ACCREDIA L'Ente Italiano di Accreditamento
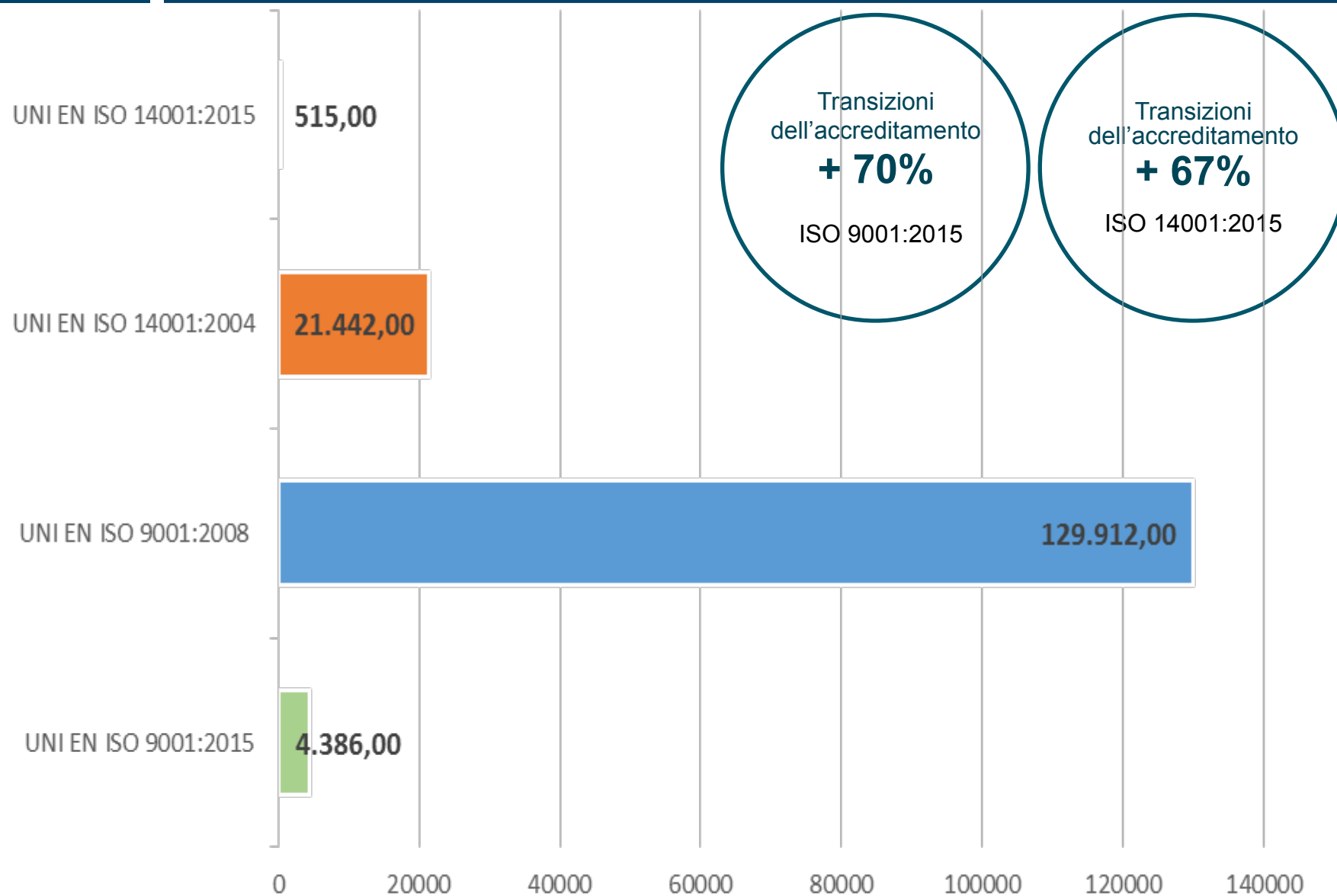
ISO 9001:2015 – situation on its application and evolution of MSs

Emanuele Riva
Direttore Dipartimento Certificazione e Ispezione

December 2016

11.08.2016 – first CD of ISO 9004

ISO/TC 176/SC 2/N 1350

Date: 2016-08-11

ISO/CD 9004

ISO/TC 176/SC 2/WG 25

Secretariat: BSI

Organizational quality – Guidance to achieve sustained success

Qualité organisationnelle - Guidance pour atteindre performances durables

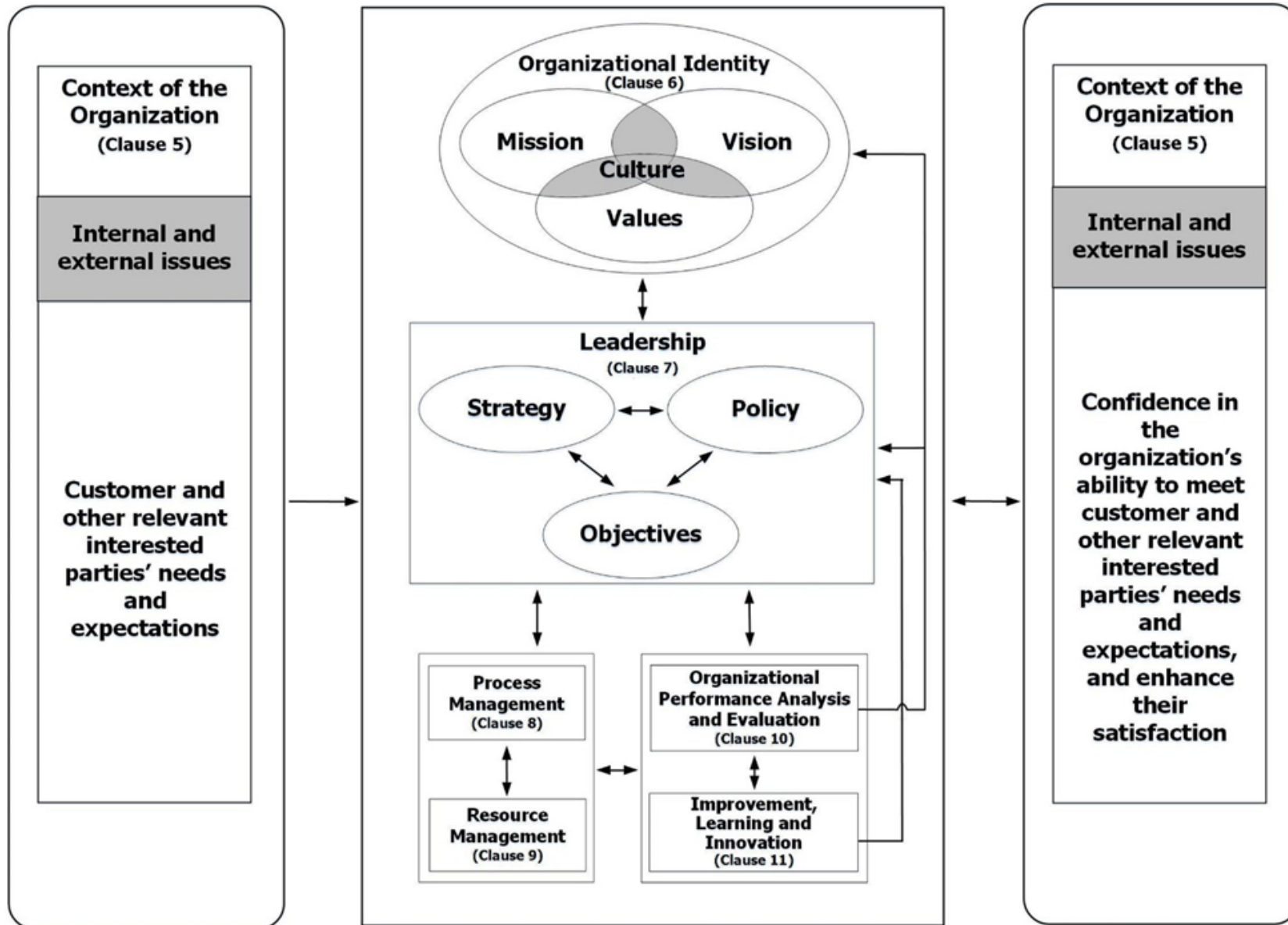| Warning |
|---|
| This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation. |

New title: Organizational quality – Guidance to achieve sustained success

- ✓ from Quality management system to a **organizational quality**. Not only simply ISO 9001 - Quality, but now it covers all the MSs. it is becomining a SUPER STANDAR… over everything.

- ✓ New standard will become subordinate to ISO 9004? The first standard will be ISO 9004, and after all the others?

- ✓ Quality management, and NOT quality management system, so ISO 9004 does not follow HLS.

✓ La 9001 is open now to interested parties: from this poit 9004 is expanding. It is growing a standrd with a lot of ambitions, and today it is diffiuclt to undestand the boarders.

✓ Interest of the consument considered in a wide way.

✓ ISO 9001:2015 satisfation of interested parties in order to reach the satistation of the client.

✓ ISO 9004:2015 satisfation of interested parties in order to reach the satistation of the organization for its success s long it is possible

✓ Organization decides to satisfy the interested parties that give and advantage to the company!

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

The concept of **balanced involvement** of interested parties is no more valid!

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

Context of the Organization
(Clause 5)

Internal and external issues

Customer and other relevant interested parties' needs and expectations

Organizational Identity
(Clause 6)

Mission   Vision
Culture
Values

Leadership
(Clause 7)

Strategy ⟷ Policy

Objectives

Process Management
(Clause 8)

Resource Management
(Clause 9)

Organizational Performance Analysis and Evaluation
(Clause 10)

Improvement, Learning and Innovation
(Clause 11)

Context of the Organization
(Clause 5)

Internal and external issues

Confidence in the organization's ability to meet customer and other relevant interested parties' needs and expectations, and enhance their satisfaction

Identità dell'organizzazione; Mission, vision, values and culture

Vision e Mission non sono la stessa cosa

✓**Mission** –the organization's purpose for existing as expressed by top management (see ISO 9000:2015, 3.5.11); **why we exist**

✓**Vision** - aspiration of what an organization would like to become as expressed by top management (see ISO 9000:2015, 3.5.10); **how we would like to be**

✓**Culture** - beliefs, history, ethics, observed behaviours and attitudes.

✓**Value -** value, value, value, value, value
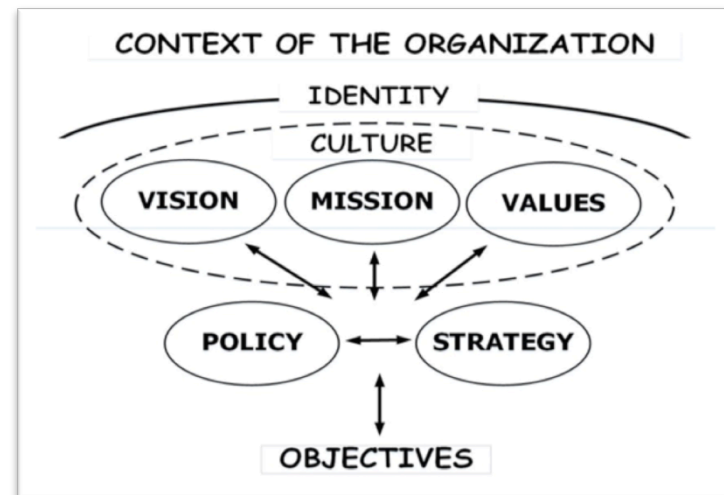
INNOVATION is reapeted 77 times into the standard!!!!

Video

11.4 Innovation

11.4.1 General

Innovation should result in improvement, that is, it should result in new or changed product or process which enables realization or redistribution of value.

Changes in the organization's internal and external issues and the relevant needs and expectations of relevant interested parties could require innovation.

The organization should:

a) identify the need for innovation;

b) establish and maintain an effective and efficient innovation process;

c) provide the related resources.

11.4.2 Application

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

a) technology or product (i.e. innovations that not only respond to the changing relevant needs and expectations of customers or other interested parties, but also to anticipate potential changes in the organization and product lifecycles);

961 b) processes (i.e. innovation in the methods for product realization, or innovation to improve process
962 stability and reduce variance);

963 c) the organization (i.e. innovation in its constitution and organizational structures);

964 d) the organization's management system (i.e. to ensure that competitive advantage is maintained and
965 new opportunities are utilized, when there are emerging changes in the organization's
966 environment).

967 **11.4.3 Timing and risk**

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

971 The timing for the introduction of an innovation should be aligned with the assessment of risk. It should
972 usually be a balance between the urgency with which it is needed versus the resources that are made
973 available for its development.

974 The organization should review, improve and innovate its management system based on the results of
975 the organisational performance evaluation (see Clause 10).

976 The organization should use a process that is in alignment with its strategy to plan and prioritize
977 innovation initiatives. The organization should support the innovation initiatives with the resources
978 needed.

979 The results of innovation should be reviewed in order to experience learning and an increase in
980 organizational knowledge.

These is no referring to sustainibility (consider that this ward is in the costitution of France and Switzerlad) but the new term is now **SUISTAINED**.

So, in order to have a sustained success, is it only implicit that it has to be sustained.

For normative reasons the new word is SUISTAINED and not sustainibility. (sustainibility is not under the competence of CT 176).

ISO 9004 is a standard for the really Top Management.
ISO 9004 uses a diffiust / high language, that does not fit for little companies with low level of competence.

Who will read it? Only the Elite? Is it useful?

DRAFT INTERNATIONAL STANDARD
ISO/IEC DIS 17021-3

Conformity assessment — Requirements for bodies providing audit and certification of management systems —

Part 3:
Competence requirements for auditing and certification of quality management systems

Évaluation de la conformité — Exigences pour les organismes procédant à l'audit et à la certification des systèmes de management —

Knowledge for QMS auditing and certification

Table A.1 provides a summary of the knowledge required for QMS auditing and certification but is informative because it only identifies the areas of knowledge for specific certification functions.

The competence requirements for each function are stated in the main text of this International standard and Table A.1 gives the reference to the specific requirement.

Table A.1 — Knowledge for QMS auditing and certification

Knowledge	Certification functions		
	Conducting the applica- tion review to determine audit team competence re- quired, to select the audit team members, and to determine the audit time	Reviewing audit reports and making certification deci- sions	Auditing and leading the audit team
Fundamentals, vocabulary, terminology, principles, prac- tices and techniques of quality management		6.3.2	5.2
Qualit y management system stand- ards/normative docu- ments	6.2.1	6.3.1	5.3
Context of the organization			5.4
Client products, processes and organization			5.5

New area of attention for the auditors, consultants and organization

✓ Elements (internal and externals) that have influence with the strategis choises of the organizations

✓ Which are the key items, referred to products and services, considered relevant for interested parties

✓ How infrastructure and envireoments influence the output.

✓ Keep the attention to regulatory requirements

It is no more an «EASY» ISO 9001

ISO/IEC DIS 17021-3:2016(E)

5.4 Context of the organisation

The audit team shall have business sector knowledge to determine that an organization has appropriately identified:

a) the external and internal issues, relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system;

b) the needs and expectations of interested parties relevant to the organisation's QMS including the requirements for the products and services of the organization;

c) the scope and its applicability to an organization's QMS.

NOTE   A business sector is understood to be the economic activities covering a broad range of related technical areas.

5.5 Client products, services, processes and organization

The audit team shall have knowledge of:

a) terminology and technology specific to the technical area;

b) statutory and regulatory requirements applicable to the product or service specific to the technical area;

ISO/TC **176**/SC **2**

Date: 2016-08-16

ISO/DTS 9002

ISO/TC 176/SC 2/WG 24

Secretariat: BSI

Quality management systems — Guidelines for the application of ISO 9001:2015

Systèmes de management de la qualité — Lignes directrices pour l'application de l'ISO 9001

The stardard give practical examples... as you can see here below

Understanding the organization and its context

Information about external and internal issue can be found from many sources, such as through internal documented information and meetings, in the national and international press, websites, publications from national statistics offices and other governament departements, professional and technical publications, conferences and meetings with relevant agencies, meetings with customers and relevant interested parties, and professional associations.

a) external issues related to:

1) economic factors such as money exchange rates, economic situation, inflation forecast, credit availability;

2) social factors such as local unemployment rates, safety perception, education levels, public holidays and working days;

3) political factors such as political stability, public investments, local infrastructure, international trade agreements;

4) technological factors such as new sector technology, materials and equipment, patent expirations, professional code of ethics;

5) market factors such as competition, including the organization's market share, similar products or services, market leader trends, customer growth trends, market stability, supply chain relationships;

6) statutory and regulatory factors which affect the work environment such as trade union regulations and regulations related to an industry;

b) internal issues related to:

1) overall performance of the organization;

2) resource factors, such as infrastructure, environment for the operation of the processes, organizational knowledge;

3) human aspects such as competence of persons, organizational behaviours and culture, relationships with unions;

4) operational factors such as process or production and service provision capabilities,

EXAMPLE 1

The following is a non-exhaustive list of some examples of relevant interested parties that can be considered relevant by an organization, but are not limited to:

— customers;

— end users or beneficiaries;

— joint venture partners;

— franchisors;

— owners of intellectual property;

— parent and subsidiary organizations;

— owners, shareholders;

— bankers;

— external providers;

— employees and others working on behalf of the organization;

— statutory and regulatory authorities (local, regional, national or international);

— trade and professional associations;

— local community groups;

— non-governmental organizations;

As the requirements of the ISO 9001:2015 are generic, this Technical Specification can be used by organizations of all types, sizes, levels of maturity and in all sectors and geographic locations. However, the way an organization applies the guidance can vary based on factors such as the size or the complexity of the organization, the management model it adopts, the range of the organization's activities and the nature of the risks and opportunities it encounters.

Risk is the level of uncertainty inherent in a quality management system. There are risks in all systems, processes and functions. Risk-based thinking ensures these risks are determined, considered and controlled throughout the design and use of the quality management system.
Risk-based thinking has been implicit in previous editions of ISO 9001 in such requirements as determining the type and extent of control for external providers based on the effect of the product that is going to be provided, or taking corrective action based on the potential effect of an identified nonconformity.

In addition, in previous editions of ISO 9001, a clause on preventive action was included. By using risk-based thinking the consideration of risk is integral. It becomes proactive rather than reactive in preventing or reducing undesired effects through early identification and action. Preventive action is built-in when a management system is risk-based.

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its quality objectives. Some need more careful and formal planning and control than others.

There is no requirement in ISO 9001 to use formal risk management in determining and addressing risks and opportunities. An organization can choose the methods that suit its needs. IEC 31010 provides a list of risk assessment tools and techniques that can be considered, depending on the organization's context.

In some cases, an organization might have a formal risk management process in place that is required by customers or statutory and regulatory requirements. In such circumstances, the

ISO 9001:2015 for Small Enterprises

What to do?

Advice from ISO/TC 176

**Riprende la ISO 9002 e ci aggiunge qualche elemento «pratico»**

There is no requirement in ISO 9001 to use formal risk management in determining and addressing risks and opportunities. You can choose the methods that suit your needs. IEC 31010 provides a list of risk assessment tools and techniques that can be considered, depending on your organizations's context

Analysis (SWOT), or Political, Economic, Social, Technological, Legal, Environmental analysis (PESTLE). Other approaches can include techniques such as Failure Mode and Effects Abalysis (FMEA); Failure Mode, Effects and Criticality Analysis (FMECA); or Hazard Analysis and Critical Control Points (HACCP). It is for you to decide which methods or tools to use. Simpler approaches include techniques such as brainsstorming, structured «what if?» (SWIFT)

There are various situations where risks and opportunities should be considered, for example strategy meetings, managements reviews, internal audits, different kind of meetings in quality, meetings to set quality objectives, the planning stages for the design and development of new products and services, and the planning stages for production.

Grazie per l'attenzione

---

www.accredia.it
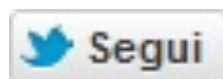
info@accredia.it

Dipartimento Certificazione e Ispezione

Dipartimento Laboratori di prova

Dipartimento Laboratori di taratura