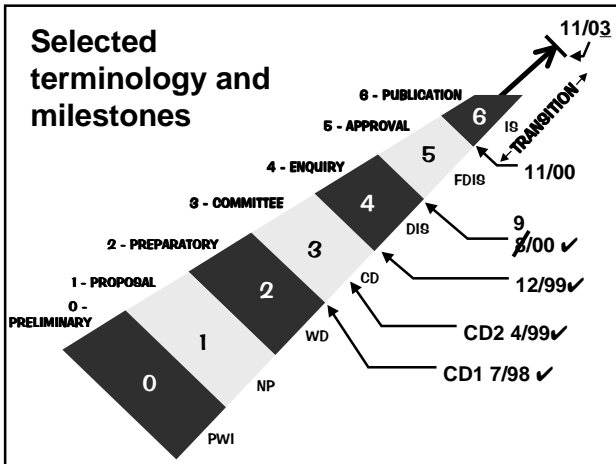


STEP NEXT TAKING THE



- ## Agenda
- Terminology and milestones
 - Inventory of the changes
 - Goals and constraints
 - ISO 9000 family
 - ISO 9001 structure
 - ISO 9001 content
 - Priorities for implementation
 - Priorities for maintenance
 - Impact on registration



Goals and constraints - revision process

The revised ISO 9001 and ISO 9004 standards are **being** developed using a simple process-based structure. ... The new process-based structure is **more generic** than the current 20-element structure and adopts the **process management** approach widely used in business today. Also the new process-based structure is **consistent with the Plan-Do-Check-Act** improvement cycle used in the ISO 14000 standards on environmental management systems. **The 20 elements in the current ISO 9001 will be clearly identifiable** in the new process-based structure.

The revision of the ISO 9000 standards **will not require the rewriting of an organization's quality management system documentation**.

... A major requirement of the ISO 9000 revision process is that **organizations which have implemented the current ISO 9000 standards will find it easy to transition to the revised standards**.

ISO/TC 176/SC 2/N 415 Section 1.5

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Goals and constraints - from the standard

BEFORE (IN '94)	AFTER (IN FDIS)
<p>Introduction The design and implementation of a quality system will be influenced by the varying needs of an organization, its particular objectives, the products and services supplied and the processes and specific practices employed. ... it is not the purpose of these International Standards to enforce uniformity of quality systems.</p> <p>4.2.2 Quality-system procedures For the purpose of this American National Standard the range and detail of the procedures that form part of the quality system depend on the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity.</p>	<p>0.1 General ... The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the purpose of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.</p> <p>4.2 General documentation requirements NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to</p> <ol style="list-style-type: none"> the size of organization and type of activities, the complexity of processes and their interactions the competence of personnel

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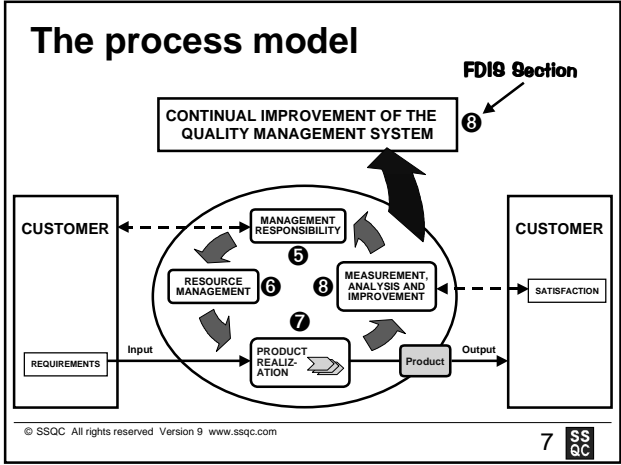
And ...

Incorporate best practice - lessons learned from guidance

- Standard more accessible
 - Less reliance on experts, guidance
- Reduce range of interpretation
 - Less variability in registrations

ISO/TC 176/SC 2/N 439

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Commitments - what ISO 9000 has always been about

WELL BEFORE (IN '87)

1 Scope The requirements specified are aimed primarily at preventing nonconformity at all stages from design through to servicing.

BEFORE (IN '94)

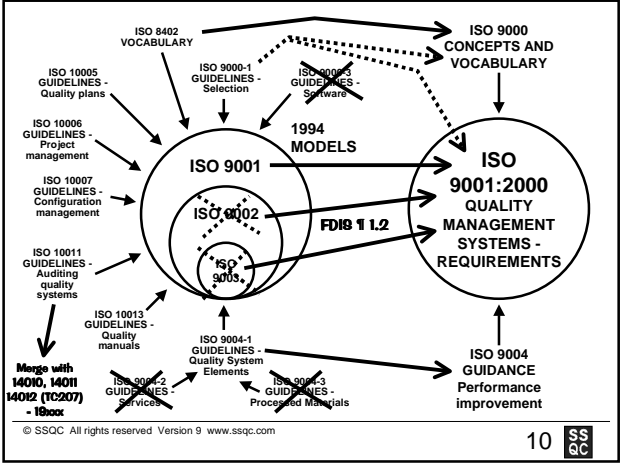
1 Scope The requirements specified are aimed primarily at achieving customer satisfaction by preventing nonconformity at all stages from design through to servicing.

AFTER (IN FDIS)

1.1 General This ... standard specifies requirements ... where an organization

- needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements
- aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

- ### Agenda
- Terminology and time frames
 - Inventory of the changes
 - Goals and constraints
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 - ISO 9001 structure
 - ISO 9001 content
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 - Priorities for maintenance
 - Impact on registration



- ### Agenda
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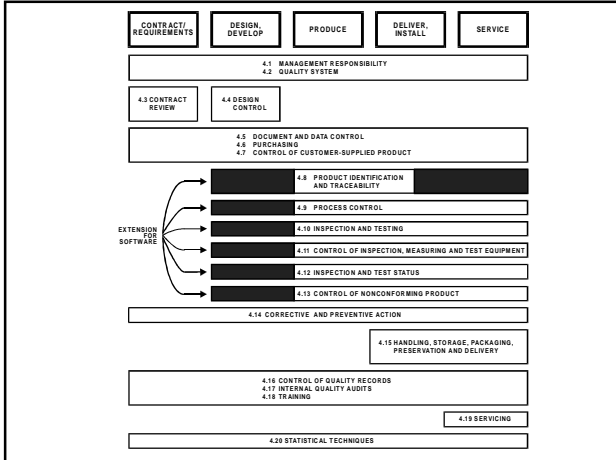
Changes to the structure of ISO 9001

ISO 9001:1994		ISO 9001:1994	
4.1	MANAGEMENT RESPONSIBILITY	4.11	CONTROL OF INSPECTION MEASURING AND TEST EQUIPMENT
4.2	QUALITY SYSTEM	4.12	INSPECTION AND TEST STATUS
4.3	CONTRACT REVIEW	4.13	CONTROL OF NONCONFORMING PRODUCT
4.4	DESIGN CONTROL	4.14	CORRECTIVE AND PREVENTIVE ACTION
4.5	DOCUMENT AND DATA CONTROL	4.15	HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY
4.6	PURCHASING	4.16	CONTROL OF QUALITY RECORDS
4.7	CONTROL OF CUSTOMER-SUPPLIED PRODUCT	4.17	INTERNAL QUALITY AUDITS
4.8	PRODUCT IDENTIFICATION AND TRACEABILITY	4.18	TRAINING
4.9	PROCESS CONTROL	4.19	SERVICING
4.10	INSPECTION AND TESTING	4.20	STATISTICAL TECHNIQUES

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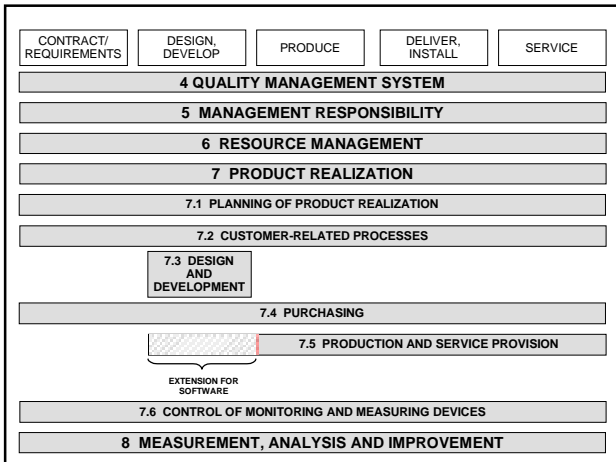
WHAT, NOT HOW

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ISO 9001:2000		ISO 9001:2000	
✓ 4	QUALITY MANAGEMENT SYSTEM	7	PRODUCT REALIZATION
✓ 4.1	GENERAL REQUIREMENTS	7.1	PLANNING OF PRODUCT REALIZATION
✓ 4.2	DOCUMENTATION REQUIREMENTS	7.2	CUSTOMER-RELATED PROCESSES
		7.3	DESIGN AND DEVELOPMENT
→ 5	MANAGEMENT RESPONSIBILITY	7.4	PURCHASING
✓ 5.1	MANAGEMENT COMMITMENT	7.5	PRODUCTION AND SERVICE PROVISION
✓ 5.2	CUSTOMER FOCUS	7.6	CONTROL OF MONITORING AND MEASURING DEVICES
✓ 5.3	QUALITY POLICY		
✓ 5.4	PLANNING	8	MEASUREMENT, ANALYSIS AND IMPROVEMENT
✓ 5.5	RESPONSIBILITY, AUTHORITY, AND COMMUNICATION	8.1	GENERAL
✓ 5.6	MANAGEMENT REVIEW	8.2	MONITORING AND MEASUREMENT
		8.3	CONTROL OF NONCONFORMING PRODUCT
→ 6	RESOURCE MANAGEMENT	8.4	ANALYSIS OF DATA
✓ 6.1	PROVISION OF RESOURCES	8.5	IMPROVEMENT
✓ 6.2	HUMAN RESOURCES		
✓ 6.3	INFRASTRUCTURE		
✓ 6.4	WORK ENVIRONMENT		

28 subdivisions
 ✓ = 23 with content
 STILL: WHAT, NOT HOW



Agenda

- Terminology and time frames
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Changes to the content of ISO 9001

- FDIS contains 140 “shall”s versus 137 in ISO 9001:1994
- What’s missing - *nothing*
- What’s new ...

What’s new according to ISO

IN OUR (HUMBLE)
OPINION, BUT DUE TO ...

- The new/more clearly defined requirements include:
 - ① Measurement of customer satisfaction
 - ② Continual improvement
 - ③ Increased attention to resource availability
 - ④ Measurements extended to processes and product
 - ⑤ Analysis of collected data on the performance of the quality management system

① Measurement of customer satisfaction

BEFORE (IN '94)

- 1 Scope The requirements specified are aimed primarily at achieving customer satisfaction by preventing nonconformity at all stages from design through to servicing
- 4.1.1 The quality policy shall be relevant to ... the expectations and needs of its customers.
- 4.14.2 a) the effective handling of customer complaints and reports of product nonconformities
- 4.14.3 the use of appropriate sources of information such as ... concessions, ... service reports, and customer complaints to detect, analyze, and eliminate potential causes of nonconformities

AFTER (IN FDIS)

- 1.1 ... where an organization
b) aims to enhance customer satisfaction ...
- 5.2 Top management shall ensure that customer requirements are ... fulfilled with the aim of enhancing customer satisfaction
- 5.6.2 Inputs to management review ...
b) Customer feedback
- 8.2.1 Customer satisfaction ... the organization shall monitor information relating to customer perception ...
- 8.4 The analysis of data shall provide information relating to
a) customer satisfaction ...
- 8.5.2 Corrective action ... a) identifying nonconformities (including customer complaints)

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② Continual improvement

BEFORE (IN '94)

- 1 Scope The requirements specified are aimed primarily at achieving customer satisfaction by preventing nonconformity at all stages from design through to servicing.
- 4.14 Corrective and preventive action
- 4.14.1 General
- 4.14.2 Corrective action
- 4.14.3 Preventive action

AFTER (IN FDIS)

- 1.1 General This ... standard specifies requirements ... where an organization
b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement ... and the assurance of conformity to applicable ... requirements.
- 8.5 Improvement
- 8.5.1 Planning for continual improvement
- 8.5.2 Corrective action
- 8.5.3 Preventive action

Corrective action

BEFORE (IN '94)

- Goal: Correct problem, prevent recurrence
- Corrective action implicit
 - Risk, magnitude criteria explicit
 - Controls explicit
 - Records results of investigation

AFTER (IN FDIS)

- Goal: Correct problem, prevent recurrence
- + Corrective action explicit
 - ± Impact criterion explicit
 - Controls implicit
 - + Record results of action;
 - + Review action taken
 - + Status in management review (5.6)

Preventive action

BEFORE (IN '94)

- Goal: Prevent occurrence
- Potential causes of nonconformities
 - Risk, magnitude criteria explicit
 - Controls explicit
 - Information on actions taken submitted for management review

AFTER (IN FDIS)

- Goal: Prevent occurrence
- + Potential nonconformities
 - ± Impact criterion explicit
 - Controls not explicit
 - + Review action taken
 - ± Status in management review (5.6)

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Improvement - continual and otherwise

- ISO/DIS 9000:2000
- ISO/FDIS 9001:2000

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DIS 9000 Section 2 Concepts and Definitions

- 2.2.12 quality improvement - part of quality management (2.2.8) focused on increasing its effectiveness (2.2.13) and efficiency (2.2.14)

NOTE - The term "continual quality improvement" is used when quality improvement is progressive and the organization (2.3.1) actively seeks and pursues improvement opportunities

- 2.2.13 effectiveness - measure of the extent to which planned activities are realized and planned results achieved

- 2.2.14 efficiency - relationship between result achieved and resources used

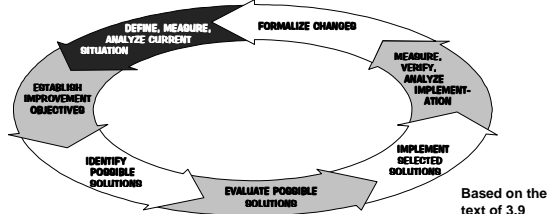
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DIS 9000 Section 3 Fundamentals

3.9 Continual improvement

Improvement refers to the actions taken to enhance the features and characteristics of products and/or to increase the effectiveness and efficiency of processes used to produce and deliver them. Results are reviewed, as necessary, to determine further opportunities for improvement. Audits, customer feedback and review of the quality management system can also be used to identify opportunities. Improvement is a continual activity.



FDIS 9001 - 8.5 Improvement

8.5 Improvement

8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

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Other references related to continual improvement in FDIS 9001

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement, and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

- f) implement actions necessary to achieve planned results and continually improve the quality management system

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Other references related to continual improvement in FDIS 9001 (cont.)

5.3 Quality policy

Top management shall ensure that the quality policy:

- b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system

6.1 Resource Management

The organization shall determine and provide the resources needed ... a) to continually improve its effectiveness

Quality planning shall include:

- c) continual improvement of the quality management system

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A digression ... the quality policy

BEFORE (IN '94)

4.1.1 Quality policy

The supplier's management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented, and maintained at all levels in the organization.

AFTER (IN FDIS)

5.3 Quality policy

Top management shall ensure that the quality policy

- a) is appropriate to the purpose of the organization;
- b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system;
- c) provides a framework for establishing and reviewing quality objectives;
- d) is communicated and understood within the organization;
- e) is reviewed for continuing suitability.

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Other references related to continual improvement in FDIS 9001 (cont.)

BEFORE (IN '94)

4.1.3 Management review

The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16).

AFTER (IN FDIS)

5.6 Management review

Top management shall review the quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the organization's quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4)


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More about management review

5.6.2 Review input
 The input to management review shall include information on

- results of audits;
- customer feedback;
- process performance and product conformity;
- status of preventive and corrective actions;
- follow-up actions from previous management reviews;
- planned changes that could affect the quality management system.
- Recommendations for improvement


⇓

 ⇓

5.6.3 Review output
 The outputs from the management review shall include any decisions and actions related to:

- improvement of the effectiveness of the quality management system and its processes;
- improvement of product related to customer requirements;
- resource needs.


③ Increased attention to resource availability

- General: 5.1
- Human resources: 6.2
- Infrastructure and work environment: 6.3, 6.4
- Information: 4.1, 4.2, 5.5.3, 7.2.2, 7.3.1, 7.3.3
- Planning:
 - 5.4.2 Quality management system planning
 - 7.1 Realization
 - 7.3.1 Design and development
 - 8.1 monitoring, measurement, analysis, and improvement
 - 8.2.2 Internal audits

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③ Increased attention to resource availability - general : 5.1

BEFORE (IN '94)	AFTER (IN FDIS)
<p>4.1.2.2 Resources The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel, for management, performance of work, and verification activities, including internal quality audits.</p>	<p>5.1 Management responsibility Top management shall provide evidence of its commitment ... by</p> <ol style="list-style-type: none"> ensuring the availability of resources

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③ Increased attention to resource availability - human resources : 6.2 and 5.4.2

BEFORE (IN '94)	AFTER (IN FDIS)
<p>4.1.2.2 Resources ... adequate resources, including trained personnel, for management, performance, and verification activities, including ... audits.</p> <p>4.4.2 Design and development planning The design and development activities shall be assigned to qualified personnel ...</p> <p>4.18 Training ... documented procedures ... identifying needs ... providing ... for all who manage, perform, and verify work affecting quality ... appropriate records maintained</p>	<p>6.2 Human resources</p> <p>6.2.1 General Personnel ... shall be competent on the basis of appropriate education, training, skills and experience</p> <p>6.2.2 Competence, awareness and training The organization shall:</p> <ol style="list-style-type: none"> determine the necessary competence ... provide training ... evaluate the effectiveness of the actions taken

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③ Increased attention to resource availability - Facilities and work environment : 6.3, 6.4

BEFORE (IN '94)	AFTER (IN FDIS)
<p>4.4.2 Design and development planning The design and development activities shall be assigned to qualified personnel equipped with adequate resources</p> <p>4.9 Process control ... identify and plan the production, installation, and servicing processes and ensure that these processes are carried out under controlled conditions</p> <ol style="list-style-type: none"> use of suitable ... equipment, and a suitable working environment compliance with reference standards, codes ... approval of processes and equipment, as appropriate suitable maintenance of equipment to ensure continuing process capability 	<p>6 Resource management</p> <p>6.3 Infrastructure The organization shall determine, provide, and maintain the infrastructure needed to achieve conformity. Infrastructure includes, for example</p> <ol style="list-style-type: none"> buildings, workspace, ... utilities process equipment, both hardware and software supporting services ... <p>6.4 Work environment The organization shall determine and manage the work environment needed to achieve conformity to product requirements.</p>

③ Increased attention to resource availability - information: 4.1, 4.2, 5.5.3, 7.2.2, 7.3.1, 7.3.3

BEFORE (IN '94)	AFTER (IN FDIS)
<p>4.2.1 General ... establish, document, maintain ... quality system</p> <p>4.3.3 Amendment to contract ... transferred to the functions concerned</p> <p>4.4.3 Organizational and technical interfaces ... necessary information documented, transmitted, and regularly reviewed.</p> <p>4.4.5 Design output Design-output documents ... reviewed</p> <p>4.5.1 General ... control all documents and data</p> <p>4.5.2 Document approval and issue ... reviewed and approved ... prior to issue ...</p> <ul style="list-style-type: none"> • ... pertinent issues available; • ... obsolete ... removed or otherwise assured against unintended use • ... obsolete ... retained for information purposes ... identified <p>4.5.3 Document and data changes ... changes reviewed and approved</p> <p>4.9 Process control a) documented procedures where ...</p>	<p>4.1 General requirements</p> <p>4.2 Documentation requirements</p> <p>5.5.3 Internal communication</p> <p>7.2.2 Review of requirements related to product</p> <p>7.3.1 Design and development planning</p> <p>7.3.3 Design and development outputs</p>

③ Increased attention to resource availability - information: 4.1, 4.2, 5.5.3, 7.2.2, 7.3.1, 7.3.3

BEFORE (IN '94)
 4.2.1 General
 ... establish, document, maintain ... quality system
 4.3.3 Amendment to contract
 ... transferred to the functions concerned
 4.4.3 Organizational and technical interfaces
 ... necessary information documented, transmitted, and regularly reviewed.
 4.4.3 Design output
 Design-output documents ... reviewed
 4.5.1 General
 ... control all documents and data
 4.5.2 Document approval and issue
 ... reviewed and approved ... prior to issue ...
 ... pertinent issues available:
 • obsolete ... removed or otherwise
 • assured against unintended use
 • obsolete ... retained for information purposes ... identified
 4.5.3 Document and data changes
 changes reviewed and approved
 4.9 Process control
 a) documented procedures where ...

AFTER (IN FDIS)
 4.1 General requirements
 ... ensure the availability of resources and information necessary to support the operation and monitoring of these processes
 4.2.3 Control of documents
 (a) ... approve for adequacy
 (b) ... review, update, reapprove
 (c) ... identify changes and current revision status
 (d) ... relevant versions available
 (e) ... legible, identifiable
 (f) ... external origin ...
 (g) ... prevent unintended use of obsolete ...
 5.5.3 Internal communication
 Top management shall ensure that appropriate communication processes are established ... and that communication takes place regarding the effectiveness of the quality management system
 7.2.2 Review of product requirements
 7.3.1 Design and/or development planning
 7.3.3 Design and/or development outputs

③ Increased attention to resource availability - information: 4.1, 4.2, 5.5.4, 5.5.6, 7.2.2, 7.3.1

BEFORE (IN '94)
 4.2.1 General
 ... establish, document, maintain ... quality system
 4.3.3 Amendment to contract
 ... transferred to the functions concerned
 4.4.3 Organizational and technical interfaces
 ... necessary information documented, transmitted, and regularly reviewed.
 4.4.3 Design output
 Design-output documents ... reviewed
 4.5.1 General
 ... control all documents and data
 4.5.2 Document approval and issue
 ... reviewed and approved ... prior to issue ...
 ... pertinent issues available:
 • obsolete ... removed or otherwise
 • assured against unintended use
 • obsolete ... retained for information purposes ... identified
 4.5.3 Document and data changes
 changes reviewed and approved
 4.9 Process control
 a) documented procedures where ...

AFTER (IN FDIS)
 4.1 General requirements
 4.2.3 Control of documents
 5.5.3 Internal communication
 7.2.2 Review of product requirements
 ... Where product requirements are changed ... documentation amended ... personnel ... made aware
 7.3.1 Design and development planning
 The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.
 7.3.3 Design and development outputs
 Design and development output ... shall be approved prior to release.

A semi-digression ... support for inter-group coordination

In addition to 5.5.3 Internal communication ISO/FDIS 9001:2000 specifies:

- 7.2.1 Determination of requirements related to the product
 The organization shall determine ... requirements for delivery and post-delivery activities
- 7.3.3 Design and/or development outputs
 Design and/or development output shall ... provide appropriate information for purchasing, production and for service provision



③ Increased attention to resource availability - planning: 7.1, 7.3.1, 8.1, 8.2.2

BEFORE (IN '94)
 4.2.2 Quality planning
 ... document how requirements for quality will be met
 4.4.2 Design and development planning
 ... plans for each design and development activity
 4.9 Process control
 ... identify and plan the production, installation, and servicing
 4.17 Internal quality audits
 ... documented procedures for planning and implementing

AFTER (IN FDIS)
 7.1 Planning of product realization
 7.3.1 Design and development planning
 8.1 General [Measurement, analysis and improvement]
 8.2.2 Internal audit
 8.5.1 Continual improvement

③ Increased attention to resource availability - planning: 7.1, 7.3.1, 8.1, 8.2.2

BEFORE (IN '94)
 4.2.2 Quality planning
 ... document how requirements for quality will be met
 4.4.2 Design and development planning
 ... plans for each design and development activity
 4.9 Process control
 ... identify and plan the production, installation, and servicing
 4.17 Internal quality audits
 ... documented procedures for planning and implementing

AFTER (IN FDIS)
 7.1 Planning of product realization
 ... the organization shall plan and develop the processes for product realization. The organization shall determine the following as appropriate:
 a) quality objectives and requirements for the product
 b) the need to establish processes, documents, and provide resources specific to the product;
 c) required verification, validation, monitoring, inspection, and test activities specific to the product, and the criteria for product acceptance;
 d) records needed to provide evidence ... processes and resulting product fulfill requirements (see 4.2.4).
 7.3.1 Design and development planning
 8.1 General
 8.2.2 Internal audit

③ Increased attention to resource availability - planning: 7.1, 7.3.1, 8.1, 8.2.2

BEFORE (IN '94)
 4.2.2 Quality planning
 ... document how requirements for quality will be met
 4.4.2 Design and development planning
 ... plans for each design and development activity
 4.9 Process control
 ... identify and plan the production, installation, and servicing
 4.17 Internal quality audits
 ... documented procedures for planning and implementing

AFTER (IN FDIS)
 7.1 Planning of realization processes
 7.3.1 Design and development planning
 ... the organization shall determine
 (a) ... stages ...
 (b) ... review, verification, validation [for] each stage
 (c) responsibilities and authorities ...
 8 Measurement, analysis and improvement
 8.1 General
 The organization shall plan and implement the monitoring, measurement, analysis and improvement processes ...
 8.2.2 Internal audit
 An audit programme shall be planned ... status ... importance ... results of previous audits

④ Measurements extended to processes and product

BEFORE (IN '94)

4.9 d) monitoring and control of ... process parameters and product characteristics

4.20.1 ... shall identify the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics.

4.20.2 ... shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1.

AFTER (IN FDIS)

4.1 General requirements

5.6.2 Review input

8 Measurement, analysis and improvement


8.1 General

8.2 Monitoring and Measurement

8.2.3 Monitoring and measurement of processes

8.2.4 Monitoring and measurement of product

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④ Measurements extended to processes and product

BEFORE (IN '94)

4.9 d) monitoring and control of ... process parameters and product characteristics

4.20.1 ... shall identify the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics.

4.20.2 ... shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1.

AFTER (IN FDIS)

4.1 General requirements

... the organization shall ... monitor, measure, and analyze these processes

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those ... for product ... are established The quality objectives shall be measurable and consistent with the quality policy.

5.6.2 Review input

Inputs to management review shall include ... process performance and product conformity


8.2 Measurement and monitoring

As one of the measurements of performance ..., the organization shall monitor customer perception ...

8.2.3 Measurement and monitoring of processes

8.2.4 Measurement and monitoring of product

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A digression ... internal audits

BEFORE (IN '94)

4.1.2.2 Resources

... identify and provide adequate resources for ... internal audits

4.17 Internal audits

The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

AFTER (IN FDIS)

5.6.2 Review input

The inputs to management review shall include information on results of audits


8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system:

(a) conforms to planned arrangements, to the requirements of this International Standard and to the ... requirements established by the organization

(b) is effectively implemented and maintained

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⑤ Analysis of collected data on the performance of the quality management system

AFTER (IN FDIS)

8.4 Analysis of data

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The organization shall analyze this data to provide information on:


a) customer satisfaction;

b) conformance to product requirements;

c) characteristics and trends of processes and products including opportunities for preventive action;

d) suppliers


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Some remarks about other changes in the FDIS

- The title
- Generic view of customer - supports COTS products
- No specific names for the different stages of testing
- References to requirements - remove "contractual" language)


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Some remarks (cont.)

- New job for management representative: "ensure the promotion of awareness of customer requirements" (5.5.2)
- Customer-supplied product changed to customer property (7.5.4)
- Verification of purchased product now addresses what the title implies - what's left of receiving inspection (7.4.3)

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Some remarks (cont.)

- ☞ New list of quality records
- ☞ One requirement for software used for testing (7.6)
- ☞ Definition of “design and development” in ISO/DIS 9000
- ☞ Still no definition of production

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Design, develop, and produce

ISO/DIS 9000:2000

2.4.7 design and development - set of processes (2.4.1) that transforms requirements (2.1.2) into specified characteristics (2.5.1) and into the specification (2.7.2) of the product (2.4.2) realization process.

NOTE 1 The terms "design" and "development" are sometimes used synonymously and sometimes used to define different stages of the overall design and development process.

NOTE 2 A qualifier may be applied to indicate the nature of what is being designed and developed (e.g. product design and development or process design and development).

American Heritage Dictionary

produce: to bring forth; yield, by physical or mental effort; to manufacture, to cause to occur or exist; to make or yield a product.

Priorities for implementers

- If you are in a hurry - read the FDIS - work from the FDIS
 - Wait for ISO 9001:2000
 - Unless you've already made a substantial start ...
 - IAF policy
- Define how you want to do business
- Compare that to the standard

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Priorities for maintainers

- Read the 1994 standard
 - IAF policy
 - Identify and understand the changes at a detailed level
 - Check with your registrar for timing
- Identify gaps
- Implement any required changes

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An assessment for maintainers

- How long will you need to implement the revisions?
- What change do you see as requiring the most resource to effect?
- What change do you see as the most difficult to effect?
- How big is the organization within the scope? **SMALL** (<50 employees), **MEDIUM** (50 to 250), **LARGE** (>250)

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An assessment for implementors

- How long will you need to achieve compliance?
- What requirement do you see as requiring the most resource to satisfy?
- What requirement do you see as the most difficult to satisfy?
- How big is the organization that will be within the scope? **SMALL** (<50 employees), **MEDIUM** (50 to 250), **LARGE** (>250)

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