



SLOVENSKI STANDARD
oSIST ISO/DIS 9002:2026
01-julij-2026

Sistemi vodenja kakovosti - Smernice za uporabo ISO 9001

Quality management systems — Guidelines for the application of ISO 9001

Systèmes de management de la qualité — Lignes directrices pour l'application de l'ISO 9001

Ta slovenski standard je istoveten z: ISO/DIS 9002

ICS:

03.100.70	Sistemi vodenja	Management systems
03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance

oSIST ISO/DIS 9002:2026

en

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

Sample Document

get full document from standards.iteh.ai



DRAFT International Standard

ISO/DIS 9002

Quality management systems — Guidelines for the application of ISO 9001

*Systèmes de management de la qualité — Lignes directrices pour
l'application de l'ISO 9001*

ICS: 03.100.70; 03.120.10

ISO/TC 176/SC 2

Secretariat: **BSI**

Voting begins on:
2026-06-16

Voting terminates on:
2026-09-08

get full document from standards.iteh.ai

This document is circulated as received from the committee secretariat.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

© ISO 2026

Reference number
ISO/DIS 9002:2026(en)

ISO/DIS 9002:2026(en)

Sample Document

get full document from standards.iteh.ai



COPYRIGHT PROTECTED DOCUMENT

© ISO 2026

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
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

© ISO 2026 – All rights reserved

ISO/DIS 9002:2026(en)

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Context of the organization	1
4.1 Understanding the organization and its context.....	1
4.2 Understanding the needs and expectations of interested parties.....	5
4.3 Determining the scope of the quality management system.....	11
4.4 Quality management system.....	12
5 Leadership	16
5.1 Leadership and commitment.....	16
5.1.1 General.....	16
5.1.2 Customer focus.....	18
5.2 Quality Policy.....	19
5.3 Roles, responsibilities and authorities.....	21
6 Planning	22
6.1 Actions to address risks and opportunities.....	22
6.1.1 Determining risks and opportunities.....	22
6.1.2 Actions to address risks.....	24
6.1.3 Actions to address opportunities.....	24
6.2 Quality objectives and planning to achieve them.....	25
6.3 Planning of changes.....	27
7 Support	28
7.1 Resources.....	28
7.1.1 General.....	28
7.1.2 People.....	29
7.1.3 Infrastructure.....	29
7.1.4 Environment for the operation of processes.....	30
7.1.5 Monitoring and measuring resources.....	30
7.1.6 Organizational knowledge.....	32
7.2 Competence.....	34
7.3 Awareness.....	34
7.4 Communication.....	35
7.5 Documented information.....	35
7.5.1 General.....	35
7.5.2 Creating and updating documented information.....	36
7.5.3 Control of documented information.....	36
8 Operation	37
8.1 Operational planning and control.....	37
8.2 Requirements for products and services.....	37
8.2.1 Customer communication.....	37
8.2.2 Determining requirements for products and services.....	39
8.2.3 Review of requirements for products and services.....	40
8.2.4 Changes to requirements for products and services.....	41
8.3 Design and development of products and services.....	42
8.3.1 General.....	42
8.3.2 Design and development planning.....	43
8.3.3 Design and development inputs.....	46
8.3.4 Design and development controls.....	47
8.3.5 Design and development outputs.....	48
8.3.6 Design and development changes.....	49

ISO/DIS 9002:2026(en)

8.4	Control of externally provided processes, products and services	50
8.4.1	General	50
8.4.2	Type and extent of control	51
8.4.3	Information for external providers	52
8.5	Production and service provision	53
8.5.1	Control of production and service provision	53
8.5.2	Identification and traceability	55
8.5.3	Property belonging to customers or external providers	57
8.5.4	Preservation	59
8.5.5	Post-delivery activities	61
8.5.6	Control of changes	62
8.6	Release of products and services	63
8.7	Control of nonconforming outputs	64
9	Performance evaluation	66
9.1	Monitoring, measurement, analysis and evaluation	66
9.1.1	General	66
9.1.2	Customer satisfaction	66
9.1.3	Analysis and evaluation	67
9.2	Internal audit	68
9.2.1	General	68
9.2.2	Internal audit programme	68
9.3	Management Review	71
9.3.1	General	71
9.3.2	Management review inputs	71
9.3.3	Management review results	72
10	Improvement	72
10.1	Continual Improvement	72
10.2	Nonconformity and corrective action	73
	Bibliography	76

get full document from standards.iteh.ai

ISO/DIS 9002:2026(en)

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This third edition cancels and replaces ISO/TS 9002:2016, which has been technically revised. The main changes are as follows:

- publication of this document as an International Standard,
- alignment with the new and revised requirements of ISO 9001:2026,
- additional guidance where clarification of existing requirements was limited or absent in the previous edition,
- expansion of examples illustrating the application of ISO 9001 in different organizational contexts,
- inclusion of cautions to draw attention to known risks in the application of certain requirements,
- clarification of the use of normative terminology, in particular the distinction between requirements and recommendations, to support consistent interpretation.

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.

ISO/DIS 9002:2026(en)

Introduction

This document assists users in implementing, maintaining, and improving a quality management system (QMS) according to ISO 9001:2026 *Quality management systems – Requirements*.

An effective QMS supports the organization's strategic direction and enhances the ability of the organization to consistently provide conforming products and services to its customers.

The guidance in this document follows the clause structure of ISO 9001:2026. Clarifications given in Annex A of ISO 9001:2026 were considered in developing this document.

This document applies the harmonized approach as published in the ISO/IEC Directives related to the development of management system standards (MSS). The intention is to support alignment and facilitate the integration of the requirements and recommendations of one or more MSS into an organization's management system. For more information, please see <https://www.iso.org/management-system-standards.html>

It is recommended that ISO 9001:2026 and Annex A be read in conjunction with this document. While Annex A of ISO 9001:2026 provides clarifications to ensure a clear interpretation of the requirements, ISO 9002 aims to provide guidance to users to implement a QMS that fulfils the requirements of ISO 9001.

The terms and definitions, along with the fundamental concepts and quality management principles described in ISO/FDIS 9000 can help users have a better understanding of ISO 9001 when developing a QMS.

ISO 9001 specifies requirements that can be objectively audited or evaluated. ISO 9002 includes examples, descriptions, and options that aid both in the implementation of a QMS and in strengthening the overall management system of an organization. While the guidelines in this document are consistent with the ISO 9001 QMS requirements, they are not intended to add, subtract, or change, the requirements of ISO 9001, nor are they to be used for audit or evaluation purposes.

The examples in this document are illustrations of what an organization can do; however, these are neither definitive nor exhaustive. Examples aim to illustrate the application of ISO 9001 in diverse organizations. They represent possibilities, not all of which are necessarily suitable for every organization.

Like ISO 9001, ISO 9002 can be used by organizations of all types, sizes, levels of maturity and in all sectors and geographic locations. However, the way an organization applies the guidance provided in this document can vary based on factors such as the size or the complexity of the organization, the way the organization operates, the range of the organization's activities and the nature of the risks and opportunities it encounters.

An ISO 9001 QMS is based on the 'process approach'. This document provides guidance to organizations to integrate the quality management principles described in ISO 9000 and the requirements specified in ISO 9001 into their processes.

The guidance in each clause of this document is structured as follows:

- The intent at the beginning states the main objective to be achieved by the implementation of the requirements of the clause, explaining why the organization does it, and the benefits of meeting the requirements in the clause.
- This is followed by practical guidance on how to apply the requirements to implement the QMS of the organization, taking a practical perspective by describing what organizations can do, and referring to existing practices, tools, and methods.
- The guidance is complemented by examples focusing on real-life applications ranging from relatively larger and complex organizations to small and medium organizations (SMEs) in different sectors.
- Finally, the guidance provides some cautions, identifying risks, limitations (if any), lessons learned, and potential pitfalls, as well as problems that have been previously encountered in QMS and in the application of ISO 9001. Such information is aimed at assisting users in the effective application of ISO 9001.

ISO/DIS 9002:2026(en)

In addition to ISO 9001:2026, ISO has published a number of other quality management standards and informative resources which can assist the user and provide additional information, including:

- the ISO handbook: ISO 9001:2015 *for Small Enterprises – What to do? Advice from ISO/TC 176*
- the ISO 9001 Auditing Practices Group (ISO 9001 APG) papers available in www.iso.org/tc176/ISO9001AuditingPracticesGroup
- public information on the ISO/TC 176/SC2 website: <https://committee.iso.org/tc176sc2>
- the "Integrated Management System — A Practical Guide (IMS-PG)".

Additional standards and documents are listed in the Bibliography.

Sample Document

get full document from standards.iteh.ai

Sample Document

get full document from standards.iteh.ai

Quality management systems — Guidelines for the application of ISO 9001

1 Scope

This document provides guidance on the intent of the requirements in ISO/DIS 9001 ISO 9001:2026, with examples of possible steps an organization can take to meet the requirements. It does not add to, subtract from, or in any way modify those requirements.

This document does not prescribe mandatory approaches to implementation or provide any preferred method of interpretation.

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/FDIS 9000, *Quality management — Fundamentals and vocabulary*

ISO/DIS 9001, *Quality management systems — Requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/FDIS 9000 apply. ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

4 Context of the organization

4.1 Understanding the organization and its context

The intent of this subclause is to ensure that the organization understands the external and internal issues that are relevant to its purpose and strategic direction and which can affect, either positively or negatively, its ability to achieve the intended results of its QMS. The external and internal issues can change, and therefore they are monitored and reviewed at planned intervals (e.g. by a management review). Early identification of relevant changes in external and internal issues enables the organization to take appropriate and timely actions.

The acquired knowledge is used by the organization to determine:

- the scope of its QMS (4.3);
- the processes required to ensure that the organization fulfils its purpose, aligns with its strategic direction, and achieves its intended results (4.4);
- the inputs required to determine risks and opportunities (6.1);
- how to plan the QMS (6.2).

ISO/DIS 9002:2026(en)

The methods for determining external and internal issues are at the discretion of the organization. For some organizations, a simple approach with brainstorming and asking "what if" questions can be sufficient. All organizations can benefit from having a process that is conducted systematically, incorporating both risk-based and opportunity-based thinking, and involving relevant interested parties. Organizations operating in multiple countries or markets should consider issues in all locations.

Tools like such as Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis and Political, Economic, Social, Technological, Legal, Environmental (PESTLE) analysis can be used to support the determination of relevant issues. An example of PESTLE is given in 4.1.3.

NOTE 1 SWOT analysis uses the term "opportunities" to refer to external factors and the term "strengths" for internal factors which are perceived as favourable to the organization. The results of SWOT analysis can result in the identification of opportunities to be pursued by the organization (6.1.3).

NOTE 2 See guidance on quality tools, ISO 10009 [\[1\]](#), 5.1 and 5.2.

When determining whether climate change is a relevant issue, the organization should consider its potential impact on achieving the intended results of the QMS. This includes evaluating how climate change can affect the organization's ability to consistently meet customer requirements, influence market expectations and customer satisfaction, disrupt the supply chain through events such as extreme weather or raw material shortages, and impact the entire product or service life cycle, from material selection and design to production, delivery, use, maintenance and end-of-life management.

To effectively determine, monitor and review relevant issues, the people involved should have a clear understanding of the organization's purpose and strategic direction, and should evaluate the relevance and impact of issues against them. In cases where there is no documented strategy, the people involved can infer the organization's strategic direction from the coordinated decisions, plans and actions it takes to achieve its objectives and fulfil its purpose.

New issues can become relevant, and others can become no longer relevant enough to be monitored. How often an issue is monitored and reviewed depends on its importance and the pace of change.

Information about external and internal issues related to the QMS can be gathered from many sources (e.g. internal reports, customer feedback, external provider meetings, professional and technical publications, national and international press, websites, national statistics, regulatory updates, conferences, technical associations).

The task of monitoring and reviewing issues can be assigned to individuals or departments (e.g. production, quality, purchasing). Assigning the task helps to ensure prompt responses to risks that can affect product conformity or service quality and supports the pursuit of identified opportunities.

Regardless of who is responsible for monitoring, top management periodically reviews the gathered insights during management reviews to ensure the QMS remains suitable, adequate and effective.

The organization can benefit from documenting both the issues and the results of monitoring and reviewing, which ensures that decisions taken can be traced to the relevant information.

Examples of external issues, as determined by PESTLE analysis, are given in [Table 1](#). This list is not exhaustive.

Table 1 — Examples of external issues using PESTLE

PESTLE	DESCRIPTION	EXAMPLES
(P) Political factors	Government policies and direction, political stability, intent to change legislation, activities of political committees (local–global), public opinion, international trade agreements, public/private investment in infrastructure.	Strong local opposition to an infrastructure project can influence the factory location. Changes in vaccination policies or public health priorities affect demand forecasts and regular pathways in healthcare.

ISO/DIS 9002:2026(en)

Table 1 (continued)

PESTLE	DESCRIPTION	EXAMPLES
(E) Economic factors	General economic situation, inflation, credit availability, exchange rates, tariffs, resource costs, market stability.	Rising fuel prices and microchip shortages impact cost structures and production planning. Increased raw material costs due to global supply chain disruptions.
(S) Socio-cultural factors	Demographic trends, patient/consumer behaviour, societal expectations, availability of skilled labour, awareness of diversity and inclusion, local perceptions, unemployment and union relations.	Changes in national union agreements regarding working conditions. Patient behaviour trends influence internal healthcare processes. Increased social awareness of diversity and inclusion requires adaptation of policies and training.
(T) Technological factors	Development of new technologies, materials and equipment; patent expirations; IT threats; digitalization and AI.	Shift toward cloud-based services and use of artificial intelligence (AI). Rapid development of AI diagnostics influencing medical device design and marketing. Physical environment such as external infrastructure, transport links or road access Access and egress; local road suitability, traffic and transport to \ from the factory, i.e., employee traffic, deliveries.
(L) Legal factors	Legal, statutory and regulatory requirements for products, services, processes and resources; working conditions; industry and union regulations.	Regulations on substances in products and processes. Minimum wage and working condition requirements. Stricter healthcare regulations affecting service provider
(E) Environmental factors	Climate change, resource availability, biodiversity, extreme weather and sustainability issues	Reduced access to clean water. Decline in pollinating insects and spread of invasive species Operational impacts or disruptions due to floods, fires

Examples of internal issues are given in [Table 2](#). This is list is not exhaustive.

Table 2 — Examples of internal issues in an organization

INTERNAL ISSUE AREA	EXAMPLES
Product or Service offering	Product and service portfolio, such as a change in the portfolio can require changed facilities, processes for manufacturing, handling and storage; and competence in purchasing new material, components and services from a different kind of supplier.
Organizational and Leadership changes	Factors in the organization's governance can include its corporate culture and values, the organizational structure, established policies and procedures for decision-making, and the defined roles and responsibilities of individuals and teams.

ISO/DIS 9002:2026(en)

Table 2 (continued)

INTERNAL ISSUE AREA	EXAMPLES
Infrastructure and Environment	Resource factors may include infrastructure (7.1.3), such as the condition, status and age of equipment and machinery. They can also include the environment for the operation of the processes (7.1.4), covering physical conditions such as temperature, cleanliness, ergonomics, etc, as well as social and psychological aspects that can influence performance. Additionally, the capability of IT systems to support both operational activities and reporting requirements can be considered, since limitations in software, hardware or connectivity can hinder efficiency and compliance (7.1.3).
People and Behaviours	Human aspects such as availability of staff (7.1.2), internal complaints, organizational behaviour and culture, hope for a career, expectations of working remotely, staff turnover, sick leave, relationships with unions (7.2).
Organizational knowledge	Issues related to organizational knowledge (7.1.6), introducing internal knowledge through training and competence of relevant employees. loss of organizational knowledge.
Communication	Internal communication issues between departments and sites, for example, the development department and the quality assurance team (7.4).
Operational Factors	Operational factors such as efficiency, waste in all forms, how processes are managed and improved to meet changes in requirements related to new products, services or changed legal requirements (Clause 8).
Nonconformity	The number and type of nonconformities can be an issue. This includes assessing whether nonconformities from all parts of the organization are addressed promptly and whether corrective actions taken are effective (10.2).

The following examples show understanding the organization and its context.

EXAMPLE 1 A medium-sized manufacturing organization is a leading company in its industry. In order to monitor and review the various aspects of its context, the company has assigned this responsibility to a cross-functional team that includes sales, production, quality, engineering and purchasing.

Top management gathers information from the cross-functional team quarterly, and the insights are summarized in a report. This report is used as an input to the management review (9.3.2). Participants are expected and encouraged to use these insights to support decision-making within the organization, while maintaining confidentiality as appropriate.

EXAMPLE 2 A Hospital is one of five hospitals in the region. It has identified the other hospitals' ability to efficiently treat patients as a relevant issue. The five hospitals share anonymized patient information to identify trends in illness types, patient ages and other factors, aiming to predict future healthcare needs. This information is also used to determine whether it is possible to identify and treat patient groups before hospital care is required.

The Hospital also monitors and reviews its own efficiency in treating patients compared to other hospitals. If suitable and possible, it initiates a benchmark study to learn from others.

EXAMPLE 3 A small, well-established organization provides architectural and project management services to its customers in the construction industry. The organization has determined that a relevant external issue is that its customers are demanding that it be certified to ISO 9001. Achieving certification could provide the organization with greater opportunities for projects in the public sector, and this would imply the organization's growth. A decision to pursue certification based on the advantages in terms of increased work was made. This introduced new internal issues which could affect the achievement of its QMS's intended results, such as hiring of additional personnel, relocation to a larger office, improving organizational knowledge and ensuring competence of new personnel.

ISO/DIS 9002:2026(en)

The organization should consider the following cautions:

- Determining, monitoring and reviewing issues in proportion to the organization's requirements and treated as an ongoing activity, since regulations, technologies and market expectations evolve.
- There is a risk of focusing only on financial and operational factors and overlooking social, political, technological, and environmental influences. Using a structured approach can ensure key areas are not missed.
- Focusing only on current problems can miss strategic factors. The organization should also include medium- and long-term trends (e.g. demographic changes, technology shifts), even if their impact is not immediately known or understood.
- QMS development is iterative: initial efforts can meet immediate requirements but can also evolve with the organization, supported by regular management reviews that clarify context and the interactions with interested parties.
- Over-reliance on a single viewpoint can create bias, so the organization should take a cross-functional approach to achieve a balanced perspective.
- When monitoring is delegated to one person, that person should report to a broader group to avoid weak or incomplete oversight.
- The insights gained from determining, monitoring and reviewing issues should be actively shared and used, as the value of this process lies in its application (see [7.4](#)).

4.2 Understanding the needs and expectations of interested parties

The intent of this subclause is to ensure that the organization determines the relevant interested parties and their relevant requirements so that they are appropriately addressed in the QMS.

The acquired knowledge is used by the organization to determine:

- the scope of its QMS ([4.3](#));
- the processes required ([4.4](#));
- the risks and opportunities ([6.1](#));
- how to plan the QMS ([6.2](#)).

When determining the relevant interested parties, the organization should consider:

- the external and internal issues ([4.1](#)), to assist in identifying relevant interested parties;
- long- and short-term time horizons;
- the entire life cycle of the products and services, including the supply chain;
- changes over time in relevant interested parties;
- the sector, industry or geographic location in which it operates.

The organization can use criteria such as the interested parties' potential influence or impact on its performance or decisions, and on its products and services.

When determining the relevant requirements of these interested parties, the organization should consider:

- the interested party's importance; its potential benefit and alignment with its strategic direction;
- the cost versus the benefit of fulfilling an expectation;
- how requirements can change over time;