

SLOVENSKI STANDARD

SIST EN ISO 16106:2020

01-junij-2020

Nadomešča:

SIST EN ISO 16106:2006

Transportna embalaža za nevarno blago - Embalaža za nevarno blago, vsebniki IBC in večja embalaža - Smernice za uporabo standarda ISO 9001 (ISO 16106:2020)

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)

Verpackungen zur Beförderung gefährlicher Güter - Gefahrgutverpackungen, Großpackmittel (IBC) und Großverpackungen - Leitfaden für die Anwendung der 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)

Ta slovenski standard je istoveten z: EN ISO 16106:2020

ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
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

SIST EN ISO 16106:2020

en,fr,de

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 16106:2020

<https://standards.iteh.ai/catalog/standards/sist/4d1aa36d-6d32-4c69-8997-04b3abf2a373/sist-en-iso-16106-2020>

EUROPEAN STANDARD

EN ISO 16106

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2020

ICS 13.300; 55.020

Supersedes EN ISO 16106:2006

English Version

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.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents	Page
European foreword.....	3

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 16106:2020](https://standards.iteh.ai/catalog/standards/sist/4d1aa36d-6d32-4c69-8997-04b3abf2a373/sist-en-iso-16106-2020)
<https://standards.iteh.ai/catalog/standards/sist/4d1aa36d-6d32-4c69-8997-04b3abf2a373/sist-en-iso-16106-2020>

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

[https://standards.iteh.ai/catalog/standards/sist/4d1aa36d-6d32-4c69-8997-](https://standards.iteh.ai/catalog/standards/sist/4d1aa36d-6d32-4c69-8997-04b3abf2a373/sist-en-iso-16106-2020)

[04b3abf2a373/sist-en-iso-16106-2020](https://standards.iteh.ai/catalog/standards/sist/4d1aa36d-6d32-4c69-8997-04b3abf2a373/sist-en-iso-16106-2020)

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 16106:2020

<https://standards.iteh.ai/catalog/standards/sist/4d1aa36d-6d32-4c69-8997-04b3abf2a373/sist-en-iso-16106-2020>

INTERNATIONAL STANDARD

ISO 16106

Second edition
2020-02

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*

[SIST EN ISO 16106:2020](https://standards.iteh.ai/catalog/standards/sist/4d1aa36d-6d32-4c69-8997-04b3abf2a373/sist-en-iso-16106-2020)

<https://standards.iteh.ai/catalog/standards/sist/4d1aa36d-6d32-4c69-8997-04b3abf2a373/sist-en-iso-16106-2020>



Reference number
ISO 16106:2020(E)

© ISO 2020

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 16106:2020

<https://standards.iteh.ai/catalog/standards/sist/4d1aa36d-6d32-4c69-8997-04b3abf2a373/sist-en-iso-16106-2020>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Context of the organization	5
4.1 Understanding the organization and its context.....	5
4.2 Understanding the needs and expectations of interested parties.....	5
4.3 Determining the scope of the quality management system.....	5
4.4 Quality management system and its processes.....	6
5 Leadership	6
5.1 Leadership and commitment.....	6
5.1.1 General.....	6
5.1.2 Customer focus.....	7
5.2 Policy.....	7
5.2.1 Establishing the quality policy.....	7
5.2.2 Communicating the quality policy.....	7
5.3 Organizational roles, responsibilities and authorities.....	7
6 Planning	8
6.1 Actions to address risks and opportunities.....	8
6.2 Quality objectives and planning to achieve them.....	8
6.3 Planning of changes.....	9
7 Support	9
7.1 Resources.....	9
7.1.1 General.....	9
7.1.2 People.....	9
7.1.3 Infrastructure.....	9
7.1.4 Environment for the operation of processes.....	10
7.1.5 Monitoring and measuring resources.....	10
7.1.6 Organizational knowledge.....	10
7.2 Competence.....	11
7.3 Awareness.....	11
7.4 Communication.....	11
7.5 Documented information.....	12
7.5.1 General.....	12
7.5.2 Creating and updating.....	12
7.5.3 Control of documented information.....	12
8 Operation	13
8.1 Operational planning and control.....	13
8.2 Requirements for products and services.....	13
8.2.1 Customer communication.....	13
8.2.2 Determining the requirements for products and services.....	13
8.2.3 Review of the requirements for products and services.....	14
8.2.4 Changes to requirements for products and services.....	14
8.3 Design and development of products and services.....	14
8.3.1 General.....	14
8.3.2 Design and development planning.....	14
8.3.3 Design and development inputs.....	15
8.3.4 Design and development controls.....	15
8.3.5 Design and development outputs.....	16
8.3.6 Design and development changes.....	16

ISO 16106:2020(E)

8.4	Control of externally provided processes, products and services.....	16
8.4.1	General.....	16
8.4.2	Type and extent of control.....	17
8.4.3	Information for external providers.....	17
8.5	Production and service provision.....	18
8.5.1	Control of production and service provision.....	18
8.5.2	Identification and traceability.....	18
8.5.3	Property belonging to customers or external providers.....	18
8.5.4	Preservation.....	19
8.5.5	Post-delivery activities.....	19
8.5.6	Control of changes.....	19
8.6	Release of products and services.....	19
8.7	Control of nonconforming outputs.....	20
9	Performance evaluation.....	20
9.1	Monitoring, measurement, analysis and evaluation.....	20
9.1.1	General.....	20
9.1.2	Customer satisfaction.....	21
9.1.3	Analysis and evaluation.....	21
9.2	Internal audit.....	22
9.3	Management review.....	22
9.3.1	General.....	22
9.3.2	Management review inputs.....	22
9.3.3	Management review outputs.....	23
10	Improvement.....	23
10.1	General.....	23
10.2	Nonconformity and corrective action.....	23
10.3	Continual improvement.....	24
Annex A	(informative) Clarification of new structure, terminology and concepts.....	25
Annex B	(informative) Other International Standards on quality management and quality management systems developed by ISO/TC 176.....	29
Annex C	(informative) Packaging specification data.....	32
Annex D	(informative) IBC specification data.....	38
Annex E	(informative) Large packaging (LP) specification data.....	42
Annex F	(informative) Notes to the packaging specifications of Annexes C, D and E.....	44
Annex G	(informative) Items and elements of verification, controls, monitoring and validation.....	45
Annex H	(informative) Examples of typical frequencies for the verification of conformity with design and performance requirements.....	50
Bibliography	53

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.

ISO 16106:2020(E)

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

ISO 16106:2020(E)

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:

- understanding and consistency in meeting requirements;
- the consideration of processes in terms of added value;
- the achievement of effective process performance;
- 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.

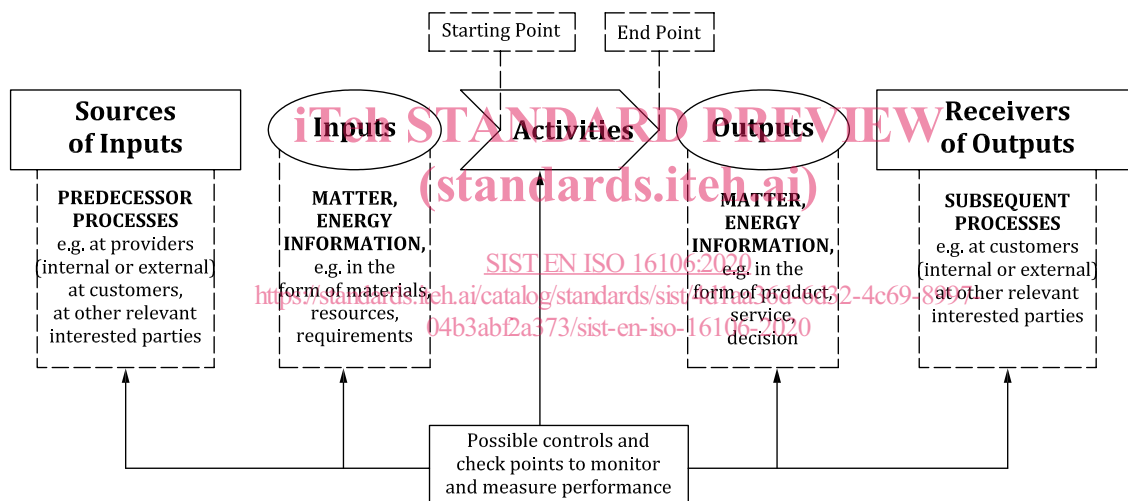


Figure 1 — Schematic representation of the elements of a single process

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.

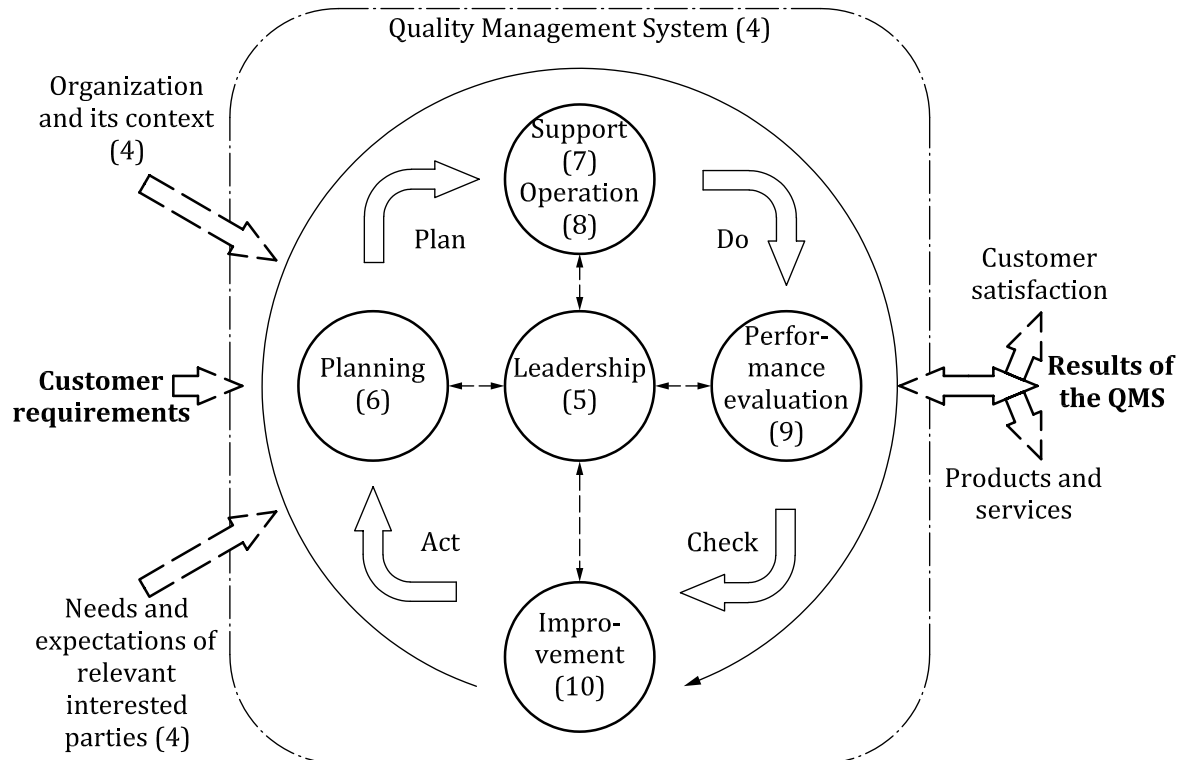


Figure 2 — Representation of the structure of this document in the PDCA cycle
 (standards.iteh.ai)

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.