QUALITY MANAGEMENT SYSTEM REQUIREMENTS

General Requirements

1. Establishing and implementing a documented quality management system
2. Implementing a documented quality management system
3. Maintaining a documented quality management system
4. Continually improving the effectiveness of the QMS
5. Determining processes
6. Determining process sequence and interaction
7. Determining criteria and methods for operation and control of processes
8. Availability of resources necessary to support the operation and control of processes
9. Availability of information necessary to support the operation and control of processes
10. Monitoring, measurement and analysis of processes
11. Restoring the status quo
12. Continual process improvement
13. Process management
14. Outsourcing processes
15. Responsibility for outsourced processes

Documentation Requirements

General

16. Documenting the quality policy and objectives
17. Documenting the quality manual
18. Documenting the quality management system procedures
19. Documenting the information needed for the effective operation and control of processes
20. Documenting records

Quality Manual

21. Establishing and maintaining a quality manual

Control of Documents

22. Controlling documents required by the QMS
23. Establishing document control procedures
24. Approval of documents
25. Review and revision of documents
26. Re-approval of documents after revision
27. Identifying revision status
28. Availability of documents
29. Identification and legibility of documents
30. Control of documents of external origin
31. Control of obsolete documents
32. Identifying obsolete documents retained for use
Control of Records
33. Establishing and maintaining records of conformity
34. Establishing and maintaining records of effectiveness
35. Ensuring legibility of records
36. Ensuring identification of records
37. Retrieval of records
38. Establishing a records control procedure

MANAGEMENT RESPONSIBILITY REQUIREMENT

Management Commitment
39. Evidence of management commitment to developing a QMS
40. Evidence of management commitment to continually improving the effectiveness of the QMS
41. Evidence of communicating the importance of meeting customer and regulatory requirements
42. Evidence of management establishing the quality policy
43. Evidence of management establishing quality objectives
44. Evidence of management commitment by conducting management reviews.
45. Evidence of management commitment by ensuring the availability of necessary resources.

Customer Focus
46. Determining customer requirements
47. Meeting customer requirements

Quality Policy
48. Purpose of organization
49. Commitment to comply with requirements
50. Commitment to continual improvement
51. Framework for quality objectives
52. Communication of quality policy
53. Review of quality policy

Planning
Quality Objectives
54. Establishing quality objectives
55. Measurement of quality objectives
56. Consistency of quality objectives
57. Objectives for meeting product requirements
58. Inclusion of quality objectives in business plan
Quality Management System Planning

59. Planning of quality management system in line with process management principles
60. Planning of quality management system to meet quality objectives
61. Maintaining integrity of quality management system

Responsibility, Authority and Communication

Responsibility and Authority

62. Defining and communicating responsibility and authority

Management Representative

63. Appointment of management representative
64. Responsibility and authority of management representative

Customer Representative

65. Designation of customer representatives

Internal Communication

66. Establishing communication processes
67. Communicating the effectiveness of the QMS

Management Review

General

68. Top management review of quality management system
69. Assessing opportunities for improvement
70. Records of management review

Review Input

71. Performance information for input to management review
72. Changes affecting the QMS
73. Analysis of field failures

Review Output

74. Decisions and action arising from management review
RESOURCE MANAGEMENT REQUIREMENTS

Provision of Resources

75. Determination and provision of resources to implement the QMS
76. Determination and provision of resources to enhance customer satisfaction

Human Resources

General

77. Competence of personnel

Competence, Awareness and Training

78. Determination of competence
79. Provision of training
80. Evaluating the effectiveness of training
81. Awareness of impact on the achievement of quality objectives
82. Records of education, training, skills and experience

Training

83. Establishing procedures for identifying training needs
84. Qualification of personnel
85. Training in specific customer requirements

Infrastructure

86. Provision and maintenance of infrastructure

Work Environment

87. Determination and management of work environment

PRODUCT REALIZATION REQUIREMENTS

Planning of Product Realization

88. Planning product realization processes
89. Consistency of process planning
90. Determining product quality objectives and requirements
91. Establishing product specific processes
92. Providing product specific documents
93. Providing product specific resources
94. Determining product specific verification and validation activities and methods
95. Determining product specific acceptance criteria
96. Determining product specific records
97. Determining process specific records
98. Ensuring suitability of planning output
Customer-Related Processes

Determination of Requirements Related to the Product

99. Determining customer specified requirements
100. Determining requirements for intended use
101. Determining statutory and regulatory requirements
102. Determining organizational requirements

Review of Requirements Related to the Product

103. Reviewing product requirements
104. Timing of product requirements review
105. Ensuring product requirements are defined
106. Resolving differing requirements
107. Ensuring the organization has the ability to meet requirements
108. Maintaining records of the results of product reviews
109. Confirming undocumented requirements
110. Amending documents affected by changed product requirements
111. Informing personnel of changed requirements

Customer Communication

112. Arrangements for communicating product information to customers
113. Arrangements for dealing with customer enquiries
114. Arrangements for dealing with contracts and orders
115. Arrangements for dealing with amendments to contracts and orders
116. Arrangements for dealing with customer feedback

Design and Development

Design and Development Planning

117. Planning product design and development
118. Controlling product design and development
119. Determining design and development stages
120. Determining review, verification and validation for each stage
121. Determining design and development responsibilities and authority
122. Managing design and development interfaces
123. Updating design and development planning

Design and Development Inputs

124. Determining design and development inputs
125. Determining functional and performance requirements
126. Determining statutory and regulatory requirements
127. Determining information from previous design
128. Determining other design and development requirements
129. Reviewing design and development inputs
130. Quality of design and development inputs
**Product Design Input**

131. Identification of customer requirements
132. Product design information deployment process
133. Product quality targets

**Design and Development Outputs**

134. Provision of design and development outputs
135. Approval of design and development outputs
136. Ensuring design output meets requirements
137. Provision of purchasing, production and service information
138. Referencing product acceptance criteria
139. Specifying product operation and safety characteristics

**Design and Development Review**

140. Performing design reviews
141. Evaluation of design
142. Identifying problems and correcting errors
143. Participants at design reviews
144. Records of design reviews

**Design and Development Verification**

145. Conducting design and development verification
146. Records of design and development verification

**Design and Development Validation**

147. Conducting design and development validation
148. Completing validation prior to the delivery or implementation of product
149. Records of design and development validation

**Control of Design and Development Changes**

150. Identification of design and development changes
151. Recording of design and development changes
152. Review, verification and validation of design changes
153. Evaluating the effects of change
154. Recording the results of design change reviews

**Purchasing**

**Purchasing Process**

155. Ensuring purchased product conforms to requirements
156. Determining supplier controls
157. Supplier evaluation
158. Establishing selection and evaluation criteria
159. Results of supplier evaluations

**Purchasing Information**

160. Description of product
161. Product approval requirements
162. Qualification of personnel
163. Quality management system requirements
164. Adequacy of purchasing requirements

**Verification of Purchased Product**

165. Ensuring purchased product meets requirements
166. Verification at supplier’s premises

**Production and Service Provision**

**Control of Production and Service Provision**

167. Planning production and service provision
168. Controlling production and service provision
169. Ensuring the availability of information describing the product
170. Ensuring the availability of work instructions
171. Using suitable equipment
172. Availability and use of monitoring and measuring devices
173. Implementing monitoring and measurement activities
174. Implementing of release activities
175. Implementing of delivery activities
176. Implementing of post-delivery activities

**Validation of Processes for Production and Service Provision**

177. Validating special processes
178. Defining criteria for review and approval
179. Approving process equipment
180. Qualifying process personnel
181. Establishing process methods and procedures
182. Defining recording requirements
183. Defining revalidation requirements
184. Scope of process validation

**Identification and Traceability**

185. Identifying product
186. Identifying product status
187. Controlling unique identification of product
Customer Property

188. Exercising care of customer property
189. Identifying customer property
190. Verifying customer property
191. Protecting customer property
192. Reporting lost or damaged customer property

Preservation of Product

193. Preserving conformity of product
194. Identifying, handling, packing storage and protection of product
195. Scope of product preservation

Control of Monitoring and Measuring Equipment

196. Determining monitoring and measurements to be undertaken
197. Determining the monitoring and measurement equipment required
198. Establishing monitoring and measurement processes
199. Calibrating and verifying measuring equipment
200. Recording the basis for calibration and verification
201. Adjusting measuring equipment
202. Determining calibration status
203. Safeguarding adjustments
204. Protecting measuring equipment
205. Assessing nonconforming equipment
206. Action on equipment found out of calibration
207. Maintaining records of calibration and verification
208. Confirming integrity of computer software used for measurement

MEASUREMENT, ANALYSIS AND IMPROVEMENT REQUIREMENTS

General

209. Establishing processes necessary to demonstrate product conformity
210. Establishing processes necessary to ensure system conformity
211. Establishing processes necessary to improve system effectiveness
212. Determining monitoring, measurement and analysis methods

Monitoring and Measurement

Customer Satisfaction

213. Monitoring customer perceptions
214. Determining customer satisfaction monitoring methods

Internal Audit

215. Conducting internal audits for conformity with planned arrangements
216. Conducting internal audits for conformity with ISO 9001:2000
217. Conducting internal audits for conformity with the organization requirements
218. Determining effective implementation and maintenance of QMS
219. Planning the internal audit program
220. Defining audit criteria, scope, frequency and methods
221. Selecting auditors
222. Documenting audit procedures
223. Ensuring prompt action on audit findings
224. Following up audit actions

**Monitoring and Measurement of Processes**

225. Monitoring QMS processes
226. Demonstrating processes achieve planned results
227. Taking action on process measurements

**Monitoring and Measurement of Product**

228. Monitoring and measurement of product characteristics
229. Determination of product monitoring and measurement stages
230. Maintaining evidence of conformity
231. Indicating product release authority
232. Holding product release

**Control of Nonconforming Product**

233. Preventing unintended use of delivery of nonconforming product
234. Documenting nonconforming product controls
235. Maintaining records of the nature of nonconformities and actions taken
236. Re-verification of nonconforming product
237. Detecting product nonconformity subsequent to delivery

**Analysis of Data**

238. Collecting and analysing data on the effectiveness of the QMS
239. Collecting data to identify improvements in system effectiveness
240. Providing information on customer satisfaction
241. Providing information on product conformity
242. Providing information on trends and characteristics
243. Providing information on suppliers
244. Supporting decision making and long-term planning

**Improvement**

**Continual Improvement**

245. Improving the effectiveness of the QMS
Corrective Action

246. Taking action to eliminate the cause of nonconformity
247. Appropriateness of corrective actions
248. Documenting corrective action procedures
249. Reviewing nonconformities including customer complaints
250. Determining the causes of nonconformities
251. Evaluating the needs for action
252. Determining and implementing action needed
253. Recording the results of corrective actions
254. Reviewing corrective actions taken

Preventive Action

255. Determining action to eliminate potential nonconformities
256. Appropriateness of preventive actions
257. Documenting preventive action procedures
258. Determining the cause of potential nonconformities
259. Evaluating the needs for action
260. Determining and implementing action
261. Recording the results of preventive actions
262. Reviewing preventive actions taken