

ISO 9001:2015

The «new systematic Approach» to the risks

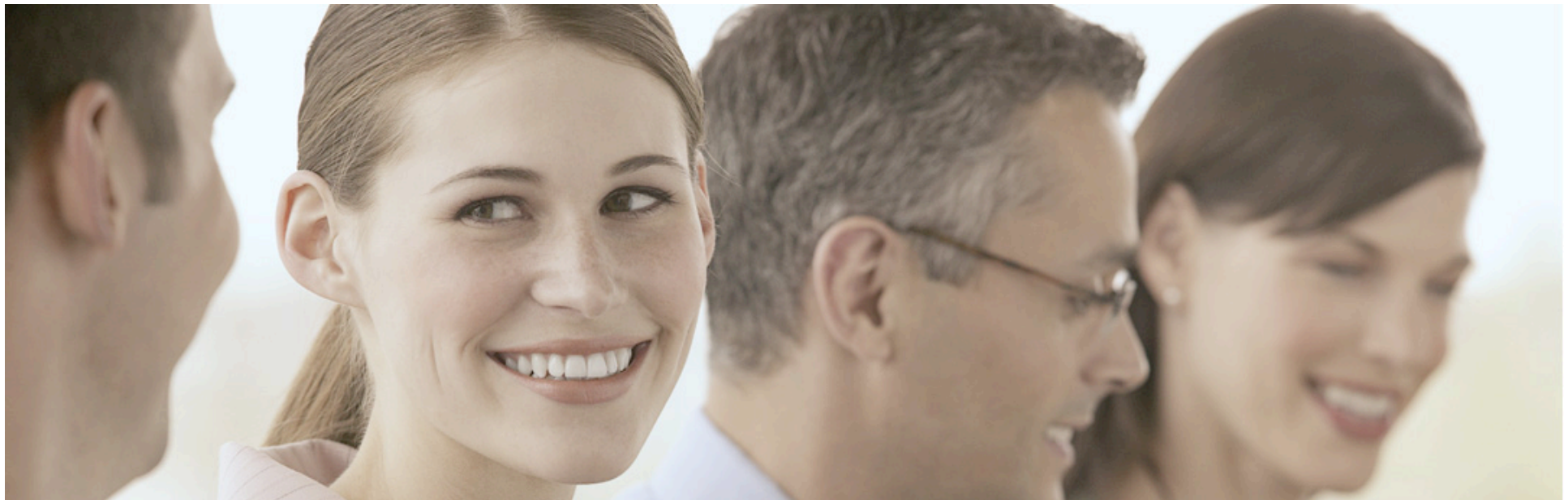
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What is the change?

ISO 9001: 2015





There is everthing inside: **sustainable development, innovation, change management, knowledge management, social considerations (no discrimination policies), safety principles (stress, burn-out), preservation, risk, FUTURE.**

ISO 9001:2015, § 0.1. Consistently meeting requirements and addressing FUTURE needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

Many standards changed so far: ISO 9001, ISO 14001, ISO 17021, MD05, MD17, ISO 17011. risk based thinking (or risk based approach) is a common element

ISO 9001:2015 define risks as “Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. ”.

The risk of the FUTURE

who, what, where, when, WHY, how

Change the way to perform audits

The new is not only in the new requirements, but in the way, *forma mentis* (thinking) of the organization and of the auditor

CONTEST (market, interested parties, competitors, environment in the country that is based the organization, technological and logistics infrastructures and ...).

Systematic approach to the risk, not only approach to the processes

Preventive actions (risks and opportunities) are no more a self standing requirements, but it is a concept hidden into all the standard

The concept of risks and opportunities is linked to OBJECTIVES / GOALS

Requirements are increased or diminished?

Administratives requirements are diminished, but the requirements are increased!.

See this point as example

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

The organization shall monitor and review information about these external and internal issues

1. The organization shall determine external issues...
2. The organization shall determine internal issues
3. The organization shall monitor information about these external
4. The organization shall monitor information about these internal
5. The organization shall review information about these external
6. The organization shall review information about these internal

Requirements are increased or diminished?

If you see clause 4.2 (*Understanding the needs and expectations of interested parties*):

The organization shall determine:

a) the interested parties that are relevant to the quality management system;

b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

Requirements are increased or diminished?

If you see clause 6.1 (*Actions to address risks and opportunities*) there are **15** elementary requirements

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

- a) give assurance that the quality management system can achieve its intended result(s);*
- b) enhance desirable effects;*
- c) prevent, or reduce, undesired effects;*
- d) achieve improvement.*

Requirements are increased or diminished?

Only 3 clause (4.1, 4.2, 6.1), established **27 new elementary requirements**

.yes, less documented evidences, but more requirements

So the point is not HOW MANY, but HOW to demonstrate the conformity.

..and the auditor has to be a NEW auditor

The importance of the boundaries and applicability

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

When determining this scope, the organization shall consider:

- a) the external and internal issues referred to in 4.1;*
- b) the requirements of relevant interested parties referred to in 4.2;*
- c) the products and services of the organization.*

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

Bibliography

- [How Change is addressed within ISO 9001:2015](#)
- [The process Approach in ISO 9001:2015](#)
- [Guidance on the requirements for Documented Information of ISO 9001:2015](#)



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