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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.