SLOVENSKI STANDARD
oSIST prEN ISO 16106:2018

01-oktober-2018

Transportna embalaža za nevarne snovi - Embalaža za nevarne snovi, vsebniki IBC in večja embalaža - Smernice za uporabo standarda ISO 9001 (ISO/DIS 16106:2018)

Transport packages for dangerous goods - Dangerous goods packagings, intermediate bulk containers (IBCs) and large packagings - Guidelines for the application of ISO 9001 (ISO/DIS 16106:2018)

Verpackungen zur Beförderung gefährlicher Güter - Gefahrgutverpackungen, Großpackmittel (IBC) und Großverpackungen - Leitfaden für die Anwendung der ISO 9001 (ISO/DIS 16106:2018)

Emballages de transport pour marchandises dangereuses - Emballages pour marchandises dangereuses, grands récipients vrac (GRV) et grands emballages - Directives pour l'application de l'ISO 9001 (ISO/DIS 16106:2018)

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13.300	Varstvo pred nevarnimi izdelki	Protection against dangerous goods
55.180.99	Drugi standardi v zvezi z distribucijo blaga s prevozom	Other standards related to freight distribution of goods

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

Emballages de transport pour marchandises dangereuses — Emballages 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by 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)*.

This second edition cancels and replaces the firstedition (ISO 16106:2006), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the integration of ISO 9001:2015;

— the revision of the sector-specific requirements on quality management systems for transport packages for dangerous goods into ISO 9001:2015

— the inclusion of Annex E " Large packaging specification";

— the inclusion of Annex F "Notes on annexes C to E";

— editorial changes.

Introduction

0.1 General

This International Standard gives guidance for the application of the 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 (ICAO TI);[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 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.

This International Standard is based on Revision 19 of the UN Model Regulations.

This International Standard is an application standard for transport packages for dangerous goods, which contains the text of ISO 9001:2015.

The conventions for the layout of this International Standard are the following.

— Those clauses, subclauses or annexes that are quoted directly and unchanged from ISO 9001:2015 and ISO 9000:2015 (under clause 3 terms and definitions) are in black text.

— Additional GMP related requirements and recommendations as well as terms and definitions relevant to the manufacturer of primary packaging materials are in blue text.

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on this International Standard are:

a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;

b) facilitating opportunities to enhance customer satisfaction;

c) addressing risks and opportunities associated with its context and objectives;

d) the ability to demonstrate conformity to specified quality management system requirements.

This International Standard can be used by internal and external parties.

It is not the intent of this International Standard to imply the need for:

— uniformity in the structure of different quality management systems;

— alignment of documentation to the clause structure of this International Standard;

— the use of the specific terminology of this International Standard within the organization.

The quality management system requirements specified in this International Standard are complementary to requirements for products and services.

This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

The process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4).

Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

In this International Standard, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Information marked as “NOTE” is for guidance in understanding or clarifying the associated requirement.

0.2 Quality management principles

This International Standard is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

The quality management principles are:

— customer focus;

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision making;

— relationship management.

0.3 Process approach

0.3.1 General

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the adoption of a process approach are included in 4.4.

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.

The application of the process approach in a quality management system enables:

a) understanding and consistency in meeting requirements;

b) the consideration of processes in terms of added value;

c) the achievement of effective process performance;

d) improvement of processes based on evaluation of data and information.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring check points, which are necessary for control, are specific to each process and will vary depending on the related risks.

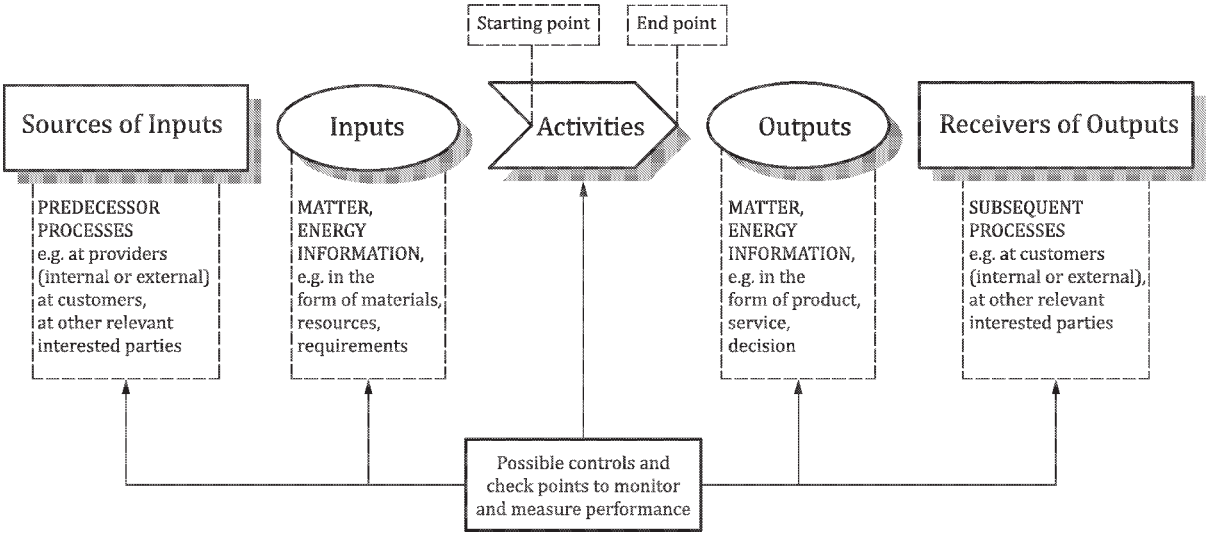
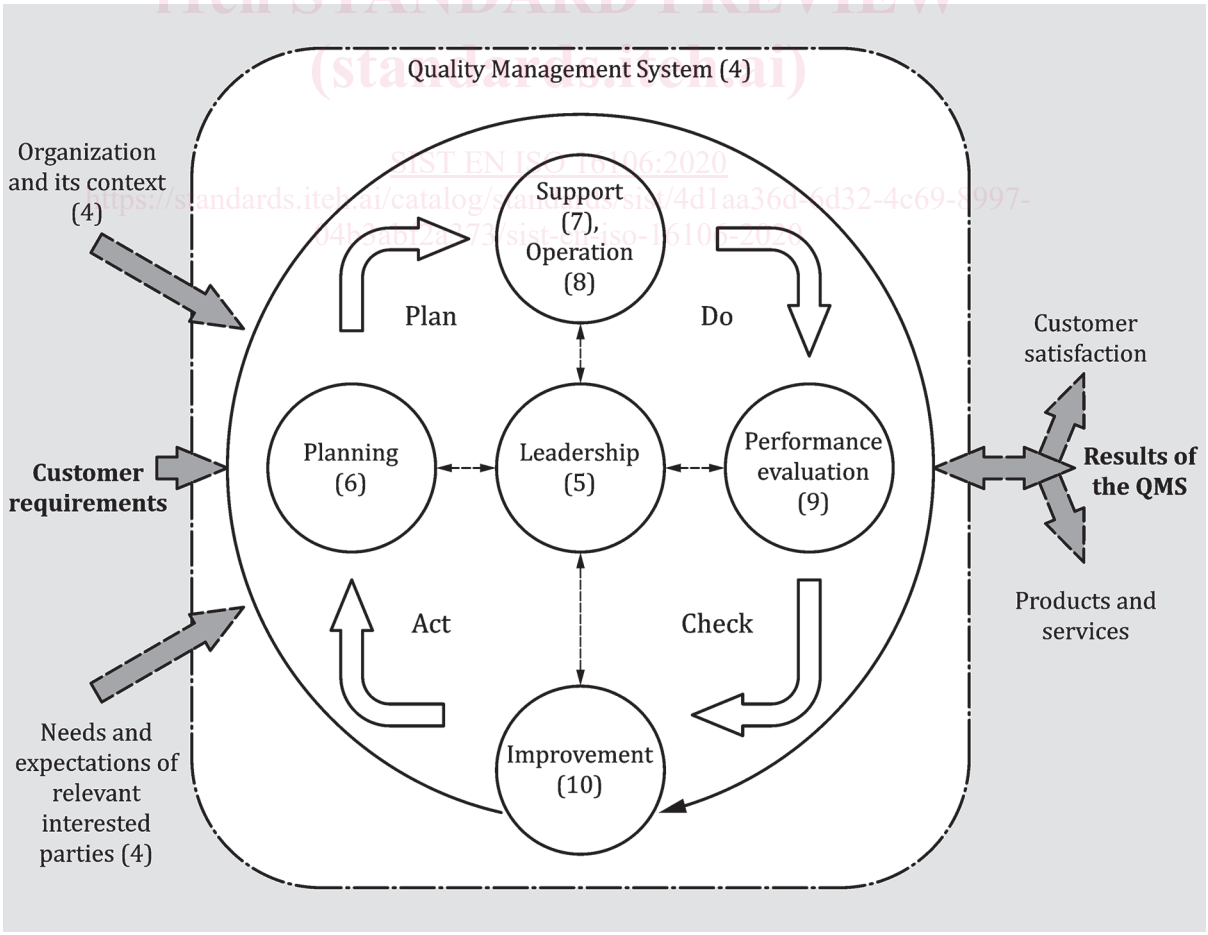


Figure 1 — Schematic representation of the elements of a single process

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.



NOTE Numbers in brackets refer to the clauses in this International Standard.

Figure 2 — Representation of the structure of this International Standard in the PDCA cycle

The PDCA cycle can be briefly described as follows:

— **Plan:** establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies and identify and address risks and opportunities;

— **Do:** implement what was planned;

— **Check:** monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;

— **Act:** take actions to improve performance, as necessary.

0.3.3 Risk-based thinking

Risk-based thinking (see Clause A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analysing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

0.4 Relationship with other management system standards

This International Standard applies the framework developed by ISO to improve alignment among its International Standards for management systems (see Clause A.1).

This International Standard enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards.

This International Standard relates to ISO 9000 and ISO 9004 as follows:

— ISO 9000 Quality management systems — Fundamentals and vocabulary provides essential background for the proper understanding and implementation of this International Standard;

— ISO 9004 Managing for the sustained success of an organization — A quality management approach provides guidance for organizations that choose to progress beyond the requirements of this International Standard.

Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176.

This International Standard does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, or financial management.

Sector-specific quality management system standards based on the requirements of this International Standard have been developed for a number of sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this International Standard within the particular sector.

A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: www.iso.org/tc176/sc02/public.

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 specifies requirements for a quality management system when an organization:

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this International Standard, the terms "product" or "service" only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

In addition to ISO 9001, 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.

It does not apply to design type testing, for which reference is made to 6.1.5, 6.3.5, 6.5.6 and 6.6.5 of the UN Model Regulations.[1]

2 Normative references

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

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

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 9000:2015 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 16106:2018