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SLOVENSKI STANDARD
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Sistemi vodenja kakovosti - Osnove in slovar (ISO/DIS 9000:2014)

Quality management systems - Fundamentals and vocabulary (ISO/DIS 9000:2014)

Qualitätsmanagementsysteme - Grundlagen und Begriffe (ISO/DIS 9000:2014)

Systèmes de management de la qualité - Principes essentiels et vocabulaire (ISO/DIS 9000:2014)

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Quality management systems — Fundamentals and vocabulary

Systèmes de management de la qualité — Principes essentiels et vocabulaire

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ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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39 # Foreword

40 ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies
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49 International Standard requires approval by at least 75 % of the member bodies casting a vote.

50 Attention is drawn to the possibility that some of the elements of this document may be the subject of patent
51 rights. ISO shall not be held responsible for identifying any or all such patent rights.

52 ISO 9000 was prepared by Technical Committee ISO/TC 176, *TC Quality management and quality*
53 *assurance*, Subcommittee SC 1, *SC Concepts and terminology*.

54 This fourth edition cancels and replaces the third edition (ISO 9000:2005).

55

56 **Introduction**

57 This International Standard provides the fundamentals and terminology of quality management systems. It is
58 the foundation of other ISO quality management system standards and serves as the normative reference for
59 many of them. It will help the user to understand the principles, systems model and terminology of quality
60 management in order to more effectively and efficiently implement a quality management system and realize
61 value from other ISO quality management system standards.

62 This management standard for quality makes the case for a well-defined quality management system based
63 on a framework that integrates established quality fundamental concepts, principles, processes and resources
64 to help organizations realize their goals Its aim is to make top management aware of their duties and
65 commitment in achieving their customers and stakeholders needs, expectations and satisfaction with their
66 products and services.

67 The terms and definitions are arranged in conceptual order according to ISO/IEC Directives. Annex A
68 provides information on how this works, including the set of diagrams of the concept systems that form the
69 concept ordering. An alphabetical list is provided at the end of the document to aid location of entries.

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Quality management systems — Fundamentals and vocabulary

1 Scope

This International Standard describes the fundamental concepts, principles and vocabulary of quality management, and defines related terms, which are universally applicable to the following:

— organizations seeking sustained success through the implementation of quality and other management systems;

— customers seeking confidence in organization's ability to provide satisfactory products;

— organizations seeking confidence in their supply chain that their product requirements will be met;

— those interested parties seeking to improve communication through a common understanding of the terminology used in quality management;

— organizations performing conformity assessments against the requirements of ISO 9001;

— those providing training in quality management;

— developers of related standards.

2 Quality management principles and fundamental concepts

2.1 General

The quality management concepts and principles described in this standard give management the capacity to meet challenges presented by an environment that is profoundly different from that of just a few decades ago. The context in which the 21st century organisation works is characterised by accelerated change, globalisation of markets, limited resources, and the emergence of knowledge as a principal resource. Society has become better educated and more demanding, making interested parties increasingly more powerful. This clause provides a way of thinking about the organisation more broadly, by providing fundamental concepts and principles to be used in the development of a Quality Management System.

2.2 Fundamental concepts

2.2.1 Quality

Quality focused organizations embrace a culture that inspires and drives behaviour, attitude, actions and processes in order to deliver value through fulfilling the requirements of interested parties.

The quality of an organization's products and services is determined by not only the ability to satisfy a particular customer but also the intended and unintended impact on other interested parties.

The quality of products and services include not only their intended function, but also their perceived value and benefit to the customer.

2.2.2 Quality management system

Quality management systems manage the interacting processes, sub-systems, procedures, and resources required to:

• provide value to all relevant interested parties, and

• realize the outputs, outcomes, or results of the whole organization

Anticipating the impact of outcomes is essential in managing performance.

Quality management systems provide a means of managing the cost of quality. Awareness of these costs enables organizations to take action in order to optimise utilization of resources.

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108 **2.2.3 Interested parties**

109 Organizations learn from relevant interested parties to develop their purpose and thereby define what outputs,
110 outcomes, or results they need to deliver to those interested parties and to society in general.

111 Organizations attract, capture and retain the support of organizations and individuals they depend upon for
112 their success.

113 **2.2.4 Context of an organization**

114 An adaptable, open and agile organization understands its context through examination of internal and
115 external issues impacting its purpose and sustainability. In addition to financial performance, organizations
116 may take environmental and social responsibility into account. An organization's purpose is expressed
117 through statements such as an organization's Vision and mission, policies, and improvement objectives.

118 **2.2.5 Management Support**

119 Active engagement and management support for the quality management system enables:

120 • the provision of adequate human and other resources,
121 • monitoring processes and outcomes,
122 • identifying risks and opportunities, and
123 • taking appropriate and robust actions.

124 Responsible acquisition, deployment, maintenance and disposal of resources satisfy the organization's
125 objectives.

126 People are one of the most important resources of the organization. The performance of the organization is
127 dependent upon how people behave within the system in which they work. A quality management system is
128 more effective when management and individuals understand and develop the competence needed to
129 perform their roles and responsibilities.

130 **2.2.5.1 Awareness**

131 People within an organization should be aligned through a common understanding of the organization's
132 desired outcomes and how they are driven by the quality policy. Awareness is evident when individuals
133 understand how their role contributes to the achievement of an organization's objectives.

134 **2.2.5.2 Communication**

135 Effective communication throughout the organization and relevant interested parties enhances involvement
136 through better understanding of:

137 • the management system and its performance, and
138 • organizational values, objectives and strategies.

139 **2.3 Quality management principles**

140 **2.3.1 General**

141 The following seven quality management principles are derived from the fundamental concepts described in
142 Sub-clause 2.1 as principles of action.
143

144 **2.3.2   Customer focus**

145 **2.3.2.1 Statement**

146 The primary focus of quality management is to meet customer requirements and to strive to exceed customer
147 expectations.

148 **2.3.2.2 Rationale**

149 Sustained success is achieved when an organization attracts and retains the confidence of customers and
150 other interested parties. Every aspect of customer interaction provides an opportunity to create more value for
151 the customer. Understanding current and future needs of customers and other interested parties contributes to
152 sustained success of the organization.

153 **2.3.2.3 Key benefits**

154 Some key benefits are:
155 • Increased customer value;
156 • Increased customer satisfaction;
157 • Improved customer loyalty;
158 • Enhanced repeat business;
159 • Enhanced reputation of the organization;
160 • Expanded customer base;
161 • Increased revenue and market share.
162
163 **2.3.2.4 Actions you can take**

164 Some actions you can take are:
165 • Recognize direct and indirect customers as those who receive value from the organization.
166 • Understand customers' current and future needs and expectations.
167 • Link the organization's objectives to customer needs and expectations.
168 • Communicate customer needs and expectations throughout the organization.
169 • Plan, design, develop, produce, deliver and support goods and services to meet customer needs and
170   expectations.
171 • Measure and monitor customer satisfaction and take appropriate actions.
172 • Determine and take actions on interested parties' needs and expectations that can affect customer
173   satisfaction.
174 • Actively manage relationships with customers to achieve sustained success.
175
176 **2.3.3   Leadership**

177 **2.3.3.1 Statement**

178 Leaders at all levels establish unity of purpose and direction and create conditions in which people are
179 engaged in achieving the organization's quality objectives.

180 **2.3.3.2 Rationale**

181 Creation of unity of purpose and direction and engagement of people enable an organization to align its
182 strategies, policies, processes and resources to achieve its objectives.

183 **2.3.3.3 Key benefits**

184 Some key benefits are:
185 • Increased effectiveness and efficiency in meeting the organization's quality objectives;
186 • Better coordination of the organization's processes;

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187 • Improved communication between levels and functions of the organization;
188 • Development and improvement of the capability of the organization and its people to deliver desired results.
189

190 **2.3.3.4 Actions you can take**

191 Some actions you can take are:
192 • Communicate the organization's mission, vision, strategy, policies and processes throughout the
193   organization;
194 • Create and sustain shared values, fairness and ethical models for behavior at all levels of the organization;
195 • Establish a culture of trust and integrity;
196 • Encourage an organization-wide commitment to quality;
197 • Ensure that leaders at all levels are positive examples to people in the organization;
198 • Provide people with the required resources, training and authority to act with accountability;
199 • Inspire, encourage and recognize people's contribution.
200

201 **2.3.4   Engagement of people**

202 **2.3.4.1 Statement**

203 Competent, empowered and engaged people at all levels throughout the organization are essential to
204 enhance the organization's capability to create and deliver value.

205 **2.3.4.2 Rationale**

206 To manage an organization effectively and efficiently, it is important to involve all people at all levels and to
207 respect them as individuals. Recognition, empowerment and enhancement of competence facilitate the
208 engagement of people in achieving the organization's quality objectives.

209 **2.3.4.3 Key benefits**

210 Some key benefits are:
211 • Improved understanding of the organization's quality objectives by people in the organization and increased
212   motivation to achieve them;
213 • Enhanced involvement of people in improvement activities;
214 • Enhanced personal development, initiatives and creativity;
215 • Enhanced people satisfaction;
216 • Enhanced trust and collaboration throughout the organization;
217 • Increased attention to shared values and culture throughout the organization.
218

219 **2.3.4.4 Actions you can take**

220 Some actions you can take are:
221 • Communicate with people to promote understanding of the importance of their individual contribution;
222 • Promote collaboration throughout the organization;
223 • Facilitate open discussion and sharing of knowledge and experience;
224 • Empower people to determine constraints to performance and to take initiatives without fear;
225 • Recognize and acknowledge people's contribution, learning and improvement;
226 • Enable self-evaluation of performance against personal objectives;
227 • Conduct surveys to assess people's satisfaction, communicate the results, and take appropriate actions.
228

229 **2.3.5   Process approach**

230 **2.3.5.1 Statement**

231 Consistent and predictable results are achieved more effectively and efficiently when activities are understood
232 and managed as interrelated processes that function as a coherent system.

233 **2.3.5.2 Rationale**

234 The quality management system consists of interrelated processes. Understanding how results are produced
235 by this system enables an organization to optimize the system and its performance.

236 **2.3.5.3 Key benefits**

237 Some key benefits are:
238 • Enhanced ability to focus effort on key processes and opportunities for improvement;
239 • Consistent and predictable outcomes through a system of aligned processes;
240 • Optimized performance through effective process management, efficient use of resources, and reduced
241   cross-functional barriers;
242 • Enabling the organization to provide confidence to interested parties as to its consistency, effectiveness and
243   efficiency.
244

245 **2.3.5.4 Actions you can take**

246 Some actions you can take are:
247 • Define objectives of the system and processes necessary to achieve them;
248 • Establish authority, responsibility and accountability for managing processes;
249 • Understand the organization's capabilities and determine resource constraints prior to action;
250 • Determine process interdependencies and analyze the effect of modifications to individual processes on the
251   system as a whole;
252 • Manage processes and their interrelations as a system to achieve the organization's quality objectives
253   effectively and efficiently;
254 • Ensure the necessary information is available to operate and improve the processes and to monitor,
255   analyze and evaluate the performance of the overall system;
256 • Manage risks which can affect outputs of the processes and overall outcomes of the quality management
257   system.
258

259 **2.3.6   Improvement**

260 **2.3.6.1 Statement**

261 Successful organizations have an ongoing focus on improvement.

262 **2.3.6.2 Rationale**

263 Improvement is essential for an organization to maintain current levels of performance, to react to changes in
264 its internal and external conditions and to create new opportunities.

265 **2.3.6.3 Key benefits**

266 Some key benefits are:
267 • Improved process performance, the organization's capabilities and customer satisfaction;
268 • Enhanced focus on root cause investigation and determination, followed by prevention and corrective
269   actions;
270 • Enhanced ability to anticipate and react to internal and external risks and opportunities;
271 • Enhanced consideration of both incremental and breakthrough improvement;

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272 • Improved use of learning for improvement;
273 • Enhanced drive for innovation.
274
275 **2.3.6.4 Actions you can take**

276 Some actions you can take are:
277 • Promote establishment of improvement objectives at all levels of the organization;
278 • Educate and train people at all levels on how to apply basic tools and methodologies to achieve
279 improvement objectives;
280 • Ensure people are competent to successfully promote and complete improvement projects;
281 • Develop and deploy processes to implement improvement projects throughout the organization;
282 • Track, review and audit the planning, implementation, completion and results of improvement projects;
283 • Integrate improvement consideration into development of new or modified goods and services and
284 processes;
285 • Recognize and acknowledge improvement.
286
287 **2.3.7   Evidence-based decision making**

288 **2.3.7.1 Statement**

289 Decisions based on the analysis and evaluation of data and information are more likely to produce desired
290 results.

291 **2.3.7.2 Rationale**

292 Decision-making can be a complex process, and it always involves some uncertainty. It often involves multiple
293 types and sources of inputs, as well as their interpretation, which can be subjective. It is important to
294 understand cause and effect relationships and potential unintended consequences. Facts, evidence and data
295 analysis lead to greater objectivity and confidence in decision making.

296 **2.3.7.3 Key benefits**

297 Some key benefits are:
298 • Improved decision making processes;
299 • Improved assessment of process performance and ability to achieve objectives;
300 • Improved operational effectiveness and efficiency;
301 • Increased ability to review, challenge and change opinions and decisions;
302 • Increased ability to demonstrate the effectiveness of past decisions.
303
304 **2.3.7.4   Actions you can take**

305 Some actions you can take are:
306 • Determine, measure and monitor key indicators to demonstrate the organization's performance;
307 • Make all data needed available to the relevant people;
308 • Ensure that data and information are sufficiently accurate, reliable and secure;
309 • Analyze and evaluate data and information using suitable methods;
310 • Ensure people are competent to analyze and evaluate data as needed;
311 • Make decisions and take actions based on evidence, balanced with experience and intuition.
312

313 ### 2.3.8   Relationship management

314 ### 2.3.8.1 Statement

315 For sustained success, organizations manage their relationships with interested parties, such as suppliers.

316 ### 2.3.8.2 Rationale

317 Interested parties influence the performance of an organization. Sustained success is more likely to be
318 achieved when the organization manages relationships with all of its interested parties to optimize their impact
319 on its performance. Relationship management with its supplier and partner networks is of particular
320 importance.

321 ### 2.3.8.3 Key benefits

322 Some key benefits are:
323 • Enhanced performance of the organization and its interested parties through responding to the opportunities
324   and constraints related to each interested party;
325 • Common understanding of goals and values among interested parties;
326 • Increased capability to create value for interested parties by sharing resources and competence and
327   managing quality related risks;
328 • A well-managed supply chain that provides a stable flow of goods and services.
329

330 ### 2.3.8.4 Actions you can take

331 Some actions you can take are:
332 • Determine relevant interested parties (such as suppliers, partners, customers, investors, employees, and
333   society as a whole) and their relationship with the organization;
334 • Determine and prioritize interested party relationships that need to be managed;
335 • Establish relationships that balance short-term gains with long-term considerations;
336 • Pool and share information, expertise and resources with relevant interested parties;
337 • Measure performance and provide performance feedback to interested parties, as appropriate, to enhance
338   improvement initiatives;
339 • Establish collaborative development and improvement activities with suppliers, partners and other
340   interested parties;
341 • Encourage and recognize improvements and achievements by suppliers and partners.
342

343 ## 2.4   Development of fundamentals into a QMS

344 ### 2.4.1   QMS model

345 Organisations share the characteristics of humans as a living and learning social organism.

346 ### 2.4.1.1 System

347 Humans use their senses to identify, engage with, understand, and adapt to their environment in order to
348 conduct their every-day activities and achieve fulfilment. Organisations also seek to understand their
349 environment and identify those whose needs and expectations that must be satisfied to achieve the
350 organisation's objective of sustained success. Although appearing the same and often comprising similar
351 sub-systems and processes, every organisation, like every human being, is unique.