



Awareness and Use of ISO 9000:2015: *Quality management systems — Fundamentals and vocabulary*

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Purpose and scope

For use by the public in providing training on the importance of ISO 9000:2015 when it comes to:

Understanding the significant differences between **ISO 9001:2008** and **ISO 9001:2015**

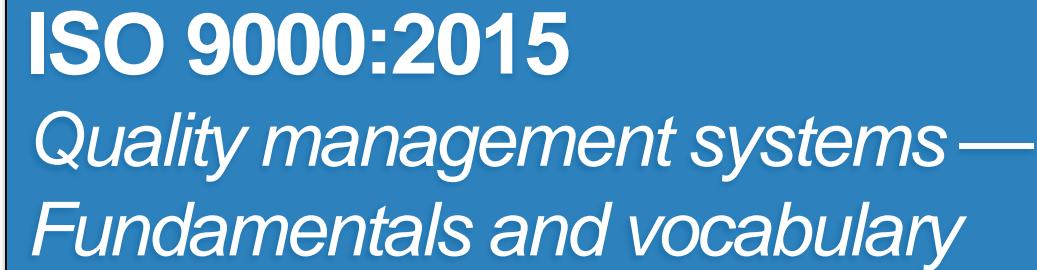
Auditing and implementing **ISO 9001:2015**

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Normative references = “indispensable”

ISO 9001:2015 identifies only one document as
“normatively referenced” and **“indispensable**
for its application”:



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“indispensable”

Merriam-Webster Dictionary:

adjective in-dis-pens-able \in-di-'spen(t)-sə-bəl\

- extremely important and necessary
- 1:** not subject to being set aside or neglected
- <an *indispensable* obligation>
- 2:** absolutely necessary: Essential
- <an *indispensable* member of the staff>

Oxford Dictionary

/,ɪndɪ'spɛnsəbl/

too important to be without

SYNONYM **essential**

Cars have become an indispensable part of our lives.

indispensable to somebody/something

She made herself indispensable to the department.

indispensable for something/for doing something

A good dictionary is indispensable for learning a foreign language.

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ISO 9000 series

Three standards in the series:

ISO 9000

ISO 9001

ISO 9004

New Revisions released together in 2015

Currently under revision

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ISO 9000 series

ISO 9000

Quality management systems—Fundamentals and vocabulary

Essential background for the proper understanding and implementation of ISO 9001

ISO 9001

Quality management systems—Requirements

Requirements aimed primarily at giving confidence in the products and services an organization provides, thereby improving customer satisfaction

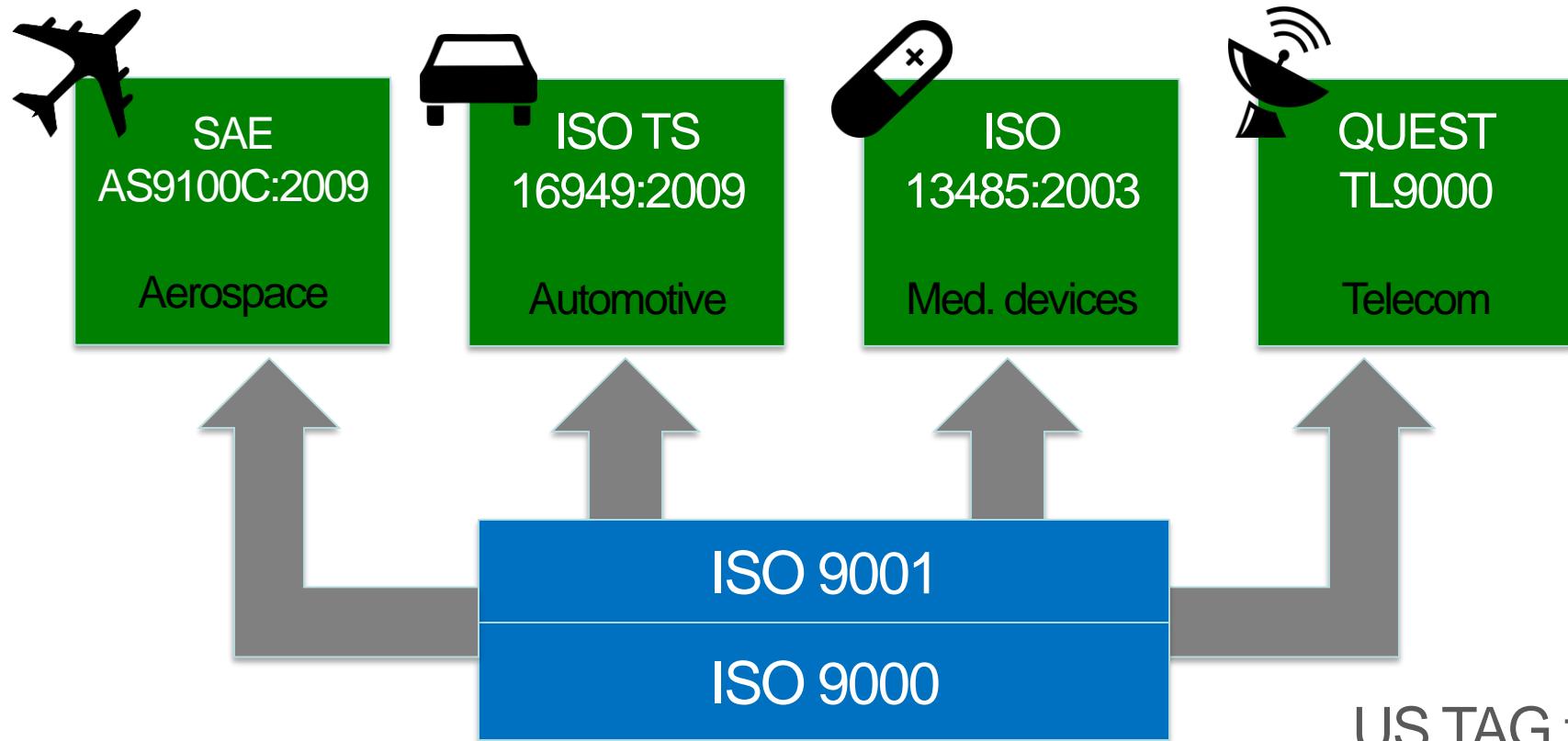
ISO 9004

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

Guidance for organizations that choose to progress beyond ISO 9001 requirements to address a broader range of topics that can lead to continual improvement of the organization's overall performance

ISO 9001 provides common ground

Quality management systems (QMS) standards for which ISO 9001 is a normative reference also require use of ISO 9000.



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ISO 9000 table of contents

Foreword & Introduction

1 Scope

2 Fundamental concepts and quality management principles

2.1 General

2.2 Fundamental concepts

2.2.1 Quality

2.2.2 Quality management system

2.2.3 Context of an organization

2.2.4 Interested parties

2.2.5 Support



Descriptive language
with no requirements

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ISO 9000 table of contents (continued)

2.3 Quality management principles

2.3.1 Customer focus

2.3.2 Leadership

2.3.3 Engagement of people

2.3.4 Process approach

2.3.5 Improvement

2.3.6 Evidence-based
decision making

2.3.7 Relationship management

- No requirements
- Ideas useful in guiding organizations' actions
- Used as a basis for developing ISO 9001

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ISO 9000 table of contents (continued)

2.4 Developing the QMS using fundamental concepts and principles

2.4.1 QMS model

2.4.2 Development of a QMS

2.4.3 QMS standards, other management systems and excellence models

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ISO 9000 table of contents (continued)

3 Terms and definitions

Terms related to ...

- | | |
|----------------------|------------------------------------|
| 3.1 person or people | 3.8 data, information and document |
| 3.2 organization | 3.9 customer |
| 3.3 activity | 3.10 characteristic |
| 3.4 process | 3.11 determination |
| 3.5 system | 3.12 action |
| 3.6 requirement | 3.13 audit |
| 3.7 result | |

Required definitions of terms used in
requirements standards such as ISO 9001

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ISO 9000 table of contents (continued)

Annex A

Concept relationships and
their graphical representation



Concept diagrams
aid in understanding
of interrelationships
among terms and
concepts

Bibliography, Alphabetical index of terms

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Properly using ISO 9000—an example

Clause 10.2.1d in ISO 9001:2015 states that the organization shall ...

Substituting “effectiveness” and “corrective action” with definitions from ISO 9000, this becomes:

“review the **effectiveness** of any **corrective action** taken”

“review the **extent to which planned activities are realized and planned results are achieved** of any **action to eliminate the cause of a nonconformity and to prevent recurrence**”

Definitions and fundamental concepts in ISO 9001:2015

Examples of new, revised or removed terms of ISO 9001

Interested party	New	Output	Revised
Risk	New	Information	Revised
Risk-based thinking	New	Information system	Revised
Provider	New	Verification	Revised
Documented information	New	Validation	Revised
Effectiveness	Revised	Corrective action	Revised
Competence	Revised	Preventive action	Removed

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New “terms” in clauses 1-6 of ISO 9001:2015

1. Scope of standard
2. Normative references
3. Terms and definitions
4. **“Context of the organization”**
 - 4.1 Understanding the organization and its **“context”**
 - 4.2 Understanding the needs and expectations of **“interested parties”**
 - 4.3 Determining the scope of the quality management system. . .
 - b) the requirements of relevant **“interested parties”**
 - 4.4 Quality management system and its processes. . .
 - 4.4.1 f) address the **“risks”**
5. **“Leadership”**
6. **“Planning”**
 - 6.1 Actions to address **“risks and opportunities”**

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Understanding “context”

From ISO 9000:2015:

2.2.3 Context of an organization

“Understanding the context of the organization is a process. This process determines factors which influence the organization’s purpose, objectives and sustainability.”

3.2.2 context of the organization

“combination of internal and external issues that can have an effect on an *organization’s* approach to developing and achieving its *objectives*. ”

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Understanding “interested parties”

When determining the scope of the organization, we shall consider the expectations of “relevant interested parties.”

All of the following can be "interested parties":

Person having an interest in the success of an organization

Person that can affect an activity

Organization that perceives itself to be affected by a decision

Stakeholder

Person having an interest in the performance of an organization

Providers' regulators

Competitors

Opposing pressure group

There are more!

Understanding “risk”

The term “risk” has been added to ISO 9001:2015 and is noted in many places throughout the standard.

From ISO 9000:2015, clause 3.7.9:
risk

effect of uncertainty...positive or negative....

Often characterized by reference to potential events....

Often expressed in terms of the consequences of an event ...
and the associated likelihood of occurrence

This may apply, for example, to a product, service,
process, provider, customer, consumer, environment,
employee, and the competition.

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Assisting organizations

ISO 9000 terms are broken down by category to promote international understanding and increase confidence in the global market



- | | |
|----------------------|------------------------------------|
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| 3.3 activity | 3.10 characteristic |
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| 3.7 result | |

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Assisting organizations

The PDF version of ISO 9000 includes click-on numerical links for defined terms:

3.3.4

quality management

management ([3.3.3](#)) with regard to *quality* ([3.6.2](#))

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About TAG (Technical Advisory Group) 176

Develops U.S. positions on ISO/TC (Technical Committee) 176, which covers quality management and assurance

ISO/TC 176 vision:

Through worldwide acceptance and use, the ISO 9000 family of standards will provide an effective means for improving the performance of individual organizations. This in turn will make people and organizations more confident that goods and services will meet their expectations, thereby enhancing trade, global prosperity, and individual well-being.

Join US TAG to ISO/TC 176

Learn how you can participate in the development of international standards related to quality terminology, systems, and technology.

Visit

asq.org/standards/standards-and-quality-management

Contact

standards@asq.org

Reference links for additional Information

- “ISO 9000:2015—What’s Normative, Anyway?” by Paul Palmes
www.insidestandards.com/iso-90002015-whats-normative-anyway/
- *Standards Connection* newsletter
asq.org/standardsconnection/
- Learn About Standards
asq.org/learn-about-quality/learn-about-standards/
- ASQ Standards Channel
videos.asq.org/asq-standards-channel
- ISO 9000 Series overview
asq.org/learn-about-quality/iso-9000/overview/overview.html
- ISO/FDIS 9000:2015 “NOTE Guidance on some additional frequently used words in the QMS standards developed by ISO/TC 176, and which have an identified dictionary meaning, is provided in a glossary available at:
www.iso.org/iso/03_terminology_used_in_iso_9000_family.pdf”