



SLOVENSKI STANDARD SIST ISO 18091:2019

01-oktober-2019

Nadomešča:
SIST ISO 18091:2014

Sistemi vodenja kakovosti - Smernice za uporabo standarda ISO 9001 v lokalni oblasti

Quality management systems - Guidelines for the application of ISO 9001 in local government

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Systèmes de management de la qualité - Lignes directrices pour l'application de l'ISO 9001 à la collectivité locale

[SIST ISO 18091:2019](https://standards.iteh.ai/catalog/standards/sist/27cd6ddc-a605-452e-b3a9-77d2103bddf3/sist-iso-18091-2019)

[https://standards.iteh.ai/catalog/standards/sist/27cd6ddc-a605-452e-b3a9-](https://standards.iteh.ai/catalog/standards/sist/27cd6ddc-a605-452e-b3a9-77d2103bddf3/sist-iso-18091-2019)

[77d2103bddf3/sist-iso-18091-2019](https://standards.iteh.ai/catalog/standards/sist/27cd6ddc-a605-452e-b3a9-77d2103bddf3/sist-iso-18091-2019)

Ta slovenski standard je istoveten z: ISO 18091:2019

ICS:

03.100.70	Sistemi vodenja	Management systems
03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
03.160	Pravo. Uprava	Law. Administration

SIST ISO 18091:2019

en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST ISO 18091:2019

<https://standards.iteh.ai/catalog/standards/sist/27cd6ddc-a605-452e-b3a9-77d2103bddf3/sist-iso-18091-2019>

INTERNATIONAL
STANDARD

ISO
18091

Second edition
2019-03

**Quality management systems —
Guidelines for the application of ISO
9001 in local government**

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST ISO 18091:2019](https://standards.iteh.ai/catalog/standards/sist/27cd6ddc-a605-452e-b3a9-77d2103bddf3/sist-iso-18091-2019)

<https://standards.iteh.ai/catalog/standards/sist/27cd6ddc-a605-452e-b3a9-77d2103bddf3/sist-iso-18091-2019>



Reference number
ISO 18091:2019(E)

© ISO 2019

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST ISO 18091:2019

<https://standards.iteh.ai/catalog/standards/sist/27cd6ddc-a605-452e-b3a9-77d2103bddf3/sist-iso-18091-2019>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

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.....	2
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.....	6
4.4 Quality management system and its processes.....	7
5 Leadership.....	8
5.1 Leadership and commitment.....	8
5.1.1 General.....	8
5.1.2 Customer focus.....	9
5.2 Policy.....	10
5.2.1 Establishing the quality policy.....	10
5.2.2 Communicating the quality policy.....	11
5.3 Organizational roles, responsibilities and authorities.....	11
6 Planning.....	12
6.1 Actions to address risks and opportunities.....	12
6.2 Quality objectives and planning to achieve them.....	13
6.3 Planning of changes.....	15
7 Support.....	16
7.1 Resources.....	16
7.1.1 General.....	16
7.1.2 People.....	16
7.1.3 Infrastructure.....	17
7.1.4 Environment for the operation of processes.....	17
7.1.5 Monitoring and measuring resources.....	18
7.1.6 Organizational knowledge.....	19
7.2 Competence.....	20
7.3 Awareness.....	21
7.4 Communication.....	21
7.5 Documented information.....	22
7.5.1 General.....	22
7.5.2 Creating and updating.....	23
7.5.3 Control of documented information.....	23
8 Operation.....	25
8.1 Operational planning and control.....	25
8.2 Requirements for products and services.....	26
8.2.1 Customer communication.....	26
8.2.2 Determining the requirements related to products and services.....	26
8.2.3 Review of the requirements related to products and services.....	27
8.2.4 Changes to requirements for products and services.....	28
8.3 Design and development of products and services.....	28
8.3.1 General.....	28
8.3.2 Design and development planning.....	29
8.3.3 Design and development inputs.....	30
8.3.4 Design and development controls.....	31
8.3.5 Design and development outputs.....	32
8.3.6 Design and development changes.....	33

ISO 18091:2019(E)

8.4	Control of externally provided processes, products and services.....	34
8.4.1	General.....	34
8.4.2	Type and extent of control.....	35
8.4.3	Information for external providers.....	35
8.5	Production and service provision.....	36
8.5.1	Control of production and service provision.....	36
8.5.2	Identification and traceability.....	37
8.5.3	Property belonging to customers or external providers.....	38
8.5.4	Preservation.....	39
8.5.5	Post-delivery activities.....	40
8.5.6	Control of changes.....	40
8.6	Release of products and services.....	41
8.7	Control of nonconforming outputs.....	42
9	Performance evaluation.....	43
9.1	Monitoring, measurement, analysis and evaluation.....	43
9.1.1	General.....	43
9.1.2	Customer satisfaction.....	43
9.1.3	Analysis and evaluation.....	44
9.2	Internal audit.....	45
9.3	Management review.....	47
9.3.1	General.....	47
9.3.2	Management review inputs.....	48
9.3.3	Management review outputs.....	49
10	Improvement.....	50
10.1	General.....	50
10.2	Nonconformity and corrective action.....	51
10.3	Continual improvement.....	52
Annex A (informative)	Local government assessment tool for integral quality management.....	53
Annex B (informative)	Processes for integral quality management.....	66
Annex C (informative)	Integral citizen observatories.....	68
Annex D (informative)	Relationship between the UN Sustainable Development Goals and other measurement and management systems with this document.....	69
Bibliography		73

iTech STANDARD PREVIEW

(standards.itech.ai)

SIST ISO 18091:2019
<https://standards.itech.ai/catalog/standards/sist/27cd6ddc-a605-452e-b3a9-7d21036d05/sist-iso-18091-2019>

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 176, *Quality management and quality assurance*.

This second edition cancels and replaces the first edition (ISO 18091:2014), which has been technically revised. The main changes compared with the previous edition are:

- the guidelines for ISO 9001:2015 have been updated;
- the structure has been changed to the ISO high level structure for management system standards;
- [Annexes A](#) and [B](#) have been switched;
- [Annex A](#) has been updated, including adding references to the United Nations Sustainable Development Goals;
- a description of citizen observatories has been added in a new [Annex C](#);
- an example how to use this document with other local government assessment systems has been added in a new [Annex D](#).

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 18091:2019(E)

Introduction

0.1 General

One of the great challenges that societies face today is the need to develop and maintain citizens' confidence in their governments and their institutions. In meeting this challenge, local governments have a mission to enable the development of a socially responsible and sustainable local community.

Achieving and maintaining a high-level of quality in how local governments operate can result in sustainable economic prosperity and social development at local levels. This includes interacting with national and regional policies in coherent, consistent and compatible ways.

Citizens expect local government to provide high-quality public products and services such as safety and security, well-maintained roads, public transportation, efficient processing of documents, transparency and accessibility of public information, health, education and infrastructure, among others. Citizens want local government to represent them and to protect or enhance their way of life.

It is possible to build stronger, more reliable and effective public policy networks at national, regional and international levels if local governments adopt quality management systems with the aim to improve their public products and services.

Improving the performance of local government can stimulate the whole system of government to provide better results overall. Applying a coherent approach across government can help to create reliable and sustainable governments at local, regional and national levels.

This document provides guidelines for local governments on understanding and implementing a quality management system that meets the requirements of ISO 9001:2015 and the needs and expectations of their citizens and other relevant interested parties.

A principle of this document is to help to make politically viable what is technically essential in local governments and their territories (see [Annex A](#)). This can be achieved by establishing links between government, citizens and governors (from the bottom to the top, see [Annex C](#)) and by facing the needs of the customers/citizens in an integral manner (see [Annex B](#)).

[Annex A](#) gives a diagnostic model that can be used as a starting point for implementing a comprehensive quality management system for reliable local government. The International Foundation for Reliable Local Governments (FIDEGOC) has the rights of these principles and share them for use in this document. [Annex B](#) provides information about typical local government processes. [Annex C](#) describes the creation of an integral citizen observatory that uses this document as a tool for citizen participation and for accountability of local government. [Annex D](#) describes how this document can help to translate different assessment systems, contents or subject matters, e.g. the United Nations Sustainable Development Goals (UN SDGs), into the indicators of public policy networks found in the diagnostic model given in [Annex A](#).

The relative stages of implementing the quality management system and the role of this document are shown in [Figure 1](#).

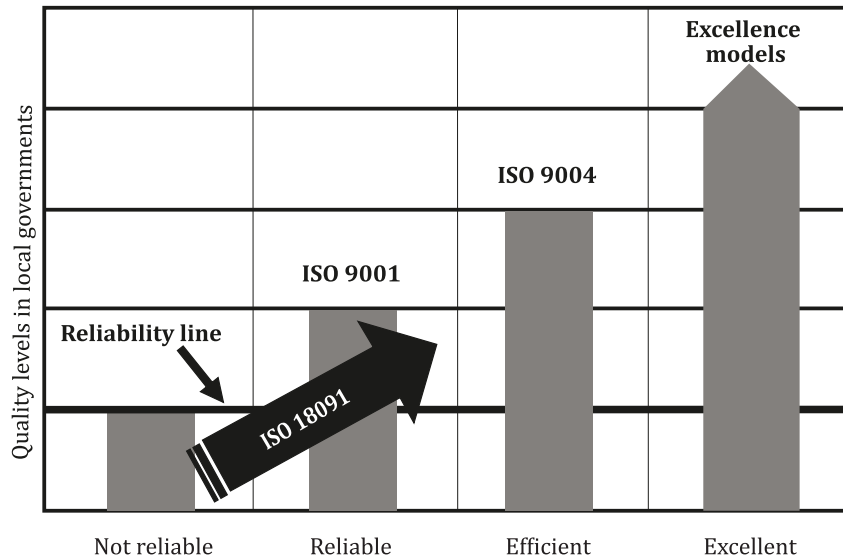


Figure 1 — Diagram showing the role of this document

In this document, the text reproduced from ISO 9001:2015 is placed in boxes to distinguish it from guidance given for each clause.

NOTE 1 Local governments seeking to improve themselves could consider the use of an excellence model to further develop the maturity of the organization and the level of its performance. Well-known excellence models include the European model for quality management (EFQM), the Malcolm Baldrige model for excellence in United States, The Deming Prize in Japan, and a number of national excellence award models used in different countries or regions. These excellence models aim to improve the satisfaction of all relevant interested parties and the sustainable development of the organization. Further information about these excellence models is available from the websites of the organizations representing the models.

NOTE 2 More examples of how the annexes can be used can be found at www.iso18091.org.

ISO 9001:2015, *Quality management systems — Requirements*

Introduction

0.1 General

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

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

- a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;
- b) facilitating opportunities to enhance customer satisfaction;
- c) addressing risks and opportunities associated with its context and objectives;
- d) the ability to demonstrate conformity to specified quality management system requirements.

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

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

- uniformity in the structure of different quality management systems;
- alignment of documentation to the clause structure of this International Standard;
- the use of the specific terminology of this International Standard within the organization.

ISO 18091:2019(E)

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

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

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

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

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

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

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

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

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

The guidelines in this document are intended to help local governments relate the concepts of quality management, as described in ISO 9000, ISO 9001, ISO 9004 and associated standards, with the practice and terminology commonly deployed in the context of local government.

NOTE 3 The use of the terms and definitions presented in these guidelines can vary according to the culture, practices and customs of each location and region in which the local government is located.

It is expected that a development plan or work programme in the short- or medium-term is received, understood and applied by the public servants and representatives of local government. However, the plan or programme itself does not ensure that the needs and expectations of the local community will be covered, as the processes needed for the effective implementation of such plans or programmes could be deficient or non-existent. To counter this problem, this document has been developed to help local governments to implement an effective quality management system.

Any quality management system will be influenced by the different policies, objectives, diverse work methods, resource availability and administrative practices that are specific for the context. Therefore, it can be expected that the details of each quality management system will vary in each local government. A detailed method of implementation of the quality management system is not what is important. What matters is that the quality management system yields effective, consistent and reliable results. It is important that the quality management system is as simple as possible in order to function properly, and that it is sufficiently understandable to meet the policies and quality objectives of the particular local government.

It is not intended that conformity to ISO 9001 be regarded as a final objective. Once a local government has achieved a level that allows it to provide consistent and conforming products and services to the local community, it is important that it looks beyond conformance to requirements, and that it considers using ISO 9004 and/or other excellence models to improve its overall effectiveness and efficiency.

According to ISO 9000, for an organization to be successful, it needs to be guided and controlled in a systematic and transparent way. This is particularly true for local government, where transparency and accountability to its customers/citizens are vital to gain their trust and confidence. Sustainable success will only result from the implementation of a comprehensive quality management system that addresses the needs and expectations of all interested parties.

It is, therefore, important that the quality management system of a reliable and successful local government covers all activities and processes that can affect its ability to satisfy the requirements of its customers/citizens, the statutory and regulatory requirements and compliance commitments applicable to the products and services, and the local government's own requirements, as well as all other relevant interested parties, such as regional or national governments.

0.2 Quality management principles

ISO 9001:2015, *Quality management systems — Requirements*

0.2 Quality management principles

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

The quality management principles are:

- customer focus;
- leadership;
- engagement of people;
- process approach;
- improvement;
- evidence-based decision making;
- relationship management.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

This document supports the application to local government of the seven quality management principles from ISO 9000.

The relevance of the seven quality management principles to local government are as follows.

- Customer/citizen focus: Local government exists to serve its customers, i.e. its citizens. Therefore, the needs and expectations of citizens should be of priority in the plans and programmes of the local government.
- Leadership: Top management is the head of local government and should create a vision and provide direction to all concerned (e.g. public servants and volunteers) to achieve goals and targets that meet the needs and expectations of the customers/citizens.
- Engagement of people: All people should be involved in local government processes, including voluntary participation and citizens taking part in the activities of local government. Engaged people are fully committed and emotionally attached to the organization, its goals and objectives. They work enthusiastically and take pride in their work. This principle envisages ensuring a high level of motivation on an ongoing basis.
- Process approach: The logical framework and the approach to results in a local government should be based on processes that describe elements such as its vision and long-term plans, and even the daily activities of local government areas.
- Improvement: It is essential for local government to maintain its performance and search for new opportunities to improve its processes and enhance the satisfaction of its customers/citizens.
- Evidence-based decision making: Use of evidence and data analysis should provide the base for improving the quality management system and its processes.
- Relationship management: Local government should pay attention to how it relates to customers/citizens, external providers and partners, and to its horizontal and vertical relationships.

ISO 18091:2019(E)

0.3 Process approach

0.3.1 General

ISO 9001:2015, *Quality management systems — Requirements*

0.3 Process approach

0.3.1 General

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

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

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

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

- 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.

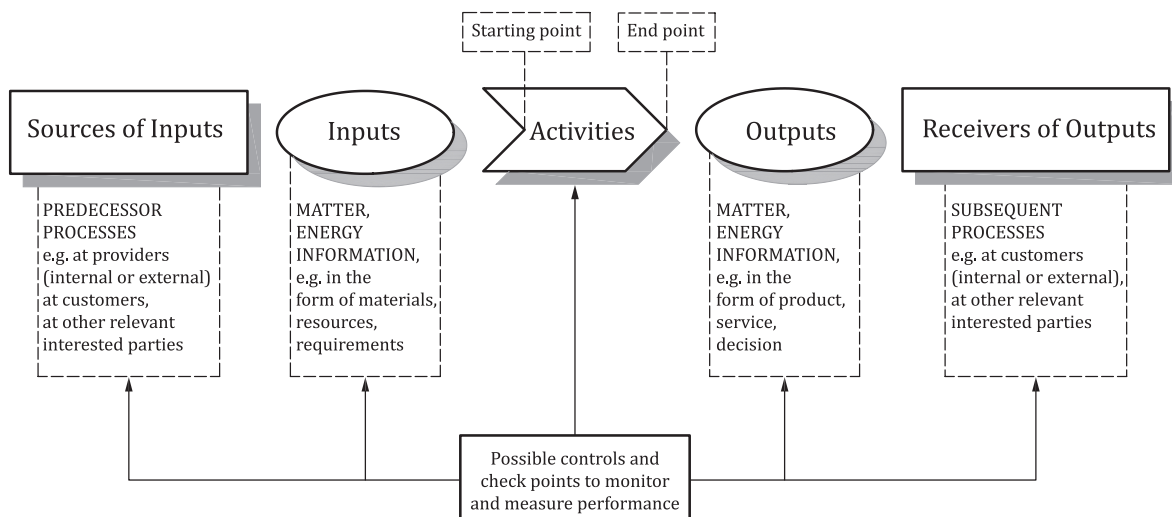


Figure 1 — Schematic representation of the elements of a single process

For local governments to be able to adopt a process approach, it is important to recognize the different types of processes that are needed to provide reliable products and service to customers/citizens, as well as their management capacity to produce the desired outputs. These include processes for management of the organization, operational processes and support processes (see Annex B). The processes needed to provide the local government's products and service are the core of the operational processes.

Typical examples of local government processes are:

- strategic management processes to determine the local government's role in the socio-economic environment;
- provision of products and services to customers/citizens;
- improvement of quality management system processes;
- transparent internal and external communication processes.

For each process, the local government should identify the following.

- Who is the customer? (Who receives the output from the process?) This might be an internal customer, within another area of the same local government, or an external customer such as a citizen who is receiving a product or service.
- What are the main inputs to the process? (For example, information, legal requirements, national and/or regional government policies, materials, energy, human and financial resources.)
- What are the desired outputs? (For example, what are the characteristics of the product/service to be provided?)
- What controls and indicators are needed to verify the process performance and/or results?
- What is the interaction with other local government processes? (Outputs from one process typically form inputs into other processes.)
- What controls are necessary to have transparency?

ITEH STANDARD PREVIEW
(standards.iteh.ai)
[SIST ISO 18091:2019](https://standards.iteh.ai/catalog/standards/sist/27cd6ddc-a605-452e-b3a9-77d2103bddf3/sist-iso-18091-2019)
<https://standards.iteh.ai/catalog/standards/sist/27cd6ddc-a605-452e-b3a9-77d2103bddf3/sist-iso-18091-2019>

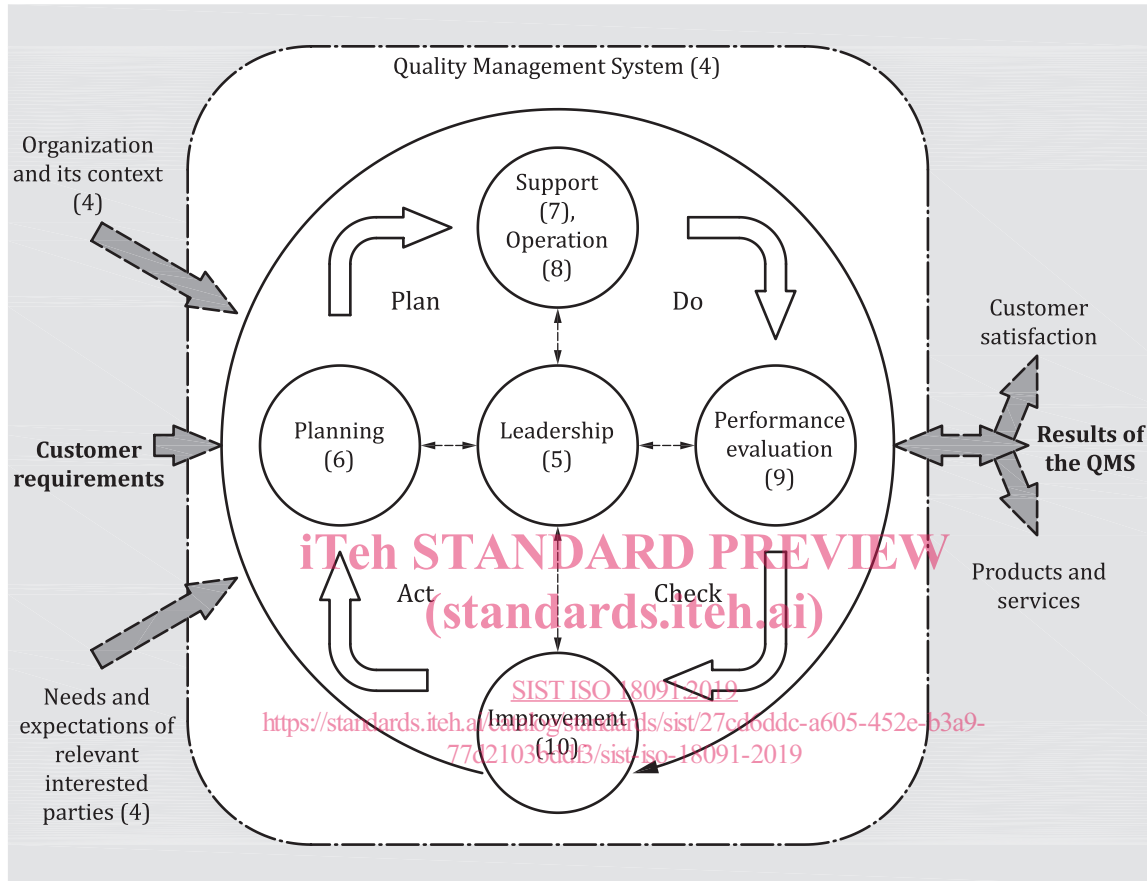
ISO 18091:2019(E)

0.3.2 Plan-Do-Check-Act cycle

ISO 9001:2015, *Quality management systems — Requirements*

0.3.2 Plan-Do-Check-Act cycle

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



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

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

The PDCA cycle can be briefly described as follows:

- Plan: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;
- Do: implement what was planned;
- Check: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;
- Act: take actions to improve performance, as necessary.

The PDCA cycle enables the top management of the local government to develop a systematic method of assessing the external and internal environment and to implement the necessary processes for the improvement of the products and services provided to its customers/citizens. The PDCA cycle can be initiated at any stage, but usually a local government that implements a quality management system for the first time or is in the process of upgrading its system can initiate the process by assessing its current performance (the Check stage) using the requirements of [Clause 9](#), "Performance evaluation". The results of performance evaluation are fed into the PDCA cycle's Act stage (see [Clause 10](#), "Improvement") where

the local government initiates the necessary actions to address the opportunities for improvement identified at the Check stage.

At the Plan stage of the PDCA cycle, the local authority not only plans the actions agreed at the previous stage, but, most importantly, it develops, by assessing the needs and expectations of its customers/citizens and its other relevant interested parties, the necessary objectives, targets and actions to address the risks and opportunities identified as per [Clause 6](#), “Planning”. At the PDCA cycle’s Do stage, the objectives and actions planned are communicated throughout the local government. New processes or changes to existing processes are implemented to ensure that agreed objectives are met.

The local government should use the PDCA cycle, with its overall focus on risk-based thinking, to design its quality management system, its processes and their interactions, in order to identify each of the necessary activities to maintain its quality level, to achieve continual improvement, to take advantage of opportunities and to prevent undesirable results. The local government should make short-, medium- and long-term plans using the PDCA cycle.

0.3.3 Risk-based thinking

ISO 9001:2015, *Quality management systems — Requirements*

0.3.3 Risk-based thinking

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

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

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

In local government, any changes in the operational environment, such as changes in policies, regulations and the expectations of relevant interested parties, can be a source of uncertainty and can lead to a deviation of performance.

Risk-based thinking is not new and can be inherent in the way the local government already operates. This document recommends that the identification of risks and opportunities is performed systematically and as part of an integral process.

The local government should address the risks and opportunities associated with its processes, for example, the provision of products and services and the performance of the quality management system. At the same time, risk and opportunities will be identified as a result of the strategic direction of the local government’s role in the socio-economic environment.

One of the most recurring risks in a local government is not being able to access the resources offered by other levels of government. One way to mitigate this risk is to identify alternative forms of financing.

Openness to citizen participation through integral citizen observatories (ICOs) can be an opportunity to develop the organization of local government and to improve its products, services and processes. However, it could also constitute a risk if citizen participation, instead of promoting the improvement of products and activities, becomes the institutionalization of complaints.