

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

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 16106:2006 sisaldab Euroopa standardi EN ISO 16106:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 28.04.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 16106:2006 consists of the English text of the European standard EN ISO 16106:2006. This document is endorsed on 28.04.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.
--	---

Käsitlusala: 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.	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.
---	---

ICS 13.300, 55.020

Võtmesõnad:

ICS 55.020; 13.300

English Version

Packaging - Transport packages for dangerous goods -
Dangerous goods packagings, intermediate bulk containers
(IBCs) and large packagings - Guidelines for the application of
ISO 9001 (ISO 16106:2006)

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
(ISO 16106:2006)

Verpackung - Verpackungen zur Beförderung gefährlicher
Güter - Gefahrgutverpackungen, Großpackmittel (IBC) und
Großverpackungen - Richtlinien für die Anwendung der ISO
9001 (ISO 16106:2006)

This European Standard was approved by CEN on 3 February 2006.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

This document (EN ISO 16106:2006) has been prepared by Technical Committee CEN/TC 261 "Packaging", the secretariat of which is held by AFNOR, in collaboration with Technical Committee ISO/TC 122 "Packaging".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2006, and conflicting national standards shall be withdrawn at the latest by September 2006.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

**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*



PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Quality management system	2
5 Management responsibility	2
6 Resource management	2
7 Product realization	2
7.1 Planning of product realization.....	2
7.2 Customer-related processes.....	2
7.3 Design and development.....	2
7.4 Purchasing.....	2
7.5 Production and service provision.....	3
7.6 Control of monitoring and measuring devices.....	3
8 Measurement, analysis and improvement	3
8.1 General.....	3
8.2 Monitoring and measurement.....	3
8.3 Control of nonconforming product.....	4
8.4 Analyses of data.....	4
8.5 Improvement.....	4
Annex A (normative) Packaging specifications	5
Annex B (normative) IBC specifications	14
Annex C (normative) Items and elements of verification, controls, monitoring and validation	19
Annex D (informative) Typical frequencies for the verification of conformity with design and performance requirements	24
Bibliography	27

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