

มาตรฐานผลิตภัณฑ์อุตสาหกรรม

THAI INDUSTRIAL STANDARD

มอก. 9004 – 2553

ISO 9004 : 2009

การบริหารงานเพื่อความสำเร็จ
ที่ยั่งยืนขององค์กรโดยใช้
แนวทางการบริหารงานคุณภาพ

MANAGING FOR THE SUSTAINED SUCCESS OF AN ORGANIZATION –
A QUALITY MANAGEMENT APPROACH

สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม

กระทรวงอุตสาหกรรม

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สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม
กระทรวงอุตสาหกรรม ถนนพระรามที่ 6 กรุงเทพฯ 10400
โทรศัพท์ 02 202 3300

ประกาศในราชกิจจานุเบกษา ฉบับประกาศและงานทั่วไป เล่ม 127 ตอนพิเศษ 144 ง
วันที่ 16 ธันวาคม พุทธศักราช 2553

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้กำหนดขึ้นเพื่อให้ข้อแนะนำด้านการบริหารงานแก่องค์กรเพื่อให้การดำเนินงานเกิดความสำเร็จที่ยั่งยืนโดยอาศัยแนวทางการบริหารงานคุณภาพ

กระทรวงอุตสาหกรรมได้ประกาศกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้มาแล้ว โดยรับมาตรฐาน ISO 9004 : 2000 Quality management systems – Guidelines for performance improvements มาใช้ในระดับเหมือนกันทุกประการ (identical) ทั้งเนื้อหาและรูปแบบ เป็นมาตรฐานเลขที่ มอก.9004-2544 โดยประกาศในราชกิจจานุเบกษา ฉบับประกาศทั่วไป เล่ม 118 ตอนที่ 70ง วันที่ 30 สิงหาคม พุทธศักราช 2544

เนื่องจากองค์การระหว่างประเทศว่าด้วยการมาตรฐาน (International Organization for Standardization : ISO) ได้ปรับปรุงแก้ไขมาตรฐาน ISO 9004 : 2000 เป็น ISO 9004 : 2009 กระทรวงอุตสาหกรรมจึงดำเนินการปรับปรุงแก้ไขมาตรฐานเลขที่ มอก.9004-2544 เป็นมาตรฐานเลขที่ มอก.9004-2553 โดยรับ ISO 9004 : 2009 Managing for the sustained success of an organization – A quality management approach มาใช้ในระดับเหมือนกันทุกประการ (identical) โดยใช้มาตรฐาน ISO ฉบับภาษาอังกฤษเป็นหลัก

คณะกรรมการมาตรฐานผลิตภัณฑ์อุตสาหกรรมได้พิจารณามาตรฐานนี้แล้ว เห็นสมควรเสนอรัฐมนตรีประกาศตาม มาตรา 15 แห่งพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ. 2511



ประกาศกระทรวงอุตสาหกรรม

ฉบับที่ 4254 (พ.ศ. 2553)

ออกตามความในพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม

พ.ศ. 2511

เรื่อง ยกเลิกและกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม

การบริหารงานเพื่อความสำเร็จที่ยั่งยืนขององค์กรโดยใช้แนวทางการบริหารงานคุณภาพ

โดยที่เป็นการสมควรปรับปรุงมาตรฐานผลิตภัณฑ์อุตสาหกรรม ระบบการบริหารงานคุณภาพ : แนวทางสำหรับการปรับปรุงสมรรถนะ มาตรฐานเลขที่ มอก.9004-2544 และกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม การบริหารงานเพื่อความสำเร็จที่ยั่งยืนขององค์กรโดยใช้แนวทางการบริหารงานคุณภาพ มาตรฐานเลขที่ มอก.9004-2553 ขึ้นใหม่

อาศัยอำนาจตามความในมาตรา 15 แห่งพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ. 2511 รัฐมนตรีว่าการกระทรวงอุตสาหกรรมจึงออกประกาศกระทรวงอุตสาหกรรมไว้ดังต่อไปนี้

1. ยกเลิกประกาศกระทรวงอุตสาหกรรมซึ่งออกตามความในพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ. 2511 จำนวน 1 ฉบับ คือ ประกาศกระทรวงอุตสาหกรรม ฉบับที่ 2845 (พ.ศ. 2544) เรื่อง ยกเลิกและกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม ระบบการบริหารงานคุณภาพ : แนวทางสำหรับการปรับปรุงสมรรถนะ มาตรฐานเลขที่ มอก.9004-2544 ลงวันที่ 25 เมษายน พ.ศ.2544

2. กำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม การบริหารงานเพื่อความสำเร็จที่ยั่งยืนขององค์กรโดยใช้แนวทางการบริหารงานคุณภาพ มาตรฐานเลขที่ มอก.9004-2553 ดังมีรายละเอียดต่อท้ายประกาศนี้

ทั้งนี้ ให้มีผลตั้งแต่วันที่ประกาศในราชกิจจานุเบกษาเป็นต้นไป

ประกาศ ณ วันที่ 20 กันยายน พ.ศ. 2553

ชัยวุฒิ บรรณวัฒน์

รัฐมนตรีว่าการกระทรวงอุตสาหกรรม

มาตรฐานผลิตภัณฑ์อุตสาหกรรม การบริหารงานเพื่อความสำเร็จ ที่ยั่งยืนขององค์กรโดยใช้ แนวทางการบริหารงานคุณภาพ

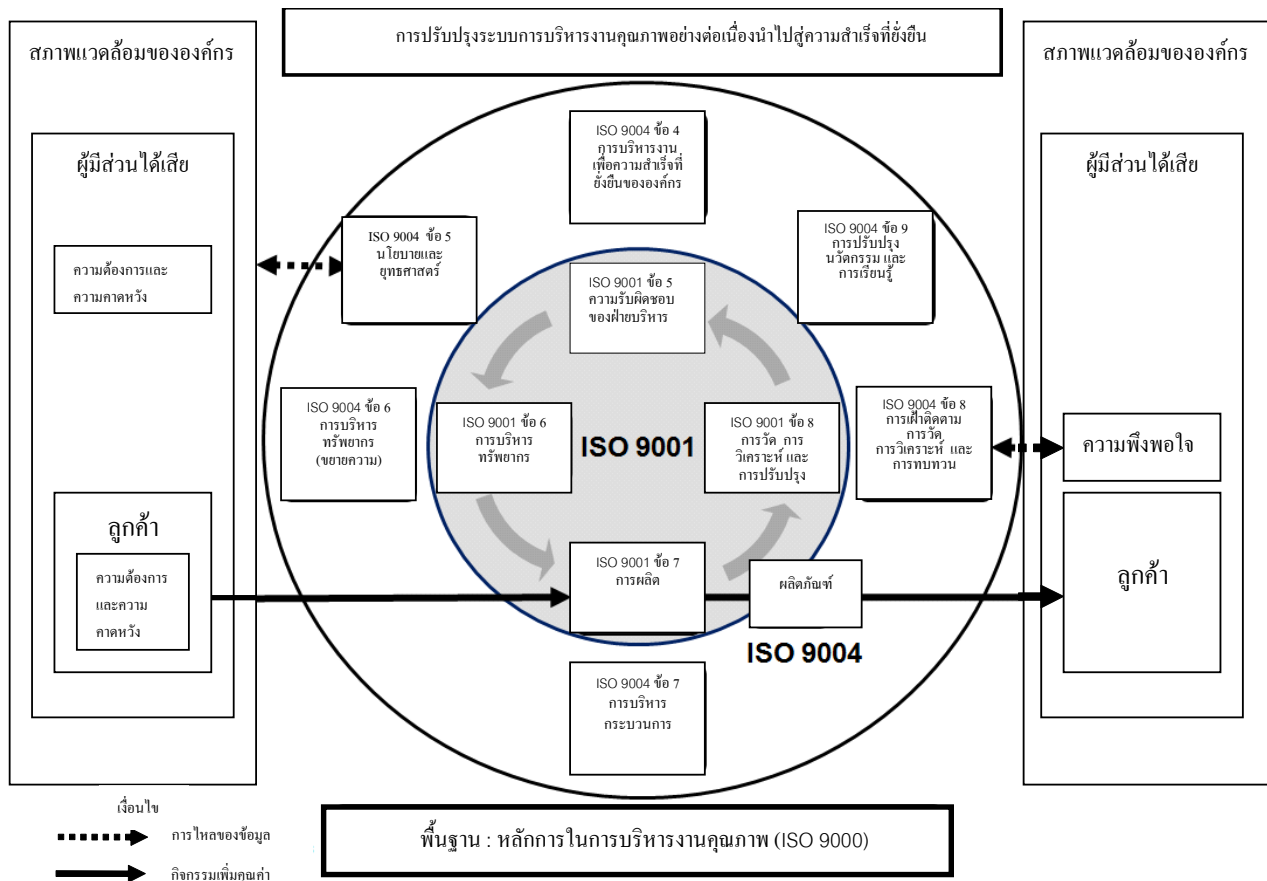
บทนำ

มาตรฐานนี้ให้คำแนะนำที่ช่วยให้องค์กรสามารถประสบความสำเร็จที่ยั่งยืนในสถานการณ์ต่าง ๆ ได้โดยใช้แนวทางการบริหารงานคุณภาพ

การที่องค์กรจะประสบความสำเร็จที่ยั่งยืนได้ต้องอาศัยความสามารถขององค์กรในการสนองความต้องการและความคาดหวังของลูกค้า และผู้มีส่วนได้เสีย ในระยะยาวและมีความสมดุล ความสำเร็จที่ยั่งยืนจะเกิดขึ้นได้โดยการบริหารงานที่มีประสิทธิผล ด้วยความคำนึงถึงสภาพแวดล้อมขององค์กร โดยการเรียนรู้ และนำไปใช้ในการปรับปรุง และทำให้เกิดนวัตกรรมตามความเหมาะสม

มาตรฐานนี้ส่งเสริมให้นำเรื่องการประเมินตนเองมาใช้เป็นเครื่องมือสำคัญในการทบทวนระดับความเจริญขององค์กรในด้านต่าง ๆ ได้แก่ ภาวะผู้นำ ยุทธศาสตร์ ระบบการบริหารงาน ทรัพยากร และกระบวนการ เพื่อชี้บ่งจุดแข็ง จุดอ่อน และโอกาส ทั้งเพื่อการปรับปรุงและการสร้างนวัตกรรม

มาตรฐานนี้ให้ความสำคัญกับการบริหารงานคุณภาพที่กว้างขวางกว่ามาตรฐาน มอก. 9001 โดยระบุความต้องการและความคาดหวังของผู้มีส่วนได้เสียที่เกี่ยวข้องทั้งหมด และให้คำแนะนำเพื่อการปรับปรุงสมรรถนะโดยรวมขององค์กรอย่างเป็นระบบและต่อเนื่อง รูปแบบระบบการบริหารงานคุณภาพเชิงกระบวนการซึ่งได้ขยายรวมข้อกำหนดของมาตรฐาน ISO 9001 และแนวทางการบริหารงานคุณภาพ ตามมาตรฐาน ISO 9004 เข้าด้วยกัน ได้แสดงไว้ดังรูปที่ 1



รูปที่ 1 รูปแบบขยายความของกระบวนการระบบการบริหารงานคุณภาพ

มาตรฐานนี้จัดทำขึ้นโดยคงรักษาให้สอดคล้องกับ มอก. 9001 และสามารถนำไปใช้ร่วมกับมาตรฐานระบบการบริหารงานอื่นได้ มาตรฐานต่าง ๆ จะเสริมซึ่งกันและกัน แต่สามารถใช้เป็นอิสระได้

ภาคผนวก ก ให้เครื่องมือสำหรับองค์กรในการประเมินจุดแข็ง และจุดอ่อนของตนเอง เพื่อกำหนดระดับความเจริญ และใช้ในการชี้บ่งโอกาสในการปรับปรุงและสร้างนวัตกรรม

ภาคผนวก ข ให้คำอธิบายของหลักการของการบริหารงานคุณภาพซึ่งเป็นพื้นฐานที่ ISO/TC176 ใช้ในการกำหนดมาตรฐานด้านการบริหารงานคุณภาพ

ภาคผนวก ค แสดงความสัมพันธ์ในแต่ละข้อของมาตรฐานนี้กับมาตรฐาน มอก. 9001-2552

ขอบข่าย

มาตรฐานนี้ให้คำแนะนำแก่องค์กร เพื่อช่วยให้ประสบความสำเร็จที่ยั่งยืนโดยการนำแนวทางการบริหารงานคุณภาพมาใช้ ซึ่งสามารถนำไปใช้กับองค์กรโดยไม่จำกัดขนาด ประเภท และกิจกรรม และไม่มีจุดมุ่งหมายให้นำไปใช้เพื่อการรับรอง การบังคับใช้เป็นกฎหมาย หรือการทำข้อตกลง รายละเอียดให้เป็นไปตามมาตรฐาน ISO 9004 : 2009 ข้อ 1

เอกสารอ้างอิง

เอกสารอ้างอิงดังต่อไปนี้เกี่ยวข้องกับการนำมาตรฐานนี้ไปใช้ สำหรับเอกสารอ้างอิงที่มีการระบุวันที่ไว้ให้ใช้ เฉพาะฉบับตามที่ระบุเท่านั้น ส่วนเอกสารอ้างอิงที่ไม่ได้ระบุวันที่ไว้ให้ใช้เอกสารอ้างอิงฉบับล่าสุด รวมถึงส่วนที่ได้มีการแก้ไขปรับปรุงด้วย

ISO 9000, Quality management systems – Fundamentals and vocabulary

รายละเอียดให้เป็นไปตามมาตรฐาน ISO 9004 : 2009 ข้อ 2

บทนิยาม

เพื่อให้เป็นไปตามวัตถุประสงค์ของมาตรฐานนี้ ความหมายของคำที่ใช้ให้เป็นไปตามมาตรฐาน ISO 9000 และคำศัพท์ดังต่อไปนี้

ความสำเร็จอย่างยั่งยืน (sustained success)

ผลของความสามารถขององค์กรที่บรรลุและรักษาวัตถุประสงค์ขององค์กรในระยะยาว

สภาพแวดล้อมขององค์กร (organization's environment)

ปัจจัยโดยรวมทั้งภายใน ภายนอก และเงื่อนไขต่าง ๆ ซึ่งจะส่งผลกระทบต่อการบริหารวัตถุประสงค์ขององค์กร และพฤติกรรมขององค์กรที่มีต่อผู้มีส่วนได้เสีย

รายละเอียดให้เป็นไปตามมาตรฐาน ISO 9004 : 2009 ข้อ 3

การบริหารงานเพื่อความสำเร็จที่ยั่งยืนขององค์กร

ให้คำแนะนำทั่วไปเกี่ยวกับการบริหารงานเพื่อความสำเร็จที่ยั่งยืนขององค์กร การประสบความสำเร็จที่ยั่งยืน สภาพแวดล้อมขององค์กร และความต้องการและความคาดหวังของผู้มีส่วนได้เสีย

รายละเอียดให้เป็นไปตามมาตรฐาน ISO 9004 : 2009 ข้อ 4

นโยบายและยุทธศาสตร์

ให้คำแนะนำทั่วไป การกำหนด การถ่ายทอด และการสื่อสารนโยบายและยุทธศาสตร์

รายละเอียดให้เป็นไปตามมาตรฐาน ISO 9004 : 2009 ข้อ 5

การบริหารทรัพยากร

ให้ข้อเสนอแนะทั่วไป ทรัพยากรด้านการเงิน บุคลากรภายในองค์กร ผู้ส่งมอบและหุ้นส่วนธุรกิจ โครงสร้างพื้นฐาน สภาพแวดล้อมในการทำงาน ความรู้ สารสนเทศและเทคโนโลยี และทรัพยากรธรรมชาติ

รายละเอียดให้เป็นไปตามมาตรฐาน ISO 9004 : 2009 ข้อ 6

การบริหารกระบวนการ

ให้ข้อเสนอแนะทั่วไป การวางแผนและควบคุมกระบวนการ และอำนาจหน้าที่และความรับผิดชอบต่อกระบวนการ

รายละเอียดให้เป็นไปตามมาตรฐาน ISO 9004 : 2009 ข้อ 7

การตรวจ การวัด การวิเคราะห์ และการทบทวน

ให้ข้อเสนอแนะทั่วไป การตรวจ การวัด การวิเคราะห์ และการทบทวนสารสนเทศที่ได้รับจากการตรวจ การวัด และการวิเคราะห์

รายละเอียดให้เป็นไปตามมาตรฐาน ISO 9004 : 2009 ข้อ 8

การปรับปรุง การสร้างนวัตกรรม และการเรียนรู้

ให้ข้อเสนอแนะเกี่ยวกับการปรับปรุง การสร้างนวัตกรรม และการเรียนรู้

รายละเอียดให้เป็นไปตามมาตรฐาน ISO 9004 : 2009 ข้อ 9

ภาคผนวก

ให้ข้อมูลเกี่ยวกับเครื่องมือสำหรับองค์กรในการประเมินตนเอง หลักการด้านการบริหารงานคุณภาพ และตารางแสดงความสัมพันธ์ระหว่าง ISO 9004 : 2009 และ ISO 9001 : 2008

รายละเอียดให้เป็นไปตามมาตรฐาน ISO 9004 : 2009 Annex A, Annex B และ Annex C

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เอกสารนี้เป็นสิทธิ์ของ ISO หากมิได้กำหนดไว้เป็นอย่างอื่นห้ามนำมาตรฐานฉบับนี้หรือ
ส่วนหนึ่งส่วนใดไปทำซ้ำหรือใช้ประโยชน์ในรูปแบบ หรือโดยวิธีใด ๆ ไม่ว่าจะเป็นรูปแบบ
อิเล็กทรอนิกส์หรือทางกล รวมถึงการถ่ายสำเนา ถ่ายไมโครฟิล์ม โดยไม่ได้รับอนุญาตเป็น
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ISO 9004:2009(E)**Foreword**

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

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

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

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

ISO 9004 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This third edition cancels and replaces the second edition (ISO 9004:2000), which has been technically revised.

Managing for the sustained success of an organization is a major change in focus for ISO 9004, leading to substantial changes to its structure and contents.

Introduction

This International Standard provides guidance to support the achievement of sustained success for any organization in a complex, demanding, and ever-changing environment, by a quality management approach.

The sustained success of an organization is achieved by its ability to meet the needs and expectations of its customers and other interested parties, over the long term and in a balanced way. Sustained success can be achieved by the effective management of the organization, through awareness of the organization's environment, by learning, and by the appropriate application of either improvements, or innovations, or both.

This International Standard promotes self-assessment as an important tool for the review of the maturity level of the organization, covering its leadership, strategy, management system, resources and processes, to identify areas of strength and weakness and opportunities for either improvements, or innovations, or both.

This International Standard provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all relevant interested parties and provides guidance for the systematic and continual improvement of the organization's overall performance. An extended model of a process-based quality management system incorporating the elements of ISO 9001 and ISO 9004 is given in Figure 1.

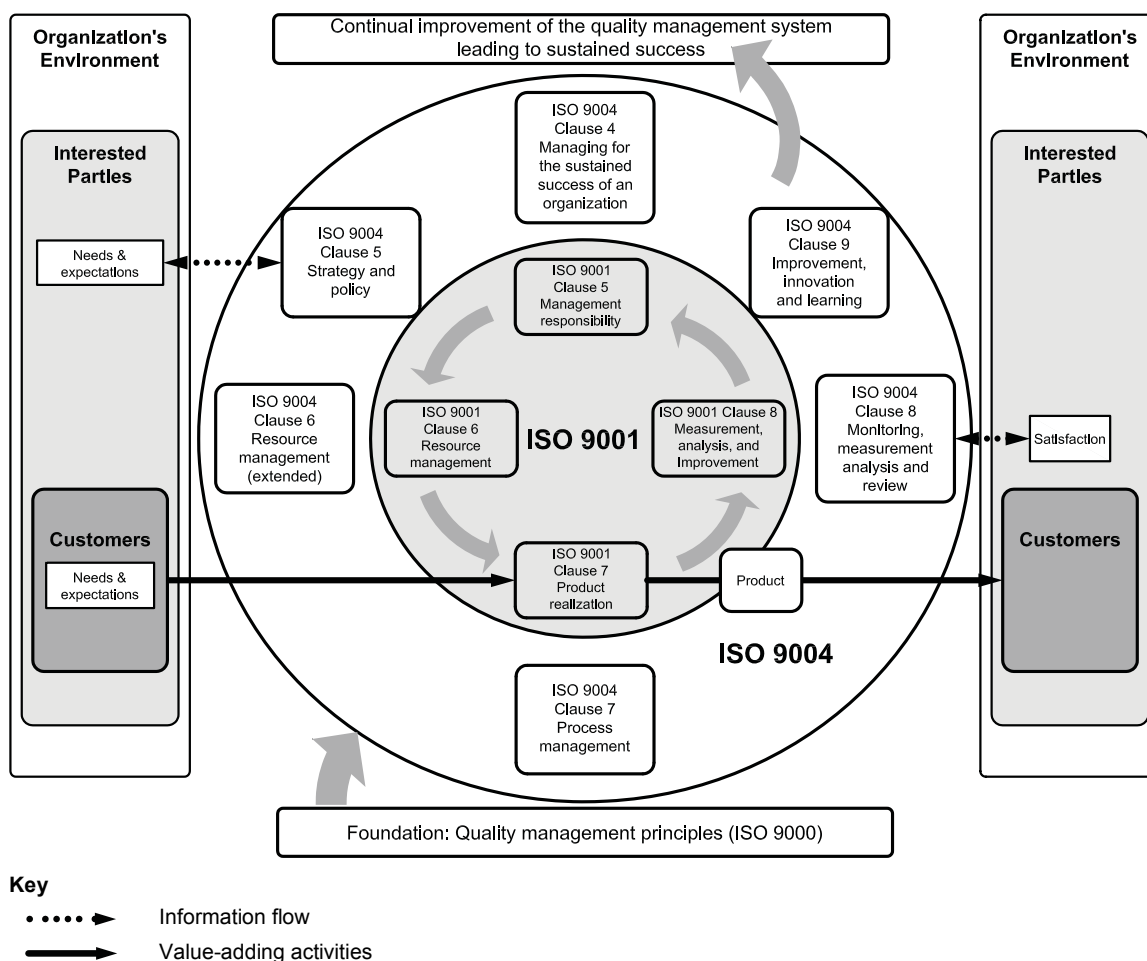


Figure 1 — Extended model of a process-based quality management system

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This International Standard has been developed to maintain consistency with ISO 9001 and be compatible with other management system standards. Such standards complement each other, but can also be used independently.

Annex A provides a tool for organizations to self-assess their own strengths and weaknesses, to determine their level of maturity, and to identify opportunities for improvement and innovation.

Annex B provides a description of the quality management principles that are the basis of the quality management standards prepared by ISO/TC 176.

Annex C gives a clause by clause correspondence between ISO 9001:2008 and this International Standard.

Managing for the sustained success of an organization — A quality management approach

1 Scope

This International Standard provides guidance to organizations to support the achievement of sustained success by a quality management approach. It is applicable to any organization, regardless of size, type and activity.

This International Standard is not intended for certification, regulatory or contractual use.

2 Normative references

The following referenced documents relate to the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

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

3.1

sustained success

⟨organization⟩ result of the ability of an organization to achieve and maintain its objectives in the long term

3.2

organization's environment

combination of internal and external factors and conditions that can affect the achievement of an organization's objectives and its behaviour towards its interested parties

4 Managing for the sustained success of an organization

4.1 General

To achieve sustained success, top management should adopt a quality management approach. The organization's quality management system should be based on the principles described in Annex B. These principles describe concepts that are the foundation of an effective quality management system. To achieve sustained success, top management should apply these principles to the organization's quality management system.

The organization should develop the organization's quality management system to ensure

— the efficient use of resources,

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- decision making based on factual evidence, and
- focus on customer satisfaction, as well as on the needs and expectations of other relevant interested parties.

NOTE In this International Standard, the term “top management” refers to the highest level of decision making authority in an organization and the term “the organization” covers all people in an organization. This is consistent with the definitions of these terms given in ISO 9000.

4.2 Sustained success

The organization can achieve sustained success by consistently meeting the needs and expectations of its interested parties, in a balanced way, over the long term.

An organization's environment is ever-changing and uncertain, and to achieve sustained success its top management should

- have a long-term planning perspective,
- constantly monitor and regularly analyse the organization's environment,
- identify all its relevant interested parties, assess their individual potential impacts on the organization's performance, as well as determining how to meet their needs and expectations in a balanced way,
- continually engage interested parties and keep them informed of the organization's activities and plans,
- establish mutually beneficial relationships with suppliers, partners and other interested parties,
- make use of a wide variety of approaches, including negotiation and mediation, to balance the often competing needs and expectations of interested parties,
- identify associated short and long-term risks and deploy an overall strategy for the organization to mitigate them,
- anticipate future resource needs (including the competences required of its people),
- establish processes appropriate to achieving the organization's strategy, ensuring that they are capable of responding quickly to changing circumstances,
- regularly assess compliance with current plans and procedures, and take appropriate corrective and preventive actions,
- ensure that people in the organization have opportunities for learning for their own benefit, as well as for maintaining the vitality of the organization, and
- establish and maintain processes for innovation and continual improvement.

4.3 The organization's environment

An organization's environment will be undergoing change continually, regardless of its size (large or small), its activities and products, or its type (for profit or not-for-profit); consequently this should be monitored constantly by the organization. Such monitoring should enable the organization to identify, assess and manage the risks related to interested parties, and their changing needs and expectations.

Top management should make decisions for organizational change and innovation in a timely manner in order to maintain and improve the organization's performance.

NOTE For more information on risk management, see ISO 31000.

4.4 Interested parties, needs and expectations

Interested parties are individuals and other entities that add value to the organization, or are otherwise interested in, or affected by, the activities of the organization. Meeting the needs and expectations of interested parties contributes to the achievement of sustained success by the organization.

In addition, the needs and expectations of individual interested parties are different, can be in conflict with those of other interested parties, or can change very quickly. The means by which the needs and expectations of interested parties are expressed and met can take a wide variety of forms, including collaboration, cooperation, negotiation, outsourcing, or by terminating an activity.

Table 1 — Examples of interested parties and their needs and expectations

Interested party	Needs and expectations
Customers	Quality, price and delivery performance of products
Owners/shareholders	Sustained profitability Transparency
People in the organization	Good work environment Job security Recognition and reward
Suppliers and partners	Mutual benefits and continuity
Society	Environmental protection Ethical behaviour Compliance with statutory and regulatory requirements

NOTE Although most organizations use similar descriptions for their interested parties (e.g. customers, owners/shareholders, suppliers and partners, people in the organization), the composition of those categories can differ significantly over time and between organizations, industries, nations and cultures.

5 Strategy and policy

5.1 General

To achieve sustained success, top management should establish and maintain a mission, a vision and values for the organization. These should be clearly understood, accepted and supported by people in the organization and, as appropriate, by other interested parties.

NOTE In this International Standard, a “mission” is a description of why the organization exists, and a “vision” describes its desired state, i.e. what the organization wants to be and how it wants to be seen by its interested parties.

5.2 Strategy and policy formulation

Top management should set out the organization's strategy and policies clearly, in order to get the mission, vision and values accepted and supported by its interested parties. The organization's environment should be regularly monitored to determine if there is a need to review and (when appropriate) revise the strategy and policies. In order to establish, adopt and sustain an effective strategy and policy, the organization should have processes to

- continually monitor and regularly analyse the organization's environment, including its customers' needs and expectations, the competitive situation, new technologies, political changes, economic forecasts, or sociological factors,
- identify and determine the needs and expectations of other interested parties,

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- assess its current process capabilities and resources,
- identify future resource and technology needs,
- update its strategy and policies, and
- identify the outputs necessary to meet the needs and expectations of the interested parties.

These processes should be established in a timely manner, with any necessary plans and resources being provided to support them.

The formulation of an organization's strategy should also consider activities such as analyses of customer or regulatory demands, its products, its strengths, weaknesses, opportunities, and threats. A defined process should exist for the formulation and review of the organization's strategy.

NOTE A "strategy" means a logically structured plan or method for achieving objectives, especially over a long period of time.

5.3 Strategy and policy deployment**5.3.1 General**

To implement a strategy and policies for sustained success, the organization should establish and maintain processes and practices that

- translate its strategy and policies into measurable objectives for all relevant levels of the organization, as appropriate,
- establish timelines for each objective and assign responsibility and authority for achieving the objective,
- evaluate strategic risks and define adequate counter measures,
- provide the resources required to deploy needed activities, and
- execute the activities needed to achieve these objectives.

5.3.2 Processes and practices

In order to ensure that its processes and practices are effective and efficient, the organization should perform activities for

- anticipating any potential conflicts arising from the different needs and expectations of its interested parties,
- assessing and understanding the organization's current performance and the root-causes of problems in the past, in order to avoid their recurrence,
- keeping interested parties informed, gaining their commitment, keeping them aware of progress against plans, and obtaining feedback and ideas for improvement from them,
- reviewing the management system and its processes, and updating them as necessary,
- monitoring, measuring, analysing, reviewing and reporting,
- providing any required resources, including those for improvement, innovation and learning,

- the development, updating and accomplishment of its objectives, including defining timeframes for their achievement, and
- ensuring that the results are consistent with the strategy.

5.3.3 Deployment

To deploy its strategy and policies, the organization should identify the relationships between its processes. A description of the sequence and interaction of the processes can assist review activities by

- showing the relationship between organizational structures, systems and processes,
- identifying potential problems in the interactions between processes,
- providing a means for prioritizing improvement and other change initiatives, and
- providing a framework for setting, aligning and deploying objectives to all relevant levels of the organization.

5.4 Strategy and policy communication

The effective communication of the strategy and policies is essential to the sustained success of the organization.

Such communication should be meaningful, timely and continual. Communication should also include a feedback mechanism, a review cycle and should incorporate provisions to proactively address changes in the organization's environment.

The organization's communication process should operate both vertically and horizontally and should be tailored to the differing needs of its recipients. For example, the same information can be conveyed differently to people within the organization than to customers or other interested parties.

6 Resource management

6.1 General

The organization should identify the internal and external resources that are needed for the achievement of the organization's objectives in the short and long term. The organization's policies and methods for resource management should be consistent with its strategy.

To ensure that resources (such as equipment, facilities, materials, energy, knowledge, finance and people) are used effectively and efficiently, it is necessary to have processes in place to provide, allocate, monitor, evaluate, optimize, maintain and protect those resources.

To ensure the availability of the resources for future activities, the organization should identify and assess the risks of potential scarcity, and continually monitor current use of resources to find opportunities for improvement of their use. In parallel, research for new resources, optimized processes and new technologies should take place.

The organization should periodically review the availability and suitability of the identified resources, including outsourced resources, and take action as necessary. The results of these reviews should also be used as inputs into the organization's reviews of its strategy, objectives and plans.

ISO 9004:2009(E)**6.2 Financial resources**

Top management should determine the organization's financial needs and establish the necessary financial resources for current and future operations. Financial resources can take many different forms such as cash, securities, loans or other financial instruments.

The organization should establish and maintain processes for monitoring, controlling and reporting the effective allocation and efficient usage of financial resources related to the organization's objectives.

Reporting of such matters can also provide means for determining ineffective or inefficient activities, and initiating suitable improvement actions. Financial reporting of activities related to the performance of the management system and product conformity should be used in management reviews.

Improving the effectiveness and efficiency of the management system can positively influence the financial results of the organization in many ways. Examples include

- internally, by reducing process and product failures and eliminating the waste of materials or time, and
- externally, by reducing product failures, costs of compensation under guarantees and warranties, product liabilities and other legal exposure, costs of lost customers and markets.

NOTE ISO 10014 provides examples of how an organization can identify and obtain financial and economic benefits from the application of the ISO 9000 quality management principles.

6.3 People in the organization**6.3.1 Management of people**

People are a significant resource of an organization and their full involvement enhances their ability to create value for interested parties. Top management should, through its leadership, create and maintain a shared vision, shared values and an internal environment in which people can become fully involved in achieving the organization's objectives.

As people are a most valuable and critical resource, it is necessary to ensure that their work environment encourages personal growth, learning, knowledge transfer and teamwork. People management should be performed through a planned, transparent, ethical and socially responsible approach. The organization should ensure that the people understand the importance of their contribution and roles.

The organization should establish processes that empower people to

- translate the organization's strategic and process objectives into individual job objectives, and to establish plans for their achievement,
- identify constraints to their performance,
- take ownership and responsibility to solve problems,
- assess personal performance against individual job objectives,
- actively seek opportunities to enhance their competence and experience,
- promote teamwork and encourage synergy between people, and
- share information, knowledge and experience within the organization.

6.3.2 Competence of people

In order to ensure that it has the necessary competences, the organization should establish and maintain a “people development plan” and associated processes; these should assist the organization in identifying, developing and improving the competence of its people through the following steps

- identifying the professional and personal competences the organization could need in the short and long term, in accordance with its mission, vision, strategy, policies, and objectives,
- identifying the competences currently available in the organization and the gaps between what is available and what is currently needed and could be needed in the future,
- implementing actions to improve and/or acquire competences to close the gaps,
- reviewing and evaluating the effectiveness of actions taken to ensure that the necessary competences have been acquired, and
- maintaining competences that have been acquired.

NOTE See ISO 10015 for further guidance on competence and training.

6.3.3 Involvement and motivation of people

The organization should motivate people to understand the significance and importance of their responsibilities and activities in relation to the creation and provision of value for the customers and other interested parties.

To enhance the involvement and motivation of its people, the organization should consider activities such as

- developing a process to share knowledge and use the competence of people, e.g. a scheme for collecting ideas for improvement,
- introducing an appropriate recognition and reward system, that is based on individual evaluations of the accomplishments of the people,
- establishing a skills qualification system and career planning, to promote personal development,
- continually reviewing the level of satisfaction and needs and expectations of people, and
- providing opportunities for mentoring and coaching.

NOTE For more information about the “involvement of people”, see the related quality management principle in Annex B.

6.4 Suppliers and partners

6.4.1 General

Partners can be suppliers of products, service providers, technological and financial institutions, governmental and non-governmental organizations or other interested parties. Partners can contribute with any type of resource, as agreed and defined in a partnership agreement.

The organization and its partners are interdependent and a mutually beneficial relationship enhances their capabilities to create value. The organization should consider partnership as a specific form of relationship with suppliers, where suppliers can invest in and share the profits or losses of the organization's area of activity.

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When an organization is developing partnerships, the organization should give consideration to issues such as

- the provision of information to partners, as appropriate, to maximize their contributions,
- supporting partners, in terms of providing them with resources (such as information, knowledge, expertise, technology, processes, and shared training),
- the sharing of profits and losses with partners, and
- improving the performance of partners.

NOTE For more information about “mutually beneficial relationships”, see the related quality management principle in Annex B.

6.4.2 Selection, evaluation and improvement of the capabilities of suppliers and partners

The organization should establish and maintain processes to identify, select, and evaluate its suppliers and partners, in order to continually improve their capabilities and to ensure that the products or other resources they provide meet the needs and expectations of the organization.

In selecting and evaluating suppliers and partners, the organization should consider issues such as

- their contribution to the organization's activities and ability to create value for the organization and its interested parties,
- the potential for continually improving their capabilities,
- the enhancement of its own capabilities that can be achieved through co-operation with the suppliers and partners, and
- the risks associated in the relationships with the suppliers and partners.

Together with its suppliers and partners, the organization should seek to continually improve the quality, price and delivery of products provided by the suppliers and partners, and the effectiveness of their management systems, based on periodic evaluation and feedback of their performance.

The organization should continually review and strengthen its relationships with its suppliers and partners, while considering the balance between its short- and long-term objectives.

6.5 Infrastructure

The organization should plan, provide and manage its infrastructure effectively and efficiently. It should periodically assess the suitability of the infrastructure to meet organizational objectives. Appropriate consideration should be given to

- the dependability of the infrastructure (including consideration of availability, reliability, maintainability, and maintenance support),
- safety and security,
- infrastructure elements related to products and processes,
- the efficiency, cost, capacity and work environment, and
- the impact of the infrastructure on the work environment.

The organization should identify and assess the risks associated with the infrastructure and take action to mitigate the risks, including the establishment of adequate contingency plans.

NOTE For more information about environmental impacts, see ISO 14001 and other standards prepared by ISO/TC 207.

6.6 Work environment

The organization should provide and manage a suitable work environment to achieve and maintain the sustained success of the organization and the competitiveness of its products. A suitable work environment, as a combination of human and physical factors, should include consideration of

- creative work methods and opportunities for greater involvement to realize the potential of people in the organization,
- safety rules and guidance and the use of protective equipment,
- ergonomics,
- psychological factors, including workload and stress,
- workplace location,
- facilities for people in the organization,
- maximization of efficiency and minimization of waste,
- heat, humidity, light, airflow, and
- hygiene, cleanliness, noise, vibration and pollution.

The work environment should encourage productivity, creativity and well-being for the people who are working in or visiting the organization's premises (e.g. customers, suppliers, and partners). At the same time, the organization should ensure that its work environment complies with applicable statutory and regulatory requirements and addresses applicable standards (such as those for environmental and occupational health and safety management).

6.7 Knowledge, information and technology

6.7.1 General

The organization should establish and maintain processes to manage knowledge, information and technology as essential resources. The processes should address how to identify, obtain, maintain, protect, use and evaluate the need for these resources. The organization should share such knowledge, information and technology with its interested parties, as appropriate.

6.7.2 Knowledge

Top management should assess how the organization's current knowledge base is identified and protected. Top management should also consider how to obtain the knowledge required to meet the present and future needs of the organization from internal and external sources, such as academic and professional institutions. There are many issues to consider when defining how to identify, maintain and protect knowledge, such as

- learning from failures, near miss situations and successes,
- capturing the knowledge and experience of people in the organization,

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- gathering knowledge from customers, suppliers and partners,
- capturing undocumented knowledge (tacit and explicit) that exists within the organization,
- ensuring the effective communication of important information content (particularly at each interface in the supply and production chains), and
- managing data and records.

6.7.3 Information

The organization should establish and maintain processes to gather reliable and useful data and for converting such data into the information necessary for decision making.

This includes the processes needed for the storage, security, protection, communication and distribution of data and information to all relevant parties. The organization's information and communication systems need to be robust and accessible, to ensure their capabilities. The organization should ensure the integrity, confidentiality and availability of information relating to its performance, process improvements, and on progress towards the achievement of sustained success.

6.7.4 Technology

Top management should consider technological options to enhance the organization's performance in areas such as product realization, marketing, benchmarking, customer interaction, supplier relations and outsourced processes. The organization should establish processes for the assessment of

- the current levels of technology inside and outside the organization, including emerging trends.
- economic costs and benefits,
- the evaluation of risks related to changes in technology,
- the competitive environment, and
- its speed and ability to react to customer requirements promptly, to ensure that it remains competitive.

NOTE For more information on how to protect knowledge, see ISO/IEC 27000 and other standards prepared by ISO/JTC 1/SC 27 on information technology security techniques.

6.8 Natural resources

The availability of natural resources is one of the factors that can influence an organization's sustained success and ability to meet the requirements of its customers and other interested parties. The organization should consider the risks and opportunities related to the availability and use of energy and natural resources in the short and long term.

The organization should give appropriate consideration to the integration of environmental protection aspects into product design and development, as well as to the development of its processes to mitigate identified risks.

The organization should seek to minimize environmental impacts over the full life cycle of its products and its infrastructure, from design, through manufacturing or service delivery, to product distribution, use and disposal.

NOTE For more information, see ISO 14001 and other standards prepared by ISO/TC 207 on environmental management.

7 Process management

7.1 General

Processes are specific to an organization and vary depending on the type, size and level of maturity of the organization. The activities within each process should be determined and adapted to the size and distinctive features of the organization.

The organization should ensure the proactive management of all processes, including outsourced processes, to ensure that they are effective and efficient, in order to achieve its objectives. This can be facilitated by adopting a "process approach" that includes establishing processes, interdependencies, constraints and shared resources.

Processes and their interrelationships should be reviewed on a regular basis and suitable actions should be taken for their improvement.

The processes should be managed as a system by creating and understanding the networks of processes, their sequences and interactions. The consistent operation of this system is often referred to as the "systems approach to management". The network can be described in a map of the processes and their interfaces.

NOTE For further information on the "process approach", see the related quality management principle in Annex B of this International Standard, as well as ISO 9000 and the ISO 9000 "Introduction and Support Package" document *Guidance on the Concept and Use of the Process Approach for management systems*^[34].

7.2 Process planning and control

The organization should determine and plan its processes and define the functions that are necessary for providing products that can continue to meet the needs and expectations of customers and other interested parties, on an ongoing basis. Processes should be planned and controlled to be in accordance with the organization's strategy and should address management activities, provision of resources, product realization, monitoring, measurement and reviewing activities.

In the planning and control of processes, consideration should be given to

- analyses of the organization's environment,
- short- and long-term forecasts of market developments,
- the needs and expectations of the interested parties,
- objectives to be achieved,
- statutory and regulatory requirements,
- potential financial and other risks,
- process inputs and outputs,
- interactions with other processes,
- resources and information,
- activities and methods,
- records that are required or desired,
- measurement, monitoring and analysis,

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- corrective and preventive actions, and
- improvement and/or innovation activities.

Process planning should include consideration of the determined needs for the organization to develop or acquire new technologies, or develop new products or product features, for added value.

7.3 Process responsibility and authority

For each process, the organization should appoint a process manager (often referred to as the “process owner”) with defined responsibilities and authorities to establish, maintain, control and improve the process and its interaction with other processes. The process manager could be a person or a team, depending on the nature of the process and the organization's culture.

The organization should ensure that the responsibilities, authorities and roles of process managers are recognized throughout the organization, and that the people associated with the individual processes have the competences needed for the tasks and activities involved.

8 Monitoring, measurement, analysis and review**8.1 General**

To achieve sustained success in an ever-changing and uncertain environment, it is necessary for the organization to regularly monitor, measure, analyse and review its performance.

8.2 Monitoring

Top management should establish and maintain processes for monitoring the organization's environment, and for collecting and managing the information that is necessary for

- identifying and understanding the present and future needs and expectations of all relevant interested parties,
- assessing strengths, weaknesses, opportunities and threats,
- determining the need for alternative, competitive or new product offerings,
- evaluating current and emerging markets and technologies,
- anticipating current and expected changes in statutory and regulatory requirements,
- understanding the labour market and its effect on the loyalty of people in the organization,
- understanding the social, economic, ecological trends and local cultural aspects relevant to the organization's activities,
- determining the need for natural resources, and their protection over the long term, and
- assessing current organizational and process capabilities (see Annex A).

NOTE For more information about “customer focus”, see the related quality management principle in Annex B.

8.3 Measurement

8.3.1 General

Top management should assess progress in achieving planned results against the mission, vision, policies strategies and objectives, at all levels and in all relevant processes and functions in the organization. A measurement and analysis process should be used to monitor this progress, to gather and provide the information necessary for performance evaluations and effective decision making. The selection of appropriate key performance indicators and monitoring methodology is critical for success of the measurement and analysis process.

The methods used for collecting information regarding key performance indicators should be practicable and appropriate to the organization. Typical examples include

- risk assessments and risk controls,
- interviews, questionnaires and surveys on customer and other interested parties' satisfaction,
- benchmarking,
- performance reviews, including suppliers and partners, and
- monitoring and recording of process variables and product characteristics.

8.3.2 Key performance indicators

Factors that are within the control of the organization and critical to its sustained success should be subject to performance measurement and identified as key performance indicators (KPIs). The KPIs should be quantifiable and should enable the organization to set measurable objectives, identify, monitor and predict trends and take corrective, preventive and improvement actions when necessary. Top management should select KPIs as a basis for making strategic and tactical decisions. The KPIs should in turn be suitably cascaded as performance indicators at relevant functions and levels within the organization to support the achievement of top level objectives.

KPIs should be appropriate to the nature and size of the organization and to its products, processes and activities. They need to be consistent with the objectives of the organization, which should, in turn, be consistent with its strategy and policies (see 5.2). Specific information relating to risks and opportunities should be considered when selecting the KPIs.

In selecting the KPIs, the organization should ensure that they provide information that is measurable, accurate and reliable, and usable to implement corrective actions when performance is not in conformity with objectives or to improve process efficiency and effectiveness. Such information should take into account

- the needs and expectations of customers and other interested parties,
- the importance of individual products to the organization, both at the present time and in the future,
- the effectiveness and efficiency of processes,
- the effective and efficient use of resources,
- profitability and financial performance, and
- statutory and regulatory requirements, where applicable.

ISO 9004:2009(E)**8.3.3 Internal audit**

Internal audits are an effective tool for determining the levels of compliance of the organization's management system against given criteria, and provide valuable information for understanding, analysing and continually improving the organization's performance. Audits should be conducted by people who are not involved in the activity being examined, in order to give an independent view on what is being performed.

Internal audits should assess the implementation and effectiveness of the management system. They can include auditing against more than one management system standard, such as ISO 9001 (quality management) and ISO 14001 (environmental management), as well as addressing specific requirements relating to customers, products, processes or specific issues.

To be effective, internal audits should be conducted in a consistent manner, by competent personnel, in accordance with an audit plan.

Internal auditing is an effective tool for identifying problems, risks and nonconformities, as well as for monitoring progress in closing previously identified nonconformities (which should have been addressed through root cause analysis and the development and implementation of corrective and preventive action plans). Verification that the actions taken have been effective can be determined through an assessment of the improved ability of the organization to fulfil its objectives. Internal auditing can also be focused on the identification of good practices (that can be considered for use in other areas of the organization) as well as on improvement opportunities.

The outputs of internal audits provide a useful source of information for

- addressing problems and nonconformities,
- benchmarking,
- promoting good practices within the organization, and
- increasing understanding of the interactions between processes.

The results of internal audits are usually presented in the form of reports containing information on compliance against the given criteria, nonconformities, and improvement opportunities. Audit reports are also an essential input for management reviews. Top management should establish a process for the review of all internal audit reports, to identify trends that can require organization-wide corrective or preventive actions.

The organization should also take the results of other audits, such as second and third party audits, as feedback for corrective and preventive actions.

NOTE See ISO 19011 for further guidance on auditing.

8.3.4 Self-assessment

Self-assessment is a comprehensive and systematic review of the organization's activities and its performance in relation to its degree of maturity (see Annex A).

Self-assessment should be used to determine the strengths and weaknesses of the organization in terms of its performance as well as its best practices, both at an overall level and at the level of its individual processes. Self-assessment can assist the organization to prioritize, plan and implement improvements and/or innovations, where necessary.

The results of self-assessments support

- continual improvement of the organization's overall performance,
- progress towards achieving and maintaining sustained success for the organization,

- innovation in the organization's processes, products and structure, when appropriate,
- recognition of best practices, and
- the identification of further opportunities for improvement.

The results of self-assessments should be communicated to relevant people in the organization. They should be used to share understanding about the organization and its future direction. The results should be an input to management review.

NOTE 1 ISO 10014 provides a self-assessment tool directed specifically towards the financial and economic benefits of a quality management system for an organization.

NOTE 2 See Annex A for more information about self-assessment.

8.3.5 Benchmarking

Benchmarking is a measurement and analysis methodology that an organization can use to search for the best practices inside and outside the organization, with the aim of improving its own performance. Benchmarking can be applied to strategies and policies, operations, processes, products and organizational structures.

- a) There are several types of benchmarking, such as
 - internal benchmarking of activities within the organization,
 - competitive benchmarking of performance or processes with competitors, and
 - generic benchmarking; comparing strategies, operations or processes with unrelated organizations.
- b) Successful benchmarking depends on factors such as
 - support by top management (as it involves mutual knowledge interchange between the organization and its benchmarking partners),
 - the methodology used to apply benchmarking,
 - estimation of benefits versus costs, and
 - understanding of the characteristics of the subject being investigated, to allow a correct comparison to the current situation in the organization.
- c) The organization should establish and maintain a methodology for benchmarking that defines rules for items such as
 - the definition of the scope of the subject for benchmarking,
 - the process for choosing benchmarking partner(s), as well as any necessary communications and confidentiality policies,
 - the determination of indicators for the characteristics to be compared, and the data collection methodology to be used,
 - the collection and analysis of data,
 - the identification of performance gaps and the indication of potential improvement areas,
 - the establishment and monitoring of corresponding improvement plans, and

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- the inclusion of gathered experience into the organization's knowledge base and learning process (see 6.7).

8.4 Analysis

Top management should analyse information gathered from monitoring the organization's environment, identify risks and opportunities, and establish plans to manage them. The organization should monitor and maintain relevant information, and analyse potential impacts on its strategy and policies.

The analysis of the information gathered should enable factual decisions to be made on strategy and policy issues such as

- potential changes in the needs and expectations of interested parties in the long term,
- those existing products and activities that currently provide the most value for its interested parties,
- new products and processes needed to meet the changing needs and expectations of its interested parties,
- the evolving demands for the organizations' products in the long term,
- the influence of emerging technologies on the organization,
- new competences that could be needed, and
- changes that can be expected in statutory and regulatory requirements, or labour markets and other resources, which would affect the organization.

8.5 Review of information from monitoring, measurement and analysis

Top management should use a systematic approach to reviewing available information and for ensuring that the information is used for decision making (see 4.2).

Data can be collected from many sources, such as

- monitoring of the organization's environment,
- measurements of the organization's performance, including key performance indicators,
- assessments of the integrity and validity of the measurement processes,
- results of internal audit, self-assessment and benchmarking activities,
- risk assessment, and
- feedback from customers and other interested parties.

The reviews should be used to evaluate the results achieved against applicable objectives.

Reviews should be performed at planned and periodic intervals, to enable trends to be determined, as well as to evaluate the organization's progress towards achieving its objectives. They should also be used to identify opportunities for improvement, innovation and learning. Reviews should address the assessment and evaluation of improvement activities performed previously, including aspects of adaptability, flexibility and responsiveness in relation to the organization's vision and objectives.

Effective reviews of data can assist in the achievement of planned results.

The outputs of reviews can be used for benchmarking internally between activities and processes and to show trends over time; they can be used externally against the results achieved by other organizations, in the same or other sectors.

The outputs of reviews can indicate the adequacy of resources provided, and how effectively resources have been used in achieving the organization's objectives.

The outputs of the reviews should be presented in a format that can facilitate the implementation of process improvement activities.

9 Improvement, innovation and learning

9.1 General

Depending on the organization's environment, improvement (of its current products, processes, etc.) and innovation (to develop new products, processes, etc.) could be necessary for sustained success.

Learning provides the basis for effective and efficient improvement and innovation.

Improvement, innovation and learning can be applied to

- products,
- processes and their interfaces,
- organizational structures,
- management systems,
- human aspects and culture,
- infrastructure, work environment and technology, and
- relations with relevant interested parties.

Fundamental to effective and efficient improvement, innovation and learning is the ability and enablement of the people in the organization to make informed judgments on the basis of data analyses and the incorporation of lessons learned.

9.2 Improvement

Improvement activities can range from small-step continual improvements at a work place to significant improvements of the entire organization.

The organization should define objectives for the improvement of its products, processes, organizational structures and its management system through the analysis of data.

The improvement processes should follow a structured approach, such as the "Plan-Do-Check-Act" (PDCA) methodology. The methodology should be applied, consistently with the process approach, for all processes.

The organization should ensure that continual improvement becomes established as a part of the organizational culture by

- providing the opportunities for people in the organization to participate in improvement activities, through their empowerment,
- providing the necessary resources,

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- establishing recognition and reward systems for improvement, and
- continual improvement of the effectiveness and efficiency of the improvement process itself.

NOTE For more information about “continual improvement”, see the related quality management principle in Annex B.

9.3 Innovation**9.3.1 General**

Changes in the organization's environment could require innovation in order to meet the needs and expectations of interested parties. The organization should

- identify the need for innovation,
- establish and maintain an effective and efficient innovation process, and
- provide the related resources.

9.3.2 Application

Innovation can be applied to issues at all levels, through changes in

- technology or product (i.e. innovations that not only respond to the changing needs and expectations of customers or other interested parties, but also to anticipate potential changes in the organization's environment and product lifecycles),
- processes (i.e. innovation in the methods for product realization, or innovation to improve process stability and reduce variance),
- the organization (i.e. innovation in its constitution and organizational structures), and
- the organization's management system (i.e. to ensure that competitive advantage is maintained and new opportunities are utilized, when there are emerging changes in the organization's environment).

9.3.3 Timing

The timing for the introduction of an innovation is usually a balance between the urgency with which it is needed versus the resources that are made available for its development. The organization should use a process that is in alignment with its strategy to plan and prioritize innovations. The organization should support the innovation initiatives with the resources needed.

9.3.4 Process

The establishment, maintenance and management of processes for innovation within the organization can be influenced by

- the urgency of the need for innovation,
- innovation objectives and their impact on products, processes and the organizational structures,
- the organization's commitment to innovation,
- people's willingness to challenge and change the status quo, and
- the availability or emergence of new technologies.

9.3.5 Risks

The organization should assess the risks related to planned innovation activities, including giving consideration to the potential impact on the organization of changes, and prepare preventive actions to mitigate those risks, including contingency plans, where necessary.

9.4 Learning

The organization should encourage improvement and innovation through learning.

For the organization to attain sustained success, it is necessary to adopt “learning as an organization” and “learning that integrates the capabilities of individuals with those of the organization”.

- a) “Learning as an organization” involves consideration of
 - collecting information from various internal and external events and sources, including success stories and failures, and
 - gaining insights through in-depth analyses of the information that has been collected.
- b) “Learning that integrates the capabilities of individuals with those of the organization” is achieved by combining the knowledge, thinking patterns, and behaviour patterns of people with the values of the organization. This involves consideration of
 - the organization's values, based on its mission, vision and strategies,
 - supporting initiatives in learning, and demonstrating leadership through the behaviour of top management,
 - stimulation of networking, connectivity, interactivity and sharing of knowledge both inside and outside the organization,
 - maintaining systems for learning and sharing of knowledge,
 - recognizing, supporting and rewarding the improvement of people's competence, through processes for learning and sharing of knowledge, and
 - appreciation of creativity, supporting diversity of the opinions of the different people in the organization.

Rapid access to, and use of, such knowledge can enhance the organization's ability to manage and maintain its sustained success.

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Annex A (informative)

Self-assessment tool

A.1 General

Self-assessment is a comprehensive and systematic review of an organization's activities and results, referenced against a chosen standard.

Self-assessment can provide an overall view of the performance of an organization and degree of maturity of the management system. It can also help to identify areas for improvement and/or innovation and to determine priorities for subsequent actions.

An organization should use self-assessment to identify improvement and innovation opportunities, set priorities and establish action plans with the objective of sustained success. The output of self-assessment will show strengths and weaknesses, the maturity level of the organization and, if repeated, the organization's progress over time. The results of an organization's self-assessment can be a valuable input into management reviews. Self-assessment also has the potential to be a learning tool, which can provide an improved vision of the organization and promote the involvement of interested parties.

The self-assessment tool given in this annex is based on the guidance detailed in this International Standard and includes separate self-assessment tables for key elements and details. The self-assessment tables can be used as given, or can be customized to suit the organization.

NOTE In contrast to self-assessments, audits are used to determine the extent to which the quality management system requirements are fulfilled. Audit findings are used to assess the effectiveness of the quality management system and to identify opportunities for improvement.

A.2 Maturity model

A mature organization performs effectively and efficiently and achieves sustained success by

- understanding and satisfying the needs and expectations of interested parties,
- monitoring changes in the organization's environment,
- identifying possible areas for improvement and innovation,
- defining and deploying strategies and policies,
- setting and deploying relevant objectives,
- managing its processes and resources,
- demonstrating confidence in its people, leading to increased motivation, commitment and involvement, and
- establishing mutually beneficial supplier and other partner relationships.

This self-assessment tool uses five maturity levels, which can be extended to include additional levels or otherwise customized as needed. Figure A.1 gives a generic example of how performance criteria can be related to the levels of maturity in a tabular format. The organization should review its performance against

specified criteria, identify current maturity levels, and determine its strengths and weaknesses. The criteria given for the higher levels can assist the organization to understand the issues it needs to consider and to help it to determine the improvements needed to reach higher levels of maturity. Tables A.1 to A.7 give examples of completed tables, based on this International Standard.

Key element	Maturity level towards sustained success				
	Level 1	Level 2	Level 3	Level 4	Level 5
Element 1	Criteria 1 Base level				Criteria 1 Best practice
Element 2	Criteria 2 Base level				Criteria 2 Best practice
Element 3	Criteria 3 Base level				Criteria 3 Best practice

Figure A.1 — Generic model for self-assessment elements and criteria related to maturity levels

A.3 Self-assessment of key elements

This self-assessment should be performed periodically by top management to obtain an overview of the organization's behaviour and its current performance (see Table A.1).

A.4 Self-assessment of detailed elements

This self-assessment is intended to be performed by operational management and process owners to obtain an in-depth overview of the organization's behaviour and current performance.

The elements of this self-assessment are contained in Tables A.2 to A.7 and relate to the clauses of this International Standard; however, the organization can define additional or different criteria to fulfil its own specific needs. If appropriate, the self-assessment can be limited to any of the tables in isolation.

A.5 Using the self-assessment tools

A step-by-step methodology for an organization to conduct a self-assessment is to:

- a) define the scope of the self-assessment in terms of the parts of the organization to be assessed and the type of the assessment, such as
 - a self-assessment of key elements,
 - a self-assessment of detailed elements, based on this International Standard, or
 - a self-assessment of detailed elements based on this International Standard, with additional or new criteria or levels.
- b) identify who will be responsible for the self-assessment and when it will be carried out,
- c) determine how the self-assessment will be carried out, either by a team (cross-functional or other appropriate team) or by individuals. The appointment of a facilitator can assist the process.

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- d) identify the maturity level for each of the organization's individual processes. This should be done by comparing the present situation in the organization to the examples that are listed in the tables, and by marking the elements that the organization is already applying; start at level 1 and progress to the higher maturity levels. The current maturity level will be the highest maturity level achieved with no preceding gaps up to that point.
- e) consolidate the results into a report. This provides a record of progress over time and can facilitate the communication of information, both internally and externally. The use of graphics in such a report can aid the communication of the results (see the example in Figure A.2).
- f) assess the current performance of the organization's processes and identify areas for improvement and/or innovation. These opportunities should be identified through the process and an action plan developed as a result of the assessment.

An organization can be at different maturity levels for the different elements. A review of the gaps can help top management in planning and prioritizing the improvement and/or innovation activities needed to move individual elements to a higher level.

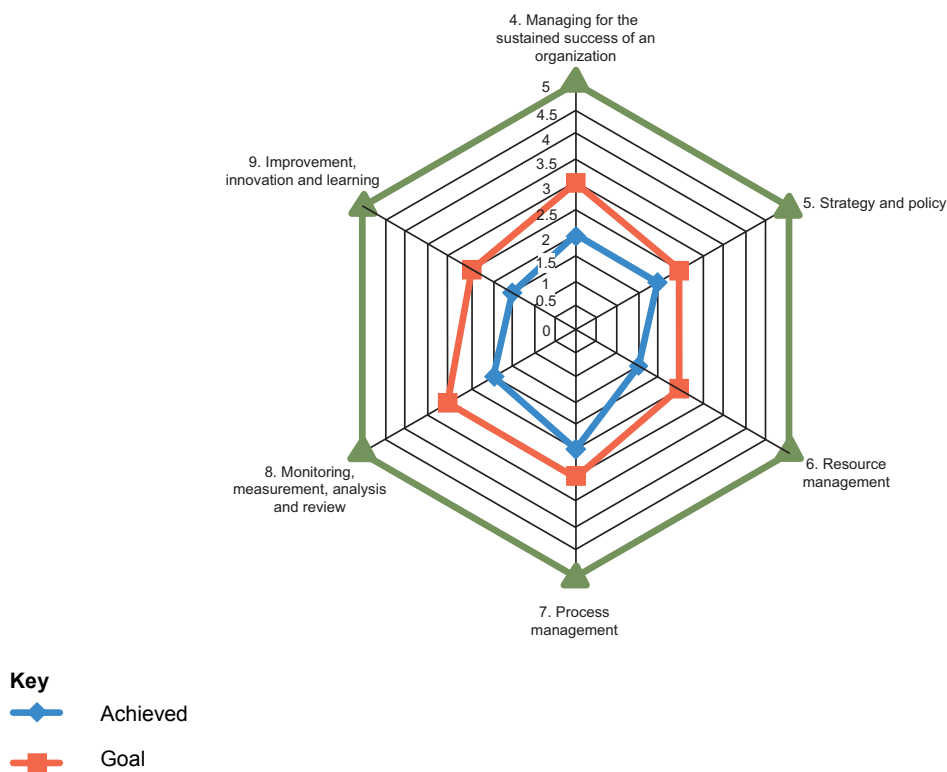


Figure A.2 — Example illustration of the results of a self-assessment

A.6 Self-assessment results and improvement and innovation planning

The completion of a self-assessment should result in an action plan for improvement and/or innovation that should be used as an input to top management for planning and review, based on the elements of this International Standard.

The information gained from the self-assessment could also be used to

- stimulate comparisons and share learning throughout the organization (the comparisons can be between the organization's processes and, where applicable, between its different units),
- benchmark with other organizations,
- monitor progress of the organization over time, by conducting periodic self-assessments, and
- identify and prioritize areas for improvement.

During this step, the organization should assign responsibilities for the chosen actions, estimate and provide the resources needed, and identify the expected benefits and any perceived risks associated with them.

Table A.1 — Self-assessment of key elements — Correlation between key elements and maturity levels

Key element	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
What is the management focus? (Managing)	The focus is on products, shareholders and some customers, with <i>ad hoc</i> reactions to changes, problems and opportunities.	The focus is on customers and statutory/regulatory requirements, with some structured reaction to problems and opportunities.	The focus is on people and some additional interested parties. Processes are defined and implemented for reacting to problems and opportunities.	The focus is on balancing the needs of identified interested parties. Continual improvement is emphasized as a part of the organization's focus.	The focus is on balancing the needs of emerging interested parties. Best in class performance is set as a primary objective.
What is the leadership approach? (Managing)	The approach is reactive, and is based on top-down instructions.	The approach is reactive, and is based on decisions by managers at different levels.	The approach is proactive, and the authority to take decisions is delegated.	The approach is proactive, with high involvement of the organization's people in its decision making.	The approach is proactive and learning-oriented, with the empowerment of people at all levels.
How is it decided what is important? (Strategy & policy)	Decisions are based on informal inputs from the market and other sources.	Decisions are based on customer needs and expectations.	Decisions are based on the strategy and linked to needs and expectations of interested parties.	Decisions are based on the deployment of the strategy into operational needs and processes.	Decisions are based on the need for flexibility, agility and sustained performance.
What is needed to get results? (Resources)	Resources are managed in an <i>ad hoc</i> manner.	Resources are managed effectively.	Resources are managed efficiently.	Resources are managed efficiently and in a way that takes into account their individual scarcity.	The management and use of resources is planned, efficiently deployed, and satisfies the interested parties.
How are the activities organized? (Processes)	There is a non-systematic approach to the organization of activities, with only some basic working procedures or instructions in place.	Activities are organized by function, with a basic quality management system in place.	Activities are organized in a process-based quality management system that is effective and efficient, and which enables flexibility.	There is a quality management system that is effective and efficient, with good interactions between its processes, and which supports agility and improvement. The processes address the needs of identified interested parties.	There is a quality management system that supports innovation and benchmarking, and which addresses the needs and expectations of emerging, as well as identified, interested parties.

Table A.1 (continued)

Key element	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
How are results achieved? (Monitoring & measurement)	Results are achieved in a random manner. Corrective actions are <i>ad hoc</i> .	Some predicted results are achieved. Corrective and preventive actions are performed in a systematic way.	Predicted results are achieved, especially for identified interested parties. There is consistent use of monitoring, measurement and improvement.	There are consistent, positive, predicted results, with sustainable trends. Improvements and innovations are performed in a systematic way.	The achieved results are above the sector average for the organization, and are maintained in the long term. There is implementation of improvement and innovation throughout the organization.
How are results monitored? (Monitoring & measurement)	Financial, commercial and productivity indicators are in place.	Customer satisfaction, key realization processes and the performance of suppliers are monitored.	The satisfaction of the organization's people and its interested parties is monitored.	Key performance indicators are aligned with the organization's strategy and are used for monitoring.	Key performance indicators are integrated into the real-time monitoring of all processes, and performance is efficiently communicated to relevant interested parties.
How are improvement priorities decided? (Improvement, innovation & learning)	Improvement priorities are based on errors, complaints or financial criteria.	Improvement priorities are based on customer satisfaction data, or corrective and preventive actions.	Improvement priorities are based on the needs and expectations of some interested parties, as well as those of suppliers and the organization's people.	Improvement priorities are based on trends and inputs from other interested parties, as well as analysis of social, environmental and economic changes.	Improvement priorities are based on inputs from emerging interested parties.
How does learning occur? (Improvement, innovation & learning)	Learning occurs randomly, at an individual level.	There is systematic learning from the organization's successes and failures.	A systematic and shared learning process is implemented in the organization.	There is a culture of learning and sharing in the organization that is harnessed for continual improvement.	The organization's processes for learning are shared with relevant interested parties, and support creativity and innovation.
NOTE The current maturity level of the organization's individual elements is the highest level achieved up to that point with no preceding gaps in the criteria.					

Table A.2 — Self-assessment of the detailed elements of Clause 4 — Managing for the sustained success of an organization

Subclause	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
4.1 (Managing for the sustained success of an organization) General	The quality management system is functionally oriented, based on procedures.	There is a process-based quality management system.	There is an organization-wide quality management system based on the eight quality management principles.	The organization's management system has been extended to integrate other disciplines, e.g. environmental management, health and safety management, etc.	The management system achieves full deployment of the organization's policy.
4.2 Sustained success	The organization's actual performance is compared with the budget in a regular yearly review.	There are periodic reviews of performance against the business plan.	The results show consistent improvement of performance over the past few years.	There has been sustained improvement in performance in the past, with evidence of planning for the short-term future (e.g. the next two years).	There has been sustained improvement in performance in the past, with evidence of planning for the long-term future (e.g. the next five years).
4.3 The organization's environment	The organization reacts to changes that impact on it.	Plans exist to mitigate any recurrence of past problems.	Risk assessments are made periodically to consider potential impacts on the organization.	Contingency plans exist to mitigate all identified risks to the organization.	Risk assessment and planning are continual processes within the organization, in order to mitigate all risks.
4.4 Interested parties, needs and expectations	The organization's overriding purpose is to make an annual profit.	The organization is driven by customer needs and expectations.	The needs and expectations of interested parties are satisfied where feasible.	The needs and expectations of interested parties are the main inputs for decisions by top management.	The needs and expectations of all relevant interested parties have been satisfied over the past few (e.g. three) years.
NOTE The current maturity level of the organization's individual elements is the highest level achieved up to that point with no preceding gaps in the criteria.					

Table A.3 — Self-assessment of the detailed elements of Clause 5 — Strategy and policy

Subclause	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
5.1 (Strategy and policy) General 5.2 Strategy and policy formulation	<p>The planning process is organized in an <i>ad hoc</i> manner.</p> <p>Strategy, policies and objectives are only partly defined.</p> <p>Inputs into policy and strategy formulation are <i>ad hoc</i>, and only product and financially related aspects are formulated.</p>	<p>A structured process for the formulation of strategy and policies is in place.</p> <p>The process of strategy and policy formulation includes an analysis of the needs and expectations of customers, along with an analysis of statutory and regulatory requirements.</p>	<p>The process of strategy and policy formulation has evolved to include an analysis of the needs and expectations of a broader range of interested parties.</p> <p>Plans are developed after assessing the needs and expectations of relevant interested parties.</p> <p>The planning process includes consideration of changing external trends and the needs of interested parties; it makes necessary re-alignments when needed.</p> <p>Beneficial outcomes can be linked to past strategic approaches.</p>	<p>Strategy, policies and objectives are formulated in a structured manner. Strategy and policies cover aspects relating to relevant interested parties.</p> <p>The outcomes of the organization's processes for strategy and policy formulation are consistent with the needs of its interested parties.</p> <p>Threats, opportunities and availability of resources are evaluated and considered before plans are confirmed.</p> <p>Structured and periodic reviews of planning processes are in place.</p>	<p>It can be demonstrated that strategies have resulted in the achievement of the organization's objectives and optimization of the needs of interested parties.</p> <p>Interested parties are engaged in and contributing to the organization's success; there is confidence that the level of their contributions will be maintained.</p> <p>There is confidence that successes will be sustained.</p> <p>Effective monitoring and reporting mechanisms are in place, including feedback from interested parties for the planning process.</p>
5.3 Strategy and policy deployment	<p>Short-term objectives are used and deployed in daily operations.</p> <p>Strategic plans are defined for product realization.</p>	<p>Strategy and policies are translated into objectives for different levels in the organization.</p> <p>Plans are developed in accordance with the balance of the needs and expectations of customers.</p> <p>Strategy and policies are evolving; customer needs are deployed into clearly defined processes and objectives. They are the basis for performance reviews and audits.</p>	<p>Measurement of progress towards achievement of the organization's strategic objectives is undertaken. Positive and negative variances against plans are analysed and acted upon.</p>	<p>Measurable objectives are defined, for each process and level of the organization, and are consistent with the strategy.</p> <p>The management system is reviewed and updated, following changes in the strategy.</p> <p>Measurement of progress towards the achievement of objectives demonstrates that many positive trends exist.</p>	<p>Strategy, planning and policy deployment are regularly reviewed and updated using data from the monitoring and analysis of the organization's environment.</p> <p>Analysis of past performance can demonstrate that the organization has succeeded in overcoming emerging or unforeseen challenges.</p>

Table A.3 (continued)

Subclause	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
5.4 Strategy and policy communication	Communication takes place in a reactive way.	A process for external and internal communication is defined and implemented.	Effective systems are in place to communicate changes in strategy and plans to relevant people within the organization.	Changes in policy are communicated to relevant interested parties, and to all levels of the organization.	The effectiveness of the communication processes is reviewed periodically. There is evidence that communication processes meet the needs of interested parties.
NOTE The current maturity level of the organization's individual elements is the highest level achieved up to that point with no preceding gaps in the criteria.					

Table A.4 — Self-assessment of the detailed elements of Clause 6 — Resource management

Subclause	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
6.1 (Resource management) General	Resources are defined and assigned in an <i>ad hoc</i> way.	A process for the planning of resources, including their identification, provision and monitoring, is implemented.	A periodic review is carried out of the availability and suitability of resources. Resource planning includes short- and long-term objectives.	The risks of the potential scarcity of resources are evaluated. The organization's approaches to managing resources are proven to be effective and efficient.	Opportunities to improve resource planning are sought through benchmarking.
6.2 Financial resources	Resources are defined and assigned in an <i>ad hoc</i> way. Short-term financial planning is used.	A process for predicting, monitoring and controlling financial resources is implemented. Financial governance is structured systematically.	There are periodic reviews of the effectiveness of the use of financial resources. Financial risks are identified.	Financial risks are mitigated. Future financial needs are forecast and planned.	Financial allocation of resources contributes to the achievement of the organization's objectives. There is an ongoing process to continually reassess the allocation.
6.3 People in the organization	People are considered to be a resource, but only a few objectives are related to the strategy of the organization. Training is provided on an <i>ad hoc</i> basis, mostly at the request of individual employees. Competence reviews are performed in a few cases.	People are recognized as a resource with given objectives, which are related to the strategy of the organization. There is a programme for competency review. Competences are developed as part of an overall plan, which is linked to the organization's strategy. Ideas for improvement are collected.	People have clear process responsibilities and targets and know how they link within the organization. A skills qualification system is established with mentoring and coaching.	Internal networking is widespread and provides collective knowledge for the organization. Training is provided to develop skills for creativity and improvement. People know their personal competences and where they can best contribute to organizational improvement. Career planning is well developed.	External networking involves people throughout the organization. People across the organization participate in the development of new processes. Best practices are recognized.

Table A.4 (continued)

Subclause	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
6.4 Partners and suppliers	Supplier communications are limited to tendering, order placement or problem resolution.	Processes are in place to communicate with, select, evaluate, re-evaluate and rank suppliers.	Suppliers and partners are identified in accordance with strategic needs or risks. Processes for developing and managing the relationships with suppliers and partners exist.	Open communication of needs and strategies occurs with partners.	Data demonstrates that partners are engaged in and are contributing to the organization's successes.
6.5 Infrastructure	Basic infrastructures are in place.	The organization's infrastructure is planned and managed. Statutory and regulatory requirements are considered.	The infrastructure and related processes are periodically reviewed with the future in mind.	Risks for the infrastructure are identified and preventive actions are in place.	The performance and cost base of the organization's infrastructure compares favourably with similar organizations. Contingency planning is used to mitigate potential threats and to explore opportunities.
6.6 Work environment	Basic provisions for the work environment are in place.	A process is in place to ensure that the work environment complies with all applicable statutory and regulatory requirements.	A periodic review is carried out of the efficiency and effectiveness of the work environment.	Data shows that the work environment encourages productivity, creativity and the well-being of people.	The processes implemented for the development of the work environment support competitiveness and compare well with similar organizations.
6.7 Knowledge, information and technology	Basic knowledge, information and technology approaches and systems are in place.	A process to identify, obtain, protect, use and evaluate information, knowledge and technology is implemented. A basic communication system for sharing information is implemented.	Information, knowledge and technology are shared within the organization, and periodic reviews are carried out. Critical technologies are controlled via patents and secondary sourcing, where needed.	Information, knowledge and technology are shared with partners and other interested parties.	The results achieved for information, technology and knowledge management compare well with other organizations.

Table A.4 (continued)

Subclause	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
6.8 Natural resources	The use of natural resources is managed in a very limited way.	A process exists to define, and control the use of, the natural resources required by the organization.	Processes are deployed to measure how efficiently natural resources are used. The risks of the scarcity of natural resources are evaluated, and actions are taken to protect the future continuity of supplies.	Processes exist to optimize the use of natural resources and to consider the use of alternative resources. The organization has processes to take into account the need for environmental protection in the total life-cycle of its products.	The organization can demonstrate that its approach to the use of natural resources meets the needs of the present, without compromising the needs of future generations of society. There is liaison with, and benchmarking against, external organizations and other interested parties over the use of natural resources.
NOTE The current maturity level of the organization's individual elements is the highest level achieved up to that point with no preceding gaps in the criteria.					

Table A.5 — Self-assessment of the detailed elements of Clause 7 — Process management

Subclause	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
7.1 (Process management) General 7.2 Process planning and control	Processes are planned and managed in an informal, <i>ad hoc</i> manner.	<p>Key processes, such as those relating to customer satisfaction and product realization, are defined and managed.</p> <p>Interactions between processes are defined and managed.</p> <p>The effectiveness of the processes is systematically measured and acted upon.</p>	<p>Process planning is integrated with strategy deployment.</p> <p>The needs and expectations of identified interested parties are used as inputs into process planning.</p> <p>Improvements in process efficiency can be demonstrated.</p> <p>Processes are delivering predictable results.</p> <p>The efficiency and effectiveness of the organization's processes is reviewed.</p>	<p>Improvements in agility, flexibility and process innovation can be demonstrated.</p> <p>All relevant interested parties are considered in process planning.</p> <p>Interaction conflicts between processes are identified and resolved in an effective way.</p>	<p>Process performance is compared to leading organizations and the results are used in process planning.</p> <p>The outcomes of key processes are above the organization's sector average.</p>
7.3 Process responsibility and authority	Process responsibilities are defined on an <i>ad hoc</i> basis.	Clear responsibility and authority for the management of processes is assigned (e.g. to "process owners").	A policy to avoid and resolve potential disputes in process management exists.	Process owners' competences are continually improved.	Learning is shared between process owners and interested parties.
NOTE The current maturity level of the organization's individual elements is the highest level achieved up to that point with no preceding gaps in the criteria.					

Table A.6 — Self-assessment of the detailed elements of Clause 8 — Monitoring, measurement, analysis and review

Subclause	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
8.1 (Monitoring, measurement, analysis and review) General 8.2 Monitoring	<p>Monitoring is performed on a sporadic basis, with no processes in place.</p> <p>The focus of monitoring is on products. Action is triggered by product problems or management problems (i.e. crisis situations).</p> <p>While information about applicable statutory and regulatory requirements is collected, changes in the requirements are only determined in an <i>ad hoc</i> way.</p>	<p>A monitoring process is performed periodically.</p> <p>The focus of monitoring is on customers.</p> <p>Customer needs and expectations are monitored systematically.</p> <p>Changes in statutory and regulatory requirements are tracked systematically through formally designed mechanisms.</p>	<p>The monitoring process is evaluated regularly to improve its effectiveness.</p> <p>The focus of monitoring is on suppliers, with a limited focus on people and other interested parties.</p> <p>Feedback from key suppliers and partners is gathered in a planned manner.</p> <p>Feedback from people is gathered by default only.</p> <p>Current process capabilities are monitored.</p> <p>The processes for tracking statutory and regulatory requirements are effective and efficient.</p>	<p>The monitoring process is performed in a systematic and planned way, and includes cross-checks with external data sources.</p> <p>Resource requirements are assessed in a systematic and planned way, over time.</p> <p>Feedback from employees and customers is gathered through professionally conducted surveys and other mechanisms, such as focus groups.</p>	<p>The monitoring process delivers reliable data and trends.</p> <p>The focus of monitoring is on trends within the organization's activity sector, technologies, and the labour situation, with optimization of the use and development of resources.</p> <p>Changes that are taking place, or are expected, in economic policies, product demands, technologies, environmental protection, or in social and cultural issues, which could have an impact on the organization's performance, are monitored in a planned way.</p>
8.3.1 (Measurement) General 8.3.2 Key performance indicators	<p>A very limited set of data from measurements and assessments is available to support management decisions or tracking of the progress of actions taken.</p> <p>Basic indicators (such as financial criteria, on-time deliveries, the number of customer complaints, legal warnings and fines) are used.</p> <p>Data are not always reliable.</p>	<p>There is a formal set of definitions for key indicators related to the organization's strategy and main processes.</p> <p>Indicators are mostly based on the use of internal data.</p> <p>Management decisions are supported by the outputs from reviews of the quality management system and additional key performance indicators.</p>	<p>Process-level objectives are related to key performance indicators.</p> <p>Data is available to show how the organization's performance compares with that of other organizations.</p> <p>The main conditions for success are identified and tracked by suitable, practical indicators.</p> <p>Management decisions are adequately supported by reliable data from the measurement systems.</p>	<p>Data is available to show progress on key performance indicators over time.</p> <p>Deployment of the strategy and objectives is monitored.</p> <p>Performance indicators are established, widely deployed and used for strategic decisions regarding trends and long-term planning.</p> <p>Systematic analysis of data allows future performance to be predicted.</p>	<p>Systematic analysis of comprehensive data allows future performance to be predicted with confidence.</p> <p>Indicators contribute to good strategic decisions.</p> <p>KPIs are selected and acted upon in a way that provides reliable information for predicting trends and for taking strategic decisions.</p> <p>Risk analysis is performed as a tool for prioritizing improvement.</p>
<p>NOTE The current maturity level of the organization's individual elements is the highest level achieved up to that point with no preceding gaps in the criteria.</p>					

Table A.6 (continued)

Subclause	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
8.3.3 Internal audit 8.3.4 Self-assessment	<p>Some data is collected, but no formal approach is used.</p> <p>Audits are reactively performed in response to problems, customer complaints, etc.</p> <p>Collected data is mostly used to resolve problems with products.</p>	<p>Some data is collected from key processes on a regular basis.</p> <p>Audit data is used systematically to review the management system.</p> <p>Self-assessment is limited.</p> <p>Data and the results of evaluations are beginning to be used in a preventive way.</p>	<p>Data gathering is embedded in a structured process.</p> <p>When necessary, qualifying studies are conducted to verify the data, particularly when the data is derived from judgments, opinions, etc.</p> <p>Audits ensure the accuracy of data and the effectiveness of the management system.</p> <p>Self-assessments are conducted and the results used to determine the organization's maturity and to improve its overall performance.</p>	<p>The data gathering processes are continually evaluated and their effectiveness and efficiency improved.</p> <p>Self-assessment outcomes are integrated into the strategic planning process.</p> <p>Identified gaps from the higher maturity levels are compared with the vision and strategy, and the organization takes action to close them in a planned way.</p>	<p>The organization involves other interested parties in its audits, in order to help identify additional opportunities for improvement.</p> <p>Self-assessments are performed by the organization at all levels.</p>
8.3.5 Benchmarking	<p>Interchange of best practices within the organization is anecdotal. Some product comparisons are made with products on the market.</p>	<p>Top management supports the identification and promulgation of best practices.</p> <p>Some products from key competitors are analysed and compared.</p>	<p>Some external benchmark activities are supported by the organization's leadership (covering products, processes and operations).</p>	<p>A benchmarking methodology is established.</p> <p>Key performance measurements are subjected to internal and external benchmarking, using a structured methodology.</p>	<p>Benchmarking is used systematically as a tool for identifying opportunities for improvement, innovation and learning.</p> <p>The organization is frequently solicited by external entities to be a benchmark partner.</p>

Table A.6 (continued)

Subclause	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
8.4 Analysis	<p>Anecdotal examples of data analysis are used.</p> <p>Only economic and financial objectives have been defined as the references for data analysis.</p> <p>There is limited analysis of customer complaints.</p>	<p>Analysis of relevant external and internal information is performed periodically.</p> <p>Some basic statistical tools are used.</p> <p>Evaluations are performed to determine the level of fulfilment of customer needs and expectations. Product improvements are based on these analyses.</p> <p>The impact of changes in statutory and regulatory requirements on processes and products is analysed periodically.</p>	<p>A systematic analysis process is supported by the wide use of statistical tools.</p> <p>Analyses are utilized for the identification of the needs and expectations of relevant interested parties.</p> <p>Effective decisions and actions are based on the analysis of information.</p>	<p>An analysis process is used for the evaluation of new resources, materials and technologies.</p> <p>The effectiveness of the analysis process is enhanced by the sharing of the analysis results with partners or other sources of knowledge.</p> <p>Distinctive product features are identified and value is added to products for interested parties, based on inputs from the analysis of information.</p>	<p>Relevant political, environmental, social, technological and comparative data is analysed and used.</p> <p>Risks and opportunities that could impact the achievement of short- and long-term objectives are identified and analysed.</p> <p>Strategy and policy decisions are based on information that is gathered and analysed in a planned way.</p>
8.5 Review of information from monitoring, measurement and analysis	<p>There is an <i>ad hoc</i> approach to reviews.</p> <p>When a review is performed, it is often reactive.</p>	<p>Periodic reviews are conducted to assess progress in the achievement of quality objectives and to assess the performance of the quality management system.</p> <p>All active projects and improvement actions are assessed during reviews, in order to evaluate progress against their plans and objectives.</p>	<p>Systematic reviews of key performance indicators and related objectives are undertaken regularly.</p> <p>Where adverse trends are identified, they are acted upon.</p> <p>Reviews give an indication of whether adequate resources have been provided.</p>	<p>The outputs from the reviews are shared with some interested parties, as a way of facilitating collaboration and learning.</p> <p>Internal comparisons are made to identify and share good practices.</p>	<p>Differing sources of information indicate good performance in all strategic and operational areas of the organization.</p> <p>Review outputs are shared with partners, and are used as an input for the improvement of products and processes that can influence their level of performance and satisfaction.</p> <p>The results of reviews demonstrate that the actions taken are effective.</p>
NOTE The current maturity level of the organization's individual elements is the highest level achieved up to that point with no preceding gaps in the criteria.					

Table A.7 — Self-assessment of the detailed elements of Clause 9 — Improvement, innovation and learning

Subclause	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
9.1 (Improvement, innovation and learning) General 9.2 Improvement	Improvement activities are <i>ad hoc</i> and based on customer or regulatory complaints.	<p>Basic improvement processes, based on corrective and preventive actions, are in place.</p> <p>The organization provides training for continual improvement.</p>	<p>Improvement efforts can be demonstrated in most of the products and key processes of the organization.</p> <p>The focus of the improvement processes is aligned with the strategy and objectives.</p> <p>Recognition systems are in place for teams and individuals generating strategically relevant improvements.</p> <p>Continual improvement processes work at some levels of the organization, and with its suppliers and partners.</p>	<p>Results generated from the improvement processes enhance the performance of the organization.</p> <p>The improvement processes are systematically reviewed.</p> <p>Improvement is applied to products, processes, organizational structures, the operating model and the organization's management system.</p>	<p>There is evidence of a strong relationship between improvement activities and the achievement of above average sector results for the organization.</p> <p>Improvement is embedded as a routine activity across the whole organization, as well as for its suppliers and partners.</p> <p>The focus is on improving the performance of the organization, including its ability to learn and change.</p>
9.3 Innovation	<p>There is limited innovation.</p> <p>New products are introduced on an <i>ad hoc</i> basis, with no planning for innovation in place.</p>	Innovation activities are based on data concerning the needs and expectations of customers.	The innovation process for new products and processes is able to identify changes in the organization's environment, in order to plan innovations.	<p>Innovations are prioritized, based on the balance between their urgency, the availability of resources and the organization's strategy.</p> <p>Suppliers and partners are involved in the innovation processes.</p> <p>The effectiveness and efficiency of the innovation processes are assessed regularly as a part of the learning process.</p> <p>Innovation is used to improve the way the organization operates.</p>	<p>Innovation activities anticipate possible changes in the organization's environment.</p> <p>Preventive plans are developed to avoid or minimize the identified risks accompanying innovation activities.</p> <p>Innovation is applied to products, processes, organizational structures, the operating model and the organization's management system.</p>

Table A.7 (continued)

Subclause	Maturity level				
	Level 1	Level 2	Level 3	Level 4	Level 5
9.4 Learning	<p>Some lessons are learned as a result of complaints.</p> <p>Learning is on an individual basis, without the sharing of knowledge.</p>	<p>Learning is generated in a reactive way from the systematic analysis of problems and other data.</p> <p>Processes exist for the sharing of information and knowledge.</p>	<p>There are planned activities, events and forums for sharing information.</p> <p>A system is in place for recognizing positive results from suggestions or lessons learned.</p> <p>Learning is addressed in the strategy and policies.</p>	<p>Learning is recognized as a key issue. Networking, connectivity and interactivity are stimulated by top management to share knowledge.</p> <p>Top management supports initiatives for learning, and leads by example.</p> <p>The organization's learning ability integrates personal competence and organizational competence.</p> <p>Learning is fundamental to the improvement and innovation processes.</p>	<p>The culture of learning permits the taking of risks and the acceptance of failure, provided this leads to learning from the mistakes and to opportunities for improvement.</p> <p>There are external engagements for the purpose of learning.</p>
NOTE The current maturity level of the organization's individual elements is the highest level achieved up to that point with no preceding gaps in the criteria.					

Annex B (informative)

Quality management principles

B.1 General

This annex describes the eight quality management principles which form the basis for the quality management standards prepared by ISO/TC 176. These principles can be used by top management as a framework to guide their organizations towards improved performance.

This annex gives the standardized descriptions of the principles. In addition, it provides examples of the benefits derived from their use and of actions that managers typically take in applying the principles to improve their organizations' performance.

B.2 Principle 1: Customer focus

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

a) Key benefits

- increased revenue and market share obtained through flexible and fast responses to market opportunities,
- increased effectiveness in the use of the organization's resources to enhance customer satisfaction,
- improved customer loyalty leading to repeat business.

b) Applying the principle of customer focus typically leads to

- researching and understanding customer needs and expectations,
- ensuring that the objectives of the organization are linked to customer needs and expectations,
- communicating customer needs and expectations throughout the organization,
- measuring customer satisfaction and acting on the results,
- systematically managing customer relationships,
- ensuring a balanced approach between satisfying customers and other interested parties (such as owners, employees, suppliers, financiers, local communities and society as a whole).

B.3 Principle 2: Leadership

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

a) Key benefits

- people will understand and be motivated towards the organization's goals and objectives,
- activities are evaluated, aligned and implemented in a unified way,
- miscommunication between levels of an organization will be minimized.

b) Applying the principle of leadership typically leads to

- considering the needs of all interested parties including customers, owners, employees, suppliers, financiers, local communities and society as a whole,
- establishing a clear vision of the organization's future,
- setting challenging goals and targets,
- creating and sustaining shared values, fairness and ethical role models at all levels of the organization,
- establishing trust and eliminating fear,
- providing people with the required resources, training and freedom to act with responsibility and accountability,
- inspiring, encouraging and recognizing people's contributions.

B.4 Principle 3: Involvement of people

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

a) Key benefits

- motivated, committed and involved people within the organization,
- innovation and creativity in furthering the organization's objectives,
- people being accountable for their own performance,
- people eager to participate in and contribute to continual improvement.

b) Applying the principle of involvement of people typically leads to

- people understanding the importance of their contribution and role in the organization,
- people identifying constraints to their performance,
- people accepting ownership of problems and their responsibility for solving them,
- people evaluating their performance against their personal goals and objectives,

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- people actively seeking opportunities to enhance their competence, knowledge and experience,
- people freely sharing knowledge and experience,
- people openly discussing problems and issues.

B.5 Principle 4: Process approach

A desired result is achieved more efficiently when activities and related resources are managed as a process.

a) Key benefits

- lower costs and shorter cycle times through effective use of resources,
- improved, consistent and predictable results,
- focused and prioritized improvement opportunities.

b) Applying the principle of process approach typically leads to

- systematically defining the activities necessary to obtain a desired result,
- establishing clear responsibility and accountability for managing key activities,
- analysing and measuring of the capability of key activities,
- identifying the interfaces of key activities within and between the functions of the organization,
- focusing on the factors, such as resources, methods, and materials, that will improve key activities of the organization,
- evaluating risks, consequences and impacts of activities on customers, suppliers and other interested parties.

B.6 Principle 5: System approach to management

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

a) Key benefits

- integration and alignment of the processes that will best achieve the desired results,
- ability to focus effort on the key processes,
- providing confidence to interested parties as to the consistency, effectiveness and efficiency of the organization.

b) Applying the principle of system approach to management typically leads to

- structuring a system to achieve the organization's objectives in the most effective and efficient way,
- understanding the interdependencies between the processes of the system,
- structured approaches that harmonize and integrate processes,

- providing a better understanding of the roles and responsibilities necessary for achieving common objectives and thereby reducing cross-functional barriers,
- understanding organizational capabilities and establishing resource constraints prior to action,
- targeting and defining how specific activities within a system should operate,
- continually improving the system through measurement and evaluation.

B.7 Principle 6: Continual improvement

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

a) Key benefits

- performance advantage through improved organizational capabilities,
- alignment of improvement activities at all levels to an organization's strategic intent,
- flexibility to react quickly to opportunities.

b) Applying the principle of continual improvement typically leads to

- employing a consistent organization-wide approach to continual improvement of the organization's performance,
- providing people with training in the methods and tools of continual improvement,
- making continual improvement of products, processes and systems an objective for every individual in the organization,
- establishing goals to guide, and measures to track, continual improvement,
- recognizing and acknowledging improvements.

B.8 Principle 7: Factual approach to decision making

Effective decisions are based on the analysis of data and information.

a) Key benefits

- informed decisions,
- an increased ability to demonstrate the effectiveness of past decisions through reference to factual records,
- increased ability to review, challenge and change opinions and decisions.

b) Applying the principle of factual approach to decision making typically leads to

- ensuring that data and information are sufficiently accurate and reliable,
- making data accessible to those who need it,

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- analysing data and information using valid methods,
- making decisions and taking action based on factual analysis, balanced with experience and intuition.

B.9 Principle 8: Mutually beneficial supplier relationships

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

a) Key benefits

- increased ability to create value for both parties,
- flexibility and speed of joint responses to changing market or customer needs and expectations,
- optimization of costs and resources.

b) Applying the principle of mutually beneficial supplier relationships typically leads to

- establishing relationships that balance short-term gains with long-term considerations,
- pooling of expertise and resources with partners,
- identifying and selecting key suppliers,
- clear and open communication,
- sharing information and future plans,
- establishing joint development and improvement activities,
- inspiring, encouraging and recognizing improvements and achievements by suppliers.

Annex C (informative)

Correspondence between ISO 9004:2009 and ISO 9001:2008

Table C.1 gives the correspondence between ISO 9001:2008 and this International Standard, and shows how the two International Standards complement each other.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes and focuses on the effectiveness of the quality management system in meeting the customer requirements.

This International Standard gives guidance for organizations whose top management wish to move beyond the requirements of ISO 9001, to address the needs and expectations of all interested parties and their satisfaction, by systematic and continual improvement of the organization's performance.

Table C.1 — Correspondence between ISO 9004:2009 and ISO 9001:2008

Subclause in ISO 9004:2009	Subclause in ISO 9001:2008
4.1 (Managing for the sustained success of an organization) General	4.1 (Quality management system) General requirements 5.1 Management commitment
—	4.2 Documentation requirements
4.2 Sustained success	—
4.3 The organization's environment	7.2 Customer related processes
4.4 Interested parties, needs and expectations	5.2 Customer focus
5.1 (Strategy and policy) General	5.3 Quality policy
5.2 Strategy and policy formulation	5.3 Quality policy
5.3 Strategy and policy deployment	5.4 Planning
5.4 Strategy and policy communication	5.5.3 Internal communication 7.2.3 Customer communication
6.1 (Resource management) General	6.1 Provision of resources
6.2 Financial resources	—
6.3 People in the organization	6.2 Human resources
6.3.1 Management of people	
6.3.2 Competence of people	6.2.2 Competence, training and awareness
6.3.3 Involvement and motivation of people	—
6.4 Suppliers and partners	7.4.1 Purchasing process
6.4.1 General	
6.4.2 Selection, evaluation and improvement of the capabilities of suppliers and partners	7.4.1 Purchasing process
6.5 Infrastructure	6.3 Infrastructure
6.6 Work environment	6.4 Work environment

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Table C.1 (continued)

Subclause in ISO 9004:2009	Subclause in ISO 9001:2008
6.7 Knowledge, information and technology	—
6.8 Natural resources	—
7.1 (Processes management) General	4.1 (Quality management system) General requirements
7.2 Process planning and control	7.1 Planning of product realization 7.5 Production and service provision
7.3 Process responsibility and authority	5.5.1 Responsibility, authority and communication
8.1 (Monitoring, measurement, analysis and review) General	8.1 General 7.6 Control of monitoring and measuring equipment
8.2 Monitoring	8.2.3 Monitoring and measurement of processes 8.2.4 Monitoring and measurement of product
8.3.1 (Measurement) General	8.2 Monitoring and measurement 8.2.1 Customer satisfaction
8.3.2 Key performance indicators	8.2.3 Monitoring and measurement of processes
8.3.3 Internal audit	8.2.2 Internal audit
8.3.4 Self-assessment	—
8.3.5 Benchmarking	—
8.4 Analysis	8.4 Analysis of data
8.5 Review of information from monitoring and measurement and analysis	5.6 Management review
9.1 (Improvement, innovation and learning) General	8.5 Improvement
9.2 Improvement	8.5 Improvement
9.3 Innovation	7.3 Design and development
9.4 Learning	—

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1) Under preparation.

2) ISO 14041:1998 and ISO 14042:2000 have jointly been cancelled and replaced by ISO 14040:2006 and ISO 14044:2006.

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3) Available from websites: <http://www.iso.org> or <http://www.iso.org/tc176/sc2>

4) Available from website: <http://www.iso.org/tc176/sc2>

5) To be updated and aligned with ISO 9001:2008.

6) A bimonthly publication which provides comprehensive coverage of international developments relating to ISO's management system standards, including news of their implementation by diverse organizations around the world. Available from ISO Central Secretariat (sales@iso.org).