ISO 22163:2023-07 (E)

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

Contents

Page

Foreword vi

Introduction viii

1 Scope 1
1.1 Scope -- Supplemental 1

2 Normative references 1

3 Terms, definitions and abbreviated terms 1
3.1 Terms and definitions 2
3.1.1 System 2
3.1.2 Process 3
3.1.3 Requirement 7
3.1.4 Product and tools 9
3.2 Abbreviated terms 11

4 Context of the organization 12
4.1 Understanding the organization and its context 12
4.1.1 Understanding the organization and its context -- Supplemental 12
4.1.2 Social responsibility 13
4.2 Understanding the needs and expectations of interested parties 13
4.3 Determining the scope of the quality management system 13
4.3.1 Determining the scope of the quality management system -- Supplemental 14
4.4 Quality management system and its processes 14
4.4.3 Quality management system and its processes -- Supplemental 14

5 Leadership 15
5.1 Leadership and commitment 15
5.1.1 General 15
5.1.2 Customer focus 16
5.2 Policy 16
5.2.1 Establishing the quality policy 16
5.2.2 Communicating the quality policy 16
5.2.3 Quality policy -- Supplemental 16
5.3 Organizational roles, responsibilities and authorities 17
5.3.1 Organizational roles, responsibilities and authorities -- Supplemental 17
5.3.2 Responsibilities and authorities of process owners 17

6 Planning 17
6.1 Actions to address risks and opportunities 17
6.1.3 Actions to address risks and opportunities -- Supplemental 18
6.1.4 Business continuity 18
6.2 Quality objectives and planning to achieve them 19
6.3 Planning of changes 20

7 Support 20
7.1 Resources 20
7.1.1 General 20
7.1.2 People 20
7.1.3 Infrastructure 21

7.1.4 Environment for the operation of processes 21
7.1.5 Monitoring and measuring resources 21
7.1.6 Organizational knowledge 22
7.2 Competence 23
7.2.1 Competence -- Supplemental 24
7.3 Awareness 24
7.4 Communication 25
7.4.1 Communication -- Supplemental 25
7.5 Documented information 25

7.5.1 General 25
7.5.2 Creating and updating 25
7.5.3 Control of documented information 26

8 Operation 27
8.1 Operational planning and control 27
8.1.1 Operational planning and control -- Supplemental 27
8.1.2 Tender management 28
8.1.3 Project management 28
8.1.4 Configuration management and change control 33
8.2 Requirements for products and services 35
8.2.1 Customer communication 35
8.2.2 Determining the requirements related to products and services 36
8.2.3 Review of requirements related to products and services 36
8.2.4 Changes to requirements for products and services 37
8.2.5 Requirements for products and services -- Supplemental 37
8.3 Design and development of products and services 38
8.3.1 General 38
8.3.2 Design and development planning 38
8.3.3 Design and development inputs 39
8.3.4 Design and development controls 40
8.3.5 Design and development outputs 42
8.3.6 Design and development changes 42
8.4 Control of externally provided processes, products and services 43
8.4.1 General 43
8.4.2 Type and extent of control 45
8.4.3 Information for external providers 47
8.4.4 Supply chain management 48
8.5 Production and service provision 49
8.5.1 Control of production and service provision 49
8.5.2 Identification and traceability 53
8.5.3 Property belonging to customers or external providers 53
8.5.4 Preservation 54
8.5.5 Post-delivery activities 54
8.5.6 Control of changes 55
8.6 Release of products and services 55
8.6.1 Release of products and services -- Supplemental 56
8.7 Control of nonconforming outputs 56
8.7.3 Control of nonconforming outputs -- Supplemental 57
8.8 Reliability, availability, maintainability, safety and life cycle costing 57
8.8.1 General 57
8.8.2 Reliability, availability and maintainability 58
8.8.3 Safety 58
8.8.4 Life cycle costing 58
8.9 First article inspection 59
8.10 Obsolescence management 59

9 Performance evaluation 60
9.1 Monitoring, measurement, analysis and evaluation 60
9.1.1 General 60
9.1.2 Customer satisfaction 61
9.1.3 Analysis and evaluation 62

9.2 Internal audit 63
9.2.3 Internal audit -- Supplemental 63
9.3 Management review 64
9.3.1 General 64
9.3.2 Management review inputs 65
9.3.3 Management review outputs 66
9.4 Process reviews 66

10 Improvement 67

10.1 General 67
10.2 Nonconformity and corrective action 67
10.2.3 Nonconformity and corrective action -- Supplemental 68
10.3 Continual improvement 68

Annex A (informative) List of processes 69

Annex B (informative) Subordinate concept of requirements for products and services 71

Annex C (informative) Performance indicators 72

Bibliography 75