

ISO 9001:2015 Required Documents Matrix

**REQUIRED RECORDS - "Documented information needed to be retained... providing evidence.**

#	Clause	Shortcut	Requirement	Title	Doc #	Rev.	Date	Distribution Location(s)
1	4.4	CONFIDENCE (AS NEEDED)	Documented information to the extent necessary to have confidence that the processes are being carried out as planned.					
2	7.1.5.1	ACCURATE MEASUREMENT RESOURCES	Evidence of fitness for purpose of monitoring and measuring resources.					
3	7.1.5.2	BASIS USED FOR CALIBRATION	Evidence of the basis used for calibration of the monitoring and measurement resources (when no international or national standards exist).					
4	7.2	COMPETENCE OF PEOPLE	Evidence of competence of person(s) doing work under the control of the organization that affects the performance and effectiveness of the QMS.					
5	8.2.3	REQUIREMENTS REVIEW	Results of the review and any new requirements for the products and services.					
6	8.3.2	D&D REQUIREMENTS MET	Records needed to demonstrate that design and development requirements have been met.					
7	8.3.3	D&D INPUTS	Records on design and development inputs.					
8	8.3.4	D&D CONTROLS	Records of the activities of design and development controls.					
9	8.3.5	D&D OUTPUTS	Records of design and development outputs.					
10	8.3.6	D&D CHANGES	Design and development changes, including the results of the review and the authorization of the changes and necessary actions.					
11	8.4.1	EXTERNAL PROVIDER (SUPPLIER) MONITORING	Records of the evaluation, selection, monitoring of performance and re-evaluation of external providers and any and actions arising from these activities.					
12	8.5.2	UNIQUE ID	Evidence of the unique identification of the outputs when traceability is a requirement.					
13	8.5.3	UNSUITABLE CUSTOMER PROPERTY	Records of property of the customer or external provider that is lost, damaged or otherwise found to be unsuitable for use and of its communication to the owner.					
14	8.5.6	CHANGES TO PRODUCT OR SERVICE	Results of the review of changes for production or service provision, the persons authorizing the change, and necessary actions taken.					
15	8.6	AUTHORIZED RELEASE	Records of the authorized release of products and services for delivery to the customer including acceptance criteria and traceability to the authorizing person(s).					
16	8.7	N/C & ACTION AUTHORITY	Records of nonconformities, the actions taken, concessions obtained and the identification of the authority deciding the action in respect of the nonconformity.					
17	9.1.1	QMS PERFORMANCE EVALUATION	Results of the evaluation of the performance and the effectiveness of the QMS.					
18	9.2.2	AUDIT PROGRAM RESULTS	Evidence of the implementation of the audit programme and the audit results.					
19	9.3.3	MANAGEMENT REVIEW	Evidence of the results of management reviews.					
20	10.2.2	NATURE & ACTION OF N/Cs	Evidence of the nature of the nonconformities and any subsequent actions taken.					
21	10.2.2	CORRECTIVE ACTION RESULTS	Results of any corrective action.					

**Key:** D&D = Design & Development | ID = Identification | N/C = Nonconformance