BS EN ISO 16106:2020

BSI Standards Publication

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

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 16106:2020. It is identical to ISO 16106:2020. It supersedes BS EN ISO 16106:2006, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee PKW/0, Packaging.

A list of organizations represented on this committee can be obtained on request to its secretary.

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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 (ISO 16106:2020)

Emballages de transport pour marchandises dangereuses - Emballages pour marchandises dangereuses, grands récipients vrac (GRV) et grands emballages - Lignes directrices pour l'application de l'ISO 9001 (ISO 16106:2020)

Verpackungen zur Beförderung gefährlicher Güter - Gefahrgutverpackungen, Großpackmittel (IBC) und Großverpackungen - Leitfaden für die Anwendung der ISO 9001 (ISO 16106:2020)

This European Standard was approved by CEN on 8 February 2020.

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European foreword

This document (EN ISO 16106:2020) has been prepared by Technical Committee ISO/TC 122 "Packaging" in collaboration with Technical Committee CEN/TC 261 “Packaging” the secretariat of which is held by AFNOR.

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of an identical text or by endorsement, at the latest by August 2020, and conflicting national standards shall be withdrawn at the latest by August 2020.

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

This document supersedes EN ISO 16106:2006.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

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

Endorsement notice

The text of ISO 16106:2020 has been approved by CEN as EN ISO 16106:2020 without any modification.

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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 of 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 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)*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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

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

— ISO 9001:2015 has been integrated;

— the sector-specific requirements on quality management systems for transport packages for dangerous goods into ISO 9001:2015 have been revised;

— new Annexes E and F have been created;

— editorial changes have been made.

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Introduction

0.1 General

The United Nations Recommendations on the Transport of Dangerous Goods[27] (referred to in this document 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)[28];

— the Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID)[29];

— the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI)[30];

— the International Maritime Dangerous Goods Code (IMDG)[31].

The application of this document should take into account the requirements of these international agreements and the national legislation for the transport of dangerous goods.

In conjunction with ISO 9001, this document gives guidance on 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 document. 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 was replaced by "measurement and monitoring" in the 2000 edition. For the purposes of this document, the latest terminology is used, in accordance with ISO 9000. This difference in terminology should not deter users from using this document.

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

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

For an explanation of how this document was prepared, see Annex A.

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 document 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 document can be used by internal and external parties.

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It is not the intent of this document to prescribe:

— uniformity in the structure of different quality management systems;

— alignment of documentation to the clause structure of this document;

— the use of the specific terminology of this document within the organization.

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

This document 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 can 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 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 can find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

0.2 Quality management principles

This document 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 document 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

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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.

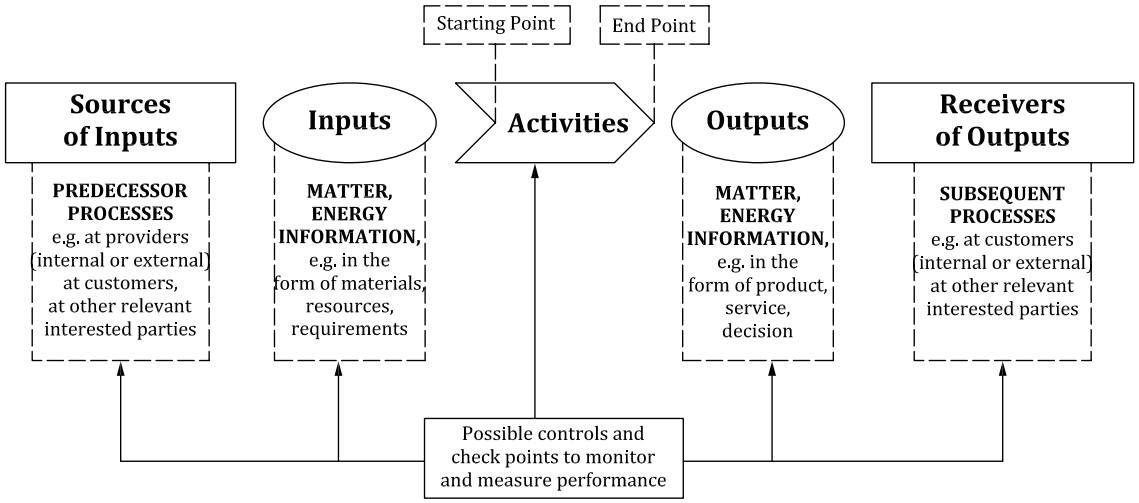

Figure 1 — Schematic representation of the elements of a single process

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 document.

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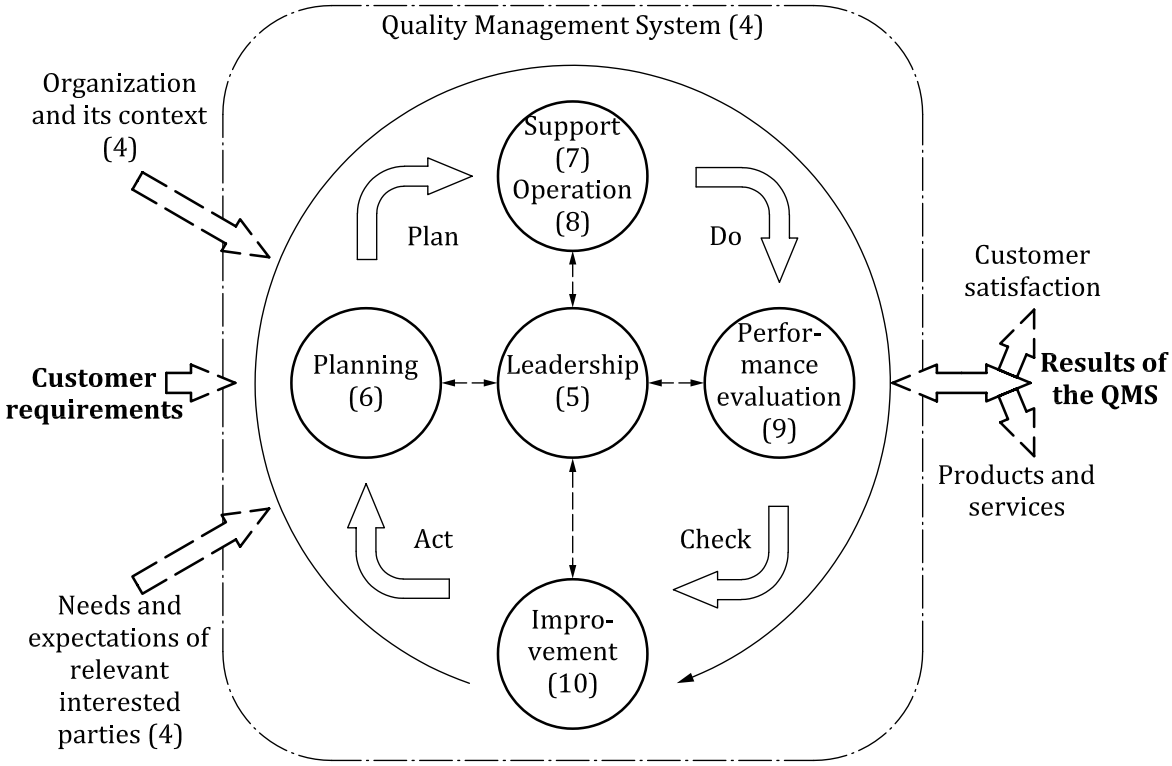

Figure 2 — Representation of the structure of this document in the PDCA cycle

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 A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking was implicit in the previous editions of this document 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 document, 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.

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0.4 Relationship with other management system standards

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

This document 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 document relates to ISO 9000 and ISO 9004 as follows:

— ISO 9000 provides essential background for the proper understanding and implementation of this document;

— ISO 9004 provides guidance for organizations that choose to progress beyond the requirements of this document.

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

Sector-specific quality management system standards based on the requirements of this document 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 document within a particular sector.

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INTERNATIONAL STANDARD **ISO 16106:2020(E)**

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 document gives guidance on the application of a quality management system in the manufacture, measuring and monitoring of design type approved dangerous goods packaging, intermediate bulk containers (IBCs) and large packaging.

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

It is applicable to an organization that:

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 guidance in this document is generic and intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

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

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[27].

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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