Quality management system requirements – enumerated

The following statements paraphrase the requirements of ISO 9001:2015 thereby producing some 266 individual requirements which may be useful as a conformity check list. Simply preface each statement with the question "What evidence is there which demonstrates that the organization is….

Understanding the organization and its context (4.1)

1. Determining external and internal issues
2. Monitoring and reviewing external and internal issues

Understanding the needs and expectations of interested parties (4.2)

3. Determining the interested parties,
4. Determining the effects of interested parties and their requirements
5. Monitoring and reviewing information about the interested parties

Scope of the quality management system (4.3)

6. Determining the boundaries of the QMS)
7. Determining the applicability of the QMS
8. Applying the requirements of ISO 9001
9. Documenting the scope of the QMS

Quality management system (4.4)

10. Establishing a quality management system including processes needed
11. Implementing a quality management system
12. Maintaining a quality management system
13. Continually improving a quality management system
14. Determining processes needed for the quality management system
15. Applying the processes of the QMS throughout the organization
16. Determining the inputs required
17. Determining the outputs expected
18. Determining process sequence
19. Determining process interaction
20. Determining the criteria to ensure effective operation and control
21. Determining methods needed to ensure effective operation and control
22. Determining the resources needed
23. Assigning responsibilities and authority for processes
24. Addressing the risks and opportunities determined when planning for the quality management system
25. Evaluating the processes and ensuring they achieve their intended results
26. Improving the processes
27. Maintaining documented information
28. Retaining documented information

5 Leadership

5.1 Leadership and commitment

29. Leadership with respect to the QMS (5.1.1a)
30. Commitment with respect to the QMS (5.1.1a)
31. Taking accountability for the QMS (5.1.1a)
32. Ensuring quality policy and quality objectives are established and are compatible (5.1.1b)
33. Ensuring integration of QMS requirements into business processes (5.1.1c)
34. Promoting use of the process approach and risk based thinking (5.1.1d)
35. Ensuring resources are available (5.1.1e)
36. Communicating the importance of effective quality management (5.1.1f)
37. Ensuring the QMS achieves its intended results (5.1.1g)
38. Encouraging contribution to the effectiveness of the QMS (5.1.1h)

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39. Promoting improvement of the QMS (5.1.1i)
40. Supporting other relevant management roles (5.1.1j)

5.2 Customer focus

41. Demonstrating leadership and commitment (5.1.2)
42. Demonstrating leadership regarding risks and opportunities
43. Maintaining focus on enhancing customer satisfaction

5.3 Policy

44. Establishing a quality policy that is appropriate (5.2.1)
45. Providing a framework for quality objectives (5.2.1b)
46. Communication and application of the quality policy (5.2.1b)
47. Maintenance of quality policy (5.2.2a)
48. Availability of quality policy (5.2.2c)

5.4 Organizational roles, responsibilities and authorities

49. Assigning and communicating responsibilities and authorities (5.3)
50. Responsibility and authority for ensuring conformity to ISO 9001 (5.3a)
51. Responsibility and authority for ensuring process performance (5.3b)
52. Responsibility and authority for reporting QMS performance (5.3c)
53. Responsibility and authority for promoting customer focus (5.3d)
54. Responsibility and authority for ensuring QMS integrity (5.3e)

6 Planning

6.1 1 Actions to address risks and opportunities

55. Risks and opportunities that need to be addressed (6.1.1)
56. Planning actions to address risks and opportunities (6.1.2a)
57. Integrating actions into QMS processes (6.1.2b (1))
58. Planning how to evaluating the effectiveness of actions (6.1.2b (2))

6.2 Quality objectives and planning to achieve them

59. Establishing quality objectives (6.2.1)
60. Ensuring consistency with quality policy (6.2.1a)
61. Ensuring quality objectives are measurable (6.2.1b)
62. Taking account of applicable requirements (6.2.1c)
63. Ensuring relevance of quality objectives (6.2.1d)
64. Monitoring quality objectives (6.2.1e)
65. Communicating quality objectives (6.2.1f)
66. Updating quality objectives (6.2.1g)
67. Maintaining information on quality objectives (6.2.1)
68. Planning to achieve quality objectives (6.2.2)

6.3 Planning of changes

69. Considering the purpose of changes to the QMS (6.3a)
70. Considering potential consequences of changes to the QMS (6.3a)
71. Considering the integrity of the QMS (6.3b)
72. Considering the availability of resources (6.3c)
73. Considering the allocation responsibilities and authorities (6.3d)

7 Support

74. Determining the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS
75. Providing the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS

7.1.2 People

76. Determining the people needed (7.1.1 & 7.1.2)
77. Providing the people needed (7.1.1 & 7.1.2)

7.1.3 Infrastructure

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78. Determining the infrastructure needed (7.1.1 & 7.1.3)
79. Providing the infrastructure needed (7.1.1 & 7.1.3)
80. Maintaining the infrastructure needed (7.1.1 & 7.1.3)

7.1.4. Environment for the operation of processes

81. Determining the environment needed for the operation of the processes and to achieve conformity of products and services
82. Providing the environment needed for the operation of the processes and to achieve conformity of products and services
83. Maintaining the environment needed for the operation of the processes and to achieve conformity of products and services

7.1.5 Monitoring and measuring resources

84. Determining and providing resources for ensuring valid and reliable results (7.1.1 & 7.1.5.1)
85. Providing resources for ensuring valid and reliable results (7.1.1 & 7.1.5.1)
86. Ensuring suitability of selected monitoring and measuring resources (7.1.5.1a)
87. Maintaining integrity of monitoring and measuring resources (7.1.5.1b)
88. Retaining evidence that monitoring and measurement resources are fit for purpose (7.1.5.1)
89. Calibration and verification of measuring equipment (7.1.5.2a)
90. Recording the basis for calibration (7.1.5.2a)
91. Indicating calibration status (7.1.5.2b)
92. Safeguarding monitoring and measuring instruments (7.1.5.2c)
93. Determining and addressing the impact of defective instruments (7.1.5.2)

7.1.6 Organizational knowledge

94. Determining organizational knowledge (7.1.6)
95. Maintaining organizational knowledge (7.1.6)
96. Availability of organizational knowledge (7.1.6)
97. Acquisition of and access to additional knowledge (7.1.6)

7.2 Competence

98. Determining competence (7.2a)
99. Assessing competence (7.2b)
100. Developing competence (7.2c)
101. Evaluating effectiveness of actions taken (7.2c)
102. Retaining evidence of competence (7.2d)

7.3 Awareness

103. Awareness of quality policy (7.3a)
104. Awareness of quality objectives (7.3b)
105. Awareness of contribution (7.3c)
106. Awareness of implications (7.3d)

7.4 Communication

107. Determining what to communicate (7.4a)
108. Determining when to communicate (7.4b)
109. Determining with whom to communicate (7.4c)
110. Determining who communicates (7.4e)
111. Determining how to communicate (7.4d)

7.5 Documented information

112. Documented information required by ISO 9001 (7.5.1a)
113. Determining documented information necessary for the QMS (7.5.1b)
114. Identifying and describing documented information (7.5.2a)
115. Determining appropriate format and media (7.5.2b)
116. Review and approval of documented information (7.5.2c)

117. Availability and suitability of documented information (7.5.3.1a & 7.5.3.2a)
118. Controlling distribution, access, retrieval and use (7.5.3.2a)
119. Protection of documented information (7.5.3.1b)
120. Storage and preservation of documented information (7.5.3.2b)
121. Controlling changes to documented information (7.5.3.2c)
122. Retention and disposal of documented information (7.5.3.2d)
123. Controlling documented information of external origin (7.5.3.2)

8 Operation

8.1 Operational planning and control

124. Planning operational processes (8.1)
125. Establishing product and services requirements (8.1a)
126. Establishing process, product and service criteria (8.1b)
127. Determining resources for operational activities (8.1c)
128. Controlling processes in accordance with the criteria (8.1c)
129. Determining, maintaining and retaining documented information (8.1e)
130. Operations planning output (8.1b)
131. Control of planned changes (8.1)
132. Review of unintended changes (8.1)
133. Control of outsourced processes (8.1)

8.2.1 Customer communication

134. Providing information relating to products and services (8.2.1a)
135. Handling customer enquiries (8.2.1b)
136. Handling customer contracts including changes (8.2.1b)
137. Handling orders including changes (8.2.1b)
138. Obtaining customer feedback (8.2.1c)
139. Communicating with customers in relation to customer complaints (8.2.1c)
140. Communicating with customers in relation to customer property (8.2.1d)
141. Establishing requirements for contingency action (8.2.1e)

8.2.2 Requirements for products and services

142. Defining product and service requirements (8.2.2a)
143. Defining applicable statutory and regulatory requirements (8.2.2b)
144. Defining organizational requirements (8.2.2c)
145. Meeting claims for products and services offered (8.2.2b)

8.2.3 Review of requirements for products and services

146. Ensuring ability before committing to supply (8.2.3.1)
147. Reviewing customer specified requirements before committing supply (8.2.3.1a)
148. Reviewing requirements necessary for intended use (8.2.3.1b)
149. Reviewing requirements specified by the organization (8.2.3.1c)
150. Reviewing statutory and regulatory requirements (8.2.3.1d)
151. Reviewing and resolving requirements differing from those previously expressed (8.2.3.1e)
152. Handling undocumented customer requirements (8.2.3.1)
153. Retaining documented result of the review (8.2.3.2)
154. Handling changes to requirements for products and services (8.2.4)

8.3.1 Design and development planning

155. Establishing a design and development process (8.3.1)
156. Considering the nature, duration and complexity of design and development (8.3.2a)
157. Considering process stages (8.3.2b)
158. Considering design and development verification and validation (8.3.2c)
159. Considering design and development responsibilities and authorities (8.3.2d)
160. Considering resource needs (8.3.2e)

161. Controlling organizational interfaces (8.3.2f)
162. Involving customers and users in the design and development process (8.3.2g)
163. Considering requirement for provision of products and services (8.3.2h)
164. Considering the level of external control (8.3.2i)
165. Confirming the documented information (8.3.2j)

8.3.3 Design and development inputs

166. Determining requirements essential for the specific type of products and services (8.3.3)
167. Considering functional and performance requirements (8.3.3a)
168. Considering information from similar designs (8.3.3b)
169. Considering statutory and regulatory requirements (8.3.3c)
170. Considering standards or codes of practice (8.3.3d)
171. Considering potential consequences of failure (8.3.3e)
172. Ensuring the adequacy of inputs (8.3.3)
173. Resolving conflicting inputs (8.3.3)
174. Retaining documented information on inputs (8.3.3)

8.3.4 Design and development controls

175. Defining design and development process objectives (8.3.4a)
176. Controlling design reviews (8.3.4b)
177. Controlling design verification (8.3.4c)
178. Controlling design validation (8.3.4d)
179. Taking necessary actions (8.3.4e)
180. Retaining documented information on design and development activities (8.3.4f)

8.3.5 Design and development outputs

181. Ensuring outputs meet input requirements (8.3.5a)
182. Ensuring outputs are adequate for subsequent processing (8.3.5b)
183. Ensuring outputs reference monitoring and measuring requirements and acceptance criteria (8.3.5c)
184. Ensuring products and services are fit for intended purpose (8.3.5d)
185. Retaining documented information on design and development outputs (8.3.5)

8.3.6 Design and development changes

186. Controlling changes during and subsequent to design and development (8.3.6)
187. Retaining information on design and development changes (8.3.6)

8.4 .1Control of externally provided processes, products and services

188. Ensuring externally provided processes, products and services conform to requirements (8.4.1)
189. Defining controls applied to products, services and their providers (8.4.2b, c & d)
190. Defining controls applied to outsourced processes and their providers (8.1, 8.4.1 & 8.4.2a)

8.4.2 Evaluation, selection and monitoring of external providers

191. Evaluation, selection and re-evaluation of external providers (8.4.1)
192. Monitoring the performance of external providers (8.4.1)
193. Retaining evidence of evaluation, selection and monitoring (8.4.1)

8.4.3 Information for external providers

194. Communicating processes, product and service requirements (8.4.3a)
195. Communicating approval requirements (8.4.3b)
196. Communicating personnel competence conditions (8.4.3c)
197. Communicating requirements for interaction (8.4.3d)
198. Communicating performance control and monitoring conditions (8.4.3e)
199. Communicating intent to perform verification on provider's premises (8.4.3f)
200. Ensuring adequacy of specified requirements (8.4.3)

8.5.1 Control of production and service provision

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201. Availability of documented information (8.5.1a)
202. Availability and use of suitable monitoring and measuring resources (8.5.1e)
203. Monitoring and measurement activities (8.5.1c)
204. Use of suitable infrastructure and environment (8.5.1d)
205. Competence and qualification of personnel (8.5.1f)
206. Validation of processes (8.5.1g)
207. Actions to prevent human error (8.5.1g)

8.5.2 Identification and traceability

208. Identifying process outputs (8.5.2)
209. Identifying the status of process outputs (8.5.2)
210. Maintaining traceability (8.5.2)

8.5.3 Property belonging to external providers

211. Care of property belonging to external providers (8.5.3)
212. Identifying property belonging to external providers (8.5.3)
213. Verifying property belonging to external providers (8.5.3)
214. Protecting property belonging to external providers (8.5.3)
215. Reporting problems to external providers (8.5.3)

8.5.4 Preservation

216. Preservation of process outputs

8.5.6 Control of changes

217. Control of changes (8.5.6)
218. Retaining information on changes (8.5.6)

8.6 Release, delivery and post-delivery of products and services

219. Verifying product and service requirements have been met (8.6)
220. Authorising release of products and services (8.5.1h & 8.6)
221. Retaining evidence of conformity (8.6)
222. Product delivery and service fulfilment (8.5.1h)
223. Post-delivery activities (8.5.1h & 8.5.5)

8.7 Control of nonconforming outputs

224. Preventing unintended use (8.7.1)
225. Taking appropriate action (8.7.1)
226. Verifying corrected nonconformities (8.7.1)
227. Retaining information of actions taken on nonconforming process outputs (8.7.2)

9 Performance evaluation

9.1.1 Monitoring, measurement, analysis and evaluation

228. Determining what needs to be monitored and measured (9.1.1a)
229. Determining monitoring, measurement, analysis and evaluation methods (9.1.1b)
230. Determining when the monitoring and measuring are to be performed (9.1.1c)
231. Determining when results are to be analysed and evaluated. (9.1.1d)
232. Retaining documented information as evidence of results (9.1.1)

9.1.2 Customer satisfaction

233. Monitoring customer perceptions (9.1.2)
234. Determining methods for monitoring and reviewing customer perceptions (9.1.2)

9.1.3 Analysis and evaluation

235. Evaluating product and service conformity (9.1.3a)
236. Evaluating process performance (9.3.2c)
237. Evaluating the performance and effectiveness of the QMS (9.1.3c)
238. Evaluating implementation of planning (9.1.3d)
239. Evaluating effectiveness of actions to address risks and opportunities (9.1.3e)
240. Evaluating performance of external providers (9.1.3f)
241. Evaluating the need for improvements to the QMS (9.1.3g)

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9.2 Internal Audit

242. Audit objectives (9.2.1)
243. Planning the audit programmes (9.2.2a)
244. Defining audit criteria and scope (9.2.2b)
245. Ensuring audit objectivity and impartiality (9.2.2c)
246. Defining the audit method
247. Reporting audit results to management (9.2.2d)
248. Undertaking correction and corrective action (9.2.2e)
249. Retaining evidence of the implementation (9.2.2f)

9.3 Management review

250. Organizing the management review (9.3.1)
251. Scheduling management reviews (9.3.1)
252. Planning and carrying out management reviews (9.3.2)
253. Deciding what actions to take (9.3.3)
254. Retaining evidence of the results of management reviews (9.3.3)

10 Improvement

10.1 General

255. Determining and selecting opportunities for improvement (10.1)
256. Improving products and services (10.1a)
257. Correcting, preventing or reducing undesirable effects (10.1b)
258. Improving quality management system results (10.1c)

10.2 Nonconformity and corrective action

259. Reacting to nonconformity (10.2.1a)
260. Evaluating the need for action to eliminate the cause (10.2.1b)
261. Implementing actions that are appropriate to the effects (10.2.1c)
262. Updating risks and opportunities during planning (10.2.1e)
263. Retaining evidence of the nature of nonconformity and actions taken (10.2.2a)
264. Reviewing effectiveness of corrective actions and retaining evidence of results (10.2.1d & 10.2.2b)

10.3 Continual improvement of the QMS

265. Continually improving the suitability adequacy and effectiveness of the QMS (10.3)
266. Determining additional opportunities for continual improvement (10.3)