### 4. QUALITY MANAGEMENT SYSTEM

### ISO 9001 mandatory procedures

* Document control procedure 4.2.3
* Control of Records procedure 4.2.4
* Internal audit procedure 8.2.2
* Control of non-conformance procedure 8.3
* Corrective action procedure 8.5.2
* Preventive action procedure 8.5.3

### ISO 9001 quality system documentation requirements

* Quality policy
* Quality objectives
* A quality manual
* Other documents required for effective planning, operation and control
* The records specified by ISO 9001

### How many procedures should I document?

It is common for larger organisations - particularly those in the Service and Manufacturing industries - to document more than the mandatory procedures required by ISO 9001. **If a process directly impacts product quality and/or customer satisfaction - you should strive to improve it.**

Other 'operational' procedures you might consider including in your ISO processes - to help you continually improve - include:

* 5.5.3 Internal Communication
* 5.6 Management Review
* 6.2.2 Training & Awareness
* 6.3 Facilities Management
* 7.1 Product Realisation & Planning
* 7.2.2 Contract Review
* 7.3 Design & Development Control
* 7.4 Purchasing
* 7.5.1 Control of Production and Service Provision
* 7.5.2 Validation of processes
* 7.5.3 Identification & Traceability
* 7.5.4 Control of Customer Property
* 7.5.5 Preservation of product
* 7.6 Control of Monitoring & Measuring Equipment
* 8.2.1 Customer Satisfaction
* 8.2.4 Monitoring and measurement of product
* 8.4 Analysis of Data
* 8.5.1 Continual Improvement

|  **WHAT IS REQUIRED** |   |
| --- | --- |
|   | 'No procedures' | 'Mandatory' | 'Service' | 'Manufacturing' |   |
| Quality Manual Template  | green-tick | green-tick | green-tick | green-tick |   |
| Quality Policy | green-tick | green-tick | green-tick | green-tick |   |
| Quality Objectives | green-tick | green-tick | green-tick | green-tick |   |
| **Mandatory Procedures** | 'No procedures' | 'Mandatory' | 'Service' | 'Manufacturing' |   |
| 4.2.3 Document Control  |   | green-tick | green-tick | green-tick |   |
| 4.2.4 Control of Records |   | green-tick | green-tick | green-tick |   |
| 8.2.2 Internal Audit  |   | green-tick | green-tick | green-tick |   |
| 8.3 Control of Non-conformance |   | green-tick | green-tick | green-tick |   |
| 8.5.2 Corrective Action |   | green-tick | green-tick | green-tick |   |
| 8.5.3 Preventive Action |   | green-tick | green-tick | green-tick |   |
| **Operating Procedures** | 'No procedures' | 'Mandatory' | 'Service' | 'Manufacturing' |   |
| 5.5.3 Internal Communication |   |   | green-tick | green-tick |   |
| 5.6 Management Review |   |   | green-tick | green-tick |   |
| 6.2.2 Training & Awareness  |   |   | green-tick | green-tick |   |
| 6.3 Facilities Management |   |   | green-tick | green-tick |   |
| 7.1 Product Realization & Planning |   |   | green-tick | green-tick |   |
| 7.2.2 Contract Review |   |   | green-tick | green-tick |   |
| 7.3 Design & Development Control |   |   |   | green-tick |   |
| 7.4 Purchasing |   |   | green-tick | green-tick |   |
| 7.5.1 Process Control |   |   | green-tick | green-tick |   |
| 7.5.2 Process Validation |   |   |   | green-tick |   |
| 7.5.3 Identification & Traceability |   |   |   | green-tick |   |
| 7.5.4 Control of Customer Property |   |   | green-tick | green-tick |   |
| 7.5.5 Preservation of Product |   |   | green-tick | green-tick |   |
| 7.6 Control of Monitoring & Measuring Equipment |   |   | green-tick | green-tick |   |
| 8.2.1 Customer Satisfaction  |   |   | green-tick | green-tick |   |
| 8.2.4 Inspection & Testing |   |   |   | green-tick |   |
| 8.4 Analysis of Data |   |   | green-tick | green-tick |   |
| 8.5.1 Continual Improvement  |   |   |   | green-tick |   |
| **Forms** | 'No procedures' | 'Mandatory' | 'Service' | 'Manufacturing' |   |
| 4.2.3 Master Document Index |   | green-tick | green-tick | green-tick |   |
| 4.2.3 Document Issue Sheet  |   | green-tick | green-tick | green-tick |   |
| 4.2.3 Document Change Request |   | green-tick | green-tick | green-tick |   |
| 4.2.4 Master Quality Record Index |   | green-tick | green-tick | green-tick |   |
| 5.6 Management Review Agenda & Minutes |   |   | green-tick | green-tick |   |
| 6.2.2 Competency Review Form  |   |   | green-tick | green-tick |   |
| 6.2.2 Training Attendance Form |   |   | green-tick | green-tick |   |
| 6.2.2 Training Evaluation Form |   |   | green-tick | green-tick |   |
| 6.3 Equipment Maintenance & Service Log |   |   | green-tick | green-tick |   |
| 7.2.2 Contract Review Checklist |   |   | green-tick | green-tick |   |
| 7.3 Design Change Request |   |   |   | green-tick |   |
| 7.3 Design Change Request Log |   |   |   | green-tick |   |
| 7.4 Supplier Evaluation |   |   | green-tick | green-tick |   |
| 7.4 Approved Supplier Index |   |   | green-tick | green-tick |   |
| 7.5.2 Production Control Plan |   |   | green-tick | green-tick |   |
| 7.5.4 Customer Property Log |   |   | green-tick | green-tick |   |
| 7.6 Controlled Equipment Log |   |   |   | green-tick |   |
| 7.6 Calibration Log |   |   |   | green-tick |   |
| 8.2.1 Customer Satisfaction Survey |   |   | green-tick | green-tick |   |
| 8.2.1 Customer Complaint & Feedback Log |   |   | green-tick | green-tick |   |
| 8.2.2 Internal Audit Schedule |   | green-tick | green-tick | green-tick |   |
| 8.2.2 Internal Audit Plan |   | green-tick | green-tick | green-tick |   |
| 8.2.2 Internal Audit Assignment |   | green-tick | green-tick | green-tick |   |
| 8.2.2 Internal Audit & Gap Analysis Checklist |   | green-tick | green-tick | green-tick |   |
| 8.2.2 Internal Audit Report |   | green-tick | green-tick | green-tick |   |
| 8.2.2 Internal Audit Feedback |   | green-tick | green-tick | green-tick |   |
| 8.2.4 Receiving Inspection Log |   |   |   | green-tick |   |
| 8.2.4 Final Inspection Log |   |   |   | green-tick |   |
| 8.2.4 Inspection & Test Report |   |   |   | green-tick |   |
| 8.3 Non-conformance Report |   | green-tick | green-tick | green-tick |   |
| 8.3 Non-conformance Report Log |   | green-tick | green-tick | green-tick |   |
| 8.5.2 Corrective Action Request |   | green-tick | green-tick | green-tick |   |
| 8.5.2 Corrective Action Request Log |   | green-tick | green-tick | green-tick |   |
| 8.5.3 Preventive Action Request |   | green-tick | green-tick | green-tick |   |
| 8.5.3 Preventive Action Request Log |   | green-tick | green-tick | green-tick |   |
| **Process Maps** | 'No procedures' | 'Mandatory' | 'Service' | 'Manufacturing' |   |
| Quality Planning | green-tick | green-tick | green-tick | green-tick |   |
| Resource Management Process Interaction | green-tick | green-tick | green-tick | green-tick |   |
| Product Realisation Process Interaction | green-tick | green-tick | green-tick | green-tick |   |
| Measurement, Analysis & Improvement Process Interaction | green-tick | green-tick | green-tick | green-tick |   |
| Sequence and Interaction of Quality Management System Processes | green-tick | green-tick | green-tick | green-tick |   |
| 5.6 Management Review |   |   | green-tick | green-tick |   |
| 6.2.2 Training  |   |   | green-tick | green-tick |   |
| 7.1 Product Realization & Planning |   |   | green-tick | green-tick |   |
| 7.6 Calibration |   |   |   | green-tick |   |
| 8.2.1 Customer Satisfaction Survey |   |   | green-tick | green-tick |   |
| 8.2.1 Customer Complaints & Feedback |   |   | green-tick | green-tick |   |
| 8.2.2 Internal Audit - |   | green-tick | green-tick | green-tick |   |
| 8.3 Control of Non-conformances |   | green-tick | green-tick | green-tick |   |
| 8.5.2 Corrective Action |   | green-tick | green-tick | green-tick |   |
| 8.5.3 Preventive Action |   | green-tick | green-tick | green-tick |   |