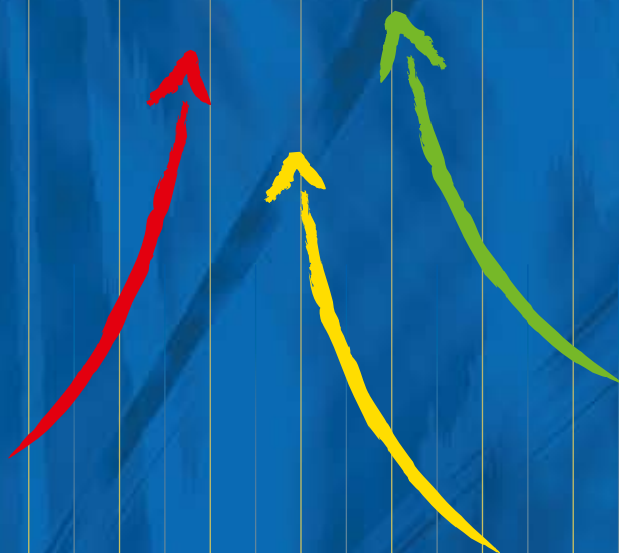Selection and use of the
**ISO 9000 family of standards**

**ISO**

## ISO and international standardization

ISO is the International Organization for Standardization. It has a membership of 158* national standards institutes from countries large and small, industrialized and developing, in all regions of the world, ISO develops voluntary technical standards which add value to all types of business operations. They contribute to the dissemination of technology and good business practice. They support the development, manufacturing and supply of more efficient, safer and cleaner products and services. They make trade between countries easier and fairer. ISO standards also safeguard users and consumers, and make many aspects of their lives simpler.

ISO develops only those standards that are required by the market. This work is carried out by experts coming from the industrial, technical and business sectors which have asked for the standard, and which subsequently put them to use. These experts may be joined by others with relevant knowledge, such as representatives of government agencies, consumer organizations, academia and testing laboratories. Published under the designation of International Standards, ISO standards represent an international consensus on the state of the art in the technology or good practice concerned.

ISO's portfolio of more than 17 800* standards and related documents addresses all three dimensions of sustainable development : economic, environmental and social.

*Mid-January 2009.*

## ISO/TC 176, *Quality management and quality assurance*

ISO technical committee ISO/TC 176 is responsible for the ISO 9000 family of standards for quality management and quality assurance. National delegations of 81* countries participate in its work, while another 21* countries have observer status.

# Selection and use of the ISO 9000 family of standards

The ISO 9000 family of international quality management standards and guidelines has earned a global reputation as a basis for establishing effective and efficient quality management systems.

The need for International Standards is very important as more organizations operate in the global economy by selling or buying products and services from sources outside their domestic market.

This brochure has been developed by ISO technical committee ISO/TC 176, *Quality management and quality assurance,* which is responsible for developing and maintaining the ISO 9000 family. Supporting guideline standards and other documents are developed and updated on a continual basis to meet the needs and expectations of users and the market itself.

The brochure explains how you can use them to improve your quality management system. It provides a general perspective of the ISO 9000 family of standards. It is an overview of the standards and demonstrates how, collectively, they form a basis for continual improvement and business excellence.

ISO 9001 specifies the basic requirements for a quality management system (QMS) that an organization must fulfil to demonstrate its ability to consistently provide products (which include services) that enhance customer satisfaction and meet applicable statutory and regulatory requirements.

The standard can be used for certification/registration and contractual purposes by organizations seeking recognition of their quality management system. ISO 9001 has been organized in a user-friendly format with terms that are easily recognized by all business sectors.

You will obtain the greatest value by using the entire family of standards in an integrated manner. It is highly recommended that you use ISO 9000 to become familiar with the basic concepts and the language used before you adopt ISO 9001 to achieve a first level of performance. The practices described in ISO 9004 may then be implemented to make your quality management system more effective and efficient in achieving your business goals and objectives. The ISO 9001 and ISO 9004 standards have been written to enable you to relate them to other management systems (e.g. environmental), or to sector specific requirements (such as ISO/TS 16949 in the automotive industry) and to assist you in gaining recognition through national or regional award programmes.

This brochure provides you with:

✓ An overview of the ISO 9000 core standards

✓ A step-by-step process to implement a quality management system

✓ Examples of typical applications of the documents, and

✓ Information on the ISO 9000 family of standards.

# The ISO 9000 family – core standards

The **ISO 9000** standard provides the fundamentals and vocabulary used in the entire ISO 9000 family of standards. It sets the stage for understanding the basic elements of quality management as described in the ISO standards. ISO 9000 introduces users to the eight Quality Management Principles as well as the use of the process approach to achieve continual improvement. (See **Figure 1**).

**ISO 9001** is used when you are seeking to establish a quality management system that provides confidence in your organization's ability to provide products that fulfil customer needs and expectations.

It is the standard in the ISO 9000 family against whose requirements your quality management system can be certified by an external body. The standard recognizes that the term "product" applies to services, processed material, hardware and software intended for your customer.

There are five sections in the standard that specify activities that need to be considered when you implement your system:

✓ Overall requirements for the quality management system and documentation

✓ Management responsibility, focus, policy, planning and objectives

✓ Resource management and allocation

✓ Product realization and process management, and

✓ Measurement, monitoring, analysis and improvement.
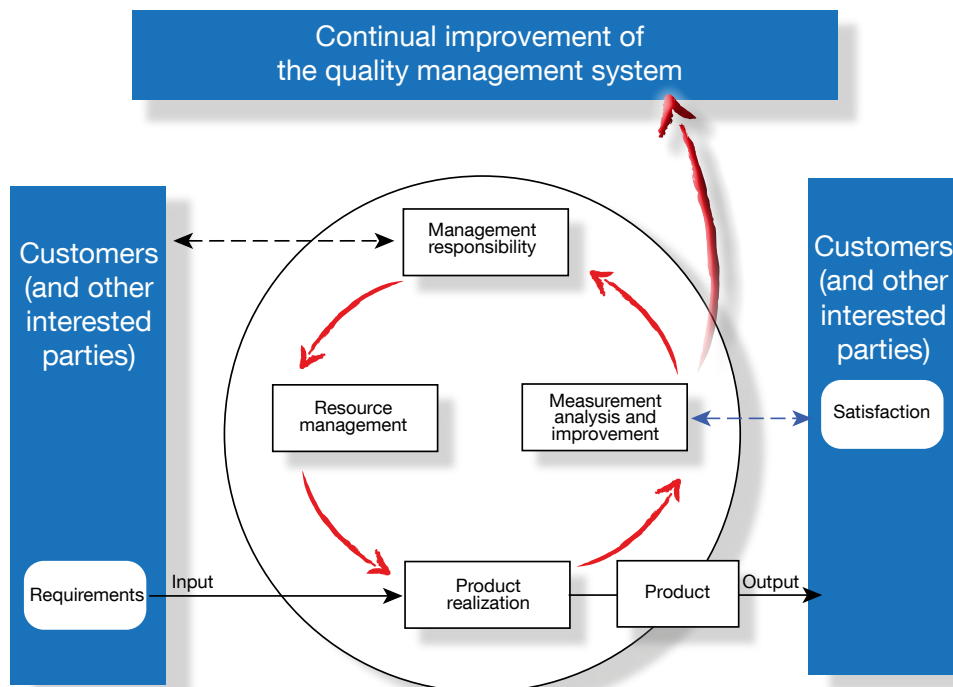


**Figure 1** – the ISO 9000 process approach

The requirements in four of the sections are applicable to all organizations – Quality management system, Management responsibility, Resource management, and Measurement, analysis and improvement. The Product realization section may be tailored to meet the needs of your organization. Your quality manual or other documentation will demonstrate how you meet the ISO 9001 requirements in your company.

Together, the five sections of ISO 9001 define what you should do to consistently provide product that meets customer and applicable statutory and regulatory requirements. In addition, you will seek to enhance customer satisfaction by continual improvement of your quality management system.

Further guidance can also be found in the ISO 9001:2008 Introduction and Support Package prepared by ISO/TC 176 subcommittee SC 2 which provides further guidance on:

✓ Terminology

✓ ISO 9001:2008 Clause 1.2 (Application)

✓ Documentation requirements

✓ The process approach

✓ Outsourced processes

✓ Implementation

✓ Frequently asked questions (FAQs).

ISO/TC 176 maintains a database of approved interpretations of the ISO 9001 standard.

**ISO 9004** is used to extend the benefits obtained from ISO 9001 to all parties that are interested in or affected by your operations. Interested parties include your employees, owners, suppliers, partners and society in general.

**ISO 9001** and **ISO 9004** are compatible and can be used separately or in combination to meet or exceed expectations of customers and interested parties. Both standards apply a process approach. Processes are recognized as consisting of one or more linked activities that require resources and must be managed to achieve predetermined output. The output of one process may directly form the input to the next process and the final product is often the result of a network or system of processes. The eight Quality Management Principles provide the basis for the performance improvement.

**ISO 9004** gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly in managing for the long-term success of an organization. ISO 9004 is recommended as a guide for organizations whose top management wishes to extend the benefits of ISO 9001 in pursuit of systematic and continual improvement of the organization's overall performance. However, it is not intended for certification or contractual purposes.

**ISO 19011** covers the area of auditing of quality management systems and environmental management systems. It provides guidance on the audit programmes, the conduct of internal or external audits, and information on auditor competence. ISO 19011 provides an overview of how an audit programme should operate and how management system audits should take place.

Effective audits ensure that an implemented QMS meets the requirements specified in ISO 9001.

The nature of your organization and your specific needs will determine how you apply these standards to achieve your goals and objectives. Useful hints and tips for conducting audits have been developed by the ISO 9001 Auditing Practices Group. Information on third party auditing has also been developed by the joint ISO-IAF (International Accreditation Forum) Accreditation Auditing Practices Group.

## Implementing and maintaining a quality management system based on the ISO 9001 standard

The implementation process is important in achieving the full benefits of the quality management system (QMS). Most new users will obtain measurable payback early in the process.

For a successful implementation of your QMS, these seven steps are recommended:

**1 Fully engage top management to**

➢ Define why you want to implement ISO 9001

➢ Define your mission, vision, and values in your organization

➢ Define your organization's stakeholders: customers, suppliers, stockholders, employees, society, etc.

➢ Define your quality policy, and

➢ Define and align organizational objectives and related product/ service quality objectives.

**2 Identify key processes and the interactions needed to meet quality objectives**

**3 Implement and manage the QMS and its processes (using process management techniques)**

## 4 — Build your ISO 9001-based QMS

- ➤ Identify ISO 9001 requirements
- ➤ Map these requirements with your implemented QMS, where applicable
- ➤ Make a gap analysis : identify where in your existing system the requirements are fulfilled, and where they are not
- ➤ Include in your QMS processes the activities, procedures and controls needed.

## 5 — Implement the system, train company staff and verify effective operation of your processes

## 6 — Manage your QMS

- ➤ Focus on customer satisfaction
- ➤ Monitor and measure the operation of your QMS
- ➤ Strive for continual improvement
- ➤ Consider implementing business excellence models in the company operations.

## 7 — If necessary, seek third party certification/registration of the QMS or alternatively, issue a self-declaration of conformity

# Process model
# of the ISO 9000 family
# of standards

The accompanying diagram depicts the relationships of the standards in the ISO 9000 family and where they may be applied when implementing your quality management system.

**Figure 2 – Application of ISO/TC 176 standards in the process approach.**

*NOTE : See page 11 for a complete listing of standards developed by TC 176.*
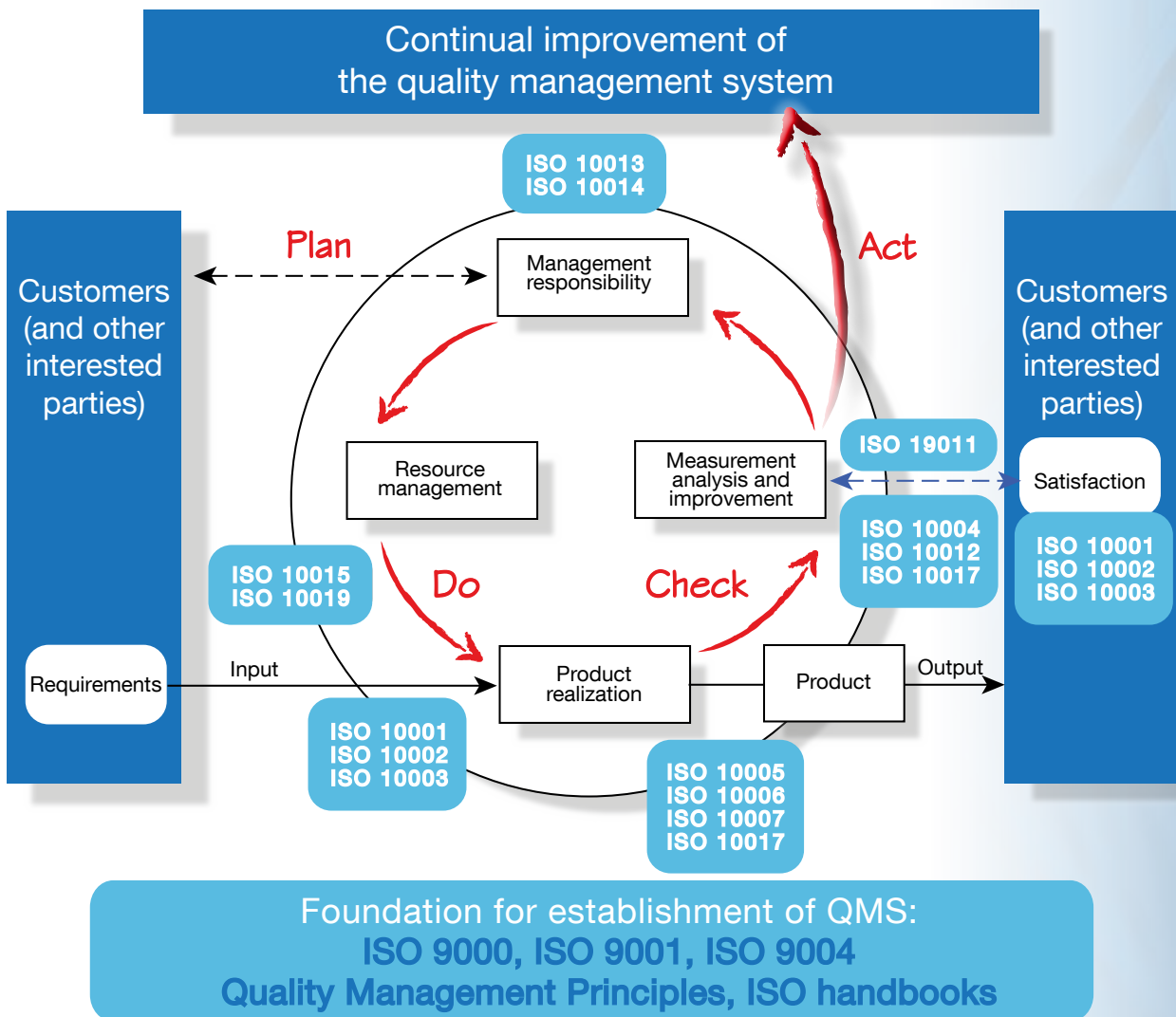
# Examples of using the ISO 9000 family of standards

## Example 1

A metal parts fabricating company recognized the need to demonstrate their capability to produce consistent quality product. They first used ISO 9000 to develop a plan to create an acceptable QMS. Next, they prepared the quality manual and quality system procedures as required by ISO 9001, excluding the requirements covering product design and development because their products are made to designs prepared by their customers. They implemented the QMS described in their manual and procedures and ensured the system functioned as planned. Later, in order to bid on the supply of parts to a major automotive company, they upgraded their quality system to meet the automotive sector specific requirements of ISO/TS 16949.

## Example 2

A welfare agency decided to improve the quality of the services it provided to clients. It adopted ISO 9004 as the basis for implementing its system and planning for improvements. The agency recognized that ISO 9000 provided very useful additional guidance in terminology and understanding and applying QMS concepts to their system. They mapped the resulting system processes to requirements identified in ISO 9001. They planned to seek certification to ISO 9001 to gain recognition and credibility from clients and supporters.

## Example 3

An electrical appliance manufacturer had a well-established company culture of continual improvement and effective production control. The management decided to improve the company's development processes and to implement ISO 9001 to obtain certification for commercial purposes. The company used ISO 9004 to guide its improvement processes and ISO 10006 to develop a project management plan. Regulatory agencies demanded products be designed and packaged recognizing the end of life disposition of products and packaging. The company was able to use the design and document control requirements in ISO 9001 to satisfy regulators of compliance to new requirements.

## Example 4

A large chemical processing company was required by its major customers to gain certification to ISO 9001 and to be environmentally friendly. To address these issues, the company leadership planned a comprehensive management strategy linking their QMS and an environmental management system (EMS). A thorough review of their business processes indicated that all elements of ISO 9001 were applicable to their quality management system and the Annex in ISO 9001 provided the information needed to effectively link it to the ISO 14001 EMS standard. The company used ISO/TR 10013 to guide the development of the required documentation in its various production divisions, ISO 10015 for guidance in the preparation of training plans for their employees and ISO 19011 for auditing both the QMS and EMS. Management achieved additional benefits and continual improvements using ISO 9000 and ISO 9004.

## Example 5

A firm of international lawyers wanted to improve their client management processes using the systematic approach found in ISO 9001, but did not intend to gain certification. Their QMS provides for the design and development of new services such as international tax planning and modifying traditional services to meet the requirements of new or amended legislation. They included purchasing control to cover the selection of computer hardware and software, as well as purchasing the services of specialist lawyers as needed. After successfully implementing ISO 9001, they used the self-assessment guidelines of ISO 9004 to monitor their progress as they improved their QMS to achieve greater client satisfaction.

## Example 6

A computer software developer serving a niche market recognized that as their user base expanded they would be faced with issues concerning product management including new product development and configuration control. Changes to base products, user hardware and regulatory requirements were compounding customer service issues. The company used ISO/IEC 90003 (QMS for software) when developing new software and incorporating new features in existing product lines. ISO 9004 provided the guidance they needed to establish documented procedures to implement change control and software improvement. ISO 10006 and ISO 10007 provided additional assistance as they managed the project and prepared procedures for configuration management. They later acquired another software developer and were able to use their QMS to guide the integration of the acquisition into their own structure very quickly with a minimum of disruption to customers.

## Example 7

A bank decided to implement a quality management system for its on-line Internet banking services. They used ISO 10019 in the selection of a consultant to guide them in their QMS implementation. They ensured that their quality manual made clear that their other conventional banking services were not included in their quality management system. While adopting the requirements of ISO 9001, the bank obtained guidance from ISO 9000 to interpret words and phrases used in the standard for their application. They applied all the requirements of the product realization section (Clause 7), recognizing that design and development is an important part of creating new service processes. The bank used ISO/TR 10013 to prepare their documentation, which they posted on their internal computer network to ensure current procedures are available to their staff.

## Example 8

A franchise organization had difficulty maintaining consistent operation by franchisees and determined that an enhanced management system was required. They learned that ISO 9001 included the tools they needed and with the help of ISO/TR 10013 they developed the quality manual and quality system procedures to be used throughout the franchise network. To ensure a consistent approach in managing customer satisfaction, they used guidance found in ISO 10001, ISO 10002 and ISO 10003. When the system was implemented, the franchise organization used ISO 19011 to establish an audit programme to confirm that the ISO 9001-based QMS continued to function as required and was improved on a continual basis.

## Maintaining the benefits and continual improvement
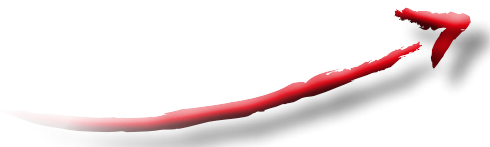
Most new users of the ISO 9000 family of standards obtain measurable benefits early in the process of implementing the requirements in their operations. These initial benefits are generally due to improvements in their organization and internal communication. The benefits must be strengthened through effective internal auditing and management review of system performance. Like all systems, it either improves or becomes less effective. It does not remain static for long.

ISO 10014 provides guidelines for realizing financial and economic benefits from the application of the ISO 9000 Quality Management Principles. It is directed to top management of the organization and complements ISO 9004 for performance improvements.

When you adopt ISO 9001, you must strive to satisfy your customers and to achieve continual improvement of your operations through the QMS. Continual improvement is a process of increasing the effectiveness of your organization to fulfill to quality policy and your quality objectives that you have established which are updated periodically. ISO 9001 requires that you plan and manage the processes necessary to continually improve your QMS.

ISO 9004 provides information you can use to go beyond ISO 9001 to strengthen the competitive position and to provide improvements to operational efficiency. It is recommended that you obtain data from various sources, both internal and external, to assess how appropriate your quality system objectives are to changing circumstances. This information can also be used to improve the performance of all your business processes.

Many organizations expand their management systems by extending the ISO 9001 structure to include the requirements of other management systems standards, including ISO 14001, *Environmental management systems.* The structural and organizational requirements of ISO management systems standards are designed to be compatible.

## Current standards from ISO/TC 176 and its subcommittees

| Standard/ document | Title | Edition |
|---|---|---|
| ISO 9000:2005 | Quality management systems – Fundamentals and vocabulary | Third |
| ISO 9001:2008 | Quality management systems – Requirements | Fourth |
| ISO 9004:2000 | Quality management systems – Guidelines for performance improvements | Second |
| ISO 10001:2007 | Quality management – Customer satisfaction – Guidelines for codes of conduct for organizations | First |
| ISO 10002:2004 | Quality management – Customer satisfaction – Guidelines for complaints handling in organizations | First |
| ISO 10003:2007 | Quality management – Customer satisfaction – Guidelines for dispute resolution external to the organization | First |
| ISO 10005:2005 | Quality management – Guidelines for quality plans | Second |
| ISO 10006:2003 | Quality management – Guidelines for quality management in projects | Second |
| ISO 10007:2003 | Quality management – Guidelines for configuration management | Second |
| ISO 10012:2003 | Measurement management systems – Requirements for measurement processes and measuring equipment | Second |
| ISO/TR 10013:2001 | Guidelines for quality management system documentation | First* |
| ISO 10014:2006 | Quality management – Guidelines for realizing financial and economic benefits | First |
| ISO 10015:1999 | Quality management – Guidelines for training | First |
| ISO/TR 10017:2003 | Guidance on statistical techniques for ISO 9001:2000 | Second |
| ISO 10019:2005 | Guidelines for the selection of quality management system consultants and use of their services | First |
| ISO/TS 16949:2002 | Quality management systems – Particular requirements for the application of ISO 9001:2000 for automotive production and relevant service part organizations | Second |
| ISO 19011:2002 | Guidelines for quality and/or environmental management systems auditing | First |

*Note: TR – Technical Report, TS – Technical Specification*
*\* First edition as a TR, replacing the International Standard ISO 10013:1995.*

## The future
## of the ISO 9000 family

In order for the ISO 9000 family to maintain its effectiveness, the standards are periodically reviewed to benefit from new developments in the quality management field and also from user feedback. ISO/TC 176, comprising experts from businesses and other organizations around the world, monitors the use of the standards to determine how they can be improved to meet user needs and expectations when the next revisions are due. All ISO standards are reviewed regularly for relevancy; changes are made when there is a demonstrated need to improve the standard.

Based on input from the user community, ISO/TC 176 will continue to evaluate and adopt new concepts in the field of quality management for incorporation into ISO standards. This can include sector specific initiatives and supporting documents within the ISO 9000 family. Most ISO technical committees recognize the structure of ISO 9001 when new management systems standards are developed for other or specific purposes.

ISO's commitment to sustaining the ISO 9000 momentum through reviews, improvement and streamlining of the standards guarantees that your investment in ISO 9000 today will continue to provide effective management solutions well into the future.

## For further information

### Web sites

**ISO :**
**www.iso.org**
**ISO/TC 176 :**
**www.tc176.org**
**ISO/TC 176 subcommittee SC 2 :**
**www.iso.org/tc176/sc2**

Information on the ISO 9000 standards is also available from **ISO's national member bodies** – **www.iso.org/ isomembers** – and from the ISO Web site – **www.iso.org** – **Management standards** pages.

Sales enquiries should also be directed to the ISO members or to the ISO Central Secretariat **sales department** – **sales@iso.org.**

ISO publishes the bimonthly magazine *ISO Management Systems* – **www.iso.org/ims** – which provides updates on its families of standards management system and news on their implementation around the world. The magazine is available in English, French and Spanish editions.

*ISO Focus magazine* – **www.iso. org/isofocus** – gives an overview of ISO and its standards and also includes articles on its management systems standards. It is published 11 times a year in English only.

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ISBN 978-92-67-10473-7

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