

ISO 9001:2026-09 (E)

Quality management systems - Requirements

Contents

Page

Foreword	v
Introduction	vi
0.1 General	vi
0.2 Quality management principles	vi
0.3 Process approach	vii
0.3.1 General	vii
0.3.2 Plan-Do-Check-Act cycle	viii
0.4 Relationship with other management system standards	viii
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Context of the organization	5
4.1 Understanding the organization and its context	5
4.2 Understanding the needs and expectations of interested parties	5
4.3 Determining the scope of the quality management system	6
4.4 Quality management system	6
5 Leadership	7
5.1 Leadership and commitment	7
5.1.1 General	7
5.1.2 Customer focus	7
5.2 Quality policy	8
5.3 Roles, responsibilities and authorities	8
6 Planning	8
6.1 Actions to address risks and opportunities	8
6.1.1 Determining risks and opportunities	8
6.1.2 Actions to address risks	9
6.1.3 Actions to address opportunities	9
6.2 Quality objectives and planning to achieve them	9
6.3 Planning of changes	10
7 Support	10
7.1 Resources	10
7.1.1 General	10
7.1.2 People	10
7.1.3 Infrastructure	11
7.1.4 Environment for the operation of processes	11
7.1.5 Monitoring and measuring resources	11
7.1.6 Organizational knowledge	12
7.2 Competence	12
7.3 Awareness	12
7.4 Communication	12
7.5 Documented information	13
7.5.1 General	13
7.5.2 Creating and updating documented information	13

7.5.3	Control of documented information	13
8	Operation	14
8.1	Operational planning and control	14
8.2	Requirements for products and services	14
8.2.1	Customer communication	14
8.2.2	Determining requirements for products and services	14
8.2.3	Review of requirements for products and services	15
8.2.4	Changes to requirements for products and services	15
8.3	Design and development of products and services	15
ISO 9001:2026(en) 8.3.1	General	15
8.3.2	Design and development planning	15
8.3.3	Design and development inputs	16
8.3.4	Design and development controls	16
8.3.5	Design and development outputs	16
8.3.6	Design and development changes	17
8.4	Control of externally provided processes, products and services	17
8.4.1	General	17
8.4.2	Type and extent of control	17
8.4.3	Information for external providers	18
8.5	Production and service provision	18
8.5.1	Control of production and service provision	18
8.5.2	Identification and traceability	19
8.5.3	Property belonging to customers or external providers	19
8.5.4	Preservation	19
8.5.5	Post-delivery activities	19
8.5.6	Control of changes	20
8.6	Release of products and services	20
8.7	Control of nonconforming outputs	20
9	Performance evaluation	21
9.1	Monitoring, measurement, analysis and evaluation	21
9.1.1	General	21
9.1.2	Customer satisfaction	21
9.1.3	Analysis and evaluation	21
9.2	Internal audit	22
9.2.1	General	22
9.2.2	Internal audit programme	22
9.3	Management review	22
9.3.1	General	22
9.3.2	Management review inputs	22
9.3.3	Management review results	23
10	Improvement	23
10.1	Continual improvement	23
10.2	Nonconformity and corrective action	23
Annex A (informative)	Clarification of structure, terminology and clauses	25
Bibliography		36