



SLOVENSKI STANDARD

oSIST ISO/DIS 10009:2023

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Vodenje kakovosti - Napotki za orodja za kakovost in njihovo uporabo

Quality management - Guidance for quality tools and their application

iTeh STANDARD PREVIEW

Management de la qualité - Lignes directrices pour des instruments et techniques
qualités pour l'ISO 9001

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Quality management — Guidance for quality tools and their application

Management de la qualité — Lignes directrices pour des instruments et techniques qualités pour 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).

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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 SC3.

This DIS edition cancels and replaces the CD2 which has been technically revised.

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.

Introduction

Organisations that maintain a quality management system want it to deliver value and implementing a quality management system should be a strategic decision for an organization.

Depending on the organisation's area of activity, value can be measured in metrics such as:

- Reduction in complaints
- Reduction in waste
- Improved turn-around times
- Improved delivery times
- Improved responsiveness
- Better staff retention
- Greater confidence in regulatory compliance
- Increase in sales and profitability

It is therefore important to any organisation not only to have an effective quality management system but one that may be seen through internal and external metrics to be a system with associated improving and stable metrics.

Most organisations are already using quality tools. Many areas of manufacturing already use statistical quality tools for process control and early warnings of when these processes become less stable. This standard is intended to be a companion standard to ISO 10017: Quality Systems: Use of Statistics. However, ISO 10009 also covers some simple statistical techniques that are not covered in detail in 10017.

In this document, the term quality tool is defined and it is essentially synonymous with a quality technique. The simplest quality tools are encountered at school so many are well known before completing formal education. Other quality tools are used by certain industries, the public sector or in specific cultural contexts. This standard aims to catalogue quality tools in general use somewhere in the world.

No proprietary quality tools have been included and all tools are used by more than one organisation. This standard is not promoting any novel quality tools which have not been accepted by the wider quality community.

The standard aims to familiarise quality practitioners with what could be called "the tool-box" of quality tools. It is intended as a reference on quality tools which may be used in a number of contexts. Some quality tools are the subject of commercially available training and certification. The aim of this standard is not to explain in detail how each quality tool works; this knowledge may be gained from various publications and training courses (references at the end of the standard may assist). One of the key concepts is the appropriate use of quality tools; this standard aims to enable users to better select quality tools that are suited for the task that they have in mind. Some of these tools may also be appropriate for use in other contexts and the reader is encouraged to consider their wider application.

Quality management — Guidance for quality tools and their application

1 Scope

This document identifies tools that may be used in a quality management system to:

- a) Characterize a process or a variable
- b) Facilitate problem solving
- c) Highlight areas for improvement
- d) Improve effectiveness

Guidance on their selection and application is provided with the aim of providing a resource to practitioners and promoting the appropriate use of quality tools.

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*

ISO 9001, *Quality management systems — Requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, *Quality Management Systems – Fundamentals and vocabulary* 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 <https://www.electropedia.org/>

3.1

quality tool

method or *procedure* (3.2) to perform an operation to achieve a *quality objective* (3.3)

3.2

procedure

specified way to carry out an activity or a *process* (3.4)

[SOURCE: ISO 9000:2015, 3.4.5]

3.3

quality objective

objective (3.5) related to *quality* (3.6)

[SOURCE: ISO 9000:2015, 3.7.2]

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3.4

process

set of interrelated or interacting activities that use inputs to deliver an intended result

[SOURCE: ISO 9000:2015, 3.4.1]

3.5

objective

result to be achieved

[SOURCE: ISO 9000:2015, 3.7.1]

3.6

quality

degree to which a set of inherent *characteristics* (3.7) of an *object* (3.8) fulfils *requirements* (3.9)

[SOURCE: ISO 9000:2015, 3.6.2]

3.7

characteristic

distinguishing feature

[SOURCE: ISO 9000:2015, 3.10.1]

3.8

object

anything perceivable or conceivable

[SOURCE: ISO 9000:2015, 3.6.1]

3.9

requirement

need or expectation that is stated, generally implied or obligatory

[SOURCE: ISO 9000:2015, 3.6.4]

4 Quality tools

4.1 General

The quality tools given in this standard have been arranged in approximate alignment with the sequence of the quality system requirements of ISO 9001. This structure is intended to assist user access and does not imply priority. A listing of the tools in relation to the PDCA (Plan-Do-Check-Act) approach is provided in [Annex A](#).

[Annex B](#) provides a quick reference tool for guiding appropriate application

[Annex C](#) gives examples of how quality tools are used in combination as storyboards

4.2 Review

Each quality tool is reviewed as follows:

- Short explanation of the tool and its context in its use within a quality system.
- How the quality tools are normally used.
- Reasons to use the quality tool and guidance on effective use..

5 Strategy

5.1 Strengths, Weaknesses, Opportunities and Threats (SWOT) Analysis

SWOT analysis is a tool designed to help develop strong business strategy by consideration of key strengths, weaknesses, opportunities and threats faced when implementing the intended strategy.

SWOT is used:

- To review the impact of external and internal factors;
- To prioritize action;
- To help identify strategic options: risks and problems to solve;
- To determine the positive points that need to be maintained. The opportunities that should be exploited and the internal and external issues that present challenges.
- To identify areas and actions to eliminate weakness

SWOT analysis is used to:

- Explore new solutions to problems;
- Identify barriers that will limit achieving objectives;
- Decide on the direction that will be most effective;
- Reveal possibilities and limitations for change; and
- To prioritize actions.

BENEFITS	POINTS TO NOTE
Focuses on actions that are most beneficial to achieve strategic objectives and sustainability	Should be reviewed frequently enough to recognise and react to changes.
Responds to new influences such as technology, legislation, market demand etc.	Output needs to be used as basis of future actions
External review includes interested parties such as competitors, customers etc.	Needs to recognise any limitations in data quality to avoid misrepresentation .
SWOT analyses benefits from the diversity of perspectives. Management alone will not have visibility of all interested parties' perspectives.	Must be carried out by the leadership team with external inputs as appropriate (not a single person).

5.2 Political, Economic, Social, Technological, Legal and Environmental (PESTLE) Analysis

PESTLE analysis, is a tool used by organizations to determine and track the environment in which it operates. PESTLE is an acronym for Political, Economic, Social, Technological, Legal and Environmental factors. It is often used in strategic planning (possibly with SWOT and Porter's 6 Forces).

PESTLE Analysis is used:

- When developing, reviewing and updating an organisation's strategic business plan;
- As a precursor to determining an organization's strategic and risks and opportunities.
- To capture relevant external issues that impact on the organisation's strategy.

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BENEFITS	POINTS TO NOTE
Uses a structured approach.	Users may wish to adjust the names of some of the PESTLE factors and/or add other factors that are particularly relevant to its context.
Forces Organisations to address factors they might not otherwise consider.	Users must update periodically to reflect incidents such as pandemic, epidemic, military situations etc.

5.3 Porter's Five or Six Forces

Harvard Professor Michael Porter developed a strategic analysis tool and also a method to understand the competing forces that organisations are facing.

These were originally the five competing forces but a sixth has been added as follows:

1. Threat of new entrants
2. Rivalry among existing firms
3. Bargaining power of Buyers
4. Threat of substitute product or services
5. Bargaining power of Suppliers
6. Complementors

Porter says "the collective strength of these forces determines the ultimate profit potential in the industry where profit potential is measured in terms of long run return on invested capital".

A useful consideration is that in performing the strategic analysis and understanding these competing forces is that the organisation needs to obtain the support, resources, technologies and infrastructure to be able to support such strategic activities. The importance of some competing forces may restrict opportunities such as growth or increased margins.

Porters Five (or six) forces model is used for analysing context to support developing strategic objectives.

BENEFITS	POINTS TO NOTE
The six competing forces can provide both risk and opportunity considerations.	Actions need to be determined based on data gathered from reliable sources.
Often provides a fresh approach to strategy	Can be used to assess the attractiveness of the industry or sector.

5.4 Vision and Mission Statements

Definitions:

Vision: A vision is the aspiration of what an organisation would like to become as expressed by top management. It describes in words or perhaps visually, how the organization wants to be perceived by the world. It can also communicate the message to the people working within it and those wanting to join it.

A Vision Statement should be underpinned by management team agreement on three key things:

- a. The Strategic Goal of satisfying customers and other stakeholders - i.e., what are the planned products, now and in the future and how they will be delivered.
- b. The unique market it wants to secure

- c. The future Horizon – e.g., the future state or end point

Mission: A Mission is a reason for the organization's being or existence as expressed by top management – it's what it does, its core competence, what it's known for. It is sometimes called a purpose.

A Mission Statement:

Clearly demonstrates ownership, credibility and sensible, achievable wording,;

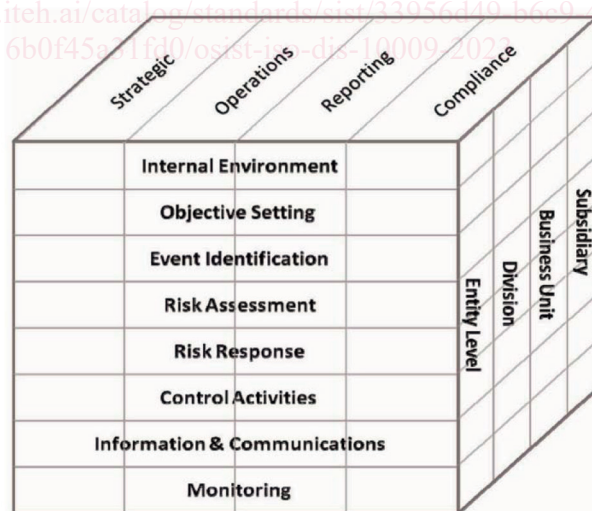
- Gives unanimity of purpose to the organization;
- Provides a basis to derive Goals and Objectives;
- Provides answers to the question: "Does this activity contribute to the organisations purpose?"

Vision and Mission are used to communicate effectively at the highest level with customers, employees and other stakeholders.

Benefits	Points to note
Provides common goals to guide all planning and direction activities	
Frames the values, beliefs, principles and governance disciplines and behaviours	
Provides a basis for distilling a complex strategy to a "Plan-on-a-Page"	

5.5 Other relevant resources

- Context of the Organisation (COTO) Diagram / Matrix / Log
- Context of the Organisation (COSO) Diagram / Matrix



6 Process Approach and Planning

6.1 SIPOC / COPIS (useful for identifying processes).

SIPOC (Supplier, Input, Process, Output, Customer) is a process mapping tool that is useful in high-level identification of main elements of any process. COPIS is the process in reverse and useful for identifying "Customer Facing Processes". It may be used to obtain high-level information about any process and to identify inputs and outputs between suppliers, process owners and customers. It is a tool used for understanding the bounds of a process and the linked processes, related controls and how effectiveness is managed.

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SIPOC is used for:

- Mapping of an existing or a new process
- Providing basic information regarding a process in a simple and short format
- Defining the scope of an improvement activity or project

BENEFITS	POINTS TO NOTE
Simple to use and understand	Avoid going into too much detail (4 – 5 key steps of the process should be identified)
Delivers results quickly	Best completed by a team, so there is a common agreement on the start and the end of the process being analysed
Provides an overview a whole process from the beginning to the end on one page	Suppliers and customers can be internal
	SIPOC can be hierarchical

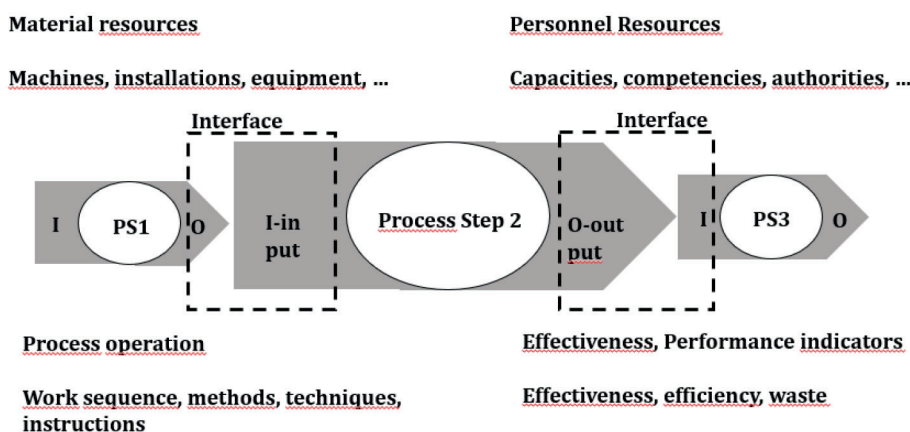
6.2 Turtle diagrams

A turtle diagram is a tool for visualizing the components or characteristics of a process. The use of a turtle diagram provides the opportunity to more closely examine a process to enable its better understanding, more effective process execution and the identification of areas for improvement. The diagram looks like a turtle, with the process components as the body, legs, head, and tail.

A turtle diagram is used:

- To describe the basic elements of a process for communication and understanding;
- To develop more detailed procedures and process flow diagrams (flowcharts);
- To help quality auditors to understand and effectively interrogate processes and

BENEFITS	POINTS TO NOTE
Uses visual and standardised methods which are easy to understand.	The turtle diagram does not necessarily document all of the information necessary to fully describe a process, but provides a good starting point.
Provides a complete view of the most important elements of a process on a single page	
Aligns process performance to higher level business strategy and objective(s)	



6.3 Control plans

A control plan provides a structured approach to determining the controls applied to a processes. Each process is listed in sequential order, typically aided by the use of a process flow diagram. Product and process criteria to be controlled are identified at each stage including special characteristics, typically using a process Failure Mode Effect Analysis (FMEA) as an input. Controls are identified with methods of measurement, frequency, method of recording results and the reaction plan to be invoked in the event that the product or process criteria do not conform with requirements.

The objective of a control plan is to provide concise and useable information to users and minimize process and product variation.

Control plans are used:

- Within manufacturing and service industries;
- Where there are processes where the conformity of the resultant output cannot be verified through inspection and testing and defects would only become apparent at a later time,;
- Where needed for process approval on the pre-launch and production phase, with linkage and information from the design risk analysis (as necessary)
- Where process/product monitoring is required to determine process capability or to assess conformity to requirements.

BENEFITS	POINTS TO NOTE
Provides a clear and structured approach to product and process control	Product and process characteristics must be unambiguously defined.
Assists in effective auditing.	Process flows, FMEA and control plans should be reviewed and updated when non-conformities occur
Helps drive conformity in “special processes”	The control plan does not replace work instructions which provide greater detail of the manufacturing process

6.4 Flow Charts / Swim Lane Diagrams / Cross-functional Flow Chart

Flowcharts provide a quick, visual way to show how a series of activities, tasks or processes are sequenced. Swim lane diagrams add the responsibilities for activities shown on a simple flow chart.

ISO 5807:1985 clause 3.3 defines a flowchart as a graphical representation of the definition, analysis, or method of solution of a problem in which symbols are used to represent operations, data, flow, equipment, etc.

In practice, they comprise symbols, text and connecting lines.

How to use

- As a starting point in documenting activities
- To communicate how activities are carried out
- To identify inefficiencies, and allow for analysis and improvement

BENEFITS	POINTS TO NOTE
Visual	The direction of flow is mainly left to right, and top to bottom
Can be quick to develop (depends on the complexity of the activities under consideration)	Arrows indicating the flow should be used whenever increased clarity will result