



Document: ISO/TC 176/SC 2/N **1147**

Secretariat of ISO/TC 176/SC 2

Date: 3 June 2013

**To the Members of
ISO/TC 176/SC 2 -
Quality Management and
Quality Assurance/
Quality Systems**

ISO/CD 9001

In accordance with the approved project plan for the revision of ISO 9001 (see SC2/N1089), please find the Committee Draft of ISO 9001 attached. This is being circulated to members for commenting and ballot (a ballot has been established on the ISO Balloting Portal for this). The closing date for the submission of comments and votes is:

10 September 2013

Please use the ISO commenting template for the submission of comments, and ***include the relevant CD line number against each comment, in the 2nd column***. We know from past experience with previous revisions to ISO 9001 that we can expect a large number of comments at the CD stage. We may therefore have to return any comments that are submitted without reference to line numbers, or if other parts of the template have not been completed correctly, as we might not be able to process them adequately.

During the development of this CD, ISO/TC 176/SC2/WG24 encountered three issues on which it needs specific input from SC2:

- the need to maintain the concept of allowing "exclusions" of specific requirements
- the use of the term "goods and services" instead of the term "product"
- the use of the term "improvement" instead of the term "continual Improvement"

A subsidiary ballot on these issues has been posted on the ISO Balloting Portal, also with a closing date of 10 September 2013. Attachment 1 provides additional information to give the context to these issues:

Please also note that whilst member bodies may choose to comment on any part of the text:

- any comments received on the revised quality management principles given in Annex A to the CD are likely to be rejected, as the QMPs have previously been approved by a separate SC2 and SC1 joint ballot.
- any proposed changes to specific elements of the "Annex SL" identical text should be supported by very clearly stated justifications, which, if considered by WG24 to be appropriate, will be referred back to SC2 for decision

We look forward to receiving your votes and comments on the CD.

Yours sincerely

Charles Corrie
For the BSI Secretariat of
ISO/TC 176/SC 2

Attachment 1 to SC2/N1147

a) Exclusions

The current "exclusions" clause 1.2 in ISO 9001 was originally introduced following the decision to withdraw the ISO 9002 and ISO 9003 standards in 2000. A means had to be found to enable organizations with quality management systems that did not include all of the requirements of ISO 9001:2000 for technical reasons, but which had previously been able to meet the requirements of ISO 9002 or ISO 9003, to be able to claim conformity to the standard. The resulting solution was clause 1.2.

This Committee Draft has taken a different approach to the way in which its requirements are stated, when compared to the earlier editions of ISO 9001; consequently, there should no longer be any technical reasons for an organization's QMS not to be able to meet all the requirements of the future standard. This makes the need for such an exclusions clause redundant. For the time being, this Committee Draft includes text to permit "exclusions" (see lines 387 to 391), but this can be modified depending on the ballot results.

Please review the CD and decide if these requirements need to be maintained, or if they can now be removed. Note that if the results of the ballot indicate that the exclusions clause should no longer be maintained, then this will also require the Design Specification for this revision of ISO 9001 (see document SC2/N1088) to be amended, as Section 3, bullet e) states "The intent of clause 1.2 of ISO 9001:2008 shall be maintained in the revised standard.". This bullet e) would need to be deleted.

b) Goods and services

ISO 9001 has sought to be generic and applicable to all types of organization producing any type of product. However, feedback received on the current version of the standard has indicated that there is a perception that it continues to be biased towards manufacturing-type organizations with "hardware" products. The feedback has also indicated that the use of the single term "product" to cover services as well as physical products has been a hindrance to service organizations understanding and applying the standard.

In developing the Committee Draft ISO/TC 176/SC2/WG24 has therefore attempted to make it more truly generic, with a particular emphasis for organizations that provide services.

Noting that the ISO/IEC Directives themselves use the term "goods and services", ISO/TC 176/SC2/WG 24 has recommended that this term be adopted in place of the term "product".

The Committee Draft has been prepared using "goods and services".

Please review whether this change is acceptable to you.

c) Improvement

The recent revision of the Quality Management Principles (see SC2/N1145) has led to a change of one of the principles from "continual improvement" to just "improvement". ISO 9001 is being developed to make more explicit use of the quality management principles, so would need to move to just using the term "improvement" to be in alignment with them.

However, the text for management systems standards given in Annex SL of the ISO/IEC Directives, Procedures specific to ISO, uses the term "continual improvement", as do other ISO management system standards. Moving to just using "improvement" would result in a deviation from the Annex SL text.

The CD has been prepared using "continual improvement", but with the "continual" being given in strike-through text format.

Please review whether the deletion of "continual" is acceptable to you.

1 **ISO/TC 176/SC 2/N1147**

2 Date: 2013-06-3

3 **ISO/CD 9001**

4 ISO/TC 176/SC 2/WG 24

5 Secretariat: BSI

6 **Quality management systems — Requirements**

7 *Systemes de management de la qualite — Exigences*

8

9 **Warning**

10 This document is not an ISO International Standard. It is distributed for review and comment. It is subject to
11 change without notice and may not be referred to as an International Standard.

12 Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of
13 which they are aware and to provide supporting documentation.

14

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31	Contents	Page
32	Foreword	vi
33	Introduction to this Committee Draft.....	vii
34	1 Scope	1
35	2 Normative references	1
36	3 Terms and definitions	1
37	4 Context of the organization	4
38	4.1 Understanding the organization and its context	4
39	4.2 Understanding the needs and expectations of interested parties	5
40	4.3 Determining the scope of the quality management system	5
41	4.4 Quality management system	6
42	5 Leadership	6
43	5.1 Leadership and commitment	6
44	5.2 Quality policy	7
45	5.3 Organizational roles, responsibilities and authorities	8
46	6 Planning	8
47	6.1 Actions to address risks and opportunities	8
48	6.2 Quality objectives and planning to achieve them	8
49	6.3 Planning of changes	9
50	7 Support	9
51	7.1 Resources	9
52	7.2 Competence	10
53	7.3 Awareness	11
54	7.4 Communication	11
55	7.5 Documented information	11
56	8 Operation	12
57	8.1 Operational planning and control	12
58	8.2 Determination of market needs and interactions with customers	12
59	8.3 Operational planning process	14
60	8.4 Control of external provision of goods and services	14
61	8.5 Development of goods and services	15
62	8.6 Production of goods and provision of services	17
63	8.7 Release of goods and services	19
64	8.8 Nonconforming goods and services	19
65	9 Performance evaluation	19
66	9.1 Monitoring, measurement, analysis and evaluation	19
67	9.2 Internal Audit	21
68	9.3 Management review	21
69	10 —— Continual improvement	22
70	10.1 Nonconformity and corrective action	22
71	10.2 Improvement	22
72	Annex A Quality management principles (Informative)	25
73	Bibliography	28
74		

75 Foreword

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

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

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

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

88 ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and Quality Assurance*,
89 Subcommittee SC 2, *Quality Systems*.

90 This fifth edition cancels and replaces the fourth edition (ISO 9001:2008), which has been technically revised
91 to adopt the unifying and agreed high level structure, identical core text and common terms and core
92 definitions of Annex SL of the ISO Directives, redraft many sections to make them more generic and more
93 easily applicable by service industries, and to change from using 'product' to 'goods and services'.

94 The transition period for users of ISO 9001:2008 to transfer to using ISO 9001:20XX has been set for three
95 years (*Note to this CD: this 3 year period is still subject to agreement by ISO/CASACO and the IAF*)

97 **Introduction to this Committee Draft**

98 **0.1 General**

99

100 This introduction is specific to this committee draft (CD) and it is not intended for incorporation to the final
101 version of the standard. The introduction to ISO 9001:2008 has not been included in this committee draft. It
102 will be revised as part of the response to the CD comments and ballots and incorporated into the draft
103 international standard (DIS).

104

105 **0.2 Annex SL**

106

107 ISO/IEC Directives, Part 1, Consolidated ISO Supplement, 2013, Annex SL, Appendix 2 sets out the high level
108 structure, identical core text and common terms and core definitions that are to form, when possible, the
109 nucleus of future and revised management system standards such as ISO 9001.

110 *'All MSS (whether they are Type A or Type B MSS) shall, in principle, use consistent structure, common text
111 and terminology so that they are easy to use and compatible with each other. The guidance and structure
112 given in Appendix 2 to this Annex SL shall, in principle, also be followed (based on ISO/TMB Resolution
113 18/2012).'*

114

115 Accordingly, ISO/CD 9001 has adopted the structure, common text and terminology provided in Annex SL,
116 Appendix 2 as the nucleus of this revision and highlighted this in the document by the use of a *red italic* font.

117

118 Annex SL, Appendix 2 allows discipline specific additions to the core text and this has been utilised for the
119 following:

- 120 a) specific quality management system requirements considered essential to meet the scope of the
121 standard;
- 122 b) requirements that may appear to be generic but are considered essential to reflect use of the Quality
123 Management Principles that form the basis for the quality management system standards within the
124 ISO 9000 family;
- 125 c) requirements and notes that enhance or clarify the core text.

126

127 **0.3 Significant Changes**

128

129 **a) Redrafting to make the standard more generic and more easily applicable by service industries.**

130

131 Continued omission of specific reference to 'services' was considered to be unsustainable if relevance to the
132 service sector was to be enhanced. On that basis 'product' has been replaced by 'goods and services' when

133 specifically referring to the deliverables for the customer. This proposed change will be subject to a specific
134 briefing note and a request for ballot input from ISO/TC 176/SC 2 member bodies.

135
136 Where possible, clauses of the standard have been revised to reduce the prescriptive nature of some
137 requirements which were originally derived from practices for the hardware sector, in particular clauses **7.1.4**
138 **Monitoring and measuring devices** and **8.5 Development of goods and services**.

139
140 **b) Context of the organisation**

141
142 Annex SL, Appendix 2 High Level Structure and core text has introduced two new clauses relating to the
143 context of the organisation, **4.1 Understanding the organization and its context** and **4.2 Understanding**
144 **the needs and expectations of interested parties**. Together these clauses require the organisation to
145 determine the issues and requirements that can impact on the planning of the quality management system
146 and can be used as an input into the development of the quality management system.

147
148 Although there is now reference to determining the requirements of relevant interested parties there is no new
149 requirement to ensure goods and services meet the needs and expectations of external parties other than
150 those already identified in ISO 9001:2008, i.e. customers, regulators, etc. Such a change would require a
151 change to the scope of the standard which is not permitted by the design specification for the revision.

152
153 **c) Process approach**

154
155 ISO 9001:2008 promoted the adoption of a process approach when developing, implementing and improving
156 the effectiveness of a quality management system. This proposed revision to the standard makes this more
157 explicit by including clause **4.4.2 Process approach** – specifying requirements considered essential to the
158 adoption of a process approach.

159
160 **d) Risk and Preventive Action**

161
162 Annex SL, Appendix 2 High Level Structure and core text does not include a clause giving specific
163 requirements for 'preventive action'. This is because one of the key purposes of a formal management system
164 is to act as a preventive tool. Consequently, the High Level Structure and Identical text require an assessment
165 of the organization's 'external and internal issues that are relevant to its purpose and that affect its ability to
166 achieve the intended outcome(s)' in clause 4.1, and to 'determine the risks and opportunities that need to be
167 addressed to: assure the quality management system can achieve its intended outcome(s); prevent, or
168 reduce, undesired effects; achieve ~~continual~~ improvement.' in clause 6.1. These two sets of requirements are
169 considered to cover the concept of 'preventive action', and also to take a wider view that looks at risks and
170 opportunities. This approach is continued in the discipline specific text added to the Annex SL core text to
171 require risk based thinking and a risk driven approach to preventive action throughout the development and
172 implementation of the quality management system. This has also facilitated some reduction in prescriptive

173 requirements and their replacement by performance based requirements. Although risks have to identified and
174 acted upon there is no requirement for formal risk management.

175

176 **e) Documented information**

177

178 The Annex SL Appendix 2 clause on Documented Information has been adopted without significant change or
179 addition. Where appropriate, text elsewhere in the standard has been aligned with its requirements.
180 Consequently the terms 'document' and 'record' have both been replaced throughout the requirements text by
181 'documented information'.

182

183 **f) Control of external provision of goods and services**

184

185 Clause **8.6 Control of external provision of goods and services** – addresses all forms of external
186 provision, whether it is by purchasing from a supplier, through an arrangement with an associate company,
187 through the outsourcing of processes and functions of the organisation or by any other means. The
188 organisation is required to take a risk based approach to determine the type and extent of controls appropriate
189 to each external provider and all external provision of goods and services.

190

191 {Drafting Note The sources of text in this revision can be identified by the font colour as follows:

192 *Red italics - Annex SL text*

193 Black – Text taken from existing ISO 9001: 2008 and text developed by WG24.}

194

195 Quality management systems — Requirements

196 1 Scope

197 This International Standard specifies requirements for a quality management system where an organization
198 a) needs to demonstrate its ability to consistently provide goods and services that meet customer and
199 applicable statutory and regulatory requirements, and
200 b) aims to enhance customer satisfaction through the effective application of the system, including
201 processes for ~~continual~~ improvement of the system and the assurance of conformity to customer and
202 applicable statutory and regulatory requirements.

203
204 NOTE 1 In this International Standard, the term “product” only applies to

- 205 a) goods and services intended for, or required by, a customer, and
- 206 b) any intended output resulting from the operational processes.

207

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

209 2 Normative references

210 The following referenced documents are indispensable for the application of this document. For dated
211 references, only the edition cited applies. For undated references, the latest edition of the referenced
212 document (including any amendments) applies.

213

214 ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

215 3 Terms and definitions

216 For the purposes of this document, the terms and definitions given in ISO 9000 apply.

217

218 {Drafting note: The Annex SL terms are currently incorporated to assist reviewers of the committee draft. At this
219 time there is no agreement to incorporate such terms in ISO 9001, and they will be moved later into ISO 9000.
220 Changes to definitions being developed by ISO/TC176/SC1 have not yet been incorporated.}

221

222 3.01

223 organization

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

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

- 229 **3.02**
230 **interested party** (preferred term)
231 **stakeholder** (admitted term)
232 person or **organization** (3.01) that can affect, be affected by, or perceive themselves to be affected by a
233 decision or activity
- 234 **3.03**
235 **requirement**
236 need or expectation that is stated, generally implied or obligatory
- 237 Note 1 to entry: “Generally implied” means that it is custom or common practice for the organization and interested
238 parties that the need or expectation under consideration is implied.
- 239 Note 2 to entry: A specified requirement is one that is stated, for example in documented information.
- 240 **3.04**
241 **management system**
242 set of interrelated or interacting elements of an **organization** (3.01) to establish **policies** (3.07) and
243 **objectives** (3.08) and **processes** (3.12) to achieve those objectives
- 244 Note 1 to entry: A management system can address a single discipline or several disciplines.
- 245 Note 2 to entry: The system elements include the organization’s structure, roles and responsibilities, planning, operation,
246 etc.
- 247 Note 3 to entry: The scope of a management system may include the whole of the organization, specific and identified
248 functions of the organization, specific and identified sections of the organization, or one or more functions across a group
249 of organizations.
- 250 **3.05**
251 **top management**
252 person or group of people who directs and controls an **organization** (3.01) at the highest level
- 253 Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.
- 254 Note 2 to entry: If the scope of the **management system** (3.04) covers only part of an organization then top
255 management refers to those who direct and control that part of the organization.
- 256 **3.06**
257 **effectiveness**
258 extent to which planned activities are realized and planned results achieved
- 259 **3.07**
260 **policy**
261 intentions and direction of an **organization** (3.01) as formally expressed by its **top management** (3.05)
- 262 **3.08**
263 **objective**
264 result to be achieved
- 265 Note 1 to entry: An objective can be strategic, tactical, or operational.
- 266 Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental
267 goals) and can apply at different levels (such as strategic, organization-wide, project, product and **process** (3.12)). An
268 objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a quality
269 objective or by the use of other words with similar meaning (e.g. aim, goal, or target).

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

272 *Note 4 to entry: In the context of quality management systems standards quality objectives are set by the organization,*
 273 *consistent with the quality policy, to achieve specific results.*

274 **3.09**
 275 **risk**
 276 *effect of uncertainty*

277 *Note 1 to entry: An effect is a deviation from the expected — positive or negative.*

278 *Note 2 to entry: Uncertainty is the state, even partial, of efficiency of information related to, understanding or knowledge*
 279 *of, an event, its consequence, or likelihood.*

280 *Note 3 to entry: Risk is often characterized by reference to potential events (ISO Guide 73, 3.5.1.3) and consequences*
 281 *(ISO Guide 73, 3.6.1.3), or a combination of these.*

282 *Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in*
 283 *circumstances) and the associated likelihood (ISO Guide 73, 3.6.1.1) of occurrence.*

284 **3.10**
 285 **competence**
 286 *ability to apply knowledge and skills to achieve intended results*

287 **3.11**
 288 **documented information**
 289 *information required to be controlled and maintained by an **organization** (3.01) and the medium on which it is*
 290 *contained*

291 *Note 1 to entry: Documented information can be in any format and media and from any source.*

292 *Note 2 to entry: Documented information can refer to*
 293 *– the management system (3.04), including related **processes** (3.12);*
 294 *– information created in order for the organization to operate (documentation);*
 295 *– evidence of results achieved (records).*

296 **3.12**
 297 **process**
 298 *set of interrelated or interacting activities which transforms inputs into outputs*

299 **3.13**
 300 **performance**
 301 *measurable result*

302 *Note 1 to entry: Performance can relate either to quantitative or qualitative findings.*

303 *Note 2 to entry: Performance can relate to the management of activities, **processes** (3.12), products (including services),*
 304 *systems or **organizations** (3.01).*

305 **3.14**
 306 **outsource** (verb)
 307 *make an arrangement where an external **organization** (3.01) performs part of an organization's function or*
 308 ***process** (3.12)*

309 *Note 1 to entry: An external organization is outside the scope of the **management system** (3.04), although the*
 310 *outsourced function or process is within the scope.*

311 **3.15**
312 **monitoring**
313 *determining the status of a system, a **process** (3.12) or an activity*

314 *Note 1 to entry: To determine the status there may be a need to check, supervise or critically observe.*

315 **3.16**
316 **measurement**
317 **process** (3.12) *to determine a value*

318 **3.17**
319 **audit**
320 *systematic, independent and documented **process** (3.12) for obtaining audit evidence and evaluating it*
321 *objectively to determine the extent to which the audit criteria are fulfilled*

322 *Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can*
323 *be a combined audit (combining two or more disciplines).*

324 *Note 2 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.*

325 **3.18**
326 **conformity**
327 *fulfilment of a **requirement** (3.03)*

328 **3.19**
329 **nonconformity**
330 *non-fulfilment of a **requirement** (3.03)*

331 **3.20**
332 **correction**
333 *action to eliminate a detected **nonconformity** (3.19)*

334 **3.21**
335 **corrective action**
336 *action to eliminate the cause of a **nonconformity** (3.19) and to prevent recurrence*

337 **3.22**
338 **continual improvement**
339 *recurring activity to enhance **performance** (3.13)*

340 **4 Context of the organization**

341 **4.1 Understanding the organization and its context**

342 *The organization shall determine external and internal issues, that are relevant to its purpose and its strategic*
343 *direction and that affect its ability to achieve the intended outcome(s) of its quality management system.*

344 The organization shall update such determinations when needed.

345 When determining relevant external and internal issues, the organization shall consider those arising from:

- 346 a) changes and trends which can have an impact on the objectives of the organization;
- 347 b) relationships with, and perceptions and values of relevant interested parties;
- 348 c) governance issues, strategic priorities, internal policies and commitments; and

352 d) resource availability and priorities and technological change.

353

354 Note 1 Understanding the external context can be facilitated by considering issues arising from legal, technological,
355 competitive, cultural, social, economic and natural environment, whether international, national, regional or local.

356

357 Note 2 When understanding the internal context the organization could consider those related to perceptions, values
358 and culture of the organization.

359 **4.2 Understanding the needs and expectations of interested parties**

360 *The organization shall determine*

361 *a) the interested parties that are relevant to the quality management system, and*

362 *b) the requirements of these interested parties*

363

364 The organization shall update such determinations in order to understand and anticipate needs or
365 expectations affecting customer requirements and customer satisfaction.

366

367 The organization shall consider the following relevant interested parties:

368 a) direct customers;

369 b) end users;

370 c) suppliers, distributors, retailers or others involved in the supply chain;

371 d) regulators; and

372 e) any other relevant interested parties.

373

374 Note Addressing current and anticipated future needs can lead to the identification of improvement and innovation
375 opportunities.

376 **4.3 Determining the scope of the quality management system**

377 *The organization shall determine the boundaries and applicability of the quality management system to*
378 *establish its scope.*

379

380 *When determining this scope, the organization shall consider*

381 *a) the external and internal issues referred to in 4.1, and*

382 *b) the requirements referred to in 4.2.*

383

384 The scope shall be stated in terms of goods and services, the main processes to deliver them and the sites of
385 the organization included.

386

387 When stating the scope, the organization shall document and justify any decision not to apply a requirement of
388 this International Standard and to exclude it from the scope of the quality management system. Any such
389 exclusion shall be limited to clause 7.1. 4 and 8 and shall not affect the organization's ability or responsibility
390 to assure conformity of goods and services and customer satisfaction, nor can an exclusion be justified on the
391 basis of a decision to arrange for an external provider to perform a function or process of the organization.

392

393 Note: An external provider can be a supplier or a sister organization (such as a headquarters or alternate site location)
394 that is outside of the organization's quality management system.

395

396 *The scope shall be available as documented information.*

397

4.4 Quality management system

398

4.4.1 General

399

400 *The organization shall establish, implement, maintain and ~~continually~~ improve a quality management system,*
401 *including the processes needed and their interactions, in accordance with the requirements of this*
402 *International Standard.*

403

404

4.4.2 Process approach

405

406 The organization shall apply a process approach to its quality management system. The organization shall:

- 407 a) determine the processes needed for the quality management system and their application throughout the
408 organization;
- 409 b) determine the inputs required and the outputs expected from each process;
- 410 c) determine the sequence and interaction of these processes;
- 411 d) determine the risks to conformity of goods and services and customer satisfaction if unintended outputs
412 are delivered or process interaction is ineffective;
- 413 e) determine criteria, methods, measurements, and related performance indicators needed to ensure that
414 both the operation and control of these processes are effective;
- 415 f) determine the resources and ensure their availability;
- 416 g) assign responsibilities and authorities for processes;
- 417 h) implement actions necessary to achieve planned results;
- 418 i) monitor, analyse and change, if needed, these processes ensuring that they continue to deliver the
419 intended outputs; and
- 420 j) ensure ~~continual~~ improvement of these processes.

421

5 Leadership

422

5.1 Leadership and commitment

423

5.1.1 Leadership and commitment with respect to the quality management system

424 *Top management shall demonstrate leadership and commitment with respect to the quality management*
425 *system by*

- 426 *a) ensuring that quality policies and quality objectives are established for the quality management system*
427 *and are compatible with the strategic direction of the organization;*
- 428 *b) ensuring the quality policy is understood and followed within the organization;*

- 429 c) *ensuring the integration of the quality management system requirements into the organization's business*
 430 *processes;*
- 431 d) promoting awareness of the process approach;
- 432 e) *ensuring that the resources needed for the quality management system are available*
- 433 f) *communicating the importance of effective quality management and of conforming to the quality*
 434 *management system requirements* and the requirements of goods and services;
- 435 g) *ensuring that the quality management system achieves its intended ~~outcomes~~ outputs;*
- 436 h) *engaging, directing and supporting persons to contribute to the effectiveness of the quality management*
 437 *system;*
- 438 i) *promoting ~~continual~~ improvement* and innovation; and
- 439 j) *supporting other relevant management roles to demonstrate their leadership as it applies to their areas of*
 440 *responsibility.*

441

442 **5.1.2 Leadership and commitment with respect to the needs and expectations of customers**

443

444 Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring
 445 that

- 446 a) the risks which can affect conformity of goods and services and customer satisfaction are identified and
 447 addressed;
- 448 b) customer requirements are determined and met;
- 449 c) the focus on consistently providing goods and services that meet customer and applicable statutory and
 450 regulatory requirements is maintained;
- 451 d) the focus on enhancing customer satisfaction is maintained;

452

453 *NOTE Reference to "business" in this International Standard should be interpreted broadly to mean those activities that*
 454 *are core to the purposes of the organization's existence.*

455 **5.2 Quality policy**

456 *Top management shall establish a quality policy that:*

- 457 a) *is appropriate to the purpose of the organization;*
- 458 b) *provides a framework for setting quality objectives;*
- 459 c) *includes a commitment to satisfy applicable requirements, and*
- 460 d) *includes a commitment to ~~continual~~ improvement of the quality management system.*

461

462 *The quality policy shall:*

- 463 a) *be available as documented information;*
- 464 b) *be communicated within the organization;*
- 465 c) *be available to interested parties, as appropriate; and*
- 466 d) *be reviewed for continuing suitability.*

467

468 **NOTE** Quality Management Principles can be used as the basis for the quality policy.

469 **5.3 Organizational roles, responsibilities and authorities**

470 *Top management shall ensure that the responsibilities and authorities for relevant roles are assigned and*
471 *communicated within the organization.*

472
473 *Top management* shall be accountable for the effectiveness of the quality management system and *shall*
474 *assign the responsibility and authority for:*

- 475 a) *ensuring that the quality management system conforms to the requirements of this International Standard*
476 *and,*
- 477 b) *ensuring that the processes interact and are delivering their intended outputs,*
- 478 c) *reporting on the performance of the quality management system to top management* and any need for
479 *improvement, and*
- 480 d) *ensuring the promotion of awareness of customer requirements throughout the organization.*

481 **6 Planning**

482 **6.1 Actions to address risks and opportunities**

483 *When planning for the quality management system, the organization shall consider the issues referred to in*
484 *4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be*
485 *addressed to*

- 486 a) *assure the quality management system can achieve its intended outcome(s),*
- 487 b) *assure that the organization can consistently achieve conformity of goods and services and customer*
488 *satisfaction,*
- 489 c) *prevent, or reduce, undesired effects, and*
- 490 d) *achieve continual improvement.*

491
492 *The organization shall plan:*

- 493 a) *actions to address these risks and opportunities, and*
- 494 b) *how to*
 - 495 1) *integrate and implement the actions into its quality management system processes (see 4.4), and*
 - 496 2) *evaluate the effectiveness of these actions.*

497
498 Any actions taken to address risks and opportunities shall be proportionate to the potential effects on
499 conformity of goods and services and customer satisfaction.

500
501 Note Options to address risks can include for example risk avoidance, risk mitigation or risk acceptance

502 **6.2 Quality objectives and planning to achieve them**

503 *The organization shall establish quality objectives at relevant functions, levels and processes.*

504 *The quality objectives shall*

- 505 a) *be consistent with the quality policy,*

- 506 *b) be relevant to conformity of goods and services and customer satisfaction,*
507 *c) be measurable (if practicable),*
508 *d) take into account applicable requirements,*
509 *e) be monitored,*
510 *f) be communicated, and*
511 *g) be updated as appropriate.*

512

513 *The organization shall retain documented information on the quality objectives.*

514

515 *When planning how to achieve its quality objectives, the organization shall determine*

- 516 *a) what will be done,*
517 *b) what resources will be required (see 7.1),*
518 *c) who will be responsible,*
519 *d) when it will be completed, and*
520 *e) how the results will be evaluated.*

521 **6.3 Planning of changes**

522 The organization shall determine the needs and opportunities for change to maintain and improve the
523 performance of the quality management system.

524

525 The organization shall undertake change in a planned and systematic manner, identifying risks and
526 opportunities and reviewing the potential consequences of change.

527

528 NOTE Specific requirements on control of changes are included in clause 8.

529 **7 Support**

530 **7.1 Resources**

531 **7.1.1 General**

532

533 *The organization shall determine and provide the resources needed for the establishment, implementation,*
534 *maintenance and ~~continual~~ improvement of the quality management system.*

535

536 The organization shall consider

- 537 a) what are existing internal resources, capabilities and limitations, and
538 b) which goods and services are to be sourced externally.

539

540 **7.1.2 Infrastructure**

541

542 The organization shall determine, provide and maintain the infrastructure necessary for its operations and to
543 assure conformity of goods and services and customer satisfaction.

544

545 Note Infrastructure can include,

- 546 a) buildings and associated utilities,
- 547 b) equipment including hardware and software, and
- 548 c) transportation, communication and information systems.

549

550 **7.1.3 Process environment**

551

552 The organization shall determine, provide and maintain the process environment necessary for its operations
553 and to assure conformity of goods and services and customer satisfaction.

554

555 NOTE Process environment can include physical, social, psychological and environmental factors (such as temperature,
556 recognition schemes, ergonomics and atmospheric composition).

557

558 **7.1.4 Monitoring and measuring devices**

559

560 The organization shall determine, provide and maintain the monitoring and measuring devices needed to
561 verify conformity to product requirements and shall ensure that the devices are fit for purpose.

562

563 The organization shall retain appropriate documented information as evidence of fitness for purpose of
564 monitoring and measuring devices.

565

566 NOTE 1 Monitoring and measurement devices can include measuring equipment and assessment methods such as
567 surveys.

568

569 NOTE 2 Monitoring and measurement devices can be calibrated or verified, or both, at specified intervals, or prior to use,
570 against measurement standards traceable to international or national measurement standards.

571

572 **7.1.5 Knowledge**

573

574 The organization shall determine the knowledge necessary for the operation of the quality management
575 system and its processes and to assure conformity of goods and services and customer satisfaction. This
576 knowledge shall be maintained, protected and made available as necessary.

577

578 Where addressing changing needs and trends the organization shall take into account its current knowledge
579 base and determine how to acquire or access the necessary additional knowledge.(See also 6.3)

580 **7.2 Competence**

581

581 *The organization shall:*

- 582 *a) determine the necessary competence of person(s) doing work under its control that affects its quality*
583 *performance, and*
- 584 *b) ensure that these persons are competent on the basis of appropriate education, training, or experience;*

- 585 c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of
586 the actions taken, and
587 d) retain appropriate documented information as evidence of competence.

588
589 *NOTE* Applicable actions may include, for example: the provision of training to, the mentoring of, or the re-assignment
590 of currently employed persons; or the hiring or contracting of competent persons.

591 **7.3 Awareness**

592 *Persons doing work under the organization's control shall be aware of*

- 593 a) the quality policy,
594 b) relevant quality objectives,
595 c) their contribution to the effectiveness of the quality management system, including the benefits of
596 improved quality performance, and
597 d) the implications of not conforming with the quality management system requirements.

598 **7.4 Communication**

599 *The organization shall determine the need for internal and external communications relevant to the quality
600 management system including*

- 601 a) on what it will communicate,
602 b) when to communicate, and
603 c) with whom to communicate.

604 **7.5 Documented information**

605 **7.5.1 General**

606

607 *The organization's quality management system shall include*

- 608 a) documented information required by this International Standard,
609 b) documented information determined by the organization as being necessary for the effectiveness of the
610 quality management system.

611

612 *NOTE* The extent of documented information for a quality management system can differ from one organization to
613 another due to

- 614 a) the size of organization and its type of activities, processes, ~~products~~ goods and services,
615 b) the complexity of processes and their interactions, and
616 c) the competence of persons.

617

618 **7.5.2 Creating and updating**

619

620 *When creating and updating documented information the organization shall ensure appropriate*

- 621 a) identification and description (e.g. a title, date, author, or reference number),
622 b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic),
623 c) review and approval for suitability and adequacy.

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7.5.3 Control of documented Information

Documented information required by the quality management system and by this International Standard shall be controlled to ensure

- a) it is available and suitable for use, where and when it is needed, and*
- b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).*

For the control of documented information, the organization shall address the following activities, as applicable

- a) distribution, access, retrieval and use,*
- b) storage and preservation, including preservation of legibility,*
- c) control of changes (e.g. version control), and*
- d) retention and disposition.*

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and controlled.

NOTE Access implies a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information, etc.

8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes needed to meet requirements and to implement the actions determined in 6.1, by

- a) establishing criteria for the processes*
- b) implementing control of the processes in accordance with the criteria, and*
- c) keeping documented information to the extent necessary to have confidence that the processes have been carried out as planned.*

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

*The organization shall ensure that ~~outsourced processes are~~ the operation of a function or process of the organization by an external provider is **controlled** (see 8.4).*

Note Operation of a function or process of the organization by an external provider is often referred to as outsourcing.

8.2 Determination of market needs and interactions with customers

8.2.1 General

662 The organization shall implement a process for interacting with customers to determine their requirements
663 relating to goods and services.

664 Note 1 A "customer" means an existing or potential customer

665 Note 2 The organization can interact with other relevant interested parties to determine additional requirements for
666 goods and services (see 4.2).

667

668 **8.2.2 Determination of requirements related to the goods and services**

669

670 The organization shall determine as applicable

- 671 a) requirements specified by the customer including the requirements for delivery and post-delivery activities,
- 672 b) requirements not stated by the customer but necessary for specified or intended use, where known,
- 673 c) statutory and regulatory requirements applicable to the goods and services, and
- 674 d) any additional requirements considered necessary by the organization.

675

676 Note: Additional requirements can include those arising from relevant interested parties

677

678 **8.2.3 Review of requirements related to the goods and services**

679

680 The organization shall review the requirements related to the goods and services. This review shall be
681 conducted prior to the organization's commitment to supply goods and services to the customer (e.g.
682 submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and
683 shall ensure that

- 684 a) goods and services requirements are defined and agreed,
- 685 b) contract or order requirements differing from those previously expressed are resolved, and
- 686 c) the organization is able to meet the defined requirements.

687

688 Documented information describing the results of the review shall be maintained.

689

690 Where the customer does not provide documented statement of their requirements, the customer
691 requirements shall be confirmed by the organization before acceptance.

692

693 Where requirements for goods and services are changed, the organization shall ensure that relevant
694 documented information is amended and that relevant personnel are made aware of the changed
695 requirements.

696

697 NOTE In some situations a formal review is impractical for each order. Instead the review can cover other relevant
698 information available to the customer.

699

700 **8.2.4 Customer communication**

701

702 The organization shall determine and implement planned arrangements for communicating with customers in
703 relation to:

- 704 a) goods and services information,
- 705 b) enquiries, contracts or order handling, including amendments,
- 706 c) customer feedback, including customer complaints (see 9.1),
- 707 d) the handling of customer property, if applicable, and
- 708 e) the specific requirements for contingency actions, where relevant.

709 **8.3 Operational planning process**

710 In preparing for the realization of goods and services, the organization shall implement a process to determine
711 the following, as appropriate,

- 712 a) requirements for the goods and services taking into consideration relevant quality objectives;
- 713 b) actions to identify and address risks related to achieving conformity of goods and services to
714 requirements;
- 715 c) the resources that will be required arising from the requirements for the goods and services;
- 716 d) the criteria for the acceptance of goods and services;
- 717 e) required verification, validation, monitoring, measurement, inspection and test activities specific to the
718 goods and services;
- 719 f) how the performance data will be established and communicated; and
- 720 g) requirements for traceability, preservation, goods and services delivery and post delivery activities.

721
722 The output of this planning process shall be in a form suitable for the organization's operations.

723
724 NOTE 1 Documented information specifying the processes of the quality management system (including the realization
725 of goods and services processes) and the resources to be applied to a specific good and service, project or contract can
726 be referred to as a quality plan.

727
728 NOTE 2 The organization can also apply the requirements given in 8.5 to the development of processes for the
729 realization of goods and services.

730 **8.4 Control of external provision of goods and services**

731 **8.4.1 General**

732
733 The organization shall ensure that externally provided goods and services conform to specified requirements.

734
735 Note Where the organization has arranged for an external provider to perform a function or process of the organization it is
736 assumed this will result in the provision of goods, services or both goods and services.

737 738 **8.4.2 Type and extent of control of external provision**

739
740 The type and extent of control applied to the external providers and the externally-provided processes, goods
741 and services shall be dependent upon

- 742
743 a) the risks identified and the potential impacts,

- 744 b) the degree to which the control of an externally provided process is shared between the organization and
745 the provider, and
746 c) the capability of potential controls.

747
748 The organization shall establish and apply criteria for the evaluation, selection, and re- evaluation of external
749 providers based on their ability to provide, goods and services in accordance with the organization's
750 requirements.

751
752 Documented information describing the results of evaluations shall be maintained.

753

754 **8.4.3 Documented information for external providers**

755

756 Documented information shall be provided to the external provider describing, where appropriate:

- 757 a) the goods and services to be provided or the process to be performed,
758 b) the requirements for approval or release of goods and services, procedures, processes or equipment,
759 c) the requirements for competence of personnel, including necessary qualification,
760 d) the quality management system requirements,
761 e) the control and monitoring of the external provider's performance to be applied by the organization,
762 f) any verification activities that the organization, or its customer, intends to perform at the external
763 provider's premises, and
764 g) the requirements for handling of external provider's property provided to the organization.

765

766 The organization shall ensure the adequacy of specified requirements prior to their communication to the
767 external provider.

768

769 The organization shall monitor the performance of external providers. Documented information describing ~~an~~
770 the results of monitoring shall be maintained.

771

772 **8.5 Development of goods and services**

773 **8.5.1 Development processes**

774

775 The organization shall plan and implement processes for the development of goods and services consistent
776 with the process approach.

777 In determining the stages and controls for the development processes, the organization shall take account of:

- 778 a) the nature, duration and complexity of the development activities,
779 b) customer, statutory and regulatory requirements specifying particular process stages or controls,
780 c) requirements specified by the organization as essential for the specific type of goods and services being
781 developed,
782 d) standards or codes of practice that the organization has committed to implement,
783 e) the determined risks and opportunities associated with the development activities with respect to

- 784 1) the nature of the goods and services to be developed and potential consequences of failure,
- 785 2) the level of control expected of the development process by customers and other relevant
- 786 interested parties, and
- 787 3) the potential impact on the organization's ability to consistently meet customer requirements and
- 788 enhance customer satisfaction.
- 789 f) internal and external resource needs for the development of goods and services,
- 790 g) the need for clarity with respect to the responsibilities and authorities of the individuals and parties
- 791 involved in the development process,
- 792 h) the need for the management of the interfaces between individuals and parties involved in the
- 793 development task or opportunity,
- 794 i) the need for involvement of customer groups and user groups in the development process and their
- 795 interface with management of the development process,
- 796 j) the necessary documented information on the application of development processes, the outputs and
- 797 their suitability, and
- 798 k) the activities needed to transfer from development to production or service provision.
- 799

800 **8.5.2 Development controls**

801

802 The controls applied to the development process shall ensure that

- 803 a) the result to be achieved by the development activities is clearly defined,
- 804 b) inputs are defined to a level sufficient for the development activities being undertaken and do not give rise
- 805 to ambiguity, conflict or lack of clarity,
- 806 c) outputs are in a form suitable for subsequent use for production of goods and provision of services and
- 807 related monitoring and measurement,
- 808 d) problems and issues arising during the development process are resolved or otherwise managed before
- 809 committing to further development work or setting priorities for that work,
- 810 e) the planned development processes have been followed, the outputs are consistent with the inputs and
- 811 the objective of the development activity has been met,
- 812 f) goods produced or services provided as a consequence of the development undertaken are fit for
- 813 purpose, and
- 814 g) appropriate change control and configuration management is maintained throughout the development of
- 815 goods and services and any subsequent modifications to goods and services.
- 816

817 **8.5.3 Development transfer**

818

819 The organization shall ensure that transfer from development to production or service provision only takes

820 place when actions outstanding or arising from development have been completed or are otherwise managed

821 such that there is no adverse impact on the organization's ability to consistently meet customer requirements,

822 statutory or regulatory requirements, or to enhance customer satisfaction.

823

824 **8.6 Production of goods and provision of services**

825 **8.6.1 Control of production of goods and provision of services**

826

827 The organization shall implement production of goods and provision of services under controlled conditions.

828 Controlled conditions shall include, as applicable:

- 829 a) the availability of documented information that describes the characteristics of the goods and services;
- 830 b) the implementation of controls;
- 831 c) the availability of documented information that describes the activities to be performed and the results
832 achieved, as necessary;
- 833 d) the use of suitable equipment;
- 834 e) the availability, implementation and use of monitoring and measuring devices;
- 835 f) the competence of personnel or their qualification;
- 836 g) the validation and approval, and periodic revalidation, of any process for production of goods and
837 provision of services where the resulting output cannot be verified by subsequent monitoring or
838 measurement;
- 839 h) the implementation of goods and services release, delivery and post-delivery activities; and
- 840 i) prevention of nonconformity due to human error, such as unintentional mistakes and intentional rule
841 violations.

842

843 NOTE Validation demonstrates the ability of these processes to achieve planned results through:

- 844 a) definition of criteria for review and approval of the processes;
- 845 b) approval of equipment and qualification of personnel;
- 846 c) use of specific methods and procedures; and
- 847 d) definition of requirements for documented information.

848

849 **8.6.2 Identification and traceability**

850

851 Where appropriate, the organization shall identify process outputs by suitable means.

852

853 The organization shall identify the status of process outputs with respect to monitoring and measurement
854 requirements throughout realization of goods and services.

855

856 Where traceability is a requirement, the organization shall control the unique identification of the process
857 outputs, and maintain it as documented information.

858

859 Note: Process outputs are the results of any activities which are ready for delivery to the customer (external or internal) or
860 become the inputs to the next process. They can include products, services, intermediate parts, components, etc.

861

862 **8.6.3 Property belonging to customers or external providers.**

863

864 The organization shall exercise care with property belonging to the customer or external providers while it is
865 under the organization's control or being used by the organization. The organization shall identify, verify,

866 protect and safeguard the customer or external provider's property provided for use or incorporation into the
867 goods and services.

868
869 If any property of the customer or external provider is lost, damaged or otherwise found to be unsuitable for
870 use, the organization shall report this to the customer or external provider and maintain documented
871 information.

872
873 NOTE Property belonging to customer or external providers can include intellectual property and confidential or
874 personal data.

875
876 **8.6.4 Preservation of goods and services**
877

878 The organization shall ensure preservation of goods and services, including any process outputs, during
879 processing and delivery to the intended destination in order to maintain conformity to requirements.
880 Preservation shall also apply to process outputs that constitutes parts of the goods or any physical process
881 output that is needed for the provision of the service.

882
883 NOTE Preservation can include identification, handling, packaging, storage and protection.

884
885 **8.6.5 Post delivery activities**
886

887 Where applicable, the organization shall determine and meet requirements for post delivery activities
888 associated with the nature and intended lifetime of the goods and services.

889
890 The extent of post delivery activities that are required shall take account of

- 891 a) the risks associated with the goods and services,
- 892 b) customer feedback, and
- 893 c) statutory and regulatory requirements.

894
895 NOTE Post-delivery activities can include, for example, actions under warranty provisions, contractual obligations such
896 as maintenance services, and supplementary services such as recycling or final disposal.

897
898 **8.6.6 Control of changes**
899

900 The organization shall undertake change in a planned and systematic manner, taking account of the review of
901 the potential consequences of changes (see 6.3) and taking action as necessary, to ensure the integrity of
902 goods and services are maintained.

903
904 Documented information describing the results of the review of changes, the personnel authorizing the change
905 and any necessary actions shall be maintained.

907 **8.7 Release of goods and services**

908 The organization shall implement the planned activities at appropriate stages to verify that goods and services
909 requirements have been met (see 8.3). Evidence of conformity with the acceptance criteria shall be
910 maintained.

911
912 The release of goods and services to the customer shall not proceed until the planned arrangements for
913 verification of conformity have been satisfactorily completed, unless otherwise approved by a relevant
914 authority and, where applicable, by the customer. Documented information shall indicate the person(s)
915 authorizing release of goods and services for delivery to the customer.

916

917 **8.8 Nonconforming goods and services**

918 The organization shall ensure that goods and services which do not conform to requirements are identified
919 and controlled to prevent their unintended use or delivery that will have a negative impact on the customer.

920

921 The organization shall take actions (including corrections if needed) appropriate to the nature of the
922 nonconformity and its effects. This applies also to nonconforming goods and services detected after delivery
923 of the goods or during the provision of the service.

924

925 When the nonconforming goods and services have been delivered to the customer, the organization shall also
926 take appropriate correction to assure that customer satisfaction is achieved.

927 Appropriate corrective actions shall be implemented (see 10.1).

928

929 NOTE The appropriate actions can include:

- 930 a) segregation, containment, returning and suspension of provision of goods and services;
- 931 b) informing the customer as appropriate; and
- 932 c) obtaining authorization for repair, regrade, use as it is, release, continuation or re-provision of the service,
933 acceptance under concession.

934

935 When the nonconforming goods and services are corrected it shall be subject to re-verification to demonstrate
936 conformity to the requirements.

937

938 Documented information describing the nature of nonconformities and any subsequent actions taken,
939 including concessions obtained, shall be maintained

940 **9 Performance evaluation**

941 **9.1 Monitoring, measurement, analysis and evaluation**

942 **9.1.1 General**

943

944 *The organization shall ~~determine~~* take into consideration the determined risks and opportunities and shall:

- 945 a) determine *what needs to be monitored and measured* in order to:
- 946 - demonstrate conformity of goods and services to requirements,
 - 947 - evaluate the performance of processes (see 4.4),
 - 948 - ensure conformity and effectiveness of the quality management system, and
 - 949 - evaluate customer satisfaction; and
- 950 b) evaluate the performance of external provider(s) (see 8.4);
- 951 c) determine *the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure*
- 952 *valid results;*
- 953 d) determine *when the monitoring and measuring shall be performed;*
- 954 e) determine *when the results from monitoring and measurement shall be analysed and evaluated;* and
- 955 f) determine what performance indicators of the quality management system are needed.

956

957 The organization shall establish processes to ensure that monitoring and measurement can be carried out and

958 are carried out in a manner that is consistent with the monitoring and measurement requirements.

959

960 *The organization shall retain appropriate documented information as evidence of the results.*

961

962 *The organization shall evaluate the ~~quality~~ performance and the effectiveness of the quality management*

963 *system.*

964

965 9.1.2 Customer satisfaction

966

967 The organization shall monitor data relating to customer perceptions of the degree to which requirements

968 have been met.

969

970 As appropriate, the organization shall obtain data relating to:

- 971 a) customer feedback, and
- 972 b) customer views and perceptions of the organization, its processes and its goods and services.

973

974 The methods for obtaining and using this data shall be determined.

975

976 The organization shall evaluate the data obtained to determine opportunities to enhance customer

977 satisfaction.

978

979 9.1.3 Analysis and evaluation of data

980

981 The organization shall analyse and evaluate appropriate data arising from monitoring, measurement (see

982 9.1.1 and 9.1.2) and other relevant sources. This shall include determination of applicable methods.

983

984 The results of analysis and evaluation shall be used:

- 985 a) to determine the suitability, adequacy and effectiveness of the quality management system,

- 986 b) to assure that the goods and services can consistently meet customer requirements,
987 c) to ensure that the operation and control of processes is effective, and
988 d) to identify improvements within the quality management system.

989

990 The results of analysis and evaluation shall be used as an input to the management review.

991 **9.2 Internal Audit**

992 *The organization shall conduct internal audits at planned intervals to provide information on whether the*
993 *quality management system;*

994 *a) conforms to*

995 *1) the organization's own requirements for its quality management system; and*

996 *2) the requirements of this International Standard;*

997 *b) is effectively implemented and maintained.*

998

999 *The organization shall:*

1000 *a) plan, establish, implement and maintain an audit programme(s), including the frequency, methods,*
1001 *responsibilities, planning requirements and reporting. The audit programme(s) shall take into*
1002 *consideration the quality objectives, the importance of the processes concerned, the related risks, and the*
1003 *results of previous audits;*

1004 *b) define the audit criteria and scope for each audit;*

1005 *c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;*

1006 *d) ensure that the results of the audits are reported to relevant management for evaluation,*

1007 *e) take appropriate action without undue delay; and*

1008 *f) retain documented information as evidence of the implementation of the audit programme and the audit*
1009 *results.*

1010

1011 NOTE See ISO 19011 for guidance.

1012

1013 **9.3 Management review**

1014 *Top management shall review the organization's quality management system, at planned intervals, to ensure*
1015 *its continuing suitability, adequacy, and effectiveness.*

1016

1017 Management review shall be planned and carried out, taking into account the changing business environment
1018 and in alignment with the strategic direction of the organization.

1019

1020 *The management review shall include consideration of:*

1021 *a) the status of actions from previous management reviews;*

1022 *b) changes in external and internal issues that are relevant to the quality management system;*

1023 *c) information on the performance of the quality management system, including trends and indicators for:*

1024 *1) nonconformities and corrective actions;*

- 025 2) *monitoring and measurement results;*
- 026 3) *audit results;*
- 027 4) *customer feedback;*
- 028 5) *supplier and external provider issues; and*
- 029 6) *process performance and product conformity;*
- 030 d) *opportunities for ~~continuous~~ improvement.*

031
032 *The outputs of the management review shall include decisions related to:*

- 033 a) *~~continuous~~ improvement opportunities, and*
- 034 b) *any need for changes to the quality management system.*

035
036 *The organization shall retain documented information as evidence of the results of management reviews*
037 *including actions taken.*

038
039 **10 ~~Continuous~~ improvement**

040 **10.1 Nonconformity and corrective action**

041 *When a nonconformity occurs, the organization shall:*

- 042 a) *react to the nonconformity, and as applicable*
 - 043 1) *take action to control and correct it; and*
 - 044 2) *deal with the consequences;*
- 045 b) *evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or*
046 *occur elsewhere, by*
 - 047 1) *reviewing the nonconformity;*
 - 048 2) *determining the causes of the nonconformity, and*
 - 049 3) *determining if similar nonconformities exist, or could potentially occur;*
- 050 c) *implement any action needed;*
- 051 d) *review the effectiveness of any corrective action taken; and*
- 052 e) *make changes to the quality management system, if necessary.*

053
054 *Corrective actions shall be appropriate to the effects of the nonconformities encountered.*

055 *The organization shall retain documented information as evidence of*
056 a) *the nature of the nonconformities and any subsequent actions taken; and*
057 b) *the results of any corrective action.*

058 **10.2 Improvement**

059 *The organization shall ~~continually~~ improve the suitability, adequacy and effectiveness of the quality*
060 *management system.*

061

- 1062 The organization shall improve the quality management system, processes and goods and services, as
1063 appropriate, through responding to:
- 1064 a) results of analysis of data;
 - 1065 b) changes in the context of the organization;
 - 1066 c) changes in identified risk (see 6.1); and
 - 1067 d) new opportunities.
- 1068
- 1069 The organization shall evaluate, prioritise and determine the improvement to be implemented.

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1073

Annex A Quality management principles (Informative)

1074 **A.1 Introduction**

1075 This document introduces the seven quality management principles on which the quality management system
1076 standards of the ISO 9000 series are based.

1077 The principles were developed and updated by international experts of ISO/TC 176, which is responsible for
1078 developing and maintaining the ISO 9000 series on quality management standards.

1079 This annex provides a “statement” describing each principle and a “rationale” explaining why an organization
1080 should address the principle.

1081

1082 **A.2 QMP 1 – Customer Focus**

1083 **a) Statement**

1084 The primary focus of quality management is to meet customer requirements and to strive to exceed customer
1085 expectations.

1086 **b) Rationale**

1087 Sustained success is achieved when an organization attracts and retains the confidence of customers and
1088 other interested parties on whom it depends. Every aspect of customer interaction provides an opportunity to
1089 create more value for the customer. Understanding current and future needs of customers and other
1090 interested parties contributes to sustained success of an organization

1091

1092 **A.3 QMP 2 – Leadership**

1093 **a) Statement**

1094 Leaders at all levels establish unity of purpose and direction and create conditions in which people are
1095 engaged in achieving the quality objectives of the organization.

1096 **b) Rationale**

1097 Creation of unity of purpose, direction and engagement enable an organization to align its strategies, policies,
1098 processes and resources to achieve its objectives.

1099

1100 **A.4 QMP 3 – Engagement of People**

1101 **a) Statement**

1102 It is essential for the organization that all people are competent, empowered and engaged in delivering value.

1103 Competent, empowered and engaged people throughout the organization enhance its capability to create
1104 value.

1105 **b) Rationale**

106 To manage an organization effectively and efficiently, it is important to involve all people at all levels and to
107 respect them as individuals. Recognition, empowerment and enhancement of skills and knowledge facilitate
108 the engagement of people in achieving the objectives of the organization.
109

110 **A.5 QMP 4 – Process Approach**

111 **a) Statement**

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

114 **b) Rationale**

115 The quality management system is composed of interrelated processes. Understanding how results are
116 produced by this system, including all its processes, resources, controls and interactions, allows the
117 organization to optimize its performance.
118

119 **A.6 QMP 5 – Improvement**

120 **a) Statement**

121 Successful organizations have an ongoing focus on improvement.

122 **b) Rationale**

123 Improvement is essential for an organization to maintain current levels of performance, to react to changes in
124 its internal and external conditions and to create new opportunities.
125

126 **A.7 QMP 6 – Evidence-based Decision Making**

127 **a) Statement**

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

130 **b) Rationale**

131 Decision-making can be a complex process, and it always involves some uncertainty. It often involves multiple
132 types and sources of inputs, as well as their interpretation, which can be subjective. It is important to
133 understand cause and effect relationships and potential unintended consequences. Facts, evidence and data
134 analysis lead to greater objectivity and confidence in decisions made.
135

136 **A.8 QMP 7 – Relationship Management**

137 **a) Statement**

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

139 **b) Rationale**

140 Interested parties influence the performance of an organization. Sustained success is more likely to be
141 achieved when an organization manages relationships with its interested parties to optimize their impact on its
142 performance. Relationship management with its supplier and partner network is often of particular importance.

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² Published in English and French, ten times per year, ISO Focus+ covers the complete range of ISO International Standards: technical, management, good practice and conformity assessment, and for products, services, processes, systems, materials and professionals. Available at <http://www.iso.org/isofocus+>