

# 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

---

<b>Contents</b>		<b>Page</b>
Foreword .....		vi
<b>0</b>	<b>Introduction .....</b>	<b>vii</b>
<b>1</b>	<b>Scope .....</b>	<b>1</b>
1.1	Scope -- Supplemental .....	1
<b>2</b>	<b>Normative references .....</b>	<b>2</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>2</b>
3.1	Terms and definitions for the rail sector .....	2
3.2	Abbreviations .....	7
<b>4</b>	<b>Context of the organization .....</b>	<b>8</b>
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
<b>5</b>	<b>Leadership .....</b>	<b>11</b>
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
<b>6</b>	<b>Planning .....</b>	<b>14</b>
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
<b>7</b>	<b>Support .....</b>	<b>17</b>
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