

Comparison between ISO 9001:2008 and ISO 9001:2000

	ISO 9001:2008	ISO 9001:2000	Rationale
0.1	Implementation of QMS influenced by <u>a) its organization environment ... b) its varying needs c) ... f) its size and organization structure</u>	Implementation of QMS influenced by varying needs ...	Emphasis
0.2	... identification and interactions of these processes, <u>and their management to produce desired outcome</u> , can be referred to identification and interactions of these processes, can be referred to	Emphasis
1.1	NOTE 1 <i>added to expand the term 'product' to include a) product <u>for</u> or <u>required by</u> customer b) any intended output resulting from realization process ...</i>		Emphasis
4.1	a) <u>determine</u> the processes ...	a) <u>identify</u> the processes ...	Consistency
4.1	e) monitor, measure <u>where applicable</u> , and analyse ...	e) monitor, measure and analyse ...	Clarity
4.1	Where an organization chooses to outsource any processes that affects product conformity <u>to</u> requirements, the organization shall ensure control over such processes. The <u>type and extent of control</u> to be applied to these out sourced processes shall be defined within the QMS. NOTE 2 <i>added to clarify what is an outsourced process</i> NOTE 3 <i>added to explain type and nature of controls</i> Organization is finally responsible	Where an organization chooses to outsource any processes that affects product conformity <u>with</u> requirements, the organization shall ensure control over such processes. <u>Control</u> of such out sourced processes shall be <u>identified</u> within the QMS.	Emphasis
4.2.1	c) doc procedures <u>and records</u> required d) doc, <u>including records, determined</u> by the organization e) <i>deleted (records)</i> NOTE 1 <i>added to indicate that one single procedure may cover multiple requirements, or vice versa</i>	c) doc procedures required by ... d) documents <u>needed</u> by the organization e) records required by this IS	Clarity
4.2.3	f) doc of ext origin <u>determined by the organization to be necessary for the planning and operation of the QMS</u> are identified ...	f) ... doc of ext origin are identified ...	Clarity
4.2.4	<i>Slight change in wording to present the same intent. Retention as one of six control requirements.</i>	<i>Retention <u>time</u> as one of six control requirements</i>	Clarity
5.5.2	Appoint a member of <u>the organization's</u> management who, ... (MR cannot be outsourced)	Appoint a member of management who, ...	Emphasis
6.2.1	... affecting <u>conformity to product requirements</u> ... <i>(using term 'product requirements'; be affected directly or indirectly by personnel)</i>	... affecting <u>product quality</u> shall be competent ...	Consistency
6.2.2	a) ... affecting <u>conformity to product requirements</u> ... b) <u>where applicable</u> , provide training .. <u>to achieve nec competence</u>	a) ... affecting <u>product quality</u> b) <u>provide training</u> or take other actions to satisfy these needs ..	Emphasis Clarity
6.3	c) supporting services (... or <u>information system</u>)	<i>Information system not mentioned in ISO 9001:2000</i>	Clarity
6.4	NOTE <i>added to explain work environment including physical, environmental and other factors (such as noise, temp, humidity ...)</i>		Clarity
7.1	c) ... validation, monitoring, <u>measurement</u> , inspection ...	c) ... validation, monitoring, inspection ...	Consistency
7.2.1	c) <i>d) touch up on wordings</i> NOTE <i>examples of post delivery activities (warranty, disposal etc)</i>		Clarity

Italic = Commentary **Bold = Attention**

	ISO 9001:2008	ISO 9001:2000	Rationale
7.3.1	NOTE on d/d review, verification and validation have distinctive purposes.		Clarity
7.3.2	The inputs ...	<u>These</u> inputs ...	Clarity
7.3.3	... shall be in a form <u>suitable for</u> verification ... NOTE added on preservation of product as information for production and service provision	... shall be <u>provided</u> in a form that <u>enables</u> verification ...	Clarity
7.5.2	... subsequent monitoring or measurement and <u>as a consequence</u> , deficiencies subsequent monitoring or measurement. <u>This includes any processes where</u> deficiencies ...	Clarity
7.5.3	... product status with respect to monitoring and measurement requirements <u>throughout product realization</u> ... shall control the unique identification of the product <u>and maintain records</u> product status <u>with respect to monitoring and measurement requirements</u> shall control <u>and record</u> the unique identification of the product.	Clarity
7.5.4	... organization shall report this to the <u>customer and maintain records</u> . NOTE includes personal data	... , this shall be reported to <u>the customer and records maintained</u> .	Clarity Emphasis
7.5.5	.. intended destination <u>in order to maintain conformity to requirements</u> . As applicable, preservation shall ...	The conformity of product during int processing and delivery to intended destination. This preservation shall ...	Consistency Clarity
7.6	... measuring equipment ... a) be calibrated or verified, <u>or both</u> , at specified intervals... NOTE on confirmation of software would typically include verification	... measuring device ... a) be calibrated or verified at specified intervals	Consistency Clarity
8.1	a) to demonstrate <u>conformity to product requirements</u> ...	a) to demonstrate <u>conformity of the product</u> ...	Consistency
8.2.1	As one of the <u>measurements</u> of ... NOTE added on input sources such as surveys, compliments, warranty claims etc	As one of the <u>indicators</u> of	Clarity
8.2.2	<i>Restructured to separate doc procedure and maintain records</i> ... shall ensure that <u>corrections and corrective actions</u> are taken shall ensure that <u>actions</u> are taken ...	Clarity Emphasis
8.2.3	... corrections and corrective actions shall be taken , as appropriate. NOTE added on <u>suitable methods</u> for organization to consider the type and extent of monitoring or measuring for each process to determine the impact on the conformity to product requirements and on the effectiveness of the QMS	... corrections and corrective actions shall be taken , as appropriate <u>to ensure conformity of the product</u> .	Emphasis
8.2.4	... the person(s) authorizing release of product for delivery <u>to the customer</u> . The release of <u>product and delivery of service to the customer</u> shall ... <i>maintain records on 'who signs off' for delivery</i>	... the person(s) authorizing release of product for delivery. Product <u>release and service delivery</u> shall not proceed...	Clarity
8.3	d) by taking <u>action appropriate to the effects, or potential effects, of the NC when NC product is detected after delivery or use has started</u> . <i>(becomes a way to deal with nonconformity)</i>	<u>When NC product is detected after delivery or use has started, the organization shall take action to the effects , or potential effects , of the NC.</u>	Clarity