



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 9001:2014**  
**01-september-2014**

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**Sistemi vodenja kakovosti - Zahteve**

Quality management systems - Requirements

Qualitätsmanagementsysteme - Anforderungen

Systèmes de management de la qualité - Exigences

**Ta slovenski standard je istoveten z: prEN ISO 9001**

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**ICS:**

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
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**oSIST prEN ISO 9001:2014**

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# DRAFT INTERNATIONAL STANDARD

## ISO/DIS 9001

ISO/TC 176/SC 2

Secretariat: **BSI**Voting begins on:  
**2014-07-10**Voting terminates on:  
**2014-10-10**

## Quality management systems — Requirements

*Systèmes de management de la qualité — Exigences*

ICS: 03.120.10

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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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## 141 Foreword

142 ISO (the International Organization for Standardization) is a worldwide federation of national standards  
143 bodies (ISO member bodies). The work of preparing International Standards is normally carried out  
144 through ISO technical committees. Each member body interested in a subject for which a technical  
145 committee has been established has the right to be represented on that committee. International  
146 organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO  
147 collaborates closely with the International Electrotechnical Commission (IEC) on all matters of  
148 electrotechnical standardization.

149 The procedures used to develop this document and those intended for its further maintenance are  
150 described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the  
151 different types of ISO documents should be noted. This document was drafted in accordance with the  
152 editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

153 Attention is drawn to the possibility that some of the elements of this document may be the subject of  
154 patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of  
155 any patent rights identified during the development of the document will be in the Introduction and/or  
156 on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

157 Any trade name used in this document is information given for the convenience of users and does not  
158 constitute an endorsement.

159 For an explanation on the meaning of ISO specific terms and expressions related to conformity  
160 assessment, as well as information about ISO's adherence to the WTO principles in the Technical  
161 Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

162 The committee responsible for this document is Technical Committee ISO/TC 176, *Quality*  
163 *management and quality assurance*, Subcommittee SC2, *Quality systems*.

164 This 5<sup>th</sup> edition of ISO 9001 cancels and replaces the 4<sup>th</sup> edition (ISO 9001:2008). This new edition  
165 represents a technical revision compared to the earlier edition, through the adoption of a revised  
166 clause sequence, the adaptation of the revised "quality management principles" and of new concepts.

167  
168 **NOTE TO THIS TEXT** (which will not be included in the published International Standard):  
169

170 This text has been prepared using the "high-level structure" (i.e. clause sequence, common text and terminology)  
171 provided in Annex SL, Appendix 2 of the ISO/IEC Directives, Part 1, Consolidated ISO Supplement, 2013. This is  
172 intended to enhance alignment among ISO's management system standards, and to facilitate their  
173 implementation for organizations that need to meet the requirements of two or more such standards  
174 simultaneously.

175  
176 The clause sequence of ISO 9001:2008 has been changed to be consistent with "Annex SL". The text of Annex  
177 SL is highlighted in the main body of the text (clauses 1 to 10) by the use of blue font. This is only to facilitate  
178 analysis and will not be incorporated in the final version of ISO 9001.

179  
180 This new harmonized approach allows for the addition of discipline-specific (in this case quality-specific) text  
181 which has been applied by including the following:

- 182  
183 a) specific quality management system requirements considered essential to meet the scope of the ISO  
184 9001 standard;  
185 b) text to reflect the use of the Quality Management Principles that form the basis for ISO's quality  
186 management system standards;  
187 c) requirements and notes to clarify and ensure consistent interpretation and implementation of the  
188 common text in the context of a quality management system.

## 189 Introduction

### 190 0.1 General

191 The adoption of a quality management system ought to be a strategic decision for an organization. A  
192 robust quality management system can help an organization to improve its overall performance and  
193 forms an integral component of sustainable development initiatives. The design and implementation of  
194 an organization's quality management system is influenced by the context of the organisation and the  
195 changes in that context, particularly with respect to:

- 196 a) its specific objectives;
- 197 b) the risks associated with its context and objectives;
- 198 c) the needs and expectations of its customers and other relevant interested parties;
- 199 d) the products and services it provides;
- 200 e) the complexity of processes it employs and their interactions;
- 201 f) the competence of persons within or working on behalf of the organization;
- 202 g) its size and organizational structure.

203 The context of an organization can include internal factors such as organizational culture, and external  
204 factors such as the socio-economic conditions under which it operates; consequently all the  
205 requirements of this International Standard are generic but the ways in which they are applied can  
206 differ from one organization to another. Accordingly, it is not the intent of this International Standard to  
207 imply the need for uniformity in the structure of different quality management systems, or uniformity of  
208 documentation to align to the clause structure of this International Standard, or to impose specific  
209 terminology to be used within the organization.

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

212 Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

213 This International Standard can be used by internal and external parties, to assess the organization's  
214 ability to consistently meet customer, statutory and regulatory requirements applicable to the products  
215 and services it provides, the organization's own requirements and its aim to enhance customer  
216 satisfaction.

### 217 0.2 The ISO standards for quality management

218 This International Standard is one of the three core standards in the ISO portfolio of quality  
219 management system standards.

- 220
- 221 • ISO 9000 *Quality management systems — Fundamentals and vocabulary* provides an essential  
222 background for the proper understanding and implementation of this International Standard. The  
223 quality management principles described in detail in ISO 9000 were developed by ISO/TC 176,  
224 and have been taken into consideration during the development of this International Standard.  
225 These principles are not requirements in themselves, but they form the foundation of the  
226 requirements specified by this International Standard. An outline of the quality management  
227 principles is included in an Annex B to this International Standard.



- 228 • ISO 9001 (this International Standard) specifies requirements aimed primarily at giving confidence  
 229 in the products and services provided by an organization and thereby improving customer  
 230 satisfaction (see clause 1 Scope). Its proper implementation can also be expected to bring other  
 231 organizational benefits such as improved internal communication, better understanding and  
 232 control of the organization's processes, and reduction in defects and waste.  
 233
- 234 • ISO 9004 *Managing for the sustained success of an organization - A quality management*  
 235 *approach* provides guidance for organizations that choose to progress beyond the requirements of  
 236 this International Standard to address a broader range of topics that can lead to continual  
 237 improvement of the organization's overall performance. ISO 9004 includes guidance on a self-  
 238 assessment methodology for an organization to be able to evaluate the level of maturity of its  
 239 quality management system.  
 240

241 Other standards that have been developed to support the implementation of a quality management  
 242 system include those in the ISO 10000 number range. These include guidelines on customer  
 243 satisfaction, quality plans, quality management in projects, configuration management, measurement  
 244 processes and measuring equipment, documentation, financial and economic benefits of quality  
 245 management, training, statistical techniques, the involvement and competence of people, selection of  
 246 quality management system consultants and auditing of management systems. These standards are  
 247 described further in Annex C of this International Standard.

### 248 0.3 Process approach

249 Consistent and predictable results are achieved more effectively and efficiently when activities are  
 250 understood and managed as interrelated processes that function as a coherent system. This  
 251 International Standard promotes the adoption of a process approach when developing, implementing  
 252 and improving the effectiveness of a quality management system, to enhance customer satisfaction by  
 253 meeting customer requirements. Clause 4.4 of this International Standard includes specific  
 254 requirements considered essential to the adoption of a process approach.

255 The process approach applies systematic definition and management of processes and their  
 256 interactions so as to achieve the intended results in accordance with the quality policy and strategic  
 257 direction of the organization. Management of the processes and the system as a whole can be  
 258 achieved using a "Plan-Do-Check-Act" (PDCA) methodology (see 0.4) with an overall focus on "Risk-  
 259 based thinking" aimed at preventing undesirable outcomes (see 0.5).

260 When used within a quality management system, the process approach ensures:

- 261 a) understanding and consistently meeting requirements;  
 262 b) consideration of processes in terms of added value;  
 263 c) the achievement of effective process performance;  
 264 d) improvement of processes based on evaluation of data and information.

265 Figure 1 illustrates the process linkages between clauses 4 to 10 of this International Standard. This  
 266 shows that customers play a significant role in defining the input requirements that the organization  
 267 needs to meet at all stages of its quality management system. In addition, the needs and expectations  
 268 of other relevant interested parties can also play a role in defining those requirements. Monitoring of  
 269 customer satisfaction requires the evaluation of information relating to customer perceptions as to  
 270 whether the organization has met these requirements.

271 The schematic model shown in Figure 1 covers all the requirements of this International Standard, but  
 272 does not show the individual processes at a detailed level. Each of these processes, and the system  
 273 as a whole, can be managed using the PDCA methodology described in clause 0.4 of this  
 274 International Standard.

275

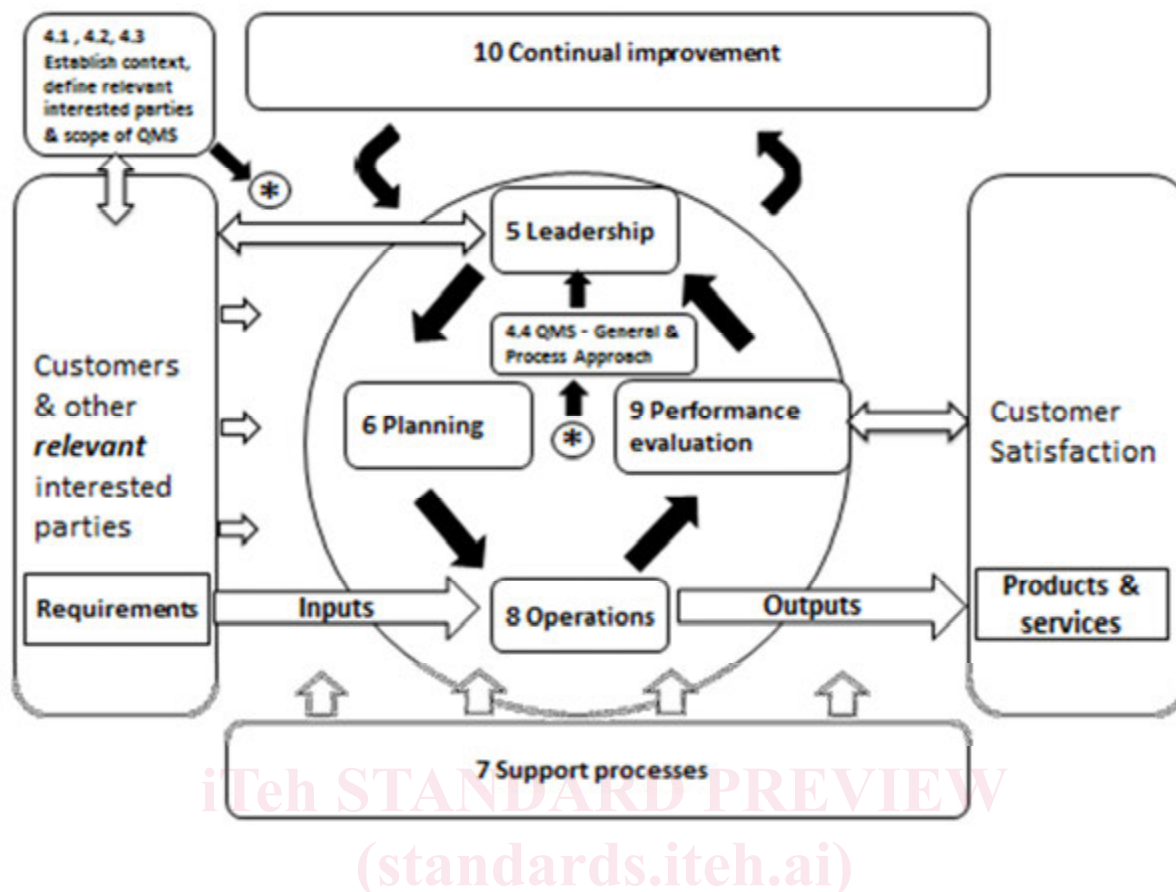


Figure 1 - Model of a process-based quality management system, showing the links to the clauses of this International Standard

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#### 0.4 Plan-Do-Check-Act cycle

The methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes and to the quality management system as a whole. The clauses of this International Standard broadly follow the PDCA cycle which can be briefly described as follows:

284

— **Plan:** establish the objectives of the system and its component processes, and the resources needed to deliver results in accordance with customers’ requirements and the organization’s policies.

288

— **Do:** implement what was planned.

289

— **Check:** monitor and (where applicable) measure processes and the resulting products and services against policies, objectives and requirements, and report the results.

290

291

— **Act:** take actions to improve process performance, as necessary.

292

Figure 2 shows schematically how a single process within the quality management system can be managed using the PDCA cycle.

293

294

295

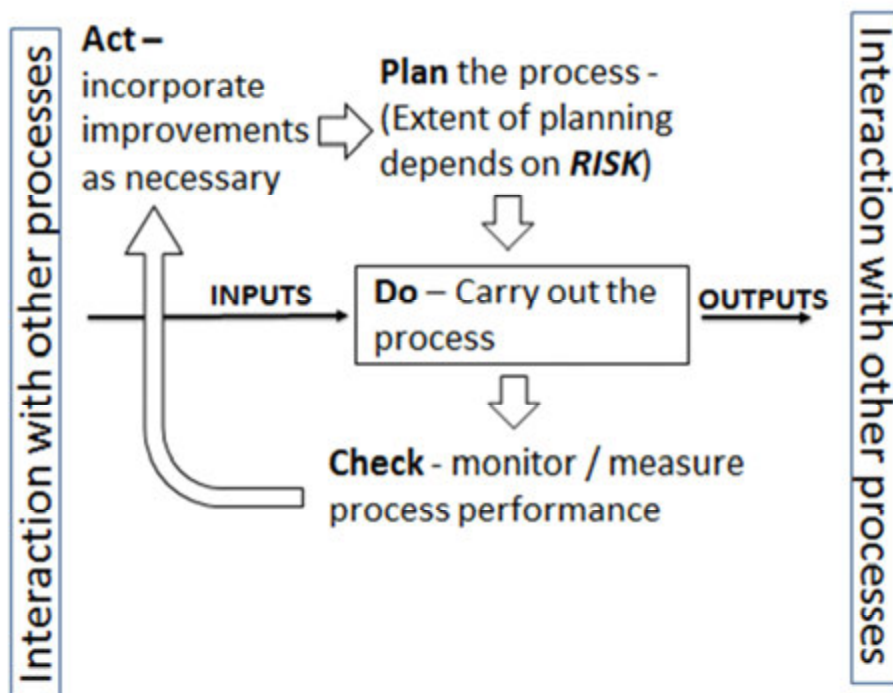


Figure 2 - Schematic representation of a single process within the system

### 0.5 “Risk-based thinking”

Risk is the effect of uncertainty on an expected result and the concept of risk-based thinking has always been implicit in ISO 9001. This International Standard makes risk-based thinking more explicit and incorporates it in requirements for the establishment, implementation, maintenance and continual improvement of the quality management system. Organizations can choose to develop a more extensive risk-based approach than is required by this International Standard, and ISO 31000 provides guidelines on formal risk management which can be appropriate in certain organizational contexts.

Not all the processes of the quality management system represent the same level of risk in terms of the organization’s ability to meet its objectives, and the consequences of process, product, service or system nonconformities are not the same for all organizations. For some organizations, the consequences of delivering nonconforming products and services can result in minor inconvenience to the customer; for others, the consequences can be far-reaching and fatal. “Risk-based thinking” therefore means considering risk qualitatively (and, depending on the organization’s context, quantitatively) when defining the rigour and degree of formality needed to plan and control the quality management system, as well as its component processes and activities.

### 0.6 Compatibility with other management system standards

This International Standard has adopted the “high-level structure” (i.e. clause sequence, common text and common terminology) developed by ISO to improve alignment among its International Standards for management systems. An explanation of some of the key elements of the “high level structure” and some of the key changes introduced in this International Standard is provided in Annex A.

This International Standard defines the requirements in an order that is consistent with organizational planning and process management, i.e.:

- 326 — Understanding the context of the organization, its quality management system and processes  
327 (Clause 4)
- 328 — Leadership, policy and responsibilities (Clause 5)
- 329 — Processes for planning and consideration of risks and opportunities (Clause 6)
- 330 — Processes for support, including resources, people and information (Clause 7)
- 331 — Operational processes related to customers and products and services (Clause 8)
- 332 — Processes for performance evaluation (Clause 9)
- 333 — Processes for improvement (Clause 10).
- 334 It is important to emphasize, however, that organizations are not required to follow an identical clause-  
335 by-clause sequence when defining their quality management system, and they are encouraged to use  
336 the Process Approach as described in clauses 0.3 to 0.5 of this International Standard.  
337
- 338 This International Standard does not include requirements specific to other management systems,  
339 such as those for environmental management, occupational health and safety management, or  
340 financial management. However, this International Standard enables an organization to use the  
341 process approach, coupled with the PDCA methodology and risk-based thinking to align or integrate  
342 its quality management system with the requirements of other management system standards as it  
343 sees fit. It is possible for an organization to adapt its existing management system in order to address  
344 the requirements of this International Standard.
- 345 A matrix showing the correlation between the clauses of this International Standard and ISO  
346 9001:2008 can be found on the ISO/TC 176/SC2 open access web site at:  
347 [www.iso.org/tc176/sc02/public](http://www.iso.org/tc176/sc02/public).
- 348 [Note to this DIS: The matrix will only be available after the June meeting of ISO/TC 176/SC2/WG23]

349 ISO (the International Organization for Standardization) is a worldwide federation of national standards  
 350 bodies (ISO member bodies). The work of preparing International Standards is normally carried out  
 351 through ISO technical committees. Each member body interested in a subject for which a technical  
 352 committee has been established has the right to be represented on that committee. International  
 353 organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO  
 354 collaborates closely with the International Electrotechnical Commission (IEC) on all matters of  
 355 electrotechnical standardization.

356 International Standards are drafted in accordance with the rules given in the ISO/IEC Directives,  
 357 Part 2.

358 The main task of technical committees is to prepare International Standards. Draft International  
 359 Standards adopted by the technical committees are circulated to the member bodies for voting.  
 360 Publication as an International Standard requires approval by at least 75 % of the member bodies  
 361 casting a vote.

362 **Attention is drawn to the possibility that some of the elements of this document may be the subject of**  
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364 ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and Quality*  
 365 *Assurance*, Subcommittee SC 2, *Quality Systems*.

366 **This second/third/... edition cancels and replaces the first/second/... edition (), [clause(s) / subclause(s)**  
 367 **/ table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.**

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## 383 **Quality management systems — Requirements**

### 384 **1 Scope**

385 This International Standard specifies requirements for a quality management system where an  
 386 organization:

387 a) needs to demonstrate its ability to consistently provide product or service that meets customer and  
 388 applicable statutory and regulatory requirements, and

389 b) aims to enhance customer satisfaction through the effective application of the system, including  
 390 processes for continual improvement of the system and the assurance of conformity to customer and  
 391 applicable statutory and regulatory requirements.

392 All requirements of this International Standard are generic and are intended to be applicable  
 393 to all organizations, regardless of type, size and product provided.

394 NOTE 1 In this International Standard, the terms “product” or “service” only apply to products and services  
 395 intended for, or required by, a customer.

396 NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

## 397 **2 Normative references**

398 *There are no normative references. This clause is included to maintain clause numbering alignment*  
 399 *with other ISO management system standards,*

## 400 **3 Terms and definitions**

401 For the purposes of this document, the following terms and definitions apply.

### 402 **3.01**

#### 403 **organization**

404 person or group of people that has its own *functions* (3.25) with responsibilities, authorities and  
 405 relationships to achieve its *objectives* (3.08)

406 Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm,  
 407 enterprise, authority, partnership, association, charity or institution, or part or combination thereof, whether  
 408 incorporated or not, public or private.

409 [SOURCE: ISO DIS 9000:2014, 3.2.1] ISO/TC 176/SC2/WG24/N111 prEN ISO 9001:2015

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### 410 **3.02**

#### 411 **interested party**

412 person or *organization* (3.01) that can affect, be affected by, or perceive themselves to be affected by  
 413 a decision or activity

414 EXAMPLE *Customers* (3.26), owners, people in an *organization* (3.01), *suppliers* (3.27), bankers, unions,  
 415 partners or society that may include competitors or opposing pressure groups.

416 [SOURCE: ISO DIS 9000:2014, 3.2.4]

### 417 **3.03**

#### 418 **requirement**

419 need or expectation that is stated, generally implied or obligatory

420 Note 1 to entry: “Generally implied” means that it is custom or common practice for the *organization* (3.01) and  
 421 *interested parties* (3.02) that the need or expectation under consideration is implied.

422 Note 2 to entry: A specified requirement is one that is stated, for example in *documented information* (3.11).

423 Note 3 to entry: A qualifier can be used to denote a specific type of requirement e.g. *product* (3.47) requirement,  
 424 *quality management* (3.30) requirement, *customer* (3.26) requirement, quality requirement.

425 Note 4 to entry: Requirements can be generated by different *interested parties* (3.02).

426 Note 5 to entry: It can be necessary for achieving high *customer satisfaction* (3.57) to fulfil an expectation of a  
 427 *customer* (3.26) even if it is neither stated nor generally implied or obligatory.

428 [SOURCE: ISO DIS 9000:2014, 3.5.4]

429 **3.04**

430 **management system**

431 set of interrelated or interacting elements of an *organization* (3.01) to establish *policies* (3.07) and  
432 *objectives* (3.08) and *processes* (3.12) to achieve those *objectives*

433 Note 1 to entry: A management system can address a single discipline or several disciplines e.g. *quality*  
434 *management* (3.30), *financial management* (3.29) or *environmental management*.

435 Note 2 to entry: The management system elements establish the *organization's* (3.01) structure, roles and  
436 responsibilities, planning, operation, *policies* (3.07), practices, rules, beliefs, *objectives* (3.08) and *processes*  
437 (3.12) to achieve those *objectives*.

438 Note 3 to entry: The scope of a management system may include the whole of the *organization* (3.01), specific  
439 and identified *functions* (3.25) of the *organization*, specific and identified sections of the *organization*, or one or  
440 more *functions* across a group of *organizations*.

441 [SOURCE: ISO DIS 9000:2014, 3.4.2.1]

442 **3.05**

443 **top management**

444 person or group of people who directs and controls an *organization* (3.01) at the highest level

445 Note 1 to entry: Top management has the power to delegate authority and provide resources within the  
446 *organization* (3.01).

447 Note 2 to entry: If the scope of the *management system* (3.04) covers only part of an *organization* (3.01), then *top*  
448 *management* refers to those who direct and control that part of the *organization*.

449 [SOURCE: ISO DIS 9000:2014, 3.1.1]

450 **3.06**

451 **effectiveness**

452 extent to which planned activities are realized and planned results achieved

453 [SOURCE: ISO DIS 9000:2014, 3.7.7]

454 **3.07**

455 **policy**

456 intentions and direction of an *organization* (3.01), as formally expressed by its *top management* (3.05)

457 [SOURCE: ISO DIS 9000:2014, 3.4.5]

458 **3.08**

459 **objective**

460 result to be achieved

461 Note 1 to entry: An objective can be strategic, tactical, or operational.

462 Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and  
463 environmental goals) and can apply at different levels (such as strategic, organization-wide, project, *product*  
464 (3.47), *service* (3.48), and *process* (3.12)).

465 Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an  
466 operational criterion, as a *quality* (3.37) objective, or by the use of other words with similar meaning (e.g. aim,  
467 goal, or target).