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