

Transition to ISO 9001:2000

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Analysis of the differences and implications

Second Edition

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A flexible approach to business improvement

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Introduction

The ISO 9000 family of International Standards used by more than 340,000 organizations world-wide to improve customer satisfaction and their competitive edge has been given a complete overhaul. This guide has two primary objectives:-

1. To provide an analysis of the differences between 2000 and 1994 versions
2. To describe the implication of the differences for organizations.

Changes in the family of standards

There were 20 standards in the 1994 family of standards. This has been significantly reduced to 4 standards as indicated in Table 1.

Changes in titles

The title of the four standards has changed to reflect the changes in scope as indicated in Table 2. ISO 8402 containing the vocabulary has been withdrawn and embodied in ISO 9000. ISO 9001 now addresses QMS requirements, expanding its application beyond product quality assurance. ISO 9004 now addresses performance improvement, expanding its application beyond the initial development of a QMS. ISO 19011 now addresses environmental auditing thereby extending the scope of ISO 10011.

Table 2 Changes in titles

Standard	1994	2000
ISO 9000	Quality systems-Guidelines for selection and use	Quality management systems - Fundamentals and Vocabulary
ISO 9001	Model for quality assurance in design/development, production, installation and servicing	Quality management systems - Requirements
ISO 9004	Quality management and quality system elements - Guidelines	Quality management systems - Guidance for performance improvements
ISO 19011	Guidelines for auditing quality systems	Guidelines for auditing quality and environmental systems

Changes in terminology

In the 1994 version the term 'supplier' was used to identify the organization implementing the requirements. This has now been replaced with the term 'organization' so as to be consistent with ISO 9004 and to overcome the confusion with organizations that provide supplies. It also avoids using the term subcontractor which is often associated with suppliers that provide goods and services to customer specific requirements. These and other changes are indicated in Table 3.

Table 1 Changes in the family

1994	2000
ISO 9000-1 ISO 8402	ISO 9000
ISO 9000-3 ISO 9001 ISO 9002 ISO 9003 ISO 1005 ISO 1007	ISO 9001
ISO 9000-3 ISO 9004 in 4 parts ISO 1005 ISO 1007	ISO 9004
ISO 10011 in 3 parts ISO 9000-4	ISO 190011 IEC 60300-1

Table 3 Changes in terminology

1994	2000
Supplier	Organization
Procedures	Processes
Executive management	Top management
Specified requirements	Customer requirements

Changes in content

The content of ISO 9001 has changed significantly as indicated in Table 4. The 20 elements have been replaced with 5 sections that group requirements into more generic categories. Most of the requirements of the 1994 version have been included in the 2000 version with the majority located in section 7.

Table 4 Changes in content

ISO 9001:1994	ISO 9001:2000
4.1 Management responsibility 4.2 Quality system 4.3 Contract review 4.4 Design control 4.5 Document & data control 4.6 Purchasing 4.7 Customer supplied product 4.8 Product identification 4.9 Process control 4.10 Inspection and testing 4.11 Inspection and test status 4.12 Inspection, measuring and test equipment 4.13 Control of nonconforming product 4.14 Corrective and preventive action 4.15 Handling, storage, packaging, preservation and delivery 4.16 Control of quality records 4.17 Internal quality audits 4.18 Training 4.19 Servicing 4.20 Statistical techniques	4 Quality management system requirements 4.1 General requirements 4.2 Documentation requirements 5 Management responsibility 5.1 Management commitment 5.2 Customer focus 5.3 Quality policy 5.4 Planning 5.5 Responsibility, authority and communication 5.6 Management review 6 Resource management 6.1 Provision of resources 6.2 Human resources 6.3 Infrastructure 6.4 Work environment 7 Product realization 7.1 Planning of product realization 7.2 Customer-related processes 7.3 Design and development 7.4 Purchasing 7.5 Production and service provision 7.6 Control of monitoring and measuring devices 8 Measurement, analysis and improvement 8.1 General 8.2 Monitoring and measurement 8.3 Control of nonconforming product 8.4 Analysis of data 8.5 Improvement

Changes in parameters

There has been a reduction in every major parameter that has been used to describe the contents of ISO 9001 as indicated in Table 5. The numbers themselves are misleading because it does not mean there are fewer things to do. Many requirements were duplicated in ISO 9001:1994 and while the number of instances where procedures, records or documents were required has reduced, the important change is not in the numbers but in the intent. (See *Changes in intent*) It should also be noted that a 'shall' statement in the 2000 version may contain more multiple requirements than in the 1994 version. Everywhere there is an 'and' or a comma there is an additional requirement.

Changes in intent

ISO 9000:2000 presents a significant change in intent as indicated by the examples given in Table 6. When reading the requirements separately the changes in intent are not obvious. One has to link the requirements together and understand the principles behind the revision to appreciate the magnitude of the changes. Further guidance is provided in the Bibliography.

Changes in requirements

ISO 9001:2000 can be read from the perspective of looking for changes in words. Many of the clause headings are the same as those in the 1994 version but their content has changed. Table 7 shows the net effect of the changes. The tables that follow address the changes in detail from which these figure were extracted. There is a 47% change numerically, which in terms of impact is more like a 70% change in direction. However, a requirement that may have the same intent to one reader may be perceived to be a new requirement to another - it all depends on how the original requirements were interpreted. For some organizations this may mean that there are 226 new requirements - a staggering 90% change. If the standard is perceived as a framework, organizations will naturally go beyond the prescribed requirements of ISO 9001 and meet its intent. If it is perceived as a specification that must be met, organizations will limit their actions to conformity and no more. To gain any real benefit from ISO 9000 it is necessary to go beyond conformity. It is also necessary to comprehend the requirements and not take each one in isolation. The fundamental requirements are contained in section 4 of ISO 9001 and it is important to read ISO 9004 and the other ISO documents (see Bibliography) in order to understand the intent of the requirements and to bear this in mind when reading the other parts of the standard.

Table 7 Changes in requirements

New requirements	119
No change in intent	107
No change in requirements	17
Less onerous requirements	7
Total	250

Table 5 Changes of parameters in ISO 9001

Parameter	1994	2000
Elements	20	5
Clauses	59	51
Shalls	138	136
Procedures	18	6
Records	20	21
Documents (Includes procedures and records)	79	30

Table 6 Changes in intent

1994	2000
Conformity	Performance
Quality Assurance	Customer Satisfaction
Documented procedures	Managed processes
Meeting product requirements	Meeting needs and expectations of all interested parties
Skills	Competence
Order driven	Market driven
Documentation for demonstrating conformity	Documentation for effective management
Product measurement	Product, process and system measurement

Key changes at a glance

Audits	Audits of QMS design, processes and conformity with ISO 9001 - no longer limited to procedure audits
Communication	Processes for internal communication rather than systems of documentation
Continual improvement	The effectiveness of the QMS to be continually improved
Contract Review	Replaced by a wide-ranging review of all product requirements including customer, organizational & regulatory requirements
Customer satisfaction	Customer perceptions of the organization's performance to be monitored as one of the measures of QMS performance
Design	If the organization designs its own products and services, design and development processes must be included in the QMS
Documentation	Determined by the organization as necessary for effective operation of its processes - not simply as required by the standard
Linkages	Organization purpose, policy, objectives, processes and results to be linked to demonstrate effective process management
Management review	Top management to review the system for its effectiveness in enabling the organization to meet requirements of customers and other interested parties - no longer limited to a review of audit results and customer complaints
Marketing	The processes employed to determine customer needs and expectations must form part of the QMS
Measurement	Required for all processes not only production, servicing and installation processes
Procedures	Only six procedures specified as requirements, others as needed for effective operation and control of the processes
Processes	All processes that serve the achievement of the organization's objectives to comprise the QMS
QMS	To be designed around the organization's processes not the elements and clauses of the standard
Quality Manual	Needs to describe the interaction between processes - is not to be a response to each clause of the standard
Quality objectives	Separate from the policy but consistent with it and established at relevant levels and functions - the driver of continual improvement in performance
Quality policy	To be appropriate to the purpose of the organization and provides framework for quality objectives - not a motherhood statement
Records	As needed to provide evidence of effective operation - all types of records not simply those referred to as quality records
Requirements	Commitment to meeting requirements of customer and other interested parties - no longer limited to the organization's own requirements
System effectiveness	To be measured, analysed and continually improved and judged by the degree to which customers are satisfied - not judged on conformity with standard
Top management	Must be involved in establishing, developing, reviewing and improving the QMS

Analysis of changes in requirements

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
4.1	The standard requires the organization to establish and document a quality management system in accordance with the requirements of ISO 9001.	4.2.1	The standard required the supplier to establish and document a quality system as a means of ensuring that product conforms to specified requirements.	There is no change in intent but the new wording loses the reasons for doing it.	NCI
4.1	The standard requires the organization to implement a quality management system in accordance with the requirements of ISO 9001.	4.2.2b	The standard required the supplier to: a) effectively implement the quality system and its documented procedures. b) include compliance with reference standards/codes, quality plans and/or documented procedures	There is no change in intent but the new wording loses the reasons for doing it. Internal audits now have to verify that the system has been effectively implemented therefore; the intent of the previous wording is retained.	NCI
4.1	The standard requires the organization to maintain a quality management system in accordance with the requirements of ISO 9001.	4.2.1	The standard required the supplier to maintain a quality system as a means of ensuring that product conforms to specified requirements.	There is no change in intent but the new wording loses the reasons for doing it.	NCI
4.1	The standard requires the organization to continually improve a quality management system in accordance with the requirements of ISO 9001.		No equivalent requirement.	This new requirement means that the organisation will need to demonstrate that it has a policy or value of continuous improvement and is implementing that policy.	NR
4.1a	The standard requires the organization to identify the processes needed for the quality management system.	4.9	The standard required the supplier to: a) identify the production, installation and servicing processes which directly affect quality. b) define the process employed for the calibration of inspection, measuring and test equipment including details of the equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory	The difference is an extension of the requirement to all processes needed for the management of the organisation's objectives.	NR
4.1b	The standard requires the organization to determine the sequence and interaction of the identified processes.		No equivalent requirement.	This new requirement means that the organisation will need to have an understanding and description of the processes and how they relate and interface.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
4.1c	The standard requires the organization to determine criteria and methods required to ensure the effective operation and control of the identified processes.		No equivalent requirement.	This new requirement means that the organisation will need to establish measurement and review mechanisms to manage the performance of their processes.	NR
4.1d	The standard requires the organization to ensure the availability of resources necessary to support the operation and monitoring of the identified processes.	4.1.2.2	The standard required the supplier to identify resource requirements and provide adequate resources for management, performance of work and verification activities.	The intent of the requirements remains unchanged but more processes are now to be resourced.	NCI
4.1d	The standard requires the organization to ensure the availability of information necessary to support the operation and monitoring of the identified processes.	4.9	The standard required the supplier to plan the production, installation and servicing processes which directly affect quality.	This new requirement means that the results of process measurement will need to be available and accessible for managing the processes.	NR
4.1e	The standard requires the organization to measure, monitor and analyze the identified processes.	4.9d	The standard required controlled conditions to include the monitoring and control of suitable process parameters and product characteristics.	In order to control suitable process parameters, organizations would have had to measure, monitor and analyze the identified processes but this was limited to production, installation and servicing processes - this new requirement extends its applicability to all processes.	NR
4.1f	The standard requires organizations to implement action necessary to achieve planned results of the (identified) processes.	4.14.2c	The standard required corrective action procedures include the determination of actions needed to eliminate the cause of process nonconformities	This new requirement means that the actions taken need to be focused on improving the ability of processes to achieve their objectives.	NR
4.1f	The standard requires organizations to implement action necessary to achieve continual improvement of the (identified) processes.		No equivalent requirement	This new requirement means that actions will need to be taken that improve the performance of processes that are already meeting the defined objectives i.e. raising standards.	NR
4.1	The standard requires the organization to manage the identified processes in accordance with the requirements of ISO 9001.	4.9	The standard required the supplier to plan the production, installation and servicing processes that directly affect quality and ensure that these processes are carried out under controlled conditions.	This new requirement goes beyond planning and implies that processes should be managed by setting objectives (5.4.1), planning and resourcing to meet the objectives (5.4.2 & 6.1) reviewing performance (8.2.3) and undertaking continual improvement (8.5.1).	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
4.1	The standard requires the organization to ensure control over outsourced processes		No equivalent requirement	An outsourced process is one that is managed by another organization on behalf of the parent organization. For a process to be outsourced, the supplier should be given an objective and given freedom to determine how that objective will be met. The processes will have a capability that enables the organization to avoid checking the outputs. The rigor applied to the internal processes will need to be applied to the outsourced process.	NR
4.2.1a	The standard requires the quality management system documentation to include documented statements of a quality policy and quality objectives	4.1.1	The standard required the supplier's management with executive responsibility to document its policy for quality including objectives for quality.	This new requirement means that separate statements of quality policy and quality objectives are needed.	NR
4.2.1b	The standard requires the quality management system documentation to include a quality manual.	4.2.1	The standard required the supplier to prepare a quality manual.	The intent of the requirement remains unchanged, but the manual needed will be very much different.	NCI
4.2.1c	The standard requires the quality management system documentation to include documented procedures required by ISO 9001.	4.2.2a	The standard required the supplier to prepare procedures consistent with the requirements of the standard and the supplier's stated quality policy.	This clarification reduces the number of procedures required.	LR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
4.2.1d	The standard requires quality management system documentation to include documents needed by the organization to ensure the effective planning, operation and control of its processes.	4.2.3 4.3.1, 4.4.1, 4.6.1, 4.10.1, 4.15.1 4.9 4.9a 4.9f 4.13.1 4.14.1	There were requirements in the previous version that went some way to meeting the intent of this new requirement. The previous version required the supplier to:- a) document how the requirements for quality will be met b) documented procedures for contract review, design control, purchasing, inspection and testing, handling, packaging, delivery etc. c) plan the production, installation and servicing processes which directly affect quality d) document procedures defining the manner of production, installation and servicing e) stipulate criteria for workmanship. f) Nonconforming product control g) Corrective and preventive actions	The intent of the requirement has changed. Documentation was previously required to demonstrate conformity - it is now required for effective operation and control implying that documentation need be produced only when there are operational benefits for the organization.	NR
4.2.1e	The standard requires the quality management system documentation to include records required by ISO 9001		No equivalent requirement	Records were not previously considered part of the system documentation and hence this new requirement may only change perceptions.	NR
4.2.2	The standard requires a quality manual to be established and maintained that includes the scope of the QMS, the documented procedures or reference to them and a description of the interaction between the processes of the QMS.	4.2.1	The standard required that the supplier prepare a quality manual covering the requirements of this International Standard that includes or makes reference to the quality system procedures and outlines the structure of the documentation used in the quality system.	The difference here is that the quality manual is now a document that describes the system that is designed to achieve the organisation's purpose and not a document that responds to each clause of the standard. A key implication is that many manuals will have to be rewritten but can be simplified and be more user friendly.	NR
4.2.3	The standard requires documents required for the quality management system to be controlled.	4.5.1	The standard required the supplier to control all documents and data that relate to the requirements of this International Standard including, to the extent applicable, documents of external origin such as standards and customer drawings.	The intent of the new requirement remains unchanged. However, key documents and data required for process management will need to be identified and controlled.	NCI

NR = New Requirement. NCI = No Change in Intent. NC = No Change. LR = Less Onerous Requirement

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
4.2.3	The standard requires that a documented procedure be established to define the controls needed for documents required by the QMS.	4.5.1	The standard required the supplier to establish and maintain documented procedures to control all documents and data that relate to the requirements of this International Standard.	The difference is the removal of 'data' and making the term procedures singular. The intent however remains the same.	NCI
4.2.3a	The standard requires that documents be approved for adequacy prior to use.	4.5.2	The standard required that documents and data be approved for adequacy by authorized personnel prior to issue.	Although this requirement no longer requires approval by authorized personnel, there is no change in the intent because authority of functions is required to be defined by 5.5.2.	NCI
4.2.3b	The standard requires that documents be reviewed and updated as necessary.	4.5.2	The standard required documents to be reviewed for adequacy by authorized personnel prior to issue.	The intent of the new requirement for document review is to establish whether the document remains suitable for its intended purpose following a period of use. The previous requirement did not prohibit documents remaining in use after they have become inadequate through neglect.	NR
4.2.3b	The standard requires that documents be re-approved.	4.5.3	The standard required changes to documents and data be reviewed and approved by the same functions/organizations that performed the original review and approval unless specifically designated otherwise.	Although the requirement is less prescriptive it meets the same intent simply because the authority is required to be defined by 5.5.1.	NCI
4.2.3c	The standard requires changes and the current revision status of documents to be identified.	4.5.2	The standard required that a) a master list or equivalent document control, procedure identifying the current revision status of documents be established and be readily available to preclude the use of invalid and/or obsolete documents b) the nature of change be identified in the document or the appropriate attachment	Although less prescriptive the requirement meets the same intent.	NCI
4.2.3d	The standard requires relevant versions of applicable documents to be available at points of use.	4.5.2a	The standard required the supplier to ensure that the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed.	The intent of the requirement remains unchanged.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
4.2.3e	The standard requires documents to remain legible and readily identifiable.	4.16	The requirements for legibility, identification and access applied only to quality records.	The impact of these changes should be negligible.	NR
4.2.3f	The standard requires documents of external origin to be identified and their distribution controlled.	4.5.1	The standard required the supplier to establish and maintain documented procedures to control documents of external origin such as standards and customer drawings.	Although an additional requirement for distribution to be controlled has been inserted, the intent remains unchanged, as control of documents should include control of their distribution.	NCI
4.2.3g	The standard requires the unintended use of obsolete documents to be prevented.	4.5.2b	The standard required the supplier to ensure that invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use.	The intent of the requirements has not changed - it is less verbose.	NCI
4.2.3g	The standard requires obsolete documents retained for any purpose to be suitably identified.	4.5.2c	The standard required that any obsolete document retained for legal and/or knowledge preservation purposes be suitably identified.	The intent of the requirement remains unchanged.	NCI
4.2.4	The standard requires records to be established and maintained to provide evidence of conformance to requirements.	4.16	The standard required that quality records be maintained to demonstrate conformance to specified requirements.	The intent of the requirement remains unchanged. The removal of the word 'quality' may alter perceptions of the type of records that this requirement now addresses.	NCI
4.2.4	The standard requires records to be established and maintained to provide evidence of effective operation of the quality management system.	4.16	The standard requires which quality records be maintained to demonstrate the effective operation of the quality system.	The intent of the requirement remains unchanged.	NCI
4.2.4	The standard requires records to remain legible.	4.16	The standard required all quality records to be legible	This requirement has not changed.	NC
4.2.4	The standard requires records to remain readily identifiable.	4.16	The standard required procedures for identification of quality records	This new requirement may impact identification methods in order that record identity can be determined independently of their location or attachment	NR
4.2.4	The standard requires records to remain retrievable.	4.16	The standard required all quality records to be retained in such a way that they are retrievable	The intent of the requirement remains unchanged	NCI
4.2.4	The standard requires a documented procedure that defines the controls needed for the identification of records.	4.16	The standard required the supplier to establish and maintain documented procedures for identification of quality records.	This requirement has not changed.	NC

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
4.2.4	The standard requires a documented procedure, which defines the controls needed for the storage of records.	4.16	The standard required the supplier to establish and maintain documented procedures for storage of quality records.	This requirement has not changed.	NC
4.2.4	The standard requires a documented procedure, which defines the controls needed for the protection of records.	4.16	The standard required the supplier to establish and maintain documented procedures for maintenance of quality records and for records to be stored in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.	The intent of the requirement remains unchanged and is less verbose.	NCI
4.2.4	The standard requires a documented procedure, which defines the controls needed for the retrieval of records.	4.16	The standard covered retrieval in five ways. It required: - a) that quality records be made available for evaluation by the customer or his representative for an agreed period, where agreed contractually b) procedures for the filing of quality records c) procedures for the access of quality records d) procedures for the indexing of quality records e) quality records to be retained in such a way that they are retrievable.	The intent of the requirement remains unchanged.	NCI
4.2.4	The standard requires a documented procedure which defines the controls needed for the retention time of records	4.16	The standard required the retention times of quality records to be established and recorded.	This requirement has not changed.	NC
4.2.4	The standard requires a documented procedure that defines the controls needed for the disposition of records.	4.16	The standard required the supplier to establish and maintain documented procedures for disposition of quality records.	This requirement has not changed.	NC

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
5.1	The standard requires that top management provide evidence of its commitment to the development and implementation of the quality management system.	4.1.1	The standard required the supplier's management with executive responsibility to define and document its commitment to quality.	This is an extension to the requirement that now links policy with the means by which it is to be implemented. This will mean that top management have to demonstrate its involvement in the development and implementation of the QMS	NR
5.1	The standard requires that top management provide evidence of its commitment to continually improving the effectiveness of the quality management system.	4.1.3	The standard required the supplier's management with executive responsibility to review the quality system to ensure its effectiveness in satisfying the requirements of ISO 9001 and the quality policy and objectives	This new requirement removes previous constraints in judging effectiveness and focuses on improvements in the ability of the QMS to fulfil its purpose. The impact is that top management will need to continually seek and implement better ways of doing things.	NR
5.1a	The standard requires that top management provide evidence of its commitment by communicating to the organization the importance of meeting customer as well as regulatory and legal requirements.		No equivalent requirement.	This new requirement means that the top management will need to demonstrate its commitment by establishing and managing processes to achieve the requirements of customers, regulatory, legal and other defined interested parties.	NR
5.1b	The standard requires that top management provide evidence of its commitment by establishing the quality policy.	4.1.1	The standard required the supplier's management with executive responsibility to define and document its policy for quality.	The intent of the requirement has not changed but has clarified the meaning of executive management.	NCI
5.1c	The standard requires that top management provides evidence of its commitment by establishing quality objectives	4.1.1	The standard required the supplier's management with executive responsibility to define and document its objectives for quality.	By rewording the phrase 'policy for quality, including objectives for quality' the new wording clarifies the original intent that quality objectives are separate from and not the same as quality policy.	NR
5.1d	The standard requires that top management provide evidence of its commitment by conducting management reviews.	4.1.3	The standard required the supplier's management with executive responsibility to review the quality system.	The intent of the requirement remains unchanged however; top management will need to demonstrate involvement not delegation.	NR
5.1e	The standard requires that top management provide evidence of its commitment by ensuring the availability of necessary resources.	4.1.2.2	The standard required the supplier to provide adequate resources.	The change in requirement places the emphasis on top management. Adequate has been changed to necessary, implying that an objective assessment of resources has been carried out.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
5.2	The standard requires top management to ensure that customer requirements are determined.	4.3.2a	The standard required the tender, contract or order to be reviewed to ensure that the requirements are adequately defined and documented.	There are two primary differences in this new requirement. Firstly the involvement of top management and secondly, that the organization should do more than react to invitations to tender, contracts or purchase orders. The implication is that the organization should be proactive and seek to establish customer needs and expectations before commencing the design of products and services and offering them for sale. (See also ISO 9000 for the definition of 'requirement') There will need to be a defined process for this.	NR
5.2	The standard requires customer requirements to be met with the aim of enhancing customer satisfaction.	Various	The previous version required the supplier to meet specified requirements.	The implication is that the organisation can no longer specify its own requirements where such requirements could neglect to take into account the needs and expectations of customers. There is also the implication that the focus of the organization should move beyond simple conformance to requirements and focus on customer satisfaction.	NR
5.3a	The standard requires the quality policy to be appropriate to the purpose of the organization.	4.1.1	The standard required the quality policy to be relevant to the supplier's organizational goals.	There has been a change in emphasis from goals to purpose, requiring there to be a clear linkage between the achievement of the quality policy and the organization's purpose.	NR
5.3b	The standard requires that the quality policy include a commitment to comply with requirements.	4.1.1	The standard stipulated that the quality policy should include objectives for quality and the supplier's commitment to quality.	The quality objectives are now separate statements and the new wording implies that a commitment to quality means a commitment to meeting requirements whatever their source. (Note: ISO 9000 defines quality as the degree to which a set of inherent characteristics fulfils requirements)	NR
5.3b	The standard requires that the quality policy includes a commitment to continually improve the effectiveness of the QMS		No equivalent requirement	This new requirement means that the continual search for and implementation of better ways of meeting requirements should be become endemic in the organization	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
5.3c	The standard requires the quality policy to provides a framework for establishing and reviewing quality objectives	4.1.1	The standard required the policy for quality to include objectives for quality	The implication of the change is that the quality objectives should not from part of the quality policy but that the policy is used as a basis for establishing quality objectives.	NR
5.3d	The standard requires that the quality policy is communicated and understood in the organization.	4.1.1	The standard required that the supplier ensured that its quality policy is understood at all levels of the organization.	It is difficult to imagine how a policy could be understood if it wasn't communicated but the change in requirement signifies that the understanding has to come about by top management communicating the policy rather than the policy being conveyed via the grape vine.	NCI
5.3e	The standard requires the quality policy to be reviewed for continued suitability.	4.1.1	The standard required that this policy be maintained.	There is no change in intent but it will impact those organizations that simply created a policy addressing an organizational goal of compliance with ISO 9000 rather than with achieving customer satisfaction. The policy will need to be reviewed for its suitability to deliver the organization's purpose.	NCI
5.4.1	The standard requires that top management ensure that quality objectives are established at relevant functions and levels within the organization.	4.1.1	The standard required the policy for quality to include objectives for quality - the levels or functions at which objectives be established were not stipulated.	The difference is that previously one statement of quality objectives would have been compliant whereas the new version implies that quality objectives should be set at corporate, process and individual levels.	NR
5.4.1	The standard requires quality objectives to be measurable.		No equivalent requirement.	The implication is that there should be a tangible result from meeting the objective and that a defined period should be specified.	NR
5.4.1	The standard requires quality objectives to be consistent with the quality policy.		No equivalent requirement.	The implication is that there is a clear relationship between the quality objectives and the statements within the quality policy.	NR
5.4.1	The standard requires quality objectives to include those needed to meet requirements for product.		No equivalent requirement.	The implication here is that quality objectives should include objectives for increasing the performance of processes, resources, activities, components and materials to deliver conforming output of the required quantity i.e. objectives for reducing nonconformity, improving reliability, safety, maintainability, availability, functionality etc.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
5.4.2a	The standard requires top management to ensure planning of the QMS is carried out in order to meet the requirements of 4.1.		No equivalent requirement.	This new requirement means that the requirements of clause 4.1 should be used when designing a QMS. This will have significant impact on the construction and operation of these systems. An element approach will not meet this requirement.	NR
5.4.2a	The standard requires top management to ensure planning of the QMS is carried out in order to meet the quality objectives	4.2.3 4.2.3b	The standard required: - a) the supplier to define and document how the requirements for quality will be met and b) the identification and acquisition of any processes that may be needed to achieve the required quality.	This new requirement changes the purpose of the QMS from a means to meet customer requirements to a means to achieve the organization's objectives. The impact is that its scope becomes much greater.	NR
5.4.2b	The standard requires the integrity of the quality management system to be maintained when changes to the QMS are planned and implemented.		No equivalent requirement.	The implication is that changes to the organization should be planned and executed concurrently with associated changes to the QMS. This will force an end to the practice of making organization or process changes and changing the documentation many months later.	NR
5.5.1	The standard requires that the responsibilities and authority be defined and communicated.	4.1.2.1	The standard required the responsibility, authority and interrelationships of personnel who manage, perform and verify work affecting quality to be defined and documented.	The intent remains unchanged. Documents are replaced by means of communication and the interrelationships are now replaced by the requirement for the sequence and interaction of processes to be defined in clause 4.1b	NCI
5.5.2	The standard requires the top management to appoint a member of the management who has certain defined responsibility and authority.	4.1.2.3	The standard required the supplier's management with executive responsibility to appoint a member of the supplier's own management with certain defined authority.	No change in requirement	NC
5.5.2	The standard requires the management representative to ensure that processes are established, implemented and maintained, performance of the QMS is reported to top management and awareness of customer requirements is promoted throughout the organization.	4.1.2.3	The standard required the management representatives to ensure that a quality system is established, implemented and maintained and to report on the performance of the quality system to the supplier's management.	This new responsibility is for ensuring there is a process for promoting the awareness of customer requirements as the responsibility for communicating is with top management as stated in clause 5.1a.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
5.5.3	The standard requires top management to ensure appropriate communication processes are established within the organization.		No equivalent requirement.	The implication is that processes for communicating all kinds of information up, down and across the organization are needed. Documentation may be only one of the means employed. These processes also need to be effective and their performance monitored, measured, analysed and improved as defined in clause 4.1.	NR
5.5.3	The standard requires top management to ensure that communication takes place regarding the effectiveness of the QMS.		No equivalent requirement.	The implication is that information that promotes understanding of the system and the measures of performance of the system and processes should be regularly displayed and conveyed to staff.	NR
5.6.1	The standard requires top management to review the quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.	4.1.3	The standard required that the quality system be reviewed at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of ISO 9001 and the supplier's stated quality policy and objectives.	There is no change in the intent of this requirement but the replacement of the term <i>defined intervals</i> with <i>planned intervals</i> indicates that the intervals should be determined with foresight and not some arbitrary period such as annually. Previously the effectiveness of the system was determined by the extent by which it satisfied the requirements of the standard and the quality policy - now the focus is on the QMS achieving the organization's objectives (adequacy), that the best way of achieving the objectives is employed (suitability) and that they are the right objectives (effectiveness).	NCI
5.6.1	The standard requires the review to assess opportunities for improvement and the need to change the quality management system, including quality policy and quality objectives.		No equivalent requirement.	The implication is that performance data on the implementation of quality policy and the achievement of quality objectives should be collected and reviewed in order to identify the need to change the system, the quality policy and quality objectives.	NR
5.6.1	The standard requires the records from the management reviews to be maintained.	4.1.3	The standard required records of management review to be maintained.	The new requirement for records <i>from</i> the reviews rather than records <i>of</i> reviews does have implications. A record of a review could be the minutes of a meeting whereas a record from the review could include the input data, analysis, conclusions, recommendations and decisions as well as minutes of any meetings that took place.	NR

NR = New Requirement. NCI = No Change in Intent. NC = No Change. LR = Less Onerous Requirement

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
5.6.2	The standard requires inputs to management review to include current performance and improvement opportunities related to various aspects of the system.		No equivalent requirement.	The implication is that data from audits, processes, etc has to be analysed relative to defined objectives to establish current performance (how are we doing) and identify improvement opportunities (can we do better).	NR
5.6.2	The standard requires review inputs to include changes that could affect the quality management system.		No equivalent requirement.	The implication is that such changes have not occurred and are therefore potential changes such as mergers, downsizing, new business initiatives, new markets etc contained in the business plan.	NR
5.6.3	The standard requires the outputs from the management review to include actions related to the improvement of the QMS its processes, products and resources.		No equivalent requirement.	The implication is that the review should result in decisions being made to improve products, processes and the system in terms of the actions required.	NR
6.1a	The standard requires the organization to determine and provide the resources needed to implement and maintain the quality management system.	4.1.2.2 4.2.3b 4.4.2	The standard required the supplier to: - a) identify resource requirements and provide adequate resources including the assignment of trained personnel, for management, performance of work and verification activities. b) identify any resources that may be needed to achieve the required quality. c) equip design and development personnel with adequate resources	Previously the requirement applied to all work, now it applies to processes of the QMS and customer satisfaction - the intent remains the same however so it should not be assumed that the resources required for new product/process development are outside the scope. As there is no constraint imposed by the requirement it can be assumed that it applies to the provision of financial resources as well as physical and human resources.	NCI
6.1a	The standard requires the organization to determine and provide the resources needed to continually improve the effectiveness of the QMS.		No equivalent requirement	The new requirement means that plans for improving the QMS need to indicate the resources required and top management will need to demonstrate support for such projects by providing the agreed resources.	NR
6.1b	The standard requires the organization to determine and provide the resources needed to enhance customer satisfaction		No equivalent requirement	The new requirement means that plans need to take account of the resources needed to understand customer needs and expectations and change products and processes accordingly – i.e. the marketing, design and supply chain processes.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
6.2.1	The standard requires personnel performing work affecting product quality to be competent on the basis of appropriate education, training, skills and experience.	4.1.2.2 4.18 4.4.2	The standard required: - a) that trained personnel be assigned for management, performance of work and verification activities including internal quality audits. b) personnel performing specific assigned tasks to be qualified on the basis of appropriate education, training and/or experience, as required c) design and development activities to be assigned to qualified personnel equipped with adequate resources.	The word <i>competent</i> is used in place of the word <i>qualified or trained</i> to overcome the situation where a person who has been trained or qualified may no longer be competent when assigned to a job. In addition, the previous requirement implied that all personnel had to be trained and then implied they had to be qualified when in fact some may be competent through education or experience rather than training.	NR
6.2.2a	The standard requires the organization to determine the necessary competence for personnel performing activities affecting product quality.	4.18	The standard required the supplier to establish and maintain documented procedures for identifying training needs.	The new requirement has a wider implication than its predecessor does. Competence is concerned with the ability to do a job whereas training is concerned with the acquisition of skills. Hence, there is a need to define the competence units required and the method of assessing competence in these units. Although limited to those performing work affecting product quality, no one should be excluded as everyone directly or indirectly affects the organization's outputs - if they didn't there would be no justification for retaining them.	NR
6.2.2b	The standard requires the organization to provide training or take other actions to satisfy these needs.	4.18 4.2.3b	The standard required the supplier to a) provide for the training of all personnel performing activities affecting quality. b) acquire any skills that may be needed to achieve the required quality.	The intent of the requirement remains unchanged. However, the scope is extended to all methods used to develop the competency of personnel.	NCI
6.2.2c	The standard requires the organization to evaluate the effectiveness of the actions taken.		No equivalent requirement.	The implication is that whatever the means used to develop competence, competence needs to be assessed, the results evaluated and action taken should the person remain insufficiently competent.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
6.2.2d	The standard requires the organization to ensure that its employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.	4.1.1	This topic was limited to requiring the supplier to ensure that the quality policy is understood at all levels in the organization.	The implication is that managers have to take responsibility for their staff perceptions - if staff perceive their work to be unimportant or an action to have no effect when the opposite is true then managers have failed to educate their staff.	NR
6.2.2e	The standard requires the organization to maintain appropriate records of education, training, skills and experience.	4.18	The standard required the supplier to maintain appropriate records of training.	The difference here is that records of training alone are insufficient and that any actions taken to improve competence should be recorded. The important point to note is that the records of competence are relevant to the activities being considered.	NR
6.3	The standard requires the organization to identify, provide and maintain the infrastructure needed to achieve conformity to product requirements, including buildings, workspace and associated utilities, process equipment and software and supporting services.	4.2.3b 4.2.3e 4.9g	The standard required: - a) the identification and acquisition of any equipment (including inspection and test equipment), fixtures and resources that may be needed to achieve the required quality b) the identification of any measuring requirements that exceeds the known state of the art in sufficient time for the needed capability to be developed; c) suitable maintenance of equipment to ensure continuing process capability.	While the intent of the requirement remains unchanged, this may have significant impact on the way it is audited. The term resources in the previous version could encompass hardware, software, and supporting services, and supporting services in the new version could encompass measurement capability.	NCI
6.4	The standard requires the organization to determine and manage the work environment needed to achieve conformity to product requirements.	4.9b 4.11.2g	The standard required: - a) controlled conditions for production, installation and servicing processes which directly affect quality to include the use of a suitable working environment b) the supplier to ensure that the environmental conditions are suitable for the calibration, inspections, measurements and tests being carried out.	Work environment is defined in ISO 9000 as including physical, social, psychological and environmental factors. As physical and environmental factors can affect both product and people producing product, the impact of factors such as heat, noise, cleanliness, light and ventilation for example, need to be managed and controlled. The social and psychological factors such as personnel safety, job security, recognition, relationships, responsibility, culture, business ethics etc influence the performance of people in an organization and processes have to be managed to provide an environment in which personnel will be motivated.	NR

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ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.1	The standard requires the organization to plan and develop the processes needed for product realization.	4.2.3	The standard required the supplier to document how the requirements for quality will be met.	The emphasis is on processes rather than procedures and documents and that the organization needs to determine what these processes are. The implication is that processes other than those identified in clause 7 are needed, through reference to clause 4.1 which includes measurement and improvement processes.	NR
7.1	The standard requires planning of product realization to be consistent with the requirements of the other processes of the quality management system.	4.2.3	The standard required that quality planning be consistent with all other requirements of the quality system.	The intent of the requirement remains unchanged but the scope has increased.	NCI
7.1a	The standard requires the organization to determine the quality objectives and requirements for the product.		No equivalent requirement.	Previously it was assumed that the customer supplied the product quality requirements. There is now a link to the organization's policy and objectives in clause 5, which means that specific product requirements have to be consistent with the organization's quality objectives.	NR
7.1b	The standard requires the organization to determine the need to establish processes specific to the product.	4.2.3b	The standard required the identification and acquisition of any controls and processes that may be needed in meeting the specified requirements for products, projects or contract.	The intent of the requirement remains unchanged.	NCI
7.1b	The standard requires the organization to determine the need to establish documents specific to the product.	4.2.3a 4.2.3c 4.2.3d	The standard required: - a) consideration to be given to the preparation of quality plans b) consideration to be given to ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation c) consideration to be given to the updating, as necessary, of quality control, inspection and testing techniques.	This new requirement is less specific than its predecessor and hence covers all types of documentation that may be needed.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.1b	The standard requires the organization to provide resources specific to the product.	4.2.3b 4.2.3d 4.2.3e	The standard required consideration to be given to: - a) the identification and acquisition of any resources, equipment, (including inspection and test equipment) and fixtures that may be needed to achieve the required quality b) the development of new instrumentation c) the identification of any measuring requirements that exceeds the known state of the art in sufficient time for the needed capability to be developed.	The intent of the requirement remains unchanged. However, the requirement is that resource provision has been planned and provided not merely considered.	NCI
7.1c	The standard requires the organization to determine the required verification, validation, monitoring, inspection and test activities.	4.2.3f	The standard required consideration to be given to the identification of suitable verification at appropriate stages in the realization of product.	The intent of the requirement remains unchanged. However, the requirement now requires action not consideration.	NCI
7.1c	The standard requires the organization to determine the criteria for product acceptance.	4.2.3g 4.9f	The standard required: - a) consideration to be given to the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element b) criteria for workmanship to be stipulated in the clearest practical manner.	The intent of the requirement remains unchanged. However, the requirement now requires action not consideration.	NCI
7.1d	The standard requires the organization to determine the records needed to provide evidence that the realization processes meet requirements.		No equivalent requirement.	The new requirement means that records will be needed to demonstrate that processes achieve their objectives. The implication is that data on the performance of all realization processes needs to be collected and analysed i.e. process capability versus targets.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.1d	The standard requires the organization to determine the records needed to provide evidence that resultant product meet requirements	4.2.3h 4.10.1	The standard required: - a) consideration to be given to the identification and preparation of quality records in meeting the specified requirements for products, projects or contracts b) the inspection and testing records to be established to be detailed in the quality plan or documented procedures	The intent of the requirement remains unchanged. However, the requirement now requires action not consideration and the product requirements may be wider and include quality, cost and delivery.	NCI
7.1	The standard requires the product realization planning to be documented in a form suitable for the organization's method of operations.	4.2.3	The standard required quality planning to be documented in a format to suit the supplier's method of operation.	The intent of the requirement remains unchanged.	NCI
7.2.1a	The standard requires the organization to determine requirements specified by the customer, including the requirements for delivery and post delivery activities.	4.3.2a	The standard required the supplier to ensure that the requirements of the tender, contract or order are adequately defined and documented.	The intent of the requirement remains unchanged but does emphasise the importance of clarifying delivery and post delivery activities.	NCI
7.2.1b	The standard requires the organization to determine requirements not specified by the customer but necessary for specified or intended use where known.		No equivalent requirement.	The implication is that the organization has to anticipate the customer's needs and expectations and deduce the requirements that are essential for the product to fulfil its intended purpose - this is commonly referred to as the market specification.	NR
7.2.1c	The standard requires the organization to determine statutory and regulatory requirements related to the product	4.4.4	This requirement was limited to new design where the standard required design input requirements relating to the product including applicable statutory and regulatory requirements, to be identified.	The new requirement extends the applicability of statutory and regulatory requirements to the products supplied whether or not the organization designed them. The implication is that resellers cannot relinquish their obligations to the society into which the product is supplied.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.2.1d	The standard requires the organization to determine any additional requirements determined by the organization.		No equivalent requirement.	The organization's product policy may impose certain requirements or prohibit use of certain technologies. Other requirements may serve to aid production or distribution that are of no consequence to the customer but necessary for the efficient and effective realization and supply of the product. The implication is that these requirements can no longer be taken for granted and must be included in the product requirement.	NR
7.2.2	The standard requires the organisation to review the requirements related to the product.	4.3.1	The standard required the supplier to establish and maintain documented procedures for contract review and for the coordination of these activities.	The requirement for procedures is now limited to one general requirement. Where this new requirement differs is that the review has to embrace all identified requirements not only those stated in the order or contract. This changes the review from a <i>contract review</i> to a <i>requirement review</i> .	NR
7.2.2	The standard requires the review to be conducted prior to the commitment to supply a product to the customer (e.g. submission of tenders, acceptance of a contracts or orders, acceptance of changes to contracts or orders).	4.3.2	The standard required that before submission of a tender, or the acceptance of a contract or order (statement of requirement), the tender, contract or order to be reviewed.	Although the wording is very similar, there is a change in requirement as the review is of the product requirement, which may or may not be initiated by the receipt of an invitation to tender, a contract or order. The implication is that there may need to be requirement reviews, transaction reviews and contract reviews.	NR
7.2.2a	The standard requires that the review of requirements ensure product requirements are defined.	4.3.2a	The standard requires that review of the tender, contract or order ensures that the requirements are adequately defined and documented.	The focus of the review has changed from contract to product and therefore implies additional work by the organization to review requirements not specified by the customer that may have previously been carried out after acceptance of contract.	NR
7.2.2b	The standard requires the review to ensure that contract or order requirements differing from those previously expressed are resolved.	4.3.2b	The standard required the review to ensure that any contract or accepted order requirements differing from those in the tender are resolved.	There is no change in requirement.	NC
7.2.2c	The standard requires that the review ensure that the organization has the ability to meet the defined requirements.	4.3.2c	The standard required that the review ensure that the supplier has the capability to meet contract or accepted order requirements.	There is no change in requirement.	NC

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.2.2	The standard requires records of the results of the review and actions arising from the review to be maintained.	4.3.4	The standard required records of contract reviews to be maintained.	The difference is that actions arising from the review now need to be recorded.	NR
7.2.2	The standard requires customer requirements to be confirmed before acceptance where the customer provides no documented statement of requirement.	4.3.2a	The standard required the supplier to ensure that where no written statement of requirement is available for an order received by verbal means, the order requirements are agreed before their acceptance.	There is no change in intent. Confirmation would in general be provided verbally or by an order acknowledgement.	NCI
7.2.2	The standard requires that where product requirements are changed, the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	4.3.3	The standard required suppliers to identify how an amendment to a contract is correctly transferred to the functions concerned.	Previously the requirements only applied to changes of requirements contained in a tender, contract or order. This new requirement embraces requirements defined by the organization and hence the need for a change management process.	NR
7.2.3a	The standard requires the organization to determine and implement effective arrangements for communicating with customers relating to product information.		No equivalent requirement.	The implication is that the QMS needs to embrace the marketing activities including advertising, promotions, and exhibitions as these communicate product information.	NR
7.2.3b	The standard requires the organization to determine and implement effective arrangements for communicating with customers relating to enquiries.		No equivalent requirement.	The implication is that the QMS has to embrace the pre-contract/order phase which draws the customer towards the organisation i.e. the sales process	NR
7.2.3b	The standard requires the organization to determine and implement effective arrangements for communicating with customers relating to contracts or order handling.		No equivalent requirement.	The implication is that the QMS has to embrace the contract/order handling processes hence extending the system beyond contract review.	NR
7.2.3b	The standard requires the organization to determine and implement effective arrangements for communicating with customers relating to contract amendments.	4.3.3	The standard required the supplier to identify how an amendment to a contract is made.	The contract amendment process now needs to go beyond handling amendments received from customers and address the process of generating, issuing, negotiating and agreeing amendments.	NR
7.2.3c	The standard requires the organization to determine and implement effective arrangements for communicating with customers relating to customer feedback, including customer complaints.	4.14.2a	The standard required the corrective action procedures to include the effective handling of customer complaints.	The customer complaint process needs to be extended to embrace all customer feedback, both positive and negative.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.3.1	The standard requires the organization to control the design and development of the product.	4.4.1	The standard required the supplier to establish and maintain procedures to control the design of the product in order to ensure that the specified requirements are met.	There is no change in this requirement except that the objective of control is now stated elsewhere and the method of control is at the organization's discretion.	NC
7.3.1	The standard requires the organization to plan the design and development of the product.	4.4.2	The standard required the supplier to prepare plans for each design and development activity.	The requirement is unchanged.	NC
7.3.1a	The standard requires the design and development planning to determine the design and development stages.	4.4.2	The standard required the plans to describe or reference each design and development activity.	The difference is a recognition that control over design is more easily accomplished by controlling the stages through which the design passes rather than controlling each design activity.	NR
7.3.1b	The standard requires design and development planning to determine review, verification and validation appropriate to each design and development stage.	4.4.7 4.4.6	The standard required: - a) design verification measures to be recorded. b) formal documented reviews of the design results to be planned at appropriate stages of design.	This new requirement has not changed the intent and has merely consolidated three separate requirements.	NCI
7.3.1c	The standard requires the design and development planning to determine responsibilities and authorities for design and development activities.	4.4.2	The standard required the design and development plans to define responsibility for the implementation of design and development activities.	The new wording rectifies inconsistencies by adding the word authorities while leaving the intent unchanged.	NCI
7.3.1	The standard requires the interfaces between different groups involved in design and development to be managed to ensure effective communication and clear assignment of responsibility.	4.4.3	The standard required organizational interfaces between different groups which input to the design process to be identified and the necessary information documented, transmitted and regularly reviewed.	The intent of the requirement remains unchanged.	NCI
7.3.1	The standard requires planning output to be updated, as appropriate, as the design and development progresses.	4.4.2	The standard requires that the design and development plans be updated as the design evolves.	The intent of the requirement remains unchanged.	NCI
7.3.2	The standard requires inputs relating to product requirements to be determined and records maintained.	4.4.4	The standard required design input requirements relating to the product to be identified and documented.	There is no change in requirement.	NC
7.3.2a	The standard requires design inputs to include functional and performance requirements.	4.4.4	Functional and performance requirements were implicit in the term "design input requirements".	Although not previously specified, such requirements are so fundamental that it is unlikely that it will require any change in the QMS.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.3.2b	The standard requires design inputs to include applicable statutory and regulatory requirements	4.4.4	The standard required design input requirements relating to the product, including applicable statutory and regulatory requirements to be identified	There is no change in requirement	NC
7.3.2c	The standard requires the design input to include information derived from previous similar designs where applicable.		The standard did not address this topic.	The implication is that processes will have to be included in the QMS to ensure that the mistakes of the past are not repeated and the past successes are.	NR
7.3.2d	The standard requires design inputs to include other requirements essential for design and development.	4.4.4 4.4 4.4.4	The standard required: - a) design input requirements relating to the product to be identified and documented b) technical interfaces between different groups which input into the design process to be identified c) design input to take into consideration the results of any contract review activities.	The reworded requirement is less prescriptive and does not change the intent of the previous requirements.	NCI
7.3.2	The standard requires design inputs to be reviewed for adequacy.	4.4.4	The standard required that the selection of design input requirements be reviewed by the supplier for adequacy.	The intent of the requirement remains unchanged.	NCI
7.3.2	The standard requires input requirements to be complete, unambiguous and not in conflict with each other.	4.4.4	The standard required that incomplete, ambiguous or conflicting requirements be resolved with those responsible for drawing up these requirements.	The change removes an unnecessary constraint, as those who drew up the requirements may in fact be no longer available for discussion.	LR
7.3.3	The standard requires that the outputs of design and development be provided in a form that enables verification against the design and development inputs.	4.4.5	The standard required that the design output be documented and expressed in terms that can be verified and validated against design-input requirements.	The implication is that design outputs are not used for validation, that validation is performed on tangible product and that the validation criteria does not form part of the design input.	LR
7.3.3	The standard requires design and development output to be approved prior to release.	4.4.5	The standard required that the design output documents be reviewed before release.	This new requirement changes the emphasis from approval of documents to approval of design. The implication is that design approval needs to be a key stage in the design and development process in addition to the control of documents.	NR
7.3.3a	The standard requires that design and development output meet the input requirements for design and development.	4.4.5a	The standard required that the design output meet the design input requirements.	There is no change in requirement.	NC

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.3.3b	The standard requires that design and development output provide appropriate information for purchasing, production and service provision		No equivalent requirement.	The implication here is that the design information has taken account of purchasing, production and service operation needs and the interface between these processes is established.	NR
7.3.3c	The standard requires design and development output to contain or reference product acceptance criteria	4.4.5b	The standard required that the design output contains or makes reference to acceptance criteria.	There is no change in requirement.	NC
7.3.3d	The standard requires design and development output to specify the characteristics of the product that are essential for its safe and proper use.	4.4.5c	The standard required that the supplier identify those characteristics of the design that are crucial to the safe and proper functioning of the product.	The intent of the requirement remains unchanged. The implication is that the conditions of use need to be understood not just product functionality.	NCI
7.3.4	The standard requires that at suitable stages, systematic reviews of design and development be performed in accordance with planned arrangements.	4.4.6	The standard required that at appropriate stages of design, formal documented reviews of the design results be conducted.	By omitting the word formal, all reviews are now required to be treated the same. The introduction of the term systematic implies that the review has to be stage-by-stage, methodical with purpose. The reference to planned arrangements means the reviews are performed at planned stages. The change will impact those organizations that pay lip service to design review.	NR
7.3.4	The standard requires design reviews to evaluate the ability of the results of design and development to meet requirements.	4.4.6	The purpose of the review was not defined.	The change will impact those organizations that treated design reviews as progress meetings.	NR
7.3.4	The standard requires design reviews to identify any problems and propose necessary actions		No equivalent requirement	Design reviews will need to result in actions that aim to correct any identified design weaknesses.	NR
7.3.4	The standard requires participants in design reviews to include representatives of functions concerned with the design and development stage(s) being reviewed.	4.4.6	The standard required that participants at each design review include representatives of all functions concerned with the design stage being reviewed as well as other specialist personnel as required.	There is no change to this requirement.	NC
7.3.4	The standard requires records of the results of the reviews and any necessary actions to be maintained.	4.4.6	The standard required records of design reviews to be maintained.	The intent of the requirement remains unchanged. However, records need to include results and actions.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.3.5	The standard requires verification to be performed in accordance with planned arrangements to ensure the design and development output have met the design and development input requirements.	4.4.7	The standard required that at appropriate stages of design, design verification to be performed to ensure that the design stage output meets the design stage input requirements.	The intent of this requirement remains unchanged.	NCI
7.3.5	The standard requires records of the results of the verification and any necessary actions to be maintained.	4.4.7	The standard required the design verification measures to be recorded.	Although verification measures and verification records are quite different, the intent was that the measures taken to verify the design were recorded. However, there is a new requirement in that these records now need to identify actions resulting from verification. The implication is that a set of results is no longer adequate.	NR
7.3.6	The standard requires design and development validation to be performed in accordance with planned arrangements to ensure that resulting product is capable of meeting the requirements for the specified application or intended use where known.	4.4.2 4.4.8	The standard required a) that the supplier to prepare plans for each design and development activity b) design validation be performed to ensure that product conforms to defined user needs and/or requirements	The intent of the requirement remains unchanged. However, as planned arrangements are referred to clause 7.1 and this clause refers to 4.1, criteria and methods for validation are needed.	NCI
7.3.6	The standard requires that wherever practicable, validation be completed prior to the delivery or implementation of the product.	4.4.8	The standard did not constrain the timing of design validation.	This new requirement will impact those systems that allowed product delivery before design validation was complete.	NR
7.3.6	The standard requires records of the validation and any necessary actions to be maintained.	4.16	The standard did not require validation results to be recorded except under the general requirement of clause 4.16 which required quality records to be maintained to demonstrate conformance to specified requirements.	This requirement will impact those systems that limited quality records to the instances where 4.16 were referenced. The addition of follow-up actions implies that recording of changes to designs, support equipment and documentation is required.	NR
7.3.7	The standard requires design and development changes to be identified.	4.4.9	The standard requires all design changes and modifications to be identified.	Development changes are modifications and hence there is no change in intent.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.3.7	The standard requires records of design and development changes to be maintained.	4.4.9	The standard requires all design changes and modifications to be documented before their implementation.	Although the intent has not changed the recording of design and development changes is not simply defining the changes made to the design but in addition defining the changes that have to be made to the product as a result of the design change. The change to records means that change records will now be controlled in the same way any other records.	NR
7.3.7	The standard requires design and development changes to be reviewed, verified and validated, as appropriate, and approved before implementation.	4.4.9	The standard required all design modifications approved by authorized personnel before their implementation.	This new requirement indicates that the approval of design changes is intended to occur before implementation in the product, not as previously implied before implementation in the design. The implication here is that design changes should be passed through the verification and validation process to maintain design integrity.	NR
7.3.7	The standard requires the review of design and development changes to include evaluation of the effect of the changes on constituent parts and products already delivered.	4.4.9	The standard required all design changes to be reviewed by authorized personnel before their implementation.	This new requirement implies that a more rigorous review is needed that takes into account the impact of the change on existing product as well as future product. A recall process may need to be in place to modify or recall product in service. Removal of the phrase by authorized personnel" does not change the intent because this condition is stated generally in clause 5.5.1.	NR
7.3.7	The standard requires records of the review of changes and any necessary actions to be maintained.		No equivalent requirement	This new requirement implies that records of design changes include results of evaluation, verification and validation and where applicable product recall.	NR
7.4.1	The standard requires the organization to ensure purchased product conforms to specified purchase requirements.	4.6.1	The standard requires the supplier to establish and maintain documented procedures to ensure that purchased product conforms to specified requirements.	The intent of the requirement remains unchanged. The changes are primarily for clarification.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.4.1	The standard requires the type and extent of control applied to the supplier and the purchased product to be dependent upon the effect of the purchased product on subsequent realization or the final product.	4.6.2b	The standard required suppliers to define the type and extent of control exercised by the supplier over subcontractors and goes on to require that these controls be dependent upon a) the type of product, b) the impact of the product on the quality of the final product and, where applicable, c) the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors.	The changed wording does not alter the intent of the requirement.	NCI
7.4.1	The standard requires the organization to evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements.	4.6.2a	The standard required the supplier to evaluate and select subcontractors on the basis of their ability to meet subcontract requirements, including the quality system and any specific quality assurance requirements.	The intent of the requirement remains unchanged.	NCI
7.4.1	The standard requires criteria for selection to be established.	4.6.2a	The selection criteria were not required to be established.	Although there was a general requirement for the QMS to be established, it would not necessarily have resulted in supplier selection criteria being established.	NR
7.4.1	The standard requires the criteria for evaluation and re-evaluation to be established.	4.6.2b	The standard required the type and extent of control exercised to be defined.	Re-evaluation is a means of controlling subcontracts and this was previously implied therefore the additional words do not alter the intent of the requirement.	NCI
7.4.1	The standard requires records of the results of evaluations and any necessary actions to be maintained	4.6.2c	The standard required records of acceptable subcontractors	The implication is that a list of approved suppliers will not meet this requirement and that the records need to contain evidence to substantiate approval	NR
7.4.2	The standard requires purchasing information to describe the product to be purchased.	4.6.3 4.6.3a	The standard required that purchasing documents to a) contain data clearly describing the product ordered. b) include, where applicable, the type, class, style, grade or other precise identification.	The intent of the requirement remains unchanged.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.4.2a	The standard requires purchasing information to include requirements for the approval of product, procedures, processes and equipment.	4.6.3b	The standard required purchasing documents to include, where applicable, the title or other positive identification, and applicable issue of specification, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures and process equipment.	Although less prescriptive the requirement remains unchanged.	NCI
7.4.2b	The standard requires purchasing information to include requirements for the qualification of personnel.	4.6.3b	The standard required purchasing documents to include, where applicable, requirements for qualification of personnel.	There is no change to this requirement.	NC
7.4.2c	The standard requires purchasing information to include quality management system requirements.	4.6.3c	The standard required purchasing documents to include, where applicable the title, number and issue of the quality system standard to be applied to the product.	The intent of the requirement remains unchanged.	NCI
7.4.2	The standard requires the organization to ensure the adequacy of specified purchase requirements prior to their communication to the supplier.	4.6.3	The standard required the supplier to review and approve purchasing documents for adequacy of specified requirements prior to release.	The intent of the requirement remains unchanged.	NCI
7.4.3	The standard requires the organization to identify and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.	4.10.2 4.6.4.1 4.6.4.2	This requirement was split into three separate requirements those for:- a) Receiving inspection and testing b) Supplier verification at subcontractor's premises c) Customer verification of subcontracted product.	Although less prescriptive the new requirement does not change the intent and is more concise.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.4.3	The standard requires that where the organization or its customer intends to perform verification at the supplier's premises, the organization is to specify the intended verification arrangements and method of product release in the purchasing information.	4.6.4.1 4.6.4.2	The standard required:- a) the supplier to specify verification arrangements and the method of product release in the purchasing documents where it is proposed that purchased product is verified at the subcontractor's premises. b) that where specified in the contract the supplier's customer or his/her representative to be afforded the right to verify at the subcontractor premises and the supplier's premises that subcontracted product conforms to specified requirement.	The intent of the requirement remains unchanged.	NCI
7.5.1	The standard requires the organization to plan production and service provision.	4.9	The standard required the supplier to plan the production, installation and services processes that directly affect quality.	The intent of the requirement remains unchanged.	NCI
7.5.1	The standard requires the organization to carry out production and service provision under controlled conditions.	4.9	The standard required that the supplier ensure that the production, installation and servicing processes are carried out under controlled conditions.	The intent of the requirement remains unchanged.	NCI
7.5.1a	The standard requires the organization to control production and service provision through the availability of information that describes the characteristics of the product.		The standard did not require information on product characteristics to be available.	The implication of this new requirement is that relevant information regarding the product characteristics related to production or service operation stages should be available. End product characteristics alone are often insufficient to control the processes.	NR
7.5.1b	The standard requires the organization to control production and service provision through the availability of work instructions where necessary.	4.9a	The standard required controlled conditions to include documented procedures defining the manner of production, installation and servicing where the absence of such instructions would adversely affect quality.	The change in wording does not change the intent of this requirement.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.5.1c	The standard requires the organization to control production and service provision through the use of suitable equipment.	4.9b 4.9g	The standard required:- a) controlled conditions to include the use of suitable production, installation and servicing equipment. b) suitable maintenance of equipment to ensure continued process capability.	There is no change in intent although, the removal of the requirement for maintenance and the phrase 'continued process capability', could imply a less stringent requirement but clearly equipment that was not maintained and was not capable would be unsuitable.	NCI
7.5.1d	The standard requires the organization to control production and service provision through the availability and use of monitoring and measuring devices.	4.9b 4.9d	The standard required the:- a) use of suitable production, installation and servicing equipment b) monitoring of suitable process parameters.	Although not explicit the requirement for use of monitoring and measuring devices is implied in the previous requirements and therefore there is no change.	NCI
7.5.1e	The standard requires the implementation of monitoring and measurement	4.9d	The standard required the monitoring and control of suitable process parameters and product characteristics	There is no change in intent	NCI
7.5.1f	The standard requires the implementation of release activities.	4.10.3b 4.10.2.3 4.10.2.1 4.12 4.15.3	The standard required the supplier to:- a) hold product until requirement inspection and tests had been completed b) positively identify product where incoming product is released for urgent production purposes prior to verification c) ensure incoming product is not used or processed until it has been inspected or otherwise verified as conforming d) ensure only product that has passed the required inspections and tests is dispatched, used or installed e) stipulate appropriate methods for authorizing receipt to and dispatch from storage areas.	This greatly simplified requirement puts the emphasis on release, whereas the previous requirement highlighted only some stages where release controls were necessary. The implication is that the QMS may well require an overhaul to identify such transition processes.	NR
7.5.1f	The standard requires the implementation of delivery activities.	4.12	The standard required the supplier to ensure only product that has passed the required inspections and tests is dispatched.	Other than this single statement, the previous delivery requirements were limited to protection measures. The implication is that the delivery process not merely the packaging processes should be included in the QMS.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.5.1f	The standard requires the implementation of post-delivery activities.	4.19	The standard required the supplier to establish and maintain documented procedures for performing, verifying and reporting that servicing meets specified requirements.	The new requirement is far less specific but enlarges the scope of servicing and hence will have implications for those systems in which servicing was limited to action on the product.	NR
7.5.2	The standard requires the organization to validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement.	4.9	The standard required special processes to be carried out by qualified operators and/or to require continuous monitoring.	Though the previous requirement identified those aspects that comprise validation, it was phrased in such a way that the intent was unclear. The implication of this change is that such processes will need to be validated prior to use in production or service operations.	NR
7.5.2	The standard requires validation to demonstrate the ability of these processes to achieve planned results.	4.9	The standard required control of process parameters to ensure that the specified requirements are met.	The intent of the requirement remains unchanged.	NCI
7.5.2	The standard requires the organization to define criteria for review and approval of the process.	4.9e	The standard required controlled conditions to include the approval of processes and equipment as appropriate.	The criteria for review and approval of processes would need to have been defined previously whether or not they were special processes therefore the intent of the requirement remains unchanged	NCI
7.5.2	The standard requires the organization to establish process validation arrangements for the approval of equipment and qualification of personnel.	4.9	The standard required that the requirements for any qualification of process operations including associated equipment and personnel be specified	Previously the requirement implied an option in the phrase 'requirement for any qualification of personnel Now the option has been removed and hence all personnel operating special processes should be qualified.	NR
7.5.2	The standard requires the organization to establish process validation arrangements that include the use of specific methods and procedures.		No equivalent requirement.	This new requirement means that organisations need to determine the validation methods to be used in a systematic manner.	NR
7.5.2	The standard requires the organization to establish process validation arrangements that include requirements for records.	4.9	The standard required that records be maintained for qualified processes, equipment and personnel, as appropriate.	The intent of the requirement remains unchanged.	NCI
7.5.2	The standard requires the organization to define process validation arrangements that include re-validation.		No equivalent requirement.	The implication is that such processes should be re-validated periodically to confirm their performance	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.5.3	The standard requires that where appropriate the organization is to identify the product by suitable means throughout product realization.	4.8	The standard required the supplier to establish and maintain documented procedures where appropriate for identifying the product by suitable means from receipt and during all stages of production, delivery and installation.	Previously the identification requirement applied only from product receipt to installation. Product realization covers all stages from identified need to satisfaction of the need and therefore includes marketing, sales, design, purchasing etc.	NR
7.5.3	The standard requires the organization to identify the product status with respect to monitoring and measurement requirements.	4.12 4.12	The standard requires the supplier to:- a) identify the inspection and test status of product by suitable means, which indicate the conformance or nonconformity of product with regard to inspection and tests performed. b) maintain the identification of inspection and test status of the product, as defined in the quality plan and/or documented procedures throughout production, installation and servicing.	The intent of the requirement remains unchanged.	NCI
7.5.3	The standard requires the organization to control and record the unique identification of the product, where traceability is a requirement.	4.8	The standard requires that where, and to the extent that traceability is a specified requirement, the supplier is to establish and maintain documented procedures for unique identification of individual product or batches and goes on to require this identification to be recorded.	The intent of the requirement remains unchanged. However, as the standard now requires organizations to identify and meet statutory and regulatory requirements, traceability may be required even though the customer does not specify it.	NCI
7.5.4	The standard requires the organization to exercise care with customer property while it is under the organization's control or being used by the organization.		No equivalent requirement.	This new requirement assigns the responsibility for care onto the organization whereas previously the requirements permitted the organization to damage product without being noncompliant.	NR
7.5.4	The standard requires the organization to identify customer property provided for use or incorporation into the product.	4.8	Previously the standard require documented procedures to be established and maintained for identifying product.	The intent here is that customer supplied property carry an identity that distinguishes it from other product. There may be implications for those systems that did not apply clause 4.8 requirements to customer-supplied product.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.5.4	The standard requires the organization to verify customer property provided for use or incorporation into the product.	4.7	The standard required the supplier to establish and maintain procedures for verification of customer-supplied product provided for incorporation into the supplies or for related activities.	The intent of the requirement remains unchanged.	NCI
7.5.4	The standard requires the organization to protect and safeguard customer property provided for use or incorporation into the product.	4.7	The standard required the supplier to establish and maintain procedures for storage of customer-supplied product provided for incorporation into the supplies or for related activities.	Protection is a better term in this context than storage. Protect and safeguard are words having the same meaning. The implication is that the organization has to provide protection wherever the customer-supplied property is located.	NR
7.5.4	The standard requires occurrence of any customer property that is lost, damaged or otherwise found to be unsuitable for use to be reported to the customer and records maintained	4.7	The standard required that any such product that is lost, damaged or is otherwise unsuitable for use be recorded and reported to the customer and again advises the supplier that verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.	The intent of the requirement remains unchanged.	NCI
7.5.5	The standard requires the organization to preserve conformity of product during internal processing and delivery to the intended destination.	4.15.2 4.15.3 4.15.4 4.15.5	The standard required the supplier to:- a) provide methods and means of handling that prevent damage or deterioration b) use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or deliver c) control packing, packaging and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements d) apply appropriate methods for preservation and segregation of product when such product is under the supplier's control.	The completely revised requirement is more concise and less prescriptive and the intent remains unchanged.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.5.5	The standard requires preservation to include identification, handling, packaging, storage and protection.	4.15.1	The standard required the supplier to:- establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product	The intent of the requirement remains unchanged.	NCI
7.5.5	The standard requires preservation to apply to constituent parts of a product.	4.15.5	The standard required the supplier to:- apply appropriate methods for preservation of product when such product is under the supplier's control.	The intent of the requirement remains unchanged even though it is more specific	NCI
7.6	The standard requires the organization to determine the monitoring and measurements to be undertaken to provide evidence of conformity of product to determined requirements (see 7.2.1).	4.11.2a	The standard required the supplier to determine the measurements to be made and the accuracy required.	Although this new requirement is similar, the purpose and hence scope is different. Previously the requirement excluded monitoring and non-physical characteristics. The implication is that all monitoring and measurements required to demonstrate compliance with product requirements needs to be determined.	NR
7.6	The standard requires the organization to determine the measuring and monitoring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).	4.11.2a 4.11.2b	The standard required the supplier to: a) select the appropriate inspection, measuring and test equipment that is capable of the accuracy and precision necessary. b) identify all inspection, measuring and test equipment including measurement devices that can affect product quality	The change is one of scope as the limitation to physical equipment has been removed. The implication is that any device (physical or non-physical) used for monitoring or measuring product or service comes within the scope of this requirement. This would include surveys, questionnaires and interviews as devices used for monitoring or measuring product.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.6	The standard requires the organization to establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.	4.11.1 4.11.1 4.11.1	The standard required the supplier to:- a) control inspection, measuring and test equipment used to demonstrate the conformance of product to the specified requirements. b) use equipment in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability. c) to maintain inspection, measuring and test equipment used to demonstrate the conformance of product to the specified requirements.	The new requirement has changed the emphasis from controlling equipment to managing a measurement process. The implication here is that wherever measurement is performed to determine achievement of objectives, the integrity or calibration of measurement methods needs to be ensured – therefore extending the requirements beyond equipment calibration.	NR
7.6a	The standard requires measuring equipment to be calibrated or verified at specified intervals against measurement standards traceable to international or national measurement standards.	4.11.2b 4.11.1 4.11.1 4.11.1	The standard required the supplier to:- a) calibrate all inspection, measuring and test equipment at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to nationally recognized standards. b) calibrate inspection, measuring and test equipment used to demonstrate the conformance of product to the specified requirements c) check and recheck at prescribed intervals, comparative references used as suitable forms of inspection to prove that they are capable of verifying the acceptability of product prior to release for use during production, installation and servicing d) establish the extent and frequency of check on comparative references and to maintain records as evidence of control.	The intent of the requirement remains unchanged.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.6a	The standard requires that where no such standards exist, the basis used for calibration or verification is to be recorded.	4.11.2b	The standard required the supplier to document the basis used for calibration where no nationally recognised standards exist.	The intent of the requirement remains unchanged.	NCI
7.6b	The standard requires measuring equipment to be adjusted or re-adjusted as necessary	4.11.2b	The standard required the supplier to calibrate and adjust all inspection, measuring and test equipment.	The intent of the requirement remains unchanged.	NCI
7.6c	The standard requires measuring equipment to be identified to enable the calibration status to be determined.	4.11.2d	The standard required the supplier to identify inspection, measuring and test equipment with a suitable indicator or approved identification records to show the calibration status	The intent of the requirement remains unchanged.	NCI
7.6d	The standard requires measuring equipment to be safeguarded from adjustments that would invalidate the measurement result.	4.11.2i	The standard required the supplier to safeguard inspection, measuring and test facilities including both test hardware and test software from adjustments that would invalidate the calibration setting.	The intent of the requirement remains unchanged.	NCI
7.6e	The standard requires measuring equipment to be protected from damage and deterioration during handling, maintenance and storage.	4.11.2h	The standard required the supplier to ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use is maintained.	The intent of the requirement remains unchanged.	NCI
7.6	The standard requires the organization to assess and record the validity of previous measuring results when the equipment is found not to conform to requirements.	4.11.2f	The standard required the supplier to assess and document the validity of previous inspection and test results when inspection, measuring and test equipment is found to be out of calibration.	The intent of the requirement remains unchanged.	NCI
7.6	The standard requires the organization to take appropriate action on the equipment and any product affected.	4.13.1	The standard required the supplier to ensure that product that does not conform to specified requirements is prevented from unintended use or installation	This new requirement implies that a product recall process is in place to recall affected equipment and product for remedial action.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
7.6	The standard requires records of the results of calibration and verification to be maintained.	4.11.2e	The standard required the supplier to maintain calibration records for inspection, measuring and test equipment.	The intent of the requirement remains unchanged.	NCI
7.6	The standard requires the ability of computer software used for measuring and monitoring of specified requirements to be confirmed prior to initial use reconfirmed as necessary.	4.11.1 4.11.1 4.11.1	The standard required the supplier to:- a) control, calibrate and maintain test software used to demonstrate the conformance of product to the specified requirements. b) test software used as suitable forms of inspection, to be checked and rechecked at prescribed intervals to prove that they are capable of verifying the acceptability of product prior to release for use during production, installation and servicing c) the supplier to establish the extent and frequency of such checks and to maintain records as evidence of control.	The intent of the requirement remains unchanged.	NCI
8.1	The standard requires the monitoring, measurement, analysis and improvement processes to include the determination of applicable methods including statistical techniques and the extent of their use.	4.20.1 4.20.2	The standard required suppliers to:- a) identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics. b) establish and maintain documented procedures to implement and control the application of statistical techniques.	This new requirement extends the application of statistical techniques to any measurement and monitoring activities and therefore will impact those system where their use was limited to product conformity and process capability	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
8.1a	The standard requires the organization to plan and implement the monitoring, measurement and analysis processes needed to demonstrate conformity of the product.	4.2.3e 4.2.3f 4.4.2 4.4.7 4.4.8 4.10.1 4.10.1 4.9.d	The standard required suppliers to: - a) give consideration to the identification of any measuring requirements that exceeds the known state of the art in sufficient time for the needed capability to be developed. b) identify suitable verification at appropriate stages in the realization of product c) prepare plans for each design and development activity d) perform design verification e) perform design validation f) establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for product are met. g) detail the required inspecting and testing to be established in the quality plan or documented procedures. h) to ensure that production, installation and servicing processes were carried out under controlled conditions that included the monitoring of suitable process parameters and product characteristics	Although the previous requirements covered some of the measurement processes, they were not as broad in their scope as this new requirement. The modified requirement goes far beyond inspection and test to embrace all measurement and monitoring not only of product but also of equipment, environment and materials and will impact those systems in which measurement was limited to product inspection and test.	NR
8.1b	The standard requires the organization to plan and implement the monitoring, measurement and analysis processes needed to ensure conformity of the quality management system	4.17	The standard required the supplier to carry out audits to verify whether quality activities and related results comply with planned arrangements.	This new requirement goes well beyond audits of procedures to the review, analysis and improvement of all processes that comprise the QMS. The implication is that checks are necessary to verify that processes fulfil their objectives.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
8.1c	The standard requires the organization to plan and implement the analysis and improvement processes needed to continually improve the effectiveness of the quality management system.	4.14.2 4.14.3 4.17	The standard required:- a) procedures for corrective action b) procedures for preventive action c) procedures for internal quality audits.	Previously the requirements focussed on nonconforming product and conformity of activities to planned arrangements. This new requirement extends improvement activities to those related to all aspects of improved efficiency and effectiveness and requires a specific process.	NR
8.2.1	The standard requires the organization to monitor information relating to customer perception as to whether the organization has met customer requirements.		No equivalent requirement.	The implication is that a customer complaint process is insufficient and that new processes will need to be put in place to monitor customer perceptions.	NR
8.2.1	The standard requires the methods for obtaining and using information relating to customer perceptions to be determined.		No equivalent requirement.	The implication is that the monitoring and analysis of customer perception is to be carried out methodically and proactively rather than simply waiting for customers to complain.	NR
8.2.2	The standard requires the organization to conduct internal audits at planned intervals to determine whether the quality management system conforms to the planned arrangements (see 7.1)	4.17	The standard required the supplier to carry out audits to verify whether quality activities and related results comply with planned arrangements.	This new requirement focuses on the design of the QMS rather than its implementation. The implication is that audits of the QMS need to verify that it has been designed to meet both clause 7.1 and 4.1.	NR
8.2.2	The standard requires the organization to conduct internal audits at planned intervals to determine whether the quality management system conforms to the requirements of this International Standard and to the QMS requirements established by the organization	4.17	The standard required the supplier to carry out audits to verify whether quality activities and related results comply with planned arrangements.	Planned arrangements in the previous version could have been the intention to meet the requirements of ISO 9001, specific contracts and organization's policies. Therefore in this context the intent of the requirement remains unchanged	NCI
8.2.2	The standard requires the organization to conduct periodic internal audits to determine whether the quality management system has been effectively implemented and maintained.	4.17	The standard required the supplier to carry out audits to determine the effectiveness of the system.	This change in wording removes an inconsistency present in the previous version as system effectiveness is evaluated through management review and effective implementation is evaluated through audits.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
8.2.2	The standard requires the organization to plan the audit program taking into consideration the status and importance of the processes and areas to be audited as well as the results of previous audits	4.17	The standard required the supplier to schedule audits on the basis of the status and importance of the activity.	The implication is that processes and areas be audited rather than activities. The additional requirement for audit planning to take into account previous audit results is a clarification, as the status of an activity should include the previous performance. There will be impact for organisations where audits were task based and planned without regard for past performance – hence a process approach to auditing is required.	NR
8.2.2	The standard requires the audit criteria, scope, frequency and methods to be defined.	4.17	The standard required the supplier to establish and maintain documented procedures for planning internal quality audits.	This change defines the planning requirement in more detail but does introduce the concept that audit criteria, scope and methods can be different and should therefore be defined for each audit.	NR
8.2.2	The standard requires the organization to ensure objectivity and impartiality of the audit process in the selection of auditors and conduct of audits.	4.17	No equivalent requirement.	The change means that selection criteria will be needed for selecting auditors that goes beyond individual responsibilities. In addition, a code of conduct will be needed to ensure auditors remain focused on the objectives and not immersed in trivia.	NR
8.2.2	The standard requires auditors not to audit their own work	4.17	The standard required that internal quality audits be carried out by personnel independent of those having direct responsibility for the activity being audited.	This change significantly increases flexibility, particularly for smaller organisations. It implies that any individuals can audit an activity provided they do not perform the activity being audited.	LR
8.2.2	The standard requires the responsibilities and requirements for planning and conducting audits, reporting results and maintaining records to be defined in a documented procedure.	4.17 4.17	The standard required: - a) the supplier to establish and maintain documented procedures for planning and implementing internal quality audits. b) the results of the audits to be recorded and brought to the attention of the personnel having responsibility in the area audited.	The intent of the requirement remains unchanged.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
8.2.2	The standard requires management responsible for the area being audited to ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.	4.17	The standard required the management personnel responsible for the area to take timely corrective action on the deficiencies found during the audit.	The intent of the requirement remains unchanged. However, it may impact those organizations that limited the correction of deficiencies to removal of the problem rather than in addition, eliminating the cause.	NCI
8.2.2	The standard requires follow-up activities to include the verification of the actions taken and the reporting of verification results.	4.17	The standard required that follow-up audit activities record the implementation and effectiveness of the corrective action taken.	The intent of the requirement remains unchanged.	NCI
8.2.3	The standard requires the organization to apply suitable methods for monitoring and, where applicable, measurement of the QMS processes and goes on to require these methods to demonstrate the ability of the processes to achieve planned results.	4.9d	The standard required controlled conditions to include the monitoring and control of suitable process parameters during production, installation and servicing.	This new requirement emphasises the requirement to monitor all processes that is stated in clause 4.1e. In addition, it lays down the criteria for judging their acceptability. The implication therefore is that each process will have provision built-in for verifying that the process is achieving its objectives.	NR
8.2.3	The standard requires that when planned results are not achieved, correction and corrective action be taken as appropriate to ensure conformity of product.	4.9 4.14.2	The standard required the supplier to:- a) control suitable process parameters and product characteristics determine the corrective action needed to eliminate the cause of nonconformities.	The intent of the requirement remains unchanged.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
8.2.4	The standard requires the organization to monitor and measure the characteristics of the product to verify that product requirements have been met.	4.4.7 4.4.8 4.10.2.1 4.10.3a 4.10.4 4.10.4	The standard required the supplier to:- a) perform design verification b) perform design validation c) ensure incoming product is not used or processed until inspected or otherwise verified as conforming to specified requirements d) inspect and test product as required by the quality plan or documented procedures. e) the supplier to carry out final inspection and testing in accordance with the quality plan and/or documented procedures. f) the quality plan or documented procedures for final inspection and testing to require that all the specified inspections and tests, including those specified either on receipt of product or in-process, have been carried out and that the data meets specified requirements.	Although less prescriptive the intent of the requirement remains unchanged.	NCI
8.2.4	The standard requires product monitoring and measurement to be carried out at appropriate stages of the product realization process in accordance with planned arrangements (see 7.1)	4.4.7 4.4.8 4.10.2.1 4.10.3a 4.10.4 4.15.3	The standard required the supplier to a) perform design verification b) perform design validation c) ensure incoming product is not used or processed until inspected or otherwise verified as conforming to specified requirements d) inspect and test product as required by the quality plan or documented procedures e) the supplier to carry out final inspection and testing in accordance with the quality plan and/or documented procedures. f) assess the condition of product in stock at appropriate intervals in order to detect deterioration	The intent of the requirement remains unchanged.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
8.2.4	The standard requires evidence of conformity with the acceptance criteria to be maintained.	4.10.5 4.10.5	The standard required that the supplier:- a) establishes and maintains records which provide evidence that the product has been inspected and/or tested. b) the inspection and test records show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria.	Although less prescriptive the intent of the requirement remains unchanged.	NCI
8.2.4	The standard requires records to indicate the person(s) authorizing release of product.	4.10.5	The standard requires that records identify the inspection authority responsible for the release of conforming product.	The intent of the requirement remains unchanged. However it could be construed as being a more stringent requirement as previously the name of a department would suffice, now it has to be the name of a person	NCI
8.2.4	The standard requires product release and service delivery not to proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and where applicable, by the customer.	4.10.4 4.12	The standard required:- a) that no product be dispatched until all the activities specified in the quality plan or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized. b) to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.	The intent of the requirement remains unchanged.	NCI
8.3	The standard requires the organization to ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.	4.13.1 4.13.1	The standard required the supplier to:- a) ensure that product that does not conform to specified requirements is prevented from inadvertent use or installation. b) provide for identification, documentation, evaluation, segregation, and disposition of nonconforming product and for notification to the functions concerned.	The intent of the requirement remains unchanged.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
8.3	The standard requires nonconforming product controls and related responsibilities to be defined in a documented procedure.	4.13.1 4.13.2 4.13.2	The standard required the supplier to:- a) establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from inadvertent use or installation b) the responsibility for review and authority for the disposition of nonconforming product to be defined c) nonconforming product to be reviewed in accordance with documented procedures	The intent of the requirement remains unchanged.	NCI
8.3	The standard requires the organization to take action to eliminate the detected nonconformity, authorize its use, release or acceptance under concession or take action to preclude its original intended use or application.	4.13.2	The standard required the supplier to:- a) review nonconforming product in accordance with documented procedures and advises that it may be reworked, accepted, re-graded, rejected or scrapped b) report for concession to the customer or customer's representative, where required by the contract, the proposed use or repair of product which does not conform to specified requirements.	The intent of the requirement remains unchanged. a) rework and re-grade are actions to eliminate the detected nonconformity but other means can now be used b) scrap is an action to preclude original use or application but other means can now be used	NCI
8.3	The standard requires records of the nature of nonconformities and any subsequent actions taken, including concessions obtained shall be maintained	4.13.2	The standard required the description of the nonconformity that has been accepted, and of repairs to be recorded to denote the actual condition	The intent of the requirement remains unchanged.	NCI
8.3	The standard requires nonconforming product to be subject to re-verification after correction to demonstrate conformity to the requirements.	4.13.2	The standard required the supplier to re-inspect repaired and reworked products in accordance with the quality plan and/or documented procedures.	The intent of the requirement remains unchanged.	NCI
8.3	The standard requires the organization to take action appropriate to the effects or potential effects of the nonconformity when nonconforming product is detected after delivery or use has started.	4.14.2a	The standard required procedures for corrective action to include the effective handling of reports of product nonconformities.	This new requirement implies that a process has been designed to manage the consequence of detected non-conforming product. For example, a process is required to inform customers users, regulatory bodies as appropriate in the case of product recall.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
8.4	The standard requires the organization to determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made - it also requires the data generated as a result of monitoring and measurement and from other sources to be included.	4.16 4.14.3a 4.1.23	The standard required:- a) documented procedures for the collection of quality records. b) the supplier to use appropriate sources of information to detect and eliminate potential causes of nonconforming product. c) the management representative to report on the performance of the quality system as a basis for improvement of the quality system	The previous requirements only addressed two aspects of the data collection and analysis processes, but the responsibility placed on the management representative covered the gap without specifying a specific action - hence it is now more explicit	NR
8.4a	The standard requires the analysis of data to provide information on customer satisfaction.		No equivalent requirement.	The implication is that the QMS will need to provide for a more objective analysis of customer satisfaction than in the past.	NR
8.4b	The standard requires the analysis of data to provide information on conformance to product requirements.	4.1.3	Requirements on this topic were limited to requiring the management representative to report on the performance of the quality system.	The implication is that the QMS will need to provide for more correlation of data with product requirements than in the past.	NR
8.4c	The standard requires the analysis of data to provide information on characteristics and trends of processes and products including opportunities for preventive action.	4.9d 4.14.3a	The standard required the supplier to:- a) monitor suitable process parameters and product characteristics b) use appropriate sources of information to detect potential causes of nonconforming product.	The intent of the requirement has changed from monitoring data for control purposes to analysing data for control and improvement purposes. It also extends the applicability of the requirement beyond production to all processes including in-service performance.	NR
8.4d	The standard requires the analysis of data to provide information on suppliers.	4.6.2b	The standard required the type and extent of control exercised by the supplier over subcontractors to be dependent upon quality records of the previously demonstrated capability and performance of subcontractors.	The previous requirement implied that supplier performance data should be collected for control purposes but the intent has now changed to analysing data for control and improvement purposes.	NR
8.5.1	The standard requires the organization to 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 actions and management review.		No equivalent requirement.	This is a new requirement. The implication is that the organization needs put in place processes (resources, tools, techniques) that cause it to actively find better ways of doing things. Another implication is that a linkage will need to be demonstrated between quality policy, objectives, process reviews, audits, and continual improvement processes.	NR

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
8.5.2	The standard requires the organization to take corrective action to eliminate the cause of nonconformities in order to prevent recurrence.	4.14.2c	The standard required corrective action procedures to include determining the corrective action needed to eliminate the cause of nonconformities.	The intent remains unchanged because corrective action was defined in ISO 8402 as action taken to prevent recurrence of nonconformity.	NCI
8.5.2	The standard requires corrective action to be appropriate to the effects of the nonconformities encountered.	4.14.1	The standard required that any corrective action taken to eliminate the causes of actual nonconformities is to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.	The intent of the requirement remains unchanged.	NCI
8.5.2a	The standard requires the documented procedure for corrective action to define requirements for reviewing nonconformities (including customer complaints).	4.14.2a	The standard required the procedures for corrective action to include effective handling of customer complaints and reports of product nonconformity.	The implication is that all nonconformities need to be identified not solely those related to product otherwise the requirement duplicates that addressed under measurement and monitoring.	NR
8.5.2b	The standard requires the documented procedure for corrective action to define requirements for determining the causes of nonconformity.	4.14.2b	The standard required the supplier to investigate the cause of nonconformities relating to product, process and quality system and recording the results of the investigation.	The intent of the requirement remains unchanged.	NCI
8.5.2c	The standard requires the documented procedure for corrective action to define requirements for evaluating the need for actions to ensure that nonconformities do not recur.		No equivalent requirement.	The implication is that even though a cause has been discovered, action may not be needed either at all or for some time hence acknowledging practicality	NR
8.5.2d	The standard requires the documented procedure for corrective action to define requirements for determining action needed.	4.14.2c	The standard required corrective action procedures to include determining the corrective action needed to eliminate the cause of nonconformities.	The intent of the requirement remains unchanged.	NCI
8.5.2d	The standard requires the documented procedure for corrective action to define requirements for implementing the action needed.	4.14.2d 4.14.1	The standard required:- a) the supplier to apply controls to ensure that corrective actions are taken. b) the supplier to implement and record changes in the documented procedures resulting from corrective action.	The intent of the requirement remains unchanged.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
8.5.2e	The standard requires the documented procedure for corrective action to define requirements for recording results of action taken.	4.14.2d	The standard required the supplier to apply controls to ensure that corrective action is taken	This additional requirement is more explicit and may impact those organisations that only recorded the action to be taken not the actual action that was taken.	NR
8.5.2f	The standard requires the documented procedure for corrective action to define requirements for reviewing corrective action taken.	4.14.2d	The standard required applying controls to ensure that corrective action is effective.	The modified wording tends to weaken the intent of the requirement from implying periodic review for effectiveness to a one-off activity	LR
8.5.3	The standard requires the organization to determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.	4.14.3a	The standard requires the supplier to use appropriate sources of information to eliminate potential causes of nonconforming product.	The intent of the requirement remains unchanged.	NCI
8.5.3	The standard requires preventive actions taken to be appropriate to the effects of the potential problems.	4.14.1	The standard required that any preventive action taken to eliminate the causes of potential nonconformities is to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.	The intent of the requirement remains unchanged. However there will be implications for those organizations that have not carried out any risk assessment or FMEA activities	NCI
8.5.3a	The standard requires the documented procedure for preventive action to define requirements for determining potential nonconformities and their causes.	4.14.3a	The standard required the supplier to use appropriate sources of information to detect potential causes of nonconforming product.	The intent of the requirement remains unchanged. However, the organizations that didn't use some form of risk assessment will now need to define appropriate methods of identifying potential nonconformities.	NCI
8.5.3b	The standard requires the documented procedure for preventive action to define requirements for evaluating the need for action to prevent occurrence of nonconformities.		No equivalent requirement	This requirement implies that before any preventive action is taken there is an evaluation of need. The implication is that action is not necessarily needed on detecting every potential nonconformity	LR
8.5.3c	The standard requires the documented procedure for preventive action to define requirements for determining and implementing action needed.	4.14.3b 4.14.3c	The standard required that the preventive action procedures include the a) determination of steps needed to deal with any problems requiring preventive action b) initiation of preventive action.	The intent of the requirement remains unchanged.	NCI

ISO 9001:2000		ISO 9001:1994		Differences and Implications	Type of change
Clause	Requirement	Clause	Requirement		
8.5.3d	The standard requires The documented procedure for preventive action to define requirements for recording results of action taken.	4.14.3d	The standard required that the preventive action procedures confirm that the relevant information on actions taken including changes to procedures is submitted for management review.	Though not explicit as to records, the previous requirement could not be implemented without records being available therefore the intent of the requirement remains unchanged.	NCI
8.5.3e	The standard requires the documented procedure for preventive action to define requirements for reviewing preventive action taken.	4.14.3c 4.14.3d	The standard required a) the application of controls to ensure preventive action is effective b) the preventive action procedures confirm that the relevant information on actions taken including changes to procedures is submitted for management review	The modified wording tends to weaken the intent of the requirement from implying periodic review for effectiveness to a one-off activity.	LR

Testing understanding

The changes in the wording are sometimes very clear and sometimes very subtle - so much so that when you place the old and new side by side it is not clear whether any different action or decision is necessary to implement the requirement. This section has been prepared to test understanding. Three statements are presented for each of a number of topics addressed by ISO 9001:2000. One of the statements comes from ISO 9001:1994, a second from ISO 9001:2000 and a third does not come from ISO 9000 at all - the order is not the same for each topic. Firstly identify the source of the statement and then explain the differences between them. If you believe there is no difference, explain your reasons. Such understanding will be necessary in order to convey to managers and auditors the requirements of ISO 9001:2000 and discuss their implications.

E-mail us your answers and we will provide feedback.

Continuous Improvement

What is the difference between:-

1. Managing processes necessary for the continuous improvement of the quality management system
2. Managing processes necessary for the continuous improvement of the quality management system and resulting products
3. Managing processes necessary for the continuous improvement in quality

Procedures

What is the difference between:-

1. The organization shall establish and maintain documented procedures that ensure purchased product conforms to specified requirements
2. The organization shall control its purchasing processes to ensure that purchased product conforms to requirements

3. The organization shall ensure that purchased product conforms to specified purchase requirements

Customer requirements

What is the difference between:-

1. Top management shall ensure customer requirements are determined
2. The organization shall ensure that customer needs and expectations are determined and converted into requirements
3. Before submission of a tender, or the acceptance of a contract or order, the tender, contract or order shall be reviewed by the organization to ensure that the requirements are adequately defined and documented

Quality manual

What is the difference between:-

1. The organization shall prepare a quality manual covering the requirements of this International Standard that includes an outline of the structure of the documentation used in the quality system
2. A quality manual shall be established and maintained that includes a description of the interaction between the processes of the quality management system
3. A quality manual shall be prepared and maintained that describes the quality management system.

QMS purpose

What is the difference between:-

1. The organization shall establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements.
2. The organization shall establish, document, implement, maintain a quality management system and continually improve its effectiveness

in accordance with the requirements of this International Standard

3. The organization shall establish, document, implement, maintain and continually improve a quality management system as a means of enabling the organization to satisfy the needs and expectation of its customers and other interested parties.

Documentation

What is the difference between:-

1. The organization shall establish and maintain a documented procedure for internal communication
2. Appropriate internal communication processes shall be established and effectively managed
3. Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS.

Measurement

What is the difference between:-

1. The organisation shall plan and implement the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of the product
2. The organization shall plan and implement the measurement and monitoring activities necessary to verify that stakeholder needs and expectations are being satisfied
3. The organization shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met

Training

1. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required.
2. Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.
3. Personnel shall be competent to carry out the work assigned to them.

Planning

What is the difference between:-

1. Top management shall ensure that the QMS is designed to enable the organization to achieve the quality objectives and implement its quality policy
2. Top management shall ensure that the planning of the QMS is carried out in order to meet the quality objectives
3. The organization shall define and document how the requirements for quality will be met.

Objectives

What is the difference between:-

1. The organization's management with executive responsibility shall define and document its policy for quality, including objectives for quality,
2. Top management shall ensure that quality objectives are established at relevant functions and levels within the organization.
3. Quality objectives shall be defined for implementing the quality policy.

Records

What is the difference between:-

1. Records required for the quality management system shall be maintained to provide evidence of conformance to requirements
2. Quality records shall be maintained to demonstrate conformance to specified requirements
3. Records shall be established and maintained to provide evidence of conformance to requirements.

Management review

What is the difference between:-

1. 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, products and resources
2. Outputs from the management review shall include actions related to improvement of the quality management system, its processes, products and resources
3. Outputs from the management review shall include actions related to improvement of the quality management system.

Documentation

What is the difference between:-

1. Documents required for the quality management system shall be controlled
2. Documents required for quality management shall be controlled
3. Documents that relate to this International Standard shall be controlled.

Contract review

What is the difference between:-

1. The organization shall review requirements related to the product
2. The tender, contract or order shall be reviewed to ensure that the requirements are adequately defined
3. The organization shall review the identified customer requirements together with additional requirements determined by the organization.

Control

What is the difference between:-

1. The organization shall control production and service operations
2. The organization shall plan and carry out production and service operations under controlled conditions
3. The organization shall plan and carry out production and service provision under controlled conditions.

Verification

What is the difference between:-

4. The organization shall determine the monitoring and measurement to be undertaken to provide evidence of conformity of product to determined requirements
5. The organization shall determine the measurements to be made to assure conformity of product to specified requirements
6. The organization shall determine the measures necessary to verify fulfilment of requirements.

Bibliography

The full standard should be purchased from the national standards body or direct from ISO at

1, rue de Varembe
Case postale 56
CH-1211 Geneva 20
Switzerland

Free publications can be downloaded from of the following websites:-

<http://www.iso.ch>
<http://www.bsi.org.uk/iso-tc176-sc2>
<http://www.tc176.org>

Those of specific interest include

- ◆ ISO Press Release of 14 December 2000
- ◆ Quality Management Principles
- ◆ Transition Planning Guidance
- ◆ Guidance on terminology used in ISO 9001 & ISO 9004
- ◆ Guidance on documentation requirements
- ◆ Guidance on clause 1.2 Application
- ◆ User survey for Y 2000 revisions
- ◆ IAF-TC176 Communiqué September 1999

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John Thompson is an experienced management consultant in business improvement and over a 20 year period held management positions in Unilever, RHP Bearings, Mars and Caradon. During the last 12 years, and prior to forming Transition Support Ltd, he was in management consultancy as a Director of Neville-Clarke Ltd and GPR Consultants Ltd. He assisted organizations in Europe, the Middle East and South East Asia in their business improvement activities, including the use of ISO 9000 Baldrige, Singapore Quality Award and EFQM frameworks. He has assisted many organizations develop improvement strategies, including the Anchor Trust, Mars, TRW and MAFF and is an adviser to the MTTA on their step change initiative. Initially trained as a Statistician, he has undertaken post-graduate studies in Business Administration and is currently completing an MA in Human Resource Management.

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