differ from one organization to another due to:

- the size of organization and type of activities;
- the complexity of processes and their interactions, and - the competence of personnel.

The organization needs to document the processes to the extent necessary to assure their effective operation and control.

Guide for Assessing Processes

Use of this sheet is optional and can be reproduced for any process. You must still enter ratings on pages 5 - 47.

Process Name:

Personnel Interviewed:

Topic	Objective Evidence
<p>Responsibilities are defined for performing this process.</p>	
<p>Process inputs are identified.</p>	
<p>There are clear linkages from other processes feeding into this process.</p>	
<p>Process is carried out under controlled conditions. (e.g., documented procedure or training, appropriate equipment and infrastructure, defined criteria for acceptability, etc.)</p>	
<p>There are measurable objectives associated with this process. (if a key process) Performance against objectives is tracked. Corrective action is taken when objectives Are not being met.</p>	
<p>If there are continual improvement goals associated with this process, action plans are evident when continual improvement is not realized.</p>	
<p>If there are no measurable objectives, the process is still monitored in some way.</p>	
<p>Process outputs are identified. (e.g., records, information, product, service)</p>	
<p>There are clear linkages to other processes that this process feeds into.</p>	
<p>There is evidence that this process is functioning effectively.</p>	

Chapter of standard: 4. Quality Management System

4.1 General requirements (4.2.1)

Assessor Guidance

1. All processes should be identified from initial customer contact through delivery of product and feedback from customer and subsequent actions. This includes processes for management activities, provision of resources, and measurements.
2. There should be evidence that the organization has examined each process to determine if there are any value-added measurements. Resulting Key processes should have defined methods for monitoring process performance.
3. The PDCA (plan-do-check-act) process should be evident for all key processes
4. Customer invoicing should generally be included. Other financial processes typically do not need to be included.
5. During interviews with top management ask what they consider to be key processes.
6. Ask top management which processes were not considered to be part of the QMS and why.

Requirement / topic	Documentation	E	Documents reviewed	Self-assessment notes	E
<p>Obligation to establish and maintain a QMS (s.5.4.2)</p> <p>a. ~ Identify processes needed for the QMS</p> <p>b. ~ Determine the sequence and interaction of these processes</p> <p>c. Determine criteria and methods required to ensure the effective operation and control of these processes</p> <p>d. Availability of resources and information necessary to support the operation and monitoring of these processes</p> <p>e. ~ Monitor, measure and analyze these processes</p> <p>f. Implement action necessary to achieve planned results and continual improvement of these processes</p>			<p>~ Quality Manual</p> <p>~ Documented processes/procedures and other applicable documents</p> <p>~ Process flow charts</p> <p>~ Management review</p> <p>~ Investment plans</p> <p>~ Action Item list</p>		

4.1 General requirements (4.2.1) continued

Assessor Guidance

1. Where the overall responsibility for product realization belongs to an organization, the fact that a specific product realization process (such as product design and development or manufacturing) is **outsourced** (or “sub-contracted”) to an external organization is not an adequate justification for the exclusion of this process from the QMS. Instead, the organization has to be able to **demonstrate that it exercises sufficient control to ensure that such processes are performed according to the relevant requirements of ISO 9001:2000**. The nature of this control will depend on the nature of the outsourced process and the risk involved. The quality manual must explain how the outsourced requirement is controlled.
2. The quality manual shall also define **interfaces** with organizations responsible for any outsourced activity.
3. Processes performed by suppliers are typically controlled under Purchasing requirement in clause 7.4. (e.g., painting, heat treating, etc.) These do not have to be listed in the quality manual as outsourced activities.

<p>~ Processes are outsourced that may affect product or service conformity</p> <p>~ Outsourced processes are properly managed and controlled</p>			
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4.2 Documentation requirements				
4.2.1 General (4.2.2)				
Assessor Guidance				
1. Although only 6 procedures are identified within ISO 9001, documentation of all significant processes is required. 2. Documentation could include software such as an order-entry screen that prompts what to check. 3. If no procedures or w/l exist, there should be training or other means to ensure employees understand their roles and responsibilities. (Test by questioning several employees doing same job) 4. The 6 required procedures do not need to be 6 independent documents. (e.g., corrective & preventive action could be 2 processes within one procedure; Control of Nonconformity could be broken down into several separate documents)				
<p>QMS documentation includes documented procedures and records required to ensure effective operation and control of processes</p> <p>a. Documented quality policy and quality objectives</p> <p>b. A quality manual</p> <p>c. Required documented procedures</p> <ul style="list-style-type: none"> - Document Control - Control of Records - Internal Audits - Control of Nonconformity - Corrective Action - Preventive Action <p>d. Documents required by the organization</p> <p>e. Quality records required by ISO 9001:2000</p> <p>Is the extent of the QMS documentation appropriate to the:</p> <p>a. Size and type of the organization;</p> <p>b. Complexity and interaction of the processes;</p> <p>c. Competency of personnel.</p>		<ul style="list-style-type: none"> ~ Quality Manual ~ Documented procedures ~ Commitment to continuous improvement ~ On-going evaluation ~ Communication within the organization <p>~</p> <ul style="list-style-type: none"> ~ Description of interactions ~ Test plans ~ Process flow charts ~ Drawings <ul style="list-style-type: none"> ~ Organizational charts ~ DP Document control ~ DP Control of quality records ~ DP Control of internal audits ~ DP Control of nonconforming product ~ DP Control of corrective action ~ DP Control of preventive action ~ Order records ~ Manufacturing records <ul style="list-style-type: none"> ~ Minutes/records ~ Checklists ~ Test certificates ~ Qualification certificates 		

4.2.2 Quality Manual (must include): (4.2.1)

Assessor Guidance

1. The QM must include all high-level processes and their **linkages**. (e.g., output of process A is input to process B, etc.)
2. The QM must address **all** ISO 9001 requirements.
3. Only Section 7 elements can be excluded. The QM must provide **justification** for any **exclusions**.
4. Control for any requirement **outsourced** must be addressed in quality manual. (e.g., if design is done by sister company, QM must address control of design as an outsourced process) See 4.1

<p>QMS manual established that includes:</p> <p>a. Scope of quality system, including details and ~ justifications for exclusions</p> <p>b. Procedures or references to procedures</p> <p>c. ~ Description of interaction between QMS processes</p>		<p>~ Quality Manual ~ Documented procedures ~ Organizational charts ~ Geographic or technical scope of application ~ Justification for exclusions from requirements as per Chapter 7</p> <p>~ Process descriptions / flow charts</p>	
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4.2.3 Control of documents (4.5.1 + 4.5.2 + 4.5.3)

Assessor Guidance

1. Control of **external** documents must include distribution.

<p>Documents required for the QMS are controlled.</p> <p>Documented procedure for:</p> <p>a. Approval before issue</p> <p>b. Review, updating as necessary, and re approval of documents</p> <p>c. Identification of the current revision status of documents</p> <p>d. Relevant versions of applicable documents are available at points of use</p> <p>e. Documents remain legible and readily identifiable</p> <p>f. Documents of external origin are identified and their distribution is controlled</p> <p>g. Preventing the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose</p>		<ul style="list-style-type: none"> ~ DP Document control ~ Quality Manual ~ Approval documents ~ Revision procedures ~ Approval procedures ~ Documented procedures ~ Test plans ~ Lists of revision status ~ Distribution list ~ Evidence of issue and receipt ~ Review of external documents 	
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4.2.4 Control of records (4.16)

Assessor Guidance

1. **Disposition** must be included in procedure. (e.g., statement that at the end of the retention time the department manager will review to determine if records should be destroyed or kept)
2. Many elements refer to **Necessary** or **Subsequent Actions**. For these, records must include follow-up actions. (e.g., records of actions taken to resolve discrepancy between quote and customer order)
3. See list of **required records** on last page of this question list

<ol style="list-style-type: none"> 1. Documented procedure that defines controls needed for the identification, storage, protection, retrieval, retention time and disposition of records 2. Quality records established and maintained that provides evidence of conformity to requirements and effective operation of the QMS 3. Are records legible, identifiable, and retrievable 4. "Necessary / Subsequent Actions" recorded for elements required by ISO 9001:2000 		<ul style="list-style-type: none"> ~ Quality Manual ~ DP Control of records ~ sales and order records ~ Manufacturing records ~ Minutes/records ~ Check lists ~ Test certificates ~ Documentation of internal audits ~ Qualification certificates ~ purchase records ~ logistic records 	
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Chapter of standard: 5. Management responsibility

5.1 Management commitment (4.1)

Assessor Guidance

1. Questioning employees will provide evidence of 5.1.a below. Employees must understand objectives at **their** level. (see also 6.2.2.d)

<p>Top Management has demonstrated commitment to the development and improvement of the effectiveness of the QMS</p> <p>a. ~ Communicating to the organization the importance of meeting customer as well as regulatory & legal requirements</p> <p>b. Establishing the quality policy</p> <p>c. Ensuring that quality objectives are established</p> <p>d. Conducting management reviews</p> <p>e. Ensuring the availability of resources</p>		<ul style="list-style-type: none"> ~ Management review ~ Written quality policy ~ Training schedules / evidence ~ Employee information (notices, agenda of informative events) ~ Manpower-development plans ~ Quality plans ~ Records of defined objectives ~ Project plans ~ Investment plans ~ Plant agreements 	
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5.2 Customer focus

Assessor Guidance

1. Ask Top Management how they ensure a customer focus.
2. Satisfying these section will be evident after assessing other processes
3. Ref. 7.2.1 (Determination of requirements related to the product)
4. Ref. 8.2.1 (Customer Satisfaction)

<p>~ Top Management ensures that customer requirements are determined and met with the aim of enhancing customer satisfaction</p>		<ul style="list-style-type: none"> ~ Evaluation of customer surveys ~ Market analyses ~ Complaint documentation / analyses ~ Product validation records ~ Standards ~ Customer-satisfaction analyses ~ external quality costs ~ ppm-statistics 	
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5.3 Quality policy (4.1.1)

Assessor Guidance

1. For 5.3.b below, the wording is optional but the policy **must** include the theme of **continuous improvement** (e.g., “continually improve” or “better tomorrow” etc.) and **commitment to meeting requirements** (stated, expected, implied, regulatory, etc.) Comment in Document Review Report.
2. Organization must demonstrate how they ensure that Quality Policy is being met (or actions in place where not)
3. Objectives are separate from policy but they support each other.
4. There must be **objectives** for both **products** and **processes**.
policy relates to them
5. Employees must understand how the

<p>Top Management ensures that the quality policy:</p> <p>a. Is appropriate to the purpose of the organization</p> <p>b. ~ Includes a commitment to meeting requirements and to continually improve the effectiveness of the QMS</p> <p>c. ~ Provides a framework for establishing and reviewing quality objectives</p> <p>d. Is communicated and understood within the organization</p> <p>e. ~ Is reviewed for continuing suitability</p>		<p>~ Quality Manual ~ Corporate guidelines and principles ~ Written quality policy ~ Training schedules and evidence ~ Employee information (notices, meetings etc.)</p> <p>~ Management review ~ Internal audits</p>	
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5.4 Planning

5.4.1 Quality objectives (4.1.1)

Assessor Guidance

1. Quality objectives should be determined based on data and parameters. (See 8.4 and 8.5.1)
2. There must be a flow-down of objectives for key processes down throughout the organization.
3. Ref. 7.1.a.for product objectives

<p>~ Quality objectives established at relevant functions and levels within the organization</p> <p>Quality objectives are measurable</p> <p>Quality objectives consistent with the quality policy</p> <p>~ Quality objectives include those needed to meet requirements for product</p>			<p>~ Quality Manual</p> <p>~ Internal/external target agreements (business plans, project plans, quality assurance agreements)</p> <p>~ company-related</p> <p>~ product-related</p> <p>~ customer-related</p> <p>~ general Employee information</p> <p>~ Records of employee interviews</p> <p>~ trend analysis</p>		
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5.4.2 Quality management system planning (4.2.3)

Assessor Guidance

1. Examples: ensuring **integrity** of QMS maintained if (1) switching responsibility for in-process inspection from Quality to Manufacturing Dept. (2) implementing new computer system
2. Output of QMS planning will typically be QMS documentation. Records of actual planning process could be in management review minutes.
3. There should be a link to identification of resource needs. (e.g., budget process)

<p>~ Steps taken to ensure that quality objectives and requirements outlined in 4.1 are satisfied</p> <p>~ Output of QMS planning is documented</p> <p>~ Changes conducted in a controlled manner and the integrity of the QMS is maintained during changes</p>			<p>~ Quality Manual</p> <p>~ Documented procedures</p> <p>~ Investment plans</p> <p>~ Strategic plans</p> <p>~ Quality plans</p> <p>~ Production plans</p> <p>~ Resource plans / records</p> <p>~ Documented procedures / process descriptions</p> <p>~ Work and test plans</p>		
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5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority (4.1.2.1)

Assessor Guidance

1. Job Descriptions are not required.

<p>- Definition and communication of responsibilities and authorities</p> <p>~ Ensured by top management</p>		<p>~ Quality Manual ~ Documented procedures (QM) ~ Job / function profiles ~ Requirement profiles</p>	
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5.5.2 Management representative (4.1.2.3)

Assessor Guidance

1. Employee interviews will demonstrate 5.5.2.c.

<p>Appointment and announcement of an independent member of management</p> <p>a. Ensuring that processes needed for the QMS are established, implemented and maintained</p> <p>b. Reporting to Top Management on the performance of the QMS, including needs for improvement</p> <p>c. ~ Ensuring the promotion of awareness of customer requirements throughout the organization</p>		<p>~ Quality Manual</p> <p>~ Organizational chart and organizational structure</p> <p>~ QMR appointment letter ~ QMR function profile</p> <p>~ QMR job profile ~ Status report /Q analyses</p> <p>~ Internal audit reports ~ Reports re: quality situation ~ Statistical evaluation</p>	
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5.5.3 Internal communication

Assessor Guidance

1. Communication channels should be established for upward and downward communication. (main focus is on downward communication; there is no nonconformance for lack of upward communication processes; but could be an opportunity for improvement)
2. This could include flow-down of information taken from management review records.

<p>~ Establishment of suitable communication processes within the organization</p> <p>~ Communication regarding quality system effectiveness</p>		<p>~ Minutes and reports of meetings ~ Team training and other meetings ~ Notice boards, internal magazines ~ Audio-visual and electronic media ~ Agenda of company events</p> <p>~ Circular letters ~ Statistics ~ Reports on quality system effectiveness</p>		
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5.6 Management review

5.6.1 General (4.1.3)

<p>Top Management review of the QMS at planned intervals, to ensure its continuing suitability, adequacy and effectiveness</p> <p>Review evaluates the need for changes to the QMS, including quality policy and quality objectives</p> <p>Opportunities for improvement and changes needed within the quality system are evaluated</p> <p>Records maintained</p>		<p>~ Management-review report ~ monthly management reports ~ controlling reports ~ finance reports ~ Q-reports ~ supplier evaluations ~ logistic reports ~ Business plans/ company business objectives</p>		
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5.6.2 Review input

Assessor Guidance

1. Inputs must include customer complaints and information on customer satisfaction.
 2. "Changes" could be those planned, expected, or those that have already occurred
 3. Agenda items can be reviewed at a combination of several meetings. However, Top Management must attend meetings and process should be defined as being made up of these several meetings. (e.g., which items reviewed at quarterly management review; which items reviewed at monthly operations meeting). Look for relationships and continuity between meetings.

<p>Management review must include: (s. 8.1+8.2+8.4+8.5)</p> <p>a. Results of audits</p> <p>b. ~ Customer feedback</p> <p>c. ~ Process performance and product conformity</p> <p>d. Status of preventive and ~ corrective actions</p> <p>e. Follow-up actions from previous management reviews</p> <p>f. ~ Significant changes that could affect the QMS</p> <p>g. ~ Recommendations for improvement</p>		<p>~ Management-review report ~ Customer-satisfaction analyses ~ Process analyses</p> <p>~ Evidence of corrective and preventive action ~ Resource deployment and application planning ~ Benchmarking results ~ Quality analyses ~ Risk analyses (technical/economic) ~ Internal audit reports ~ Process audits ~ Product audits / reports ~ Action reports ~ Investment planning</p>	
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5.6.3 Review output

Assessor Guidance

1. Records must include evidence that inputs (a-g) were addressed.
 2. There should be conclusion statement if no actions were deemed necessary.

<p>Do management review outputs include decisions and actions related to:</p> <p>a. ~ Improvement of the effectiveness of the QMS and its processes</p> <p>b. ~ product improvements</p> <p>c. ~ Resource needs</p>		<p>~ Management-review report ~ Business plan ~ Strategic plans</p> <p>~ Investment plans ~ Human-resources plans ~ new objectives ~ Projects ~ action plans</p>	
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Chapter of standard: 6. Resource management

6.1 Provision of resources (4.1.2.2)

Assessor Guidance

1. Ask how customer

data is used as an input to determining resource needs.

Determined and provided needed resources

a. to implement and maintain the QMS and to continually **improve** its **effectiveness**?

b. ~ to ensure that **customer satisfaction** is **enhanced**?

- ~ Quality Manual
- ~ Investment plans
 - ~ relating to personnel
 - ~ relating to equipment
 - ~ relating to real estate
- ~ Staffing schedules
- ~ Other target plans

6.2 Human resources				
6.2.1 General (4.1.2.2)				
- Personnel performing work affecting product quality must be competent based on: - education - training - skills - experience.		~ Quality Manual ~ Job / function profiles ~ Employment contracts		
		~ Manpower-development plans ~ Qualification documentation ~ Records of employee interviews ~ Employee certificates ~ qualification matrix		
6.2.2 Competence, awareness and training (4.18)				
Assessor Guidance				
1. Competency is more than qualification; it is the demonstrated ability to apply knowledge and skills. Competency is demonstrated through testing or a judgment being made.				
2. A resume is sufficient to demonstrate education.				
3. Grandfathering the determination of initial competence is allowed, but criteria should be defined.				
4. Management must be included in program. (i.e., at least overview of the QMS and their role)				
How has the organization: a. ~ Determined the necessary competency for personnel b. Provided training or other actions to satisfy competency needs c. ~ Evaluated the effectiveness of actions taken d. ~ Ensure personnel are aware of their role in the QMS and how they contribute to the achievement of the quality objectives e. Maintained appropriate records of education, training, skills and experience		~ Records of quality requirements ~ Job / function profiles ~ Induction plans ~ Records of employee interviews ~ Training schedules ~ Training certificates ~ Records on the evaluation of training effectiveness ~ Training objectives ~ Training benefits ~ Training efficiency ~ Company benefits ~ practice in the trained part		

6.3 Infrastructure (4.9)

Assessor Guidance

1. There should be Preventive Maintenance for both equipment and facilities, as appropriate.
2. Use visual observations during audit to help determine compliance

<p>Organization determines, provides and maintains the infrastructure as applicable :</p> <p>a. ~ Buildings, workspace and associated utilities</p> <p>b. Process equipment, hardware and software</p> <p>c. ~ Supporting services such as transportation or communication</p> <p>.</p>		<ul style="list-style-type: none"> ~ Workplace investigations ~ Investment plans ~ Maintenance and servicing plans and records ~ Records of process capability studies ~ Records of <ul style="list-style-type: none"> ~ supplier evaluation ~ (including service providers) 	
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6.4 Work environment (4.9)

Assessor Guidance

1. There are no requirements tied to worker welfare. The focus here is on aspects of the work environment that affect product. (e.g., improve lighting to reduce defects)

<p>~ Determined and manages work-environment factors needed to achieve product conformity.</p>		<ul style="list-style-type: none"> ~ Evidence of instruction in occupational safety ~ Evidence of the satisfaction of statutory and regulatory requirements or conditions ~ Maintenance / servicing plans (records) ~ Workplace investigations ~ Benchmarking re work environment ~ Employee -satisfaction analyses ~ Analyses re labor turnover / absenteeism 	
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Chapter of standard: 7. Product realization

7.1 Planning of product realization (4.2.3 + 4.10.1)

Assessor Guidance

1. Examples of product objective would be

- 90% first pass yield,
- MTBF of 10,000 hours
- Returns = 0

Planning of the realization processes is consistent with the other QMS processes (ref. 4.1)

Realization processes are **documented** in a form suitable for the organization's method of operations. (ref. 8.2.4)

Organization determines the following, as appropriate:

- a. ~ quality **objectives** and requirements for the **product**
- b. need to establish processes and documents, and provide resources specific to the product
- c. verification, validation, **monitoring**, inspection and test activities and the criteria for product acceptability
- d. ~ **records** necessary to provide evidence of conformity of processes and resulting product meet requirements?

- ~ Project-strategy approaches
- ~ Specifications
- ~ Quality plans
- ~ Project-development plans
- ~ Milestone plans
- ~ Feasibility records
- ~ Measurement and test strategies
- ~ Logistic strategies
- ~ Records relating to risk assessment and process evaluation (technical, economic)
- ~ FMEA
- ~ criteria for process release

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product (4.3.2 + 4.4.4)

Assessor Guidance

1. Examples of 7.2.1.d would be
 (a) MTBF of 100,000 hours
 (b) critical dimension of $x \pm y$.

<p>Organization determined:</p> <p>a. Product requirements specified by the customer, including delivery and post delivery activities</p> <p>b. ~ Product requirements not specified by customer but necessary for intended use,</p> <p>c. Statutory / regulatory requirements</p> <p>d. Additional requirements determined by the organization</p>		<p>~ Order letter ~ Customer inquiries</p> <p>~ Records of consultations with customers ~ specifications ~ drawings ~ Trend analyses ~ Competitor analyses ~ Research re standards and statutory requirements</p>		
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7.2.2 Review of requirements related to the product (4.3.2 + 4.3.3 + 4.3.4)

<p>Review product related requirements before submitting quotes, accepting orders, accepting change orders</p> <p>Review ensures</p> <p>a. Product/service requirements are defined</p> <p>b. Contract or order requirements differing from those previously expressed are resolved</p> <p>c. The organization has the ability to meet defined requirements</p> <p>d. Confirm requirements when not documented by customer (e.g. for verbal orders)</p> <p>Records of review and</p> <p>~ actions arising from review</p> <p>Where product requirements are changed, the organization ensures that relevant documentation is amended and relevant personnel informed</p>		<p>~ Evidence of quotations, contracts, contract review</p> <p>~ Documentation of amendments</p> <p>~ Feasibility analysis records</p> <p>~ Feasibility studies</p> <p>~ Confirmations of orders</p> <p>~ calculations</p> <p>~ price lists</p> <p>~ delivery schedules</p>	
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7.2.3 Customer communication (4.3.2)

<p>~ Determined and implemented arrangements for communication with Customers relating to:</p> <p>a. ~ Product information</p> <p>b. ~ Inquiries, contracts or order handling, including amendments</p> <p>c. ~ Customer feedback, including customer complaints</p>		<ul style="list-style-type: none"> ~ process description ~ work instructions ~ Customers' product specifications ~ Inquiry documents ~ Contracts ~ Confirmation of order ~ Advertising / Marketing material ~ Customer surveys and reports of customer visits ~ Customer-satisfaction analyses ~ Queries, complaints ~ Complaint analyses ~ Customer requests for changes ~ Internet site 		
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7.3 Design and development

7.3.1 Design and development planning (4.4.2 +4.4.3)

<p>Assessor Guidance</p> <p>1. Suggested practice: First engineering personnel. followed, results being recorded,</p> <p>2. There may be no completed. However, the audit team steps may be incomplete, of an actual design</p>	<p>audit one or more project files to verify all steps in a design project. Then randomly interview (i.e., verify design inputs are at latest revision, design inputs were reviewed / approved, plan being etc.)</p> <p>design projects at the time of a certification audit due to the time required in some industries. must be able to obtain sufficient objective evidence to verify an effective system. Although some the self-assessment team may still be able to make a positive judgment. If there will be very little evidence it is acceptable if an organization creates a “dummy” file to demonstrate their system.</p>			
<p>During design planning, determine:</p> <p>a. the design and development stages</p> <p>b. Review, verification and validation appropriate to each stage</p> <p>c. Responsibilities and authorities</p> <p>How does the organization manage the interfaces between different groups involved in design?</p> <p>Are planning outputs updated as the design and development progresses?</p>		<ul style="list-style-type: none"> ~ Project plans ~ Design and development plans and flow charts ~ Milestone plans ~ Measurement and test plans ~ Verification and validation specifications ~ Approval provisions ~ Responsibility matrix ~ Risk assessment 		

7.3.2 Design and development inputs (4.4.4)

<p>Design and development inputs relating to product requirements are defined and documented</p> <p>Inputs include:</p> <p>a. Functional and performance requirements</p> <p>b. Applicable statutory and regulatory requirements</p> <p>c. Applicable information derived from previous similar designs</p> <p>d. Any other requirements essential for design and development</p> <p>Design and development inputs are reviewed for adequacy, and are incomplete, ambiguous or conflicting requirements resolved</p>		<ul style="list-style-type: none"> ~ Specifications / terms of reference ~ Statutory and/or regulatory implementing guidelines ~ Result reports from previous similar design and development activities ~ Evaluation of customer-requirement analyses ~ Patent research ~ Approval documents ~ trend in customer complaints ~ trends in ppm-statistics ~ guaranties evaluations ~ FMEA's 	
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7.3.3 Design and development outputs (4.4.5)

<p>Outputs are in a form that enables verification against the design and development inputs</p> <p>Design and development output:</p> <p>a. Meet the design and development input requirements</p> <p>b. ~ Provide appropriate information for purchasing, production and service operations</p> <p>c. Contain or reference product acceptance criteria</p> <p>d. Define the characteristics of the product that are essential to its safe and proper use</p> <p>Outputs approved before release</p>		<ul style="list-style-type: none"> ~ drawings ~ FE-calculations ~ QM-plans ~ Acceptance certificates ~ Order documents containing specifications ~ Risk analyses (e.g. FMEA) ~ Test records (for production. verification and validation) ~ Approval documents ~ sample test 	
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7.3.4 Design and development review (4.4.6)	
<p>Systematic reviews of design and development conducted at suitable stages</p> <p>Reviews are planned (ref. 7.3.1)?</p> <p>Do these reviews evaluate the ability to meet requirements?</p> <p>Do reviews Identify problems and propose necessary actions?</p> <p>Do participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed?</p> <p>Review results and subsequent follow-up actions are recorded</p>	<ul style="list-style-type: none"> ~ Intermediate / final design and development reports ~ Appropriate test records, e.g. of laboratory or field testing ~ Minutes of meetings ~ Milestone and phase reviews ~ FMEA ~ Models and simulations ~ Approval documents
7.3.5 Design and development verification (4.4.7)	
<p>Verification are activities planned (ref. 7.3.1)</p> <p>Is design and development verification performed to ensure the output meets the design and development inputs?</p> <p>Results of the verification and subsequent follow-up actions are recorded?</p>	<ul style="list-style-type: none"> ~ Test plans (verification requirements) ~ Prototypes / test samples ~ Test records / reports ~ Records of alternative calculations /analyses ~ Test / simulation reports ~ Records of experiments / trials ~ Description of follow-up measures ~ Approval documents

7.3.6 Design and development validation (4.4.8)

Assessor Guidance

1. Customers can do validation. (e.g., Beta testing) If customers conduct validation, there must be records of validation.
 This could be a note of a telephone call with the customer on validation results. Contract review process could be used to verify customer participation in validations.

<p>Validation activities are planned (ref. 7.3.1)</p> <p>Validation ensures</p> <ul style="list-style-type: none"> • product is capable of intended use • ~ wherever practical completed prior to delivery <p>Results of validation and subsequent follow-up actions are recorded</p>		<ul style="list-style-type: none"> ~ Test plans (validation requirements) ~ laboratory tests ~ environmental tests ~ Results of pilot series / field testing ~ Test records / reports <ul style="list-style-type: none"> ~ (possibly from customers, too) ~ Results of -life testing ~ field testing ~ Customer Beta testing ~ Evaluation results from other bodies ~ Validation approvals 	
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7.3.7 Control of design and development changes (4.4.9)

Assessor Guidance

1. Example of effect of changes: Need to update a Service Manual.
 2. Needed verification and/or validation could be subsets of original verification / validation.

<p>~ Process include evaluation of the effect of the changes on constituent parts and delivered products</p> <p>~ Changes are verified and validated, as appropriate, and approved before implementation?</p> <p>~ Record results of change review and subsequent follow up actions</p>		<ul style="list-style-type: none"> ~ Documented requests for changes (e.g. by the customer, production, ...) ~ New revision status of e.g. specifications, drawings, process descriptions, test procedures, measurement systems, ~ Comments, test reports in connection with changes ~ Approval documents in connection with implemented changes ~ Communication of changes to customers, units ~ Withdrawn documents ~ history of changes 	
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7.4 Purchasing

7.4.1 Purchasing process (4.6.2)

The organization controls its purchasing processes to ensure purchased product conforms to requirements

The type and extent of **control** is **dependent** upon the effect of **subsequent** realization processes and their output

Evaluates and selects suppliers based on their ability to supply product in accordance with the organization's requirements

~ **Criteria for selection, evaluation and periodic re evaluation** are defined

Record results of evaluations and subsequent follow up actions

- ~ Product specifications
- ~ Supplier's quality system documentation
- ~ Checklist
- ~ Evidence of supplier evaluation
- ~ List / database of approved suppliers
- ~ Evaluation criteria
- ~ complaints
- ~ ppm-statistics
- ~ specifications

7.4.2 Purchasing information (4.6.3)

Assessor Guidance

1. Services must be included, not just raw materials, if they can impact the quality of product / service. (e.g., service providers such as trucking, calibration, packaging, heat-treating, printing of manuals, etc.)

<p>Do purchasing documents contain information describing the product to be purchased?</p> <p>Do these documents include where appropriate:</p> <p>a. Requirements for approval of product, procedures, processes, equipment</p> <p>b. Personnel qualification</p> <p>c. Quality Management</p> <p>System requirements</p> <p>Ensures adequacy of specified requirements before communication to supplier</p>		<ul style="list-style-type: none"> ~ Product specifications ~ Order forms ~ purchasing specifications in EDP ~ Order lists, piece lists ~ Performance / delivery contracts ~ Quality assurance agreements ~ Order approval documents 	
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7.4.3 Verification of purchased products (4.6.4) (4.10.2)

Assessor Guidance

1. Controls for drop shipments directly from suppliers to customers must be established.

<p>Identified and implemented inspection or other activities necessary for the verification of purchased product</p> <p>For verification measures conducted at the supplier's premises, the intended verification measures and methods must be defined. (i.e., source inspection)</p>		<ul style="list-style-type: none"> ~ Acceptance criteria ~ Inspection / Verification plans ~ Test regulations ~ Regulations for re-approval under concession ~ Test records of suppliers or of organization's own incoming inspection ~ Certifications ~ incoming inspection ~ Statistical data ~ Receiving / Receiving Inspection procedures ~ Source inspection procedures 	
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7.5 Production and service provision				
7.5.1 Control of production and service		provision (4.9 + 4.15.6 + 4.19)		
<p>In this context: (see. 7.1)</p> <p>a. product characteristics must be defined,</p> <p>b. work instructions, as necessary, must be made available,</p> <p>c. suitable equipment must be used,</p> <p>d. monitoring and measuring devices must be made available,</p> <p>e. activities must be monitored and measured</p> <p>f. ~ post-delivery activities must be implemented</p>		<ul style="list-style-type: none"> ~ Acceptance criteria ~ Work instructions ~ Test plans ~ drawings ~ Maintenance plans ~ Installation plans ~ Service contracts ~ Operating instructions ~ Process flow charts 		

7.5.2 Validation of processes for production and service provision (4.9)				
Assessor Guidance				
1. Example would include having no final required. 2. Data from history is sufficient to demonstrate 3. Validation below required for „special“		inspections, therefore, customer first to see defect. Process validation would be validation of a process. processes as referenced in ISO 9001:1994.		
Validation must demonstrate process capability. In this context, the following must be taken into account: Validation of all production processes where the resulting output cannot be verified by subsequent monitoring or measurement. This includes all processes where deficiencies become apparent only after the product has been delivered. Validation must include (where appropriate): Establish arrangements for validation to include as applicable: a. Criteria for review and approval of processes b. Approval of equipment and qualification of personnel c. Use of specific methods and procedures d. Requirements for records e. Possible necessity of Revalidation		~ Evidence of machinery and process capability ~ Process descriptions ~ data of process control ~ Skills documentation and training certificates ~ Qualification certificates ~ Validation specifications		

7.5.3 Identification and traceability (4.8 + 4.10.5 + 4.12)

<ul style="list-style-type: none"> - Where appropriate, the product must be identified throughout product realization - The product status must be identified with respect to monitoring and measurement requirements. - Identification must be controlled and recorded, if traceability is required 		<ul style="list-style-type: none"> ~ Work instructions ~ Accompanying documents, e.g. <ul style="list-style-type: none"> routing slips ~ production plans ~ IT records ~ Product identification ~ Test certificates ~ Segregation slips ~ Approvals 	
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7.5.4 Customer property (4.7)

Assessor Guidance

1. Intellectual property = information, software, drawings, etc. The organization should ensure confidentiality of intellectual property as appropriate.

<p>In this context, the following must be observed:</p> <ul style="list-style-type: none"> - ~ careful handling (also where intellectual property is concerned) - identification, verification, protection and maintenance - Record and report to the customer If any customer property is lost or damaged 		<ul style="list-style-type: none"> ~ Inventory of customer property ~ Identification (e.g. labels, stickers) ~ Correspondence with customers ~ Records on verification and maintenance conducted ~ Incoming inspection 		
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7.5.5 Preservation of product (4.15.2 + 4.15.3 + 4.15.4 + 4.15.5)

Assessor Guidance

1. Shelf-life controls are required as appropriate.

<ul style="list-style-type: none"> - This refers to both internal processing and delivery and must include: <ul style="list-style-type: none"> - preservation of product conformity - identification - handling - packaging - storage - protection ~ This also applies to the constituent parts of products. 		<ul style="list-style-type: none"> ~ Regulations on packing, storage, preservation and delivery ~ Piece lists ~ Inventory lists ~ Stock-replenishment and -withdrawal plans ~ Regulations on storage periods and segregation (where appropriate) ~ delivery labels ~ Assembly / operating instructions 		
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7.6 Control of monitoring and measuring devices (4.11.1 + 4.11.2)

Assessor Guidance:

1. Investigate methods in which measurement and monitoring devices are controlled to ensure fitness for use
2. Tape measures (like any gage) if used for acceptance of product must be calibrated. However, the calibration required shall be commensurate with the accuracy required and associated risks. If the tape measure is used to sort 2-foot length of material from 3-foot length of material, calibration may be comparison to another tape measure and inspection to verify no damage. Re-calibration may not be required for several years. The key here is the planning and identification of measurements to be made and accuracy required.
3. Software used to accept product (e.g., automatic test equipment software developed by client) shall be verified before production use. Re-verification would typically only be required for software changes or product design changes that could potentially affect ATE test results.

<p>Identify the measurements to be made and the measuring and monitoring devices needed to assure conformity of product to determined requirements</p> <p>Measuring and monitoring devices are used and controlled to ensure that measurement capability is consistent with the measurement requirements</p> <p>Where necessary, measuring and monitoring devices are:</p> <ol style="list-style-type: none"> a. Calibrated or verified at specified intervals or prior to use, against standards traceable to International or national standards; where no such standards exist, is the basis used for calibration recorded b. Adjusted or re-adjusted as necessary c. Be identified to enable calibration status to be determined d. Safeguarded from adjustments that would invalidate the calibration e. Protected from damage and deterioration during handling, maintenance and storage 		<ul style="list-style-type: none"> ~ Test certificates including acceptance criteria ~ Evidence of capability of monitoring and measuring devices ~ List or use of database for monitoring and measuring devices ~ Calibration instructions ~ Calibration records ~ Gauging records ~ Calibration standards ~ Calibration certificates ~ Records on comparative measurements and inter-laboratory tests ~ Records on software qualification testing 	
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<p>Record results of calibration</p> <p>Validity of previous results reassessed if they are subsequently found out of calibration and corrective action taken</p> <p>When used in monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed prior to initial use and reconfirmed as necessary</p>			
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Chapter of standard: 8. Measurement, analysis and improvement

8.1 General (4.10 + 4.20.1 + 4.20.2)

Assessor Guidance

- The organization must measure "key performance indicators." Metrics should support the organizations strategic goals and the quality policy. Many of the lower level metrics should support the upper metrics as well as demonstrate that the processes are functioning effectively.

<p>~ Organization plans and implements the monitoring, measurement, analysis and improvement processes needed to:</p> <p>a) demonstrate product conformity b) ensure conformity of the QMS c) continually improve QMS effectiveness</p> <p>This include determination of methods including statistical techniques and the extent of their use</p>		<p>~ Design and development flow charts ~ Design and development test plans</p> <p>~ company data system ~ objectives and the actualization ~ Improvement schemes</p> <p>~ Statistics ~ Progress reports ~ Information boards ~ inputs for continual improvements</p>	
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8.2 Monitoring and measurement

8.2.1 Customer satisfaction

Assessor Guidance

- Measures must be proactive. There must be established methods for determining customer **perceptions**. (frequency, methods, etc. may vary among customers)
- The organization cannot rely solely on measure of dissatisfaction such as complaints and returns.
- Examples of possible methods include: Third party surveys, internet or mail-in surveys, customer focus groups, etc.

<p>~ Monitor information relating to customer perceptions as to whether the organization has met customer requirements (see also 5.2)</p> <p>~ Determined methods for obtaining and using information</p>		<p>~ Action Item list ~ Customer-satisfaction analyses</p> <p>~ Benchmarking ~ Checklists ~ Evaluation of mailing and telephone initiatives ~ Evaluation records (general) ~ Records of target requirement review</p>	
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8.2.2 Internal audit (4.17)

Assessor Guidance:

1. Internal Auditors within same department but not responsible for activity may audit that activity. (e.g., Quality Manager may audit Corrective Action if he/she is not administering corrective action process and did not write procedure.)
2. Although a "process" based approach to internal audits may be the most beneficial, the organization is free to structure audits in any manner. (e.g., clauses of standards, procedures, processes, etc.) However, the organization must ensure that internal audits cover all requirements of ISO 9001:2000.
3. After the initial certification to ISO 9001:2000, there is no requirement to audit entire system once per year. The

organization must schedule audits based on status and importance of process (i.e., risks) and previous audit results. Some processes may be audited several times per year and others once in 18 months.

<p>Internal quality audits conducted at planned intervals to determine whether the QMS</p> <p>a. Conforms to planned arrangements and ISO 9001:2000</p> <p>b. is effectively implemented and maintained</p> <p>Internal quality audits planned taking into consideration the status and importance of the activities and areas to be audited as well as the results of previous audits</p> <p>Audit scope, frequency and methodologies defined.</p> <p>Audits conducted by personnel other than those who performed the work being audited.</p> <p>Documented procedure that include the responsibilities and requirements for conducting audits, ensuring their independence, recording results and reporting to management</p> <p>Personnel conducting internal audits been trained.</p>		<ul style="list-style-type: none"> ~ DP internal audits ~ Audit plans ~ Audit reports ~ Nonconformance reports ~ Action Item list for the establishment of corrective action ~ Test records etc. ~ Management reviews ~ Reports on effectiveness of corrective action ~ Evidence of auditor qualification 	
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Management takes corrective **action without** undue **delay**

Follow-up actions include the verification of the action and the reporting of verification results

8.2.3 Monitoring and measurement of processes (4.17 + 4.20.1 + 4.20.2)

Assessor Guidance

1. This clause contains the implementation of planning requirements from clause 7.1.
2. See also clauses 4.1 and 8.5

<p>~ Suitable methods for monitoring and measurement of quality system processes must be determined, applied, reviewed and corrective and preventive action implemented, where appropriate. (s. 7.1+5.1)</p> <p>Are QMS processes measured and monitored by suitable methods to ensure that requirements are met?</p> <p>Do these methods demonstrate the ability of the processes to achieve planned results?</p> <p>When planned results are not achieved, is corrective action taken to ensure conformity of the product?</p>		<ul style="list-style-type: none"> ~ company data ~ Process data ~ controlling data ~ statistic analysis ~ Quality data ~ SPC-data and evaluations ~ Work instructions ~ Risk analysis records (FMEA) ~ Maintenance and servicing plans and implementation measures ~ Q records ~ Test plans ~ Test records 	
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8.2.4 Monitoring and measurement of product (4.10.2 + 4.10.3 + 4.10.4 + 4.10.5 + 4.20.1 + 4.20.2)

Assessor Guidance

1. Includes in-process and final inspection / verification steps identified in planning under clause 7.1
2. There should be established methods for at least one inspection / verification point.

<p>- Product characteristics:</p> <ul style="list-style-type: none"> - monitoring - measuring - verification - documentation <p>- at appropriate stages of product realization.(s. 7.1)</p> <p>- Products or service may only be approved after conformity has been established.</p> <p>The responsible person for release must be identified in each case.</p>		<ul style="list-style-type: none"> ~ Test plans ~ Test instructions ~ Test records ~ Sampling plans (attribute and variable) ~ Checklists ~ Comparative samples ~ Q records ~ Approval under concession by the customer or an authority (where appropriate) 	
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8.3 Control of nonconforming product (4.13.1 + 4.13.2)

Assessor Guidance

1. If nonconforming product detected after delivery, the organization must determine how the customer will be potentially affected when deciding on appropriate action.

<p>Activities including responsibilities and authorities defined in a documented procedure</p> <p>Is nonconforming product dealt with in one or more of the following ways:</p> <p>a) Taking action to eliminate detected nonconformity</p> <p>b) Authorizing its use, release or acceptance under concession by a relevant authority (where applicable, the customer)</p> <p>c) Taking action to preclude its original intended use or application</p> <p>Records include the nature of the nonconformities and any subsequent actions taken, including concessions</p> <p>Corrected nonconforming product must be re-verified</p> <p>~ When nonconforming product detected after delivery or use has started, is appropriate action taken to the effects, or potential effects of the nonconformity</p>		<ul style="list-style-type: none"> ~ DP control of nonconforming product ~ Nonconformance records ~ Test regulations ~ Test certificates ~ Customer information ~ Additional test plans, where appropriate ~ Approval records ~ Expert opinions ~ Approval under concession ~ Identification requirements 	
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8.4 Analysis of data (4.20.1 + 4.20.2)

<p>~ Appropriate data to demonstrate quality system suitability and effectiveness must be:</p> <ul style="list-style-type: none"> ~ determined ~ collected ~ analyzed <p>~ to evaluate here continual improvement can be made to QMS effectiveness</p> <p>~ Data analyzed to provide information on:</p> <ol style="list-style-type: none"> a. Customer satisfaction b. Conformity to product requirements c. Characteristics of processes, product and their trends including opportunities for preventive action d. Suppliers 		<ul style="list-style-type: none"> ~ Measurement and test records ~ Nonconformance records ~ Records of customer complaints ~ Customer-satisfaction analyses ~ Audit reports ~ Q reports ~ Records relating to field experience ~ Target/performance comparison reports 	
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8.5 Improvement

8.5.1 Continual improvement (4.1.3)

<p>Assessor Guidance</p>			
<p>1. Continual Improvement establishing objectives and audit conclusions,</p>	<p>= Recurring activity to increase the ability to fulfill requirements. NOTE The process of finding opportunities for improvement is a continual process through the use of audit findings of data, management reviews or other means and generally leads to corrective action or</p>		
<p>~ Continual improvement of the QMS must be made possible through the use of</p> <ul style="list-style-type: none"> - the quality policy - quality objectives - audit results - data analysis - corrective and preventive action - management review. (s. 4.1) 		<ul style="list-style-type: none"> ~ Quality management plans ~ Project plans ~ Documentation of target requirements ~ Progress reports ~ Management reviews ~ Corrective Action Log ~ Preventive Action Log ~ inputs for continual improvements 	

8.5.2 Corrective action (4.14.1 + 4.14.2)

<p>To prevent the recurrence of nonconformances, the documented procedure must cover the following aspects:</p> <p>Is there a documented procedure for corrective action which defines requirements for:</p> <p>a. Reviewing nonconformities (including customer complaints)</p> <p>b. Determining the causes of nonconformities</p> <p>c. Evaluating the need for actions to ensure that nonconformities do not recur</p> <p>d. Determining and implementing the corrective action needed</p> <p>e. Recording results of action taken</p> <p>f. Reviewing corrective action taken</p> <p>Corrective action appropriate to the effects of the problems encountered</p>		<ul style="list-style-type: none"> ~ DP Control of corrective action ~ Nonconformance records ~ 8-D-reports ~ Statistical evaluations ~ Test / result records ~ Instructions re corrective action ~ Training plans ~ Training certificates ~ Complaints analyses ~ Amended delivery contracts (where appropriate), ~ Quality agreements ~ Investment plans ~ Documentation of reviews 	
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Self-assessment question list (topic list)

ISO 9001:1994 and ISO 9001:2000

8.5.3 Preventive action (4.14.1 + 4.14.3)				
Assessor Guidance				
<p>1. A key difference between Corrective Action and Preventive Action is how the activity is initiated. (corrective action is reactive to a nonconformance; preventive action is proactive based on identification of potential nonconformances)</p> <p>2. Procedures must describe how potential nonconformities are identified. Identifying potential nonconformances is typically accomplished through the analysis of records and/or other relevant sources of information. (e.g., information from Statistical process control documents, Customer complaints, Nonconforming product trends, Process metric trends, etc.)</p> <p>3. Another example of a preventive action activity is FMEA's (failure mode and effects analysis)</p>				
<p>Documented procedure for preventive action that defines requirements for</p> <p>a. Determining potential nonconformities and their causes;</p> <p>b. Evaluating the need for action to prevent occurrence</p> <p>c. Determining and ensuring the implementation of preventive action needed;</p> <p>d. Recording results of action taken;</p> <p>e. Reviewing preventive action taken.</p> <p>Preventive actions taken appropriate to the effects of the potential problems</p>		<ul style="list-style-type: none"> ~ DP Control of preventive action ~ Risk analyses (economic / technical) ~ Nonconformance records ~ 8-D-reports ~ Analyses records ~ Test records ~ Action Item list ~ Training plans ~ Training certificates ~ Amended delivery contracts ~ Q agreements ~ Investment plans ~ Trend analysis ~ cost evaluations ~ inputs for continuous improvement ~ FMEA 		

Self-assessment question list (topic list)

ISO 9001:1994 and ISO 9001:2000

Records required by ISO 9001:2000

Clause	Record required
5.6.1	Management reviews
6.2.2 (e)	Education, training, skills and experience
7.1 (d)	Evidence that the realization processes and resulting product fulfill requirements
7.2.2	Results of the review of requirements related to the product and actions arising from the review
7.3.2	Design and development inputs relating to product requirements
7.3.4	Results of design and development reviews and any necessary actions
7.3.5	Results of design and development verification and any necessary actions
7.3.6	Results of design and development validation and any necessary actions
7.3.7	Results of the review of design and development changes and any necessary actions
7.4.1	Results of supplier evaluations and any necessary actions arising from the evaluations
7.5.2 (d)	As required by the organization to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement
7.5.3	The unique identification of the product, where traceability is a requirement
7.5.4	Customer property that is lost, damaged or otherwise found to be unsuitable for use
7.6 (a)	Basis used for calibration or verification of measuring equipment where no international or national measurement standards exist
7.6	Validity of the previous measuring results when the measuring equipment is found not to conform to requirements
7.6	Results of calibration and verification of measuring equipment
8.2.2	Internal audit results and follow-up actions
8.2.4	Indication of the person(s) authorizing release of product.
8.3	Nature of the product nonconformities and any subsequent actions taken, including concessions obtained
8.5.2	Results of corrective action
8.5.3	Results of preventive action