

DIN EN ISO 22163:2024-07 (E)

Railway applications - Railway quality management system - ISO 9001:2015 and specific requirements for application in the railway sector (ISO 22163:2023)

Contents		Page
European foreword		5
Foreword		6
Introduction		8
1	Scope	13
1.1	Scope — Supplemental	13
2	Normative references	13
3	Terms, definitions and abbreviated terms	13
3.1	Terms and definitions	14
3.1.1	System	14
3.1.2	Process	15
3.1.3	Requirement	19
3.1.4	Product and tools	21
3.2	Abbreviated terms	23
4	Context of the organization	24
4.1	Understanding the organization and its context	24
4.1.1	Understanding the organization and its context — Supplemental	24
4.1.2	Social responsibility	25
4.2	Understanding the needs and expectations of interested parties	25
4.3	Determining the scope of the quality management system	25
4.3.1	Determining the scope of the quality management system — Supplemental	26
4.4	Quality management system and its processes	26
4.4.3	Quality management system and its processes — Supplemental	26
5	Leadership	27
5.1	Leadership and commitment	27
5.1.1	General	27
5.1.2	Customer focus	28
5.2	Policy	28
5.2.1	Establishing the quality policy	28
5.2.2	Communicating the quality policy	28
5.2.3	Quality policy — Supplemental	28
5.3	Organizational roles, responsibilities and authorities	29
5.3.1	Organizational roles, responsibilities and authorities — Supplemental	29
5.3.2	Responsibilities and authorities of process owners	29
6	Planning	29
6.1	Actions to address risks and opportunities	29
6.1.3	Actions to address risks and opportunities — Supplemental	30
6.1.4	Business continuity	30
6.2	Quality objectives and planning to achieve them	31
6.3	Planning of changes	32
7	Support	32
7.1	Resources	32
7.1.1	General	32
7.1.2	People	32
7.1.3	Infrastructure	33
7.1.4	Environment for the operation of processes	33
7.1.5	Monitoring and measuring resources	33

	7.1.6	Organizational knowledge	34
7.2		Competence	35
	7.2.1	Competence — Supplemental	36
7.3		Awareness	36
7.4		Communication	37
	7.4.1	Communication — Supplemental	37
7.5		Documented information	37
	7.5.1	General	37
	7.5.2	Creating and updating	37
	7.5.3	Control of documented information	38
8		Operation	39
8.1		Operational planning and control	39
	8.1.1	Operational planning and control — Supplemental	39
	8.1.2	Tender management	40
	8.1.3	Project management	40
	8.1.4	Configuration management and change control	45
8.2		Requirements for products and services	47
	8.2.1	Customer communication	47
	8.2.2	Determining the requirements related to products and services	48
	8.2.3	Review of requirements related to products and services	48
	8.2.4	Changes to requirements for products and services	49
	8.2.5	Requirements for products and services — Supplemental	49
8.3		Design and development of products and services	50
	8.3.1	General	50
	8.3.2	Design and development planning	50
	8.3.3	Design and development inputs	51
	8.3.4	Design and development controls	52
	8.3.5	Design and development outputs	54
	8.3.6	Design and development changes	54
8.4		Control of externally provided processes, products and services	55
	8.4.1	General	55
	8.4.2	Type and extent of control	57
	8.4.3	Information for external providers	59
	8.4.4	Supply chain management	60
8.5		Production and service provision	61
	8.5.1	Control of production and service provision	61
	8.5.2	Identification and traceability	65
	8.5.3	Property belonging to customers or external providers	65
	8.5.4	Preservation	66
	8.5.5	Post-delivery activities	66
	8.5.6	Control of changes	67
8.6		Release of products and services	67
	8.6.1	Release of products and services — Supplemental	68
8.7		Control of nonconforming outputs	68
	8.7.3	Control of nonconforming outputs — Supplemental	69
8.8		Reliability, availability, maintainability, safety and life cycle costing	69
	8.8.1	General	69
	8.8.2	Reliability, availability and maintainability	70
	8.8.3	Safety	70
	8.8.4	Life cycle costing	70
8.9		First article inspection	71
8.10		Obsolescence management	71
9		Performance evaluation	72
9.1		Monitoring, measurement, analysis and evaluation	72
	9.1.1	General	72
	9.1.2	Customer satisfaction	73
	9.1.3	Analysis and evaluation	74
9.2		Internal audit	75
	9.2.3	Internal audit — Supplemental	75

9.3	Management review	76
9.3.1	General	76
9.3.2	Management review inputs	77
9.3.3	Management review outputs	78
9.4	Process reviews	78
10	Improvement	79
10.1	General	79
10.2	Nonconformity and corrective action	79
10.2.3	Nonconformity and corrective action — Supplemental	80
10.3	Continual improvement	80
Annex A (informative) List of processes		81
Annex B (informative) Subordinate concept of requirements for products and services		83
Annex C (informative) Performance indicators		84
Bibliography		87