The following information is based upon the ISO 9001:2008 issued by the International Organization for Standardization (ISO) on November 15, 2008. The content has been prepared by James McLarty of JJ Management Services for the understanding of the changes to the third edition of the ISO 9001:2000 Quality Management System Standard by the quality community.

ISO and IAF have indicated that organizations will have twenty-four months from the issuance of the ISO 9001:2008 (November 15, 2008) standard to be in conformance to the revised 4th version. Certification / registrations to the ISO 9001:2000 standard will not be valid after the twenty four month period, that is November 14, 2010.

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ISO 9001:2008 Requirement	Changes in Text
Introduction	
0.1 General	-Revised introduction to this standard about influences to an organization's Quality Management System (QMS) by adding comment in: *a) its organizational environment, changes in that environment, or risks associated with that environment and b) its varying needs….* -A reference (paragraph 4) is made that this standard can be used to assess an organization's ability to meet ...*statutory and regulatory requirements applicable to the product…..*
0.2 Process Approach	-Paragraph 2 indicates that organization needs *to determine and manage numerous linked activities* rather than ~~*identify*~~ *and manage numerous linked activities.* Added the fact that a process can be a set of activities as follows; A process can be *an activity or a set of activities.* -Added to the phrase to paragraph 3, to produce the desired outcome as follows; ….*and their management, to produce the desired outcome, can be referred to as the process approach.*
0.3 Relationship with ISO 9004	-Reference is made to the relationship with ISO 9004 which is being revised but is not completed as of the publication of ISO 9001:2008.
0.4 Compatibility with other management systems	-Reference revised to include ISO 14001:2004
1 Scope	
1.1 Scope - General	-Added applicable *statutory and* regulatory requirements in both a) and b) -Added the following to NOTE 1 b) *any intended output resulting from the product realization processes.* -Added *NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.*
1.2 Application	-Added the phrase "statutory and" as follows: …*product that meets customer and applicable statutory and regulatory requirements.*
2 Normative reference	-Updated reference to ISO 9000:2005
3 Terms and definitions	-Definitions and relationships of supplier, organization and customer have been deleted from this edition.

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4 Quality management system	
4.1 QMS - General requirements	-Revised wording in a) now uses *Determine the processes* rather than ~~identify the processes~~… e) Addition of *where applicable* applies to the term *measure* -Fourth paragraph uses revised wording; product conformity *to* requirements, replaces ~~with~~ requirements -Paragraph 4, revision in wording requires that the type and extent of control of outsourced processes be included in the QMS as follows: *The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system*. -NOTE 1 added the words in italics … measurement, *analysis and improvement* to make a direct reference to Section 8 of the standard. -Added *NOTE 2* as follows; *An "outsourced process" is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.* -Added NOTE 3 which lists some ways that control of outsourced processes can be accomplished. *NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as* *a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,* *b) the degree to which the control for the process is shared,* *c) the capability of achieving the necessary control through the application of 7.4.*
4.2 Documentation requirements	
4.2.1 Documentation requirements - General	-c) and d) Revised wording to indicate that such documents, *including records*, required by the standard (c),) and determined by the organization to be *necessary* rather than needed by the organization (d),) to ensure effective planning, operation and control of its processes. Part e) has been replaced by the wording above. -Added content to NOTE 1 to clarify that one document can include multiple required procedures or that multiple procedures can be used to meet a documented procedure requirement.
4.2.2 Quality manual	No changes
4.2.3 Control of documents	-f) Qualifier added to indicate that only external documents *determined by the organization to be necessary for the planning and operation of the quality management system* need to be identified and controlled and.
4 2.4 Control of records	-Revision of wording to clarify the requirement for control of records to *provide evidence of conformity of requirements and of the effective operation of the quality management system.*

ISO 9001:2008 Requirement	Changes in Text
	-Grammatical changes to re-phrase the paragraphs. No change in requirements. -Requirement for a documented procedure is the second requirement rather than the third requirement in this section.
5 Management Responsibility	
5.1 Management commitment	No change
5.2 Customer focus	No change
5.3 Quality policy	No change
5.4 Planning	
5.4.1 Quality objectives	No change
5.4.2 Quality management system planning	No change
5.5 Responsibilities, authorities and communication	
5.5.1 Responsibility & authority	No changes
5.5.2 Management representative	-Added a qualifier as to who can be the organization's management representative by stating that the management representative is to be a *member of the organization's management.*
5.5.3 Internal communication	No changes
5.6 Management review	
5.6.1 Management review	No changes
5.6.2 Management Review Input	No changes
5.6.3 Management Review output	No changes
6 Resource management	
6.1 Provision of resources	No changes
6.2 Human resources	
6.2.1 Human resources General	-Added a note to suggest that all personnel within the organization may impact conformity to product requirements. *NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.*
6.2.2 *Competence, training and awareness* (revised title)	-Several revisions to wording throughout - focus of all revisions in this section is to ensure conformity to product requirements and to ensure the competence of its personnel. -Revised wording for a) ...*for personnel performing work affecting conformity to product requirements* whereas previously it was …~~*for personnel performing work affecting quality requirements*~~ -Revised wording in part b) the phrase *where applicable* and *achieve the necessary competence* are added in that; *where applicable, provide training or take other actions to achieve necessary competence*; -c) revised wording, to *ensure that the necessary competence has been achieved* (refers to previous section b)
6.3 Infrastructure	-Added the phrase *information systems* to ensure that this is also included in Infrastructure *c)…communication. or information systems*.
6.4 Work environment	-Note added to indicate that the *work environment relates to conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).*
7 Product realization	
7.1 Planning of product realization	-Revised wording adds *and* now states for b) *the need to establish processes and documents…* where previously the phrase was *the*

ISO 9001:2008 Requirement	Changes in Text
	need to develop processes, documents, and to provide….. -Added the word *measurement* in subsection c) after monitoring.
7.2 Customer related processes	
7.2.1 Determination of requirements related to the product	-Part c) added the word *applicable* referring to statutory and regulatory requirements rather than ~~related~~ to the product. -Wording revised to include the following in to part d) *any additional requirements considered necessary by the organization* rather than ~~*determined*~~ *by the organization.* -Note added to indicate what *post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.*
7.2.2 Review of requirements related to the product	No changes
7.2.3 Customer communication	No changes
7.3 Design and development	
7.3.1 Design and development planning	-Note added that indicates that *Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination as suitable for the product and the organization.*
7.3.2 Design and development inputs	-Changed the preposition in the first paragraph from ~~These~~ to *The inputs….*
7.3.3 Design and development output	-Revised wording as follows: *The outputs of design and development shall be provided in a form suitable for verification….whereas the previous version stated: shall be in a form that enables verification….* -NOTE added to indicate that *information for product and service provision may include details for the preservation of the product.* Grammatical change to requirement b) to eliminate the word *for* before *service provision.*
7.3.4 Design and development review	No changes
7.3.5 Design and development verification	No changes
7.3.6 Design and development validation	No changes
7.3.7 Control of design and development changes	Paragraphs are now merged into one paragraph. No change to the text.
7.4 Purchasing	
7.4.1 Purchasing process	No changes
7.4.2 Purchasing information	No changes
7.4.3 Verification of purchased product	No changes
7.5 Production and service provision	
7.5.1 Control of product and service provision	-d) Changed wording from monitoring and measuring ~~*devices*~~ to monitoring and measuring *equipment* (See section 7.6). -f) Added the word *product* before release, *the implementation of product release, delivery and post delivery activities.*
7.5.2 Validation of processes for product & service provision	-Revised wording when validation of processes is applicable should be apparent as it now also includes the consequence of not being able to monitor or measure product during production as follows: *…the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.*
7.5.3 Identification and traceability	-Revised wording to maintain product status throughout the product

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	realization process as follows*: …shall identify the product status with respect to monitoring and measurement requirements throughout product realization.* -Revised wording as follows: *…shall control the unique identification of the product and maintain records (see 4.2.4).*
7.5.4 Customer property	-Revised wording regarding customer property… *report this to the customer and maintain records (see 4.2.4)* whereas the previous requirement was to have ~~*records maintained*~~ (see 4.2.4). Additional wording in the NOTE which now states that customer property can include *personal data.*
7.5.5 Preservation of product	Wording is revised to clarify this requirement. It now states that *the organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements.* -Added the phrase *as applicable* to paragraph 1 which now states: *As applicable preservation shall include …..…*
7.6 Control of monitoring & measuring equipment	-Title and word change, ~~*devices*~~ is now *equipment* throughout this section -b) Added option of both calibration and verification…*equipment shall be calibrated or verified or both, …* -c) revised wording to clarify that equipment shall have identification so that its calibration status can be determined *Shall have identification in order to determine its calibration status,* -Note added to clarify software confirmation which would typically include *its verification and configuration management to maintain its suitability for use.*
8 Measurement analysis & improvement	
8.1 Measurement, analysis & improvement - General	-a) revised wording changes the focus *to conformity to product requirements* rather than the conformity of the product.
8.2 Monitoring and measurement	
8.2.1 Monitoring & measurement -Customer satisfaction	-NOTE added to provide clarity to the understanding of monitoring customer perception; *NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports.*
8.2.2 Monitoring & measurement - Internal audit	-Revised wording regarding the documented procedure for internal auditing; *A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.* -Revised wording regarding records of internal audits; *Records of the audits and their results shall be maintained (see 4.2.4).* -Wording revised to include the use of *any corrections and corrective actions* to provide clarity to management responsible for the area being audited in that they *shall ensure that any necessary corrections and corrective actions are taken without undue delay.* -Updated NOTE now refers to *ISO 19011 for guidance*
8.2.3 Monitoring & measurement of processes	-Revised wording regarding the actions to be taken, now says *When planned results are not achieved, correction and corrective action shall be taken as appropriate~~, to ensure the conformity of product~~.*

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	-Note added to provide clarity to the monitoring and measurement of processes; *NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.*
8.2.4 Monitoring & measurement of product	-Revised paragraphs 1 and 2 without change in content. Paragraph 2 added to *for delivery to the customer* in reference to records of the individuals releasing product, as follows; *Records shall indicate the person(s) authorizing release of product for delivery to the customer.* -Paragraph 3 added *for delivery to the customer* in reference to product and service delivery, as follows: *The release of product and delivery of service to the customer shall not proceed…*
8.3 Control of nonconforming product	-Revised wording for the documented procedure requirement as follows: *A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.* Note; Appendix B1, section 8.3 incorrectly indicates that this reference to the documented procedure is deleted but in actuality it has been added as identified above. -Added the phrase *where applicable* as follows; *where applicable, the organization shall deal with nonconforming product….* -Added another option for managing nonconforming product, *d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.* -Paragraphs 3 and 4 have been revised / moved to provide additional clarity. No change in requirements other than those listed above.
8.4 Analysis of data	-b) corrected reference to the standard, now correctly references *(see 8.2.4)* rather than ~~(see 7.2.1).~~ -c) Added standard references regarding; *characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4) and,* -d) Added standard reference as follows: *suppliers (see 7.4).*
8.5 Improvement	
8.5.1 Continual improvement	No changes
8.5.2 Corrective action	-Made the word ~~*cause*~~ plural, -*causes*, as follows: ….*shall take action to eliminate the causes of nonconformities.*….to be consistent with part b). -f) Added the words … *Reviewing the effectiveness of corrective action taken*
8.5.3 Preventive action	e) Added the words … *Reviewing the effectiveness of preventive action taken*
Annex A	Annex A tables now reflect the requirements of ISO 14001:2004
Annex B	Additions and deletions of ISO 9001:2008 with ISO 9001:2000