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Packaging — Transport packages for dangerous goods — Dangerous goods packagings, intermediate bulk containers (IBCs) and large packagings — Guidelines for the application of ISO 9001

Emballage — Emballage de transport pour marchandises dangereuses — Emballage pour marchandises dangereuses, grands récipients vrac (GRV) et grands emballages — Directives pour l'application de l'ISO 9001

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 16106 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 261, *Packaging*, in collaboration with Technical Committee ISO/TC 122, *Packaging*, Subcommittee SC 3, *Performance requirements and tests for means of packaging, packages and unit loads (as required by ISO/TC 122)*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Introduction

This International Standard gives guidance for the application of the ISO 9000 quality management system to the manufacture, measuring and monitoring of design type approved dangerous goods packagings, Intermediate Bulk Containers (IBCs) and large packagings.

The United Nations Recommendations on the Transport of Dangerous Goods [1] (referred to in this International Standard as the UN Model Regulations) require the application of a quality assurance programme for the manufacture and testing of packagings, IBCs and large packagings that satisfies the competent authority in order to ensure that each manufactured packaging, IBC and large packaging meets the requirements.

The UN Model Regulations are given legal entity by the provision of a series of international modal agreements and national legislation for the transport of dangerous goods. These international agreements include

— the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) [2];

— the Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID) [3];

— the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air [4];

— the International Maritime Dangerous Goods Code (IMDG) [5].

The application of this International Standard will need to take into account the requirements of these international agreements and the national legislation for the transport of dangerous goods.

Compliance with this International Standard does not replace the agreement of competent authorities with quality assurance programmes. In conjunction with ISO 9001, this International Standard specifies a system for applying quality processes and assurance to the production of dangerous goods packagings, IBCs and large packagings.

The change in terminology in the ISO 9000 series from "quality assurance programmes" (1987 edition), over "quality systems" (1994 edition) to "quality management systems" (2000 edition), is not reflected in the UN Model Regulations and the international agreements referred to in the bibliography of this International Standard. The former term "quality assurance programme" is still used there. Furthermore, the term "testing", which was used in the 1994 edition of the ISO 9000 series in the context of product inspection and testing has now been replaced by "measurement and monitoring" in the 2000 edition. For the purposes of this International Standard, the latest terminology is used in accordance with ISO 9000. This difference in terminology should not deter users from using this International Standard.

The reasons for establishing this International Standard in addition to the ISO 9000 series are as follows.

a) The wording of the requirements in 6.1.1.4, 6.5.1.6.1 and 6.6.1.2 of the UN Model Regulations is restricted to the bare need that a quality assurance programme be applied that satisfies the competent authority. This allows different interpretations.

b) Dangerous goods packagings, IBCs and large packagings are subject to legal requirements. The conformity of any manufactured item with the relevant legal provisions is based on the principle of official design type testing and approval, which requires that specific measures be applied in order to secure the conformity of any of the unlimited number of items with the requirements of an approved design. Quality assurance can help standardize these specific measures.

c) In view of the cost implications of quality assurance/quality management measures, complete freedom of interpretation could have an avoidable negative impact on competition.

d) The establishment of quality assurance/quality management measures is, particularly for smaller companies, a large undertaking and calls for further guidance.

e) Interactions between companies and competent authorities on the adequacy of quality assurance/quality management programmes need to be rationalized to minimize unnecessary effort.

This International Standard is based on Revision 14 of the UN Model Regulations.

Clause referencing in this International Standard corresponds to ISO 9001:2000, with the exception of the annexes.

Packaging — Transport packages for dangerous goods — Dangerous goods packagings, intermediate bulk containers (IBCs) and large packagings — Guidelines for the application of ISO 9001

1 Scope

This International Standard gives guidance on quality management provisions applicable to the manufacture, measuring and monitoring of design type approved dangerous goods packagings, intermediate bulk containers (IBCs) and large packagings.

This International Standard can only be used in combination with ISO 9001:2000 and is not a stand-alone document.

It does not apply to design type testing, for which reference is made to 6.1.5, 6.5.4 and 6.6.5 of the UN Model Regulations [1].

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 9001:2000, *Quality management systems — Requirements*

ISO/IEC 17050-2, *Conformity assessment — Supplier's declaration of conformity — Part 2: Supporting documentation*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and the following apply.

3.1
competent authority
any national regulatory body or authority designated, or otherwise recognized as such, for any purpose in connection with the international agreements referred to in the bibliography of ISO 16106:2006

3.2
design type approved packaging, IBC or large packaging
dangerous goods packaging that has been tested and approved in accordance with chapters 6.1.5, 6.5.4 and 6.6.5 of the UN Model Regulations, the modal agreements listed in the bibliography of ISO 16106:2006 or with national regulations

4 Quality management system

The management system requirements of ISO 9001:2000, Clause 4 apply.

Documentation specified in ISO 9001:2000, 4.2.4 should be kept during the assumed lifetime of packagings, IBCs and large packagings or for five years, whichever is longer.

5 Management responsibility

The management system requirements of ISO 9001:2000, Clause 5 apply.

NOTE Documentation can be subject to audit by the competent authority.

6 Resource management

The management system requirements of ISO 9001:2000, Clause 6 apply.

7 Product realization

7.1 Planning of product realization

The management system requirements of ISO 9001:2000, 7.1 apply.

The product specifications for packaging and IBCs should conform to Annex A and Annex B.

NOTE Annex A and Annex B are extracted from ISO 16104:2003, Annex G and ISO 16467:2003, Annex C, respectively.

7.2 Customer-related processes

The management system requirements of ISO 9001:2000, 7.2 apply.

7.3 Design and development

The management system requirements of ISO 9001:2000, 7.3 apply.

For the design validation process, specified in ISO 9001:2000, 7.3.6, reference should be made to the official design validation process (design type testing and approval procedure) which is completed by the allocation of the UN marking, as required in 6.1.3, 6.5.2 and 6.6.3 of the UN Model Regulations.

7.4 Purchasing

The management system requirements of ISO 9001:2000, 7.4 apply.

Purchased products should conform to customer requirements and the approved design type specification. Verification of conformity by certificates of conformity in accordance with ISO/IEC 17050-2 or any other documentation providing the same level of confidence, or, where those are not provided with the delivery, by tests, should be based on the criteria given in C.1.

The conformity of components with the approved design type specification should be verified in accordance with the minimum specification data given in Annex A and Annex B.

7.5 Production and service provision

7.5.1 Control of production and service provision

The management system requirements of ISO 9001:2000, 7.5.1 apply.

After any change in process parameters, visual inspection should be carried out to ensure that the changes do not impair or change the specified design type criteria.

NOTE Changes in process parameters can change the design characteristics and require retesting in accordance with 6.1.5, 6.5.4 and 6.6.5 of the UN Model Regulations.

7.5.2 Validation of processes for production and service provision

Manufacturing processes should be validated using the control parameters given in C.2.

The design type test and approval procedure is also required as validation of the manufacturing process and the equipment, personnel and procedures involved.

7.5.3 Identification and traceability

The management system requirements of ISO 9001:2000, 7.5.3 apply

7.5.4 Customer property

The management system requirements of ISO 9001:2000, 7.5.4 apply

7.5.5 Preservation of product

The management system requirements of ISO 9001:2000, 7.5.5 apply

7.6 Control of monitoring and measuring devices

The management system requirements of ISO 9001:2000, 7.6 apply.

8 Measurement, analysis and improvement

8.1 General

The management system requirements of ISO 9001:2000, 8.1 apply.

8.2 Monitoring and measurement

The management system requirements ISO 9001:2000, 8.2 apply.

Monitoring of production should be based on visual or computer-aided automated monitoring of the manufacturing process to identify any need for adjustment to the function of machines and installations.

At initial production, first samples should be checked for conformity with the design type specifications as described in Annex A and Annex B. Where applicable, conformity of the following should be verified:

— dimensions;

— masses;

— quality of openings;

— quality of seams.

Monitoring and measurement of the manufactured packagings, IBCs and large packagings should include (as a minimum) the items/elements given in C.3.

Conformity with the approved performance levels of packaging, IBC and large packaging design types should be verified periodically as specified in a test plan or procedure (including frequency and acceptance limits) to confirm the continuing ability of the manufacturing process to satisfy its intended purpose.

NOTE 1 See 6.1.5, 6.5.4 and 6.6.5 of the UN Model Regulations for the relevant regulatory requirements.

NOTE 2 See Annex D for examples of typical frequencies for the verification of conformity.

Performance test conditions should be specified. For the execution of the performance tests listed in C.4 and C.5, the design type performance test requirements should be met.

NOTE 3 For the purpose of production monitoring, the test conditions may differ from the design type test requirements and may be restricted to comparisons with previous test results.

NOTE 4 The monitoring and measurement of product can also be used to demonstrate compliance with 6.1.5.1.3, 6.5.1.6.7 and 6.6.5.1.3 of the UN Model Regulations. For this purpose, performance tests at random may be performed on production samples at intervals agreed with the competent authority.

8.3 Control of nonconforming product

The management system requirements of ISO 9001:2000, 8.3 apply.

If controls have previously shown nonconformities during production, appropriate measures, such as final inspection of the complete lot, or performance testing at a higher frequency, should be carried out in context with corrective/preventive actions.

NOTE Corrective actions can be subject to the agreement of the competent authority.

8.4 Analyses of data

The management system requirements of ISO 9001:2000, 8.4 apply.

8.5 Improvement

The management system requirements of ISO 9001:2000, 8.5 apply.

NOTE In order to achieve conformity with the approved design type specifications, the procedures for corrective action may require agreement with the competent authority.

Annex A
(normative)

Packaging specifications

NOTE This annex is a modified extract of ISO 16104:2003, Annex G.

A.1 Specification data

Tables A.1.1, A.1.2, A.2.1, A.2.2, A.3.1, A.3.2, A.4, A.5.1 and A.5.2 correlate the different packaging types with data, which are necessary for the identification of test packagings by users, test facilities and competent authorities.

Specification data in this annex are grouped for the following five categories of packagings:

1) drums, jerricans, bottles, jars, etc. — Tables A.1.1 and A.1.2;

2) boxes — Tables A.2.1 and A.2.2;

3) bags — Tables A.3.1 and A.3.2;

4) inner receptacles of composite packagings — Table A.4;

5) inner packagings of combination packagings — Tables A.5.1 and A.5.2.

Tables A.1.1, A.2.1, A.3.1 and A.5.1 apply to all packagings in that category. Tables A.1.2, A.2.2, A.3.2 and A.5.2 apply only to particular packaging types when indicated by an "S".

Each item in the tables is numbered and at the end of this annex there are explanatory notes for many of the numbers to assist in interpretation.

Table A.1.1 — Drums, jerricans, bottles, jars, etc.: packaging specification detail applicable to all

No.		No.	
1	Packaging description (code and trade name)	17	Closure(s), [or neck(s)] position(s)
2	Manufacturer's name and address	18	Closure(s), material(s) and grade
3	Method of construction	19	Closure(s), type, identification
4	Nominal capacity	20	Closure(s), thread, type and pitch
5	Brimful capacity	21	Closure(s) mass
6	Diameter, nominal (cylindrical) internal	22	Closure manufacturer's name and address
7	Diameter, external at widest point	23	Closure torque(s)
8	Nominal diameters (conical, i.e. pails)	24	Type of overseal
9	Body/section dimensions (non-round)	25	Closure(s) seal, material
10	Recess of ends	26	Neck internal diameter
11	Height overall	27	Height to neck face
12	Stacking height	28	Neck height (external)
13	End seams type	29	Neck thread, type and pitch
14	Side seam type	30	Neck thread number of starts
15	Handles: material type, number and position	31	Tare mass
16	Closure(s), diameter(s) and design		
NOTE See A.2.			