ISO/TS 22163:2017-05 (E)

Railway applications - Quality management system - Business management system requirements for rail organizations: ISO 9001:2015 and particular requirements for application in the rail sector

Contents

Page

Foreword vi

0 Introduction vii

1 Scope 1
1.1 Scope -- Supplemental 1

2 Normative references 2

3 Termsanddefinitions 2
3.1 Terms and definitions for the rail sector 2
3.2 Abbreviations 7

4 Context of the organization 8
4.1 Understanding the organization and its context 8
4.2 Understanding the needs and expectations of interested parties 8
4.3 Determining the scope of the quality management system 9
4.4 Quality management system and its processes 10
4.4.3 Quality management system and its processes -- Supplemental 10

5 Leadership 11
5.1 Leadership and commitment 11
5.1.1 General 11
5.1.2 Customer focus 11
5.2 Policy 12
5.2.1 Establishing the quality policy 12
5.2.2 Communicating the quality policy 12
5.2.3 Quality policy -- Supplemental 12
5.2.4 Safety policy 12
5.3 Organizational roles, responsibilities and authorities 13
5.3.1 Organizational roles, responsibilities and authorities -- Supplemental 13
5.3.2 Responsibilities and authorities of process owners 13

6 Planning 14
6.1 Actions to address risks and opportunities 14
6.1.3 Actions to address risks and opportunities -- Supplemental 14
6.1.4 Contingency planning 15
6.2 Quality objectives and planning to achieve them 15
6.3 Planning of changes 16
6.4 Business planning 16

7 Support 17
7.1 Resources 17
7.1.1 General 17
7.1.2 People 17
7.1.3 Infrastructure 18
7.1.4 Environment for the operation of processes 18
7.1.5 Monitoring and measuring resources 18
7.1.6 Organizational knowledge 20

7.2 Competence ... 21
7.2.1 Competence -- Supplemental ... 21
7.3 Awareness ... 22
7.3.1 Awareness -- Supplemental ... 22
7.4 Communication ... 22
7.5 Documented information ... 23
7.5.1 General ... 23
7.5.2 Creating and updating ... 23
7.5.3 Control of documented information ... 24

8 Operation ... 25

8.1 Operational planning and control ... 25
8.1.1 Planning for the outsourcing or transfer of processes ... 25
8.1.2 Tender management ... 26
8.1.3 Project management ... 26
8.1.4 Configuration management ... 30
8.1.5 Change management ... 31
8.2 Requirements for products and services ... 33
8.2.1 Customer communication ... 33
8.2.2 Determining the requirements related to products and services ... 33
8.2.3 Review of requirements related to products and services ... 34
8.2.4 Changes to requirements for products and services ... 34
8.2.5 Requirements for products and services -- Supplemental ... 34
8.3 Design and development of products and services ... 35
8.3.1 General ... 35
8.3.2 Design and development planning ... 36
8.3.3 Design and development inputs ... 37
8.3.4 Design and development controls ... 38
8.3.5 Design and development outputs ... 40
8.3.6 Design and development changes ... 41
8.4 Control of externally provided processes, products and services ... 41
8.4.1 General ... 41
8.4.2 Type and extent of control ... 44
8.4.3 Information for external providers ... 46
8.4.4 Supply chain management ... 47
8.5 Production and service provision ... 48
8.5.1 Control of production and service provision ... 48
8.5.2 Identification and traceability ... 51
8.5.3 Property belonging to customers or external providers ... 52
8.5.4 Preservation ... 52
8.5.5 Post-delivery activities ... 53
8.5.6 Control of changes ... 54
8.5.7 Production scheduling ... 54
8.6 Release of products and services ... 55
8.6.1 Release of products and services -- Supplemental ... 55
8.7 Control of nonconforming outputs ... 56
8.7.3 Control of nonconforming outputs -- Supplemental ... 56
8.8 RAMS / LCC ... 57
8.9 First article inspection ... 58
8.10 Obsolescence management ... 58
8.11 Innovation management ... 59

9 Performance evaluation ... 59
9.1 Monitoring, measurement, analysis and evaluation ... 59
9.1.1 General ... 59
9.1.2 Customer satisfaction ... 61
9.1.3 Analysis and evaluation ... 61
9.2 Internal audit ... 62
9.2.3 Internal audit -- Supplemental ... 62
9.3 Management review ... 63
9.3.1 General ... 63

9.3.2 Management review inputs 64
9.3.3 Management review outputs 65
9.4 Process reviews 65

10 Improvement 66
10.1 General 66
10.2 Nonconformity and corrective action 67
10.2.3 Nonconformity and corrective action -- Supplemental 67
10.3 Continual improvement 68

Bibliography 69