

DIN EN ISO 16106:2020-06 (E)

Transport packages for dangerous goods - Dangerous goods packagings, intermediate bulk containers (IBCs) and large packagings - Guidelines for the application of ISO 9001 (ISO 16106:2020)

Contents		Page
European foreword		4
Foreword		5
Introduction		6
1	Scope	11
2	Normative references	11
3	Terms and definitions	11
4	Context of the organization	15
4.1	Understanding the organization and its context	15
4.2	Understanding the needs and expectations of interested parties	15
4.3	Determining the scope of the quality management system	15
4.4	Quality management system and its processes	16
5	Leadership	16
5.1	Leadership and commitment	16
5.1.1	General	16
5.1.2	Customer focus	17
5.2	Policy	17
5.2.1	Establishing the quality policy	17
5.2.2	Communicating the quality policy	17
5.3	Organizational roles, responsibilities and authorities	17
6	Planning	18
6.1	Actions to address risks and opportunities	18
6.2	Quality objectives and planning to achieve them	18
6.3	Planning of changes	19
7	Support	19
7.1	Resources	19
7.1.1	General	19
7.1.2	People	19
7.1.3	Infrastructure	19
7.1.4	Environment for the operation of processes	20
7.1.5	Monitoring and measuring resources	20
7.1.6	Organizational knowledge	20
7.2	Competence	21
7.3	Awareness	21
7.4	Communication	21
7.5	Documented information	22
7.5.1	General	22
7.5.2	Creating and updating	22
7.5.3	Control of documented information	22
8	Operation	23
8.1	Operational planning and control	23
8.2	Requirements for products and services	23
8.2.1	Customer communication	23
8.2.2	Determining the requirements for products and services	23
8.2.3	Review of the requirements for products and services	24
8.2.4	Changes to requirements for products and services	24
8.3	Design and development of products and services	24
8.3.1	General	24
8.3.2	Design and development planning	24
8.3.3	Design and development inputs	25

8.3.4	Design and development controls	25
8.3.5	Design and development outputs	26
8.3.6	Design and development changes	26
8.4	Control of externally provided processes, products and services	26
8.4.1	General	26
8.4.2	Type and extent of control	27
8.4.3	Information for external providers	27
8.5	Production and service provision	28
8.5.1	Control of production and service provision	28
8.5.2	Identification and traceability	28
8.5.3	Property belonging to customers or external providers	28
8.5.4	Preservation	29
8.5.5	Post-delivery activities	29
8.5.6	Control of changes	29
8.6	Release of products and services	29
8.7	Control of nonconforming outputs	30
9	Performance evaluation	30
9.1	Monitoring, measurement, analysis and evaluation	30
9.1.1	General	30
9.1.2	Customer satisfaction	31
9.1.3	Analysis and evaluation	31
9.2	Internal audit	32
9.3	Management review	32
9.3.1	General	32
9.3.2	Management review inputs	32
9.3.3	Management review outputs	33
10	Improvement	33
10.1	General	33
10.2	Nonconformity and corrective action	33
10.3	Continual improvement	34
	Annex A (informative) Clarification of new structure, terminology and concepts	35
	Annex B (informative) Other International Standards on quality management and quality management systems developed by ISO/TC 176	39
	Annex C (informative) Packaging specification data	42
	Annex D (informative) IBC specification data	48
	Annex E (informative) Large packaging (LP) specification data	52
	Annex F (informative) Notes to the packaging specifications of Annexes C, D and E	54
	Annex G (informative) Items and elements of verification, controls, monitoring and validation	55
	Annex H (informative) Examples of typical frequencies for the verification of conformity with design and performance requirements	60
	Bibliography	63