



DPC: 14 / 30273523 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 14 May 2014

Origin: European

Latest date for receipt of comments: 31 August 2014

Project No. 2012/03288

Responsible committee: QS/1/-/2 Quality terminology

Interested committees:

Title: Draft BS EN ISO 9001 Quality Management Systems - Requirements

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

**WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD.
THIS DRAFT IS NOT CURRENT BEYOND 31 August 2014**

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <http://shop.bsigroup.com> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <http://standardsdevelopment.bsigroup.com>

Responsible Committee Secretary: Ms Sally Swingewood (BSI)

Direct tel:

E-mail: sally.swingewood@bsigroup.com

Introduction

This draft standard is based on European discussions in which the UK has taken an active part. Your comments on this draft are welcome and will assist in the preparation of the consequent British Standard. Comment is particularly welcome on national, legislative or similar deviations that may be necessary.

Even if this draft standard is not approved by the UK, if it receives the necessary support in Europe, the UK will be obliged to publish the official English Language text unchanged as a British Standard and to withdraw any conflicting standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with reasons) or positive vote on this draft.

Submission of Comments

- The guidance given below is intended to ensure that all comments receive efficient and appropriate attention by the responsible BSI committee. **Annotated drafts are not acceptable and will be rejected.**
- All comments must be submitted, preferably electronically, to the Responsible Committee Secretary at the address given on the front cover. Comments should be compatible with version 6.0 or version 97 of Microsoft Word for Windows, if possible; otherwise comments in ASCII text format are acceptable. **Any comments not submitted electronically should still adhere to these format requirements.**
- All comments submitted should be presented as given in the example below. Further information on submitting comments and how to obtain a blank electronic version of a comment form are available from the BSI website at: <http://drafts.bsigroup.com/>

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

1	2	(3)	4	5	(6)	(7)
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/ Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

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

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.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.



Reference number
ISO/DIS 9001:2014(E)

© ISO 2014

Copyright notice

This ISO document is a Draft International Standard and is copyright-protected by ISO. Except as permitted under the applicable laws of the user's country, neither this ISO draft nor any extract from it may be reproduced, stored in a retrieval system or transmitted in any form or by any means, electronic, photocopying, recording or otherwise, without prior written permission being secured.

Requests for permission to reproduce should be addressed to either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Reproduction may be subject to royalty payments or a licensing agreement.

Violators may be prosecuted.

60	Contents	Page
61	Foreword	5
62	Introduction	6
63	0.1 General	6
64	0.2 The ISO standards for quality management	6
65	0.4 Plan-Do-Check-Act cycle	8
66	0.5 “Risk-based thinking”	9
67	0.6 Compatibility with other management system standards	9
68	1 Scope	11
69	2 Normative references	12
70	3 Terms and definitions	12
71	4 Context of the organization	25
72	4.1 Understanding the organization and its context	25
73	4.2 Understanding the needs and expectations of interested parties	25
74	4.3 Determining the scope of the quality management system	25
75	4.4 Quality management system and its processes	26
76	5 Leadership	26
77	5.1 Leadership and commitment	26
78	5.2 Quality policy	27
79	5.3 Organizational roles, responsibilities and authorities	28
80	6 Planning for the quality management system	28
81	6.1 Actions to address risks and opportunities	28
82	6.2 Quality objectives and planning to achieve them	29
83	6.3 Planning of changes	29
84	7 Support	30
85	7.1 Resources	30
86	7.1.1 General	30
87	7.1.2 People	30
88	7.1.3 Infrastructure	30
89	7.1.4 Environment for the operation of processes	30
90	7.1.5 Monitoring and measuring resources	30
91	7.1.6 Organizational knowledge	31
92	7.2 Competence	31
93	7.3 Awareness	31
94	7.4 Communication	32
95	7.5 Documented information	32
96	7.5.1 General	32
97	7.5.2 Creating and updating	32
98	8 Operation	33
99	8.1 Operational planning and control	33
100	8.2 Determination of requirements for products and services	33
101	8.2.1 Customer communication	33
102	8.2.2 Determination of requirements related to products and services	34
103	8.2.3 Review of requirements related to products and services	34
104	8.3 Design and development of products and services	34
105	8.3.1 General	34
106	8.3.2 Design and development planning	35
107	8.3.3 Design and development Inputs	35
108	8.3.4 Design and development controls	35

109	8.3.5	Design and development outputs.....	36
110	8.3.6	Design and development changes	36
111	8.4	Control of externally provided products and services	36
112	8.4.1	General	36
113	8.4.2	Type and extent of control of external provision	36
114	8.4.3	Information for external providers.....	37
115	8.5	Production and service provision	37
116	8.5.1	Control of production and service provision	37
117	8.5.2	Identification and traceability.....	38
118	8.5.3	Property belonging to customers or external providers.....	38
119	8.5.4	Preservation.....	38
120	8.5.5	Post-delivery activities.....	38
121	8.5.6	Control of changes.....	39
122	8.6	Release of products and services	39
123	8.7	Control of nonconforming process outputs, products and services	39
124	9	Performance evaluation.....	40
125	9.1	Monitoring, measurement, analysis and evaluation.....	40
126	9.1.1	General	40
127	9.1.2	Customer satisfaction.....	40
128	9.1.3	Analysis and evaluation.....	40
129	9.2	Internal audit.....	41
130	9.3	Management review	41
131	10	Improvement	42
132	10.1	General	42
133	10.2	Nonconformity and corrective action.....	42
134	10.3	Continual improvement	43
135		Annex A (informative) Clarification of new structure, terminology and concepts	44
136		Annex B (informative) Quality management principles	47
137		Annex C (informative) The ISO 10000 portfolio of quality management standards	49
138		Bibliography.....	52
139			
140			

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).

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).

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 5th edition of ISO 9001 cancels and replaces the 4th 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).

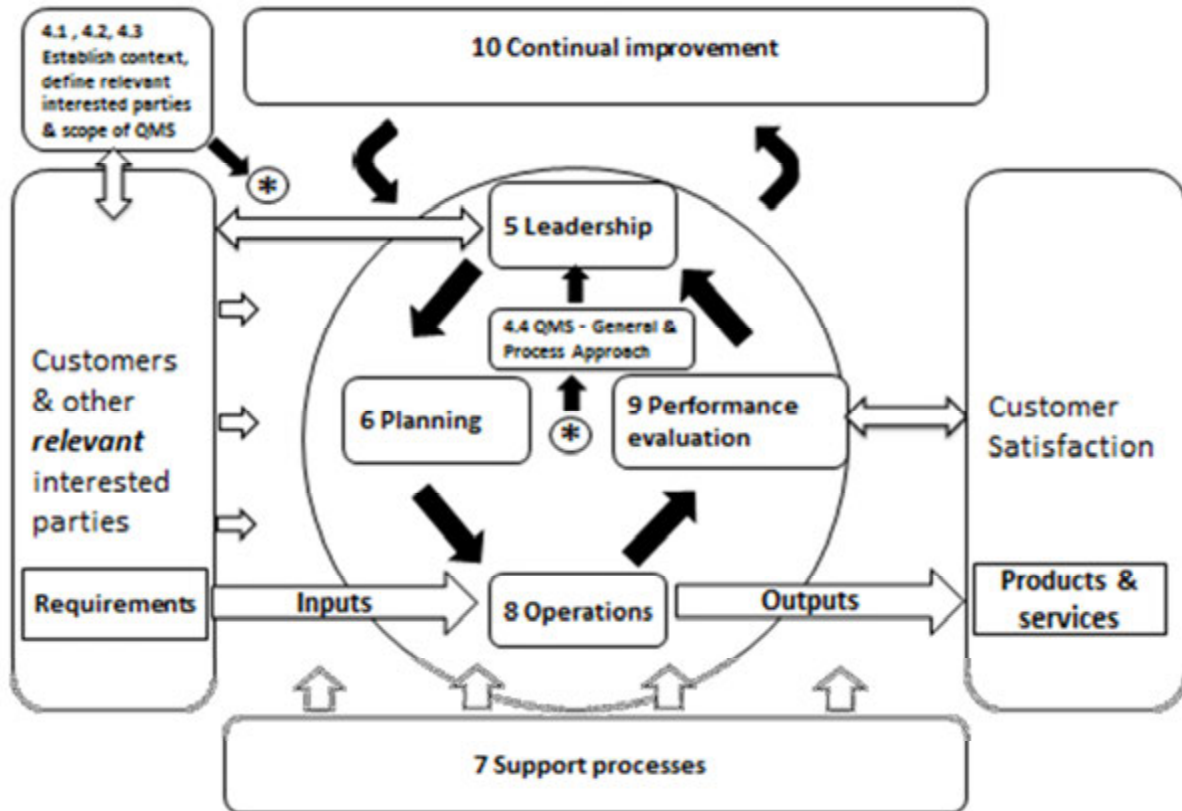
260 When used within a quality management system, the process approach ensures:

- 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



276

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

279

280 **0.4 Plan-Do-Check-Act cycle**

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

284

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

288 — **Do:** implement what was planned.

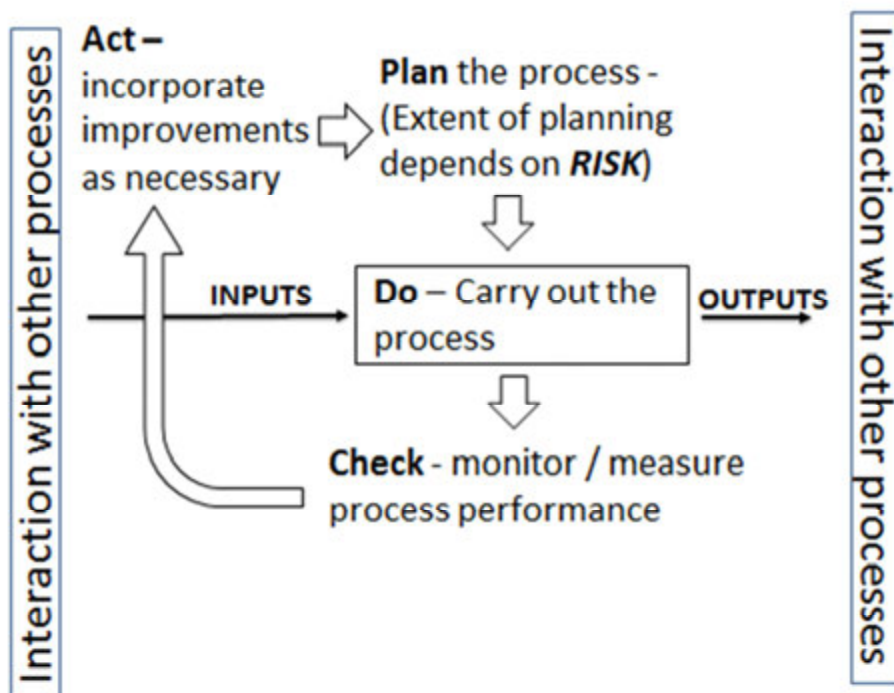
289 — **Check:** monitor and (where applicable) measure processes and the resulting products and
 290 services against policies, objectives and requirements, and report the results.

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
 293 managed using the PDCA cycle.

294

295



296

297

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

298

299 **0.5 “Risk-based thinking”**

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

307

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

316

317 **0.6 Compatibility with other management system standards**

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

322

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

325

- 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.
- 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**
363 **patent rights. ISO shall not be held responsible for identifying any or all such patent rights.**

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.**

368 **Copyright notice**

369 This ISO document is a Draft International Standard and is copyright-protected by ISO. Except as
370 permitted under the applicable laws of the user's country, neither this ISO draft nor any extract from
371 it may be reproduced, stored in a retrieval system or transmitted in any form or by any means,
372 electronic, photocopying, recording or otherwise, without prior written permission being secured.

373 Requests for permission to reproduce should be addressed to either ISO at the address below or
374 ISO's member body in the country of the requester.

375 ISO copyright office
376 Case postale 56 • CH-1211 Geneva 20
377 Tel. + 41 22 749 01 11
378 Fax + 41 22 749 09 47
379 E-mail copyright@iso.org
380 Web www.iso.org

381 Reproduction may be subject to royalty payments or a licensing agreement.

382 Violators may be prosecuted.

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