

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