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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 — Lignes directrices 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 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.

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.

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

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.

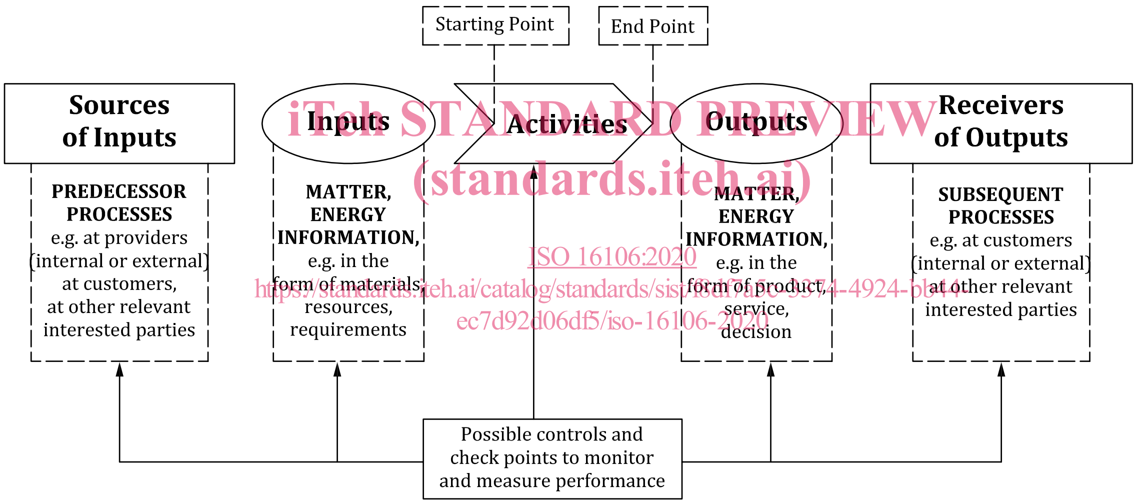

Figure 1 — Schematic representation of the elements of a single process

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.

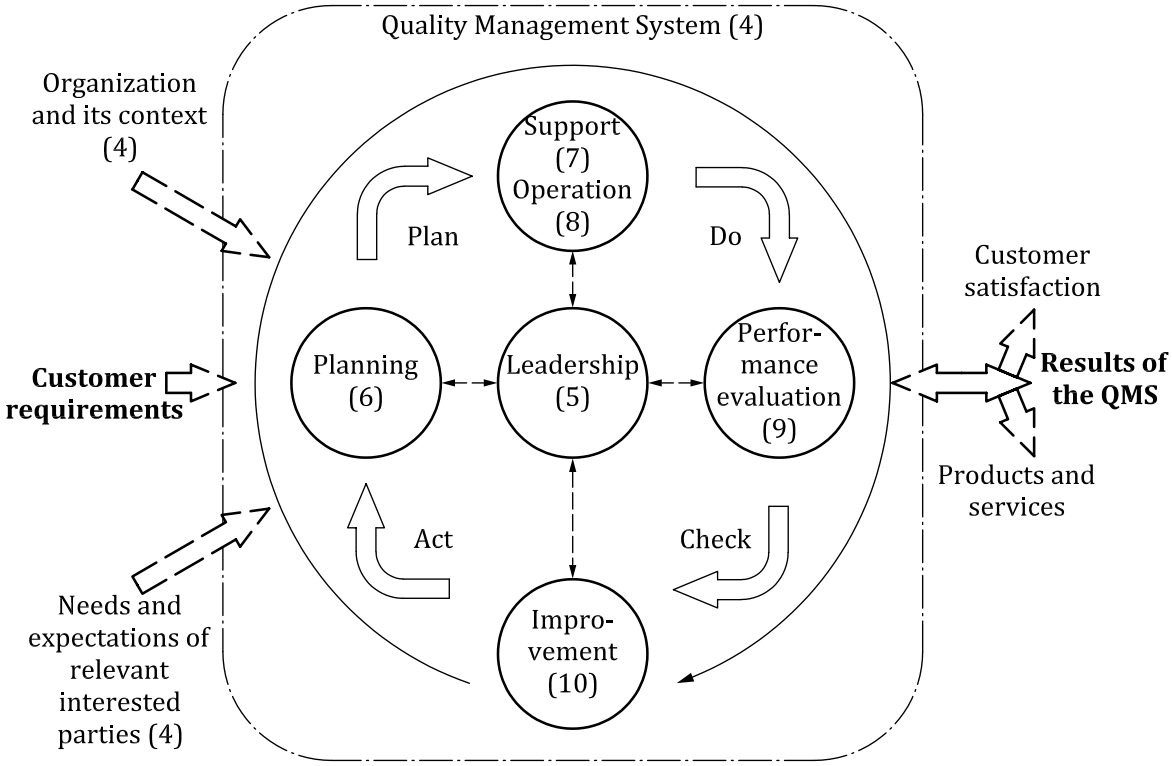

Figure 2 — Representation of the structure of this document in the PDCA cycle

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.

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.

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/

3.1
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.8)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

3.2
interested party
stakeholder
person or *organization* (3.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity

3.3
requirement
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, e.g. in documented information.

3.4
management system
set of interrelated or interacting elements of an *organization* (3.1) to establish *policies* (3.7) and *objectives* (3.8) and *processes* (3.12) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The system elements include the organization's structure, roles and responsibilities, planning and operation.

Note 3 to entry: The scope of a management system can include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

3.5
top management
person or group of people who directs and controls an *organization* (3.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the *management system* (3.4) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

3.6
effectiveness
extent to which planned activities are realized and planned results achieved

3.7
policy
intentions and direction of an *organization* (3.1), as formally expressed by its *top management* (3.5)

3.8
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and *process* (3.12)).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a quality objective, or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of quality management systems, quality objectives are set by the organization, consistent with the quality policy, to achieve specific results.

3.9
risk
effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential "events" (as defined in ISO Guide 73) and "consequences" (as defined in ISO Guide 73), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated "likelihood" (as defined in ISO Guide 73) of occurrence.

3.10
competence
ability to apply knowledge and skills to achieve intended results

3.11
documented information
information required to be controlled and maintained by an *organization* (3.1) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media, and from any source.

Note 2 to entry: Documented information can refer to:

— the management *system* (3.4), including related *processes* (3.12);

— information created in order for the organization to operate (documentation);

— evidence of results achieved (records).

3.12
process
set of interrelated or interacting activities which transforms inputs into outputs

3.13
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to managing activities, *processes* (3.12), products (including services), systems or *organizations* (3.1).

3.14
outsource (verb)
make an arrangement where an external *organization* (3.1) performs part of an organization's function or *process* (3.12)

Note 1 to entry: An external organization is outside the scope of the *management system* (3.4), although the outsourced function or process is within the scope.

3.15
monitoring
determining the status of a system, a *process* (3.12) or an activity

Note 1 to entry: To determine the status, there can be a need to check, supervise or critically observe.

3.16
measurement
process (3.12) to determine a value

3.17
audit
systematic, independent and documented *process* (3.12) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the organization itself, or by an external party on its behalf.

Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

3.18
conformity
fulfilment of a *requirement* (3.3)

3.19
nonconformity
non-fulfilment of a *requirement* (3.3)

3.20
corrective action
action to eliminate the cause(s) of a *nonconformity* (3.19) and to prevent recurrence

3.21
continual improvement
recurring activity to enhance *performance* (3.13)

3.22
competent authority
any national regulatory body or authority designated, or otherwise recognized as such, for any purpose in connection with the international agreements

Note 1 to entry: International agreements are referred to in the Bibliography.

3.23
design type approved packaging
IBC
large packaging
dangerous goods packaging that has been tested and approved in accordance with:

— 6.1.5, 6.3.5, 6.5.6 and 6.6.5 of the UN Model Regulations; or

— national regulations

Note 1 to entry: The modal agreements are referred to in the Bibliography.

4 Context of the organization

4.1 Understanding the organization and its context

The organization should determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

The organization should monitor and review information about these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

4.2 Understanding the needs and expectations of interested parties

Due to their effect, or potential effect, on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization should determine:

a) the interested parties that are relevant to the quality management system;

b) the requirements of these interested parties that are relevant to the quality management system.

The organization should monitor and review information about these interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system

The organization should determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization should consider:

a) the external and internal issues referred to in 4.1;

b) the requirements of relevant interested parties referred to in 4.2;

c) the products and services of the organization.

The organization should apply all the requirements of this document if they are applicable within the determined scope of its quality management system.

The scope of the organization's quality management system should be available and be maintained as documented information. The scope should state the types of products and services covered, and provide justification for any requirement of this document that the organization determines is not applicable to the scope of its quality management system.

Conformity to this document may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.