ACCREDIA L'Ente Italiano di Accreditamento

Il futuro dei sistemi di gestione, la nuova ISO 9001 per una qualità sostenibile

La nuova norma ISO 9001:2015 - Stato dell'arte su applicazione e nuove linee guida

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ACCREDIA è l'Ente italiano per l'accreditamento dei Laboratori di prova e taratura e degli Organismi di certificazione, ispezione e verifica

✓ **Legge n. 99 del 2009**
Attuazione del Regolamento (CE) n. 765/2008, in materia di accreditamento e vigilanza del mercato (art. 4)

✓ **Decreti Ministeriali 22 dicembre 2009**
Designazione di ACCREDIA in qualità di Ente unico italiano di accreditamento

L'Ente unico italiano di accreditamento è tenuto a rispettare:

❑ **Normativa europea - Regolamento CE n. 765/2008**
❑ **Prescrizioni emanate dal Governo - D.M. 22.12.2009**
❑ **Standard internazionali - ISO/IEC 17011**

Valutazione della competenza, indipendenza e imparzialità

LABORATORI DI PROVA	ORGANISMI DI CERTIFICAZIONE ISPEZIONE E VERIFICA	LABORATORI DI TARATURA

Valutazione della conformità di prodotti, servizi, professionisti a regole obbligatorie, norme e specifiche tecniche

IMPRESE	ISTITUZIONI	CONSUMATORI

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L'ENTE ITALIANO DI ACCREDITAMENTO

Gli schemi di accreditamento

LABORATORI DI PROVA

PROVE	ISO/IEC 17025
ANALISI MEDICHE	ISO 15189
PTP	ISO/IEC 17043

CERTIFICAZIONE E ISPEZIONE

CERTIFICAZIONI

SISTEMI DI GESTIONE	ISO/IEC 17021
PRODOTTI E SERVIZI	ISO/IEC 17065
PERSONE	ISO/IEC 17024

ISPEZIONI	ISO/IEC 17020
VERIFICHE	ISO 14065
	(ISO/IEC 17029)

LABORATORI DI TARATURA

TARATURE	ISO/IEC 17025
PMR	ISO GUIDE 34
	(ISO/IEC 17034)
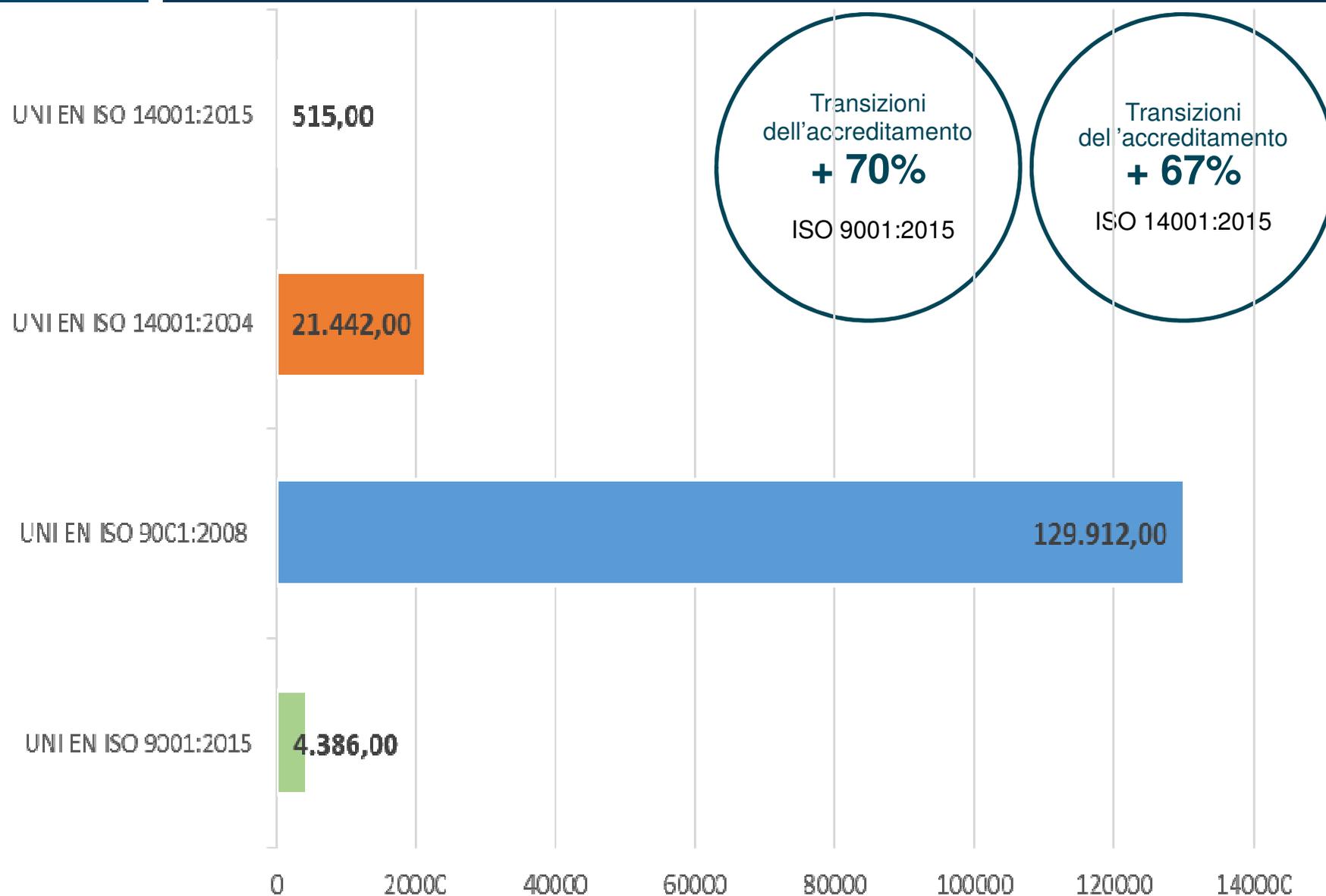
11.08.2016 – è stato pubblicato il primo CD della ISO 9004

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

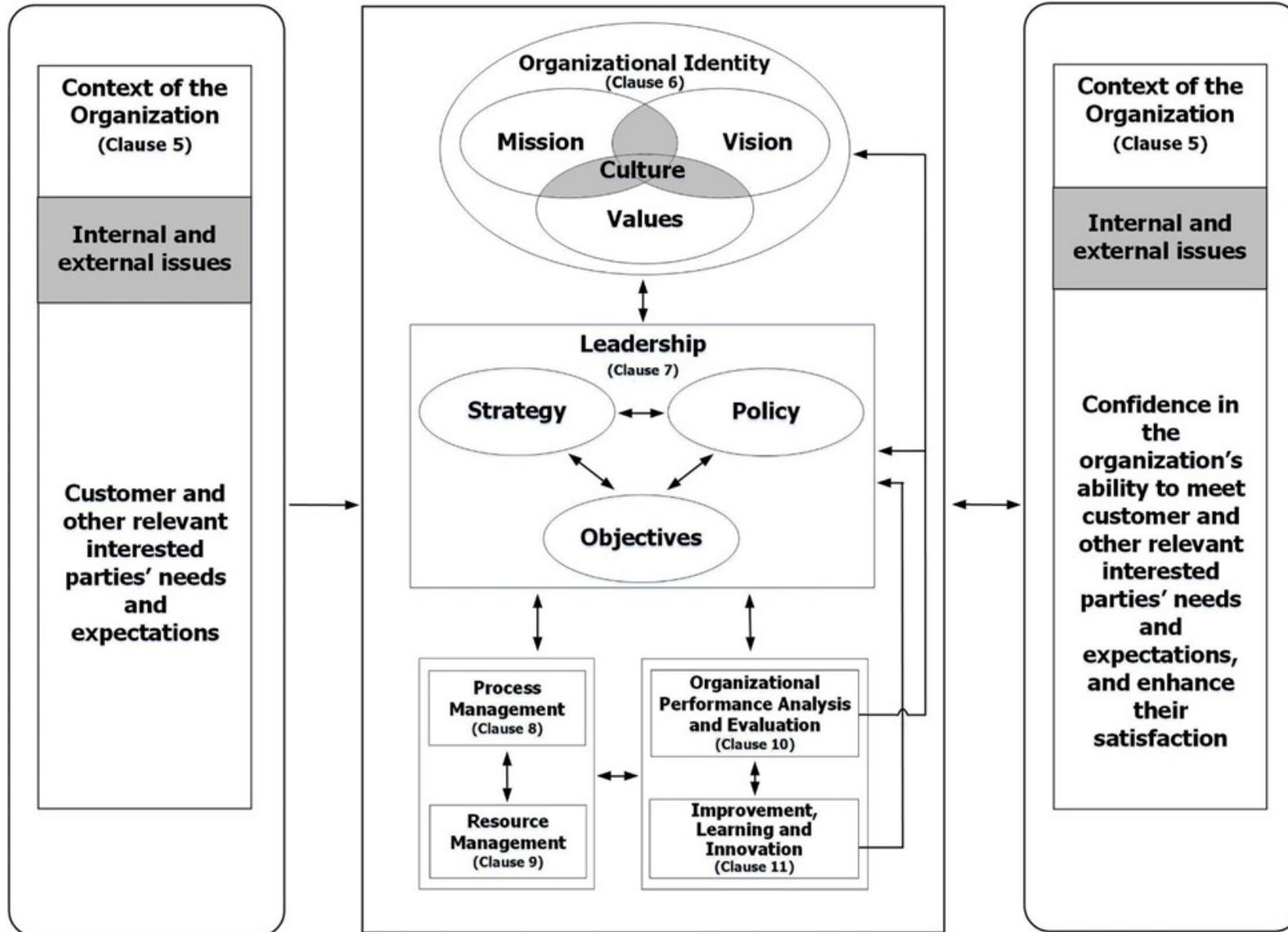| Warning |
|---|
| This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

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. |

La norma ha un nuovo titolo: Organizational quality – Guidance to achieve sustained success (successo duraturo).

- ✓ Si sposta il tema da Sistema di gestione per la qualità a **qualità organizzativa**. Non più solo ISO 9001, ma abbraccia tutti i sistemi, non solo sistemi di gestione per la qualità. Sta diventando una "Super" norma... sopra tutto.

- ✓ Le nuove norme diventeranno subordinate alla ISO 9004? La norma principale diventerà la ISO 9004, cui discendono tutti le altre?

- ✓ Si parla di Quality management, e non di quality management system, quindi non segue l'HLS.

- ✓ La 9001 ha aperto lo sguardo sul contesto e le parti interessate: da qui la 9004 si sta espandendo. Sta nascendo quindi una norma molto ambiziosa, di cui è difficile comprendere oggi i confini.

- ✓ Interesse del consumatore in un concetto molto ampio.

- ✓ ISO 9001:2015 Soddisfazione delle parte interessate in quanto strumentali alla soddisfazione del cliente.

- ✓ ISO 9004:2015 Soddisfazione delle parte interessate in quanto strumentali alla soddisfazione dell'azienda per un suo successo il più duraturo possibile

- ✓ L'organizzazione decide di soddisfare quelle parti interessate che siano funzionali al suo successo nel tempo

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.
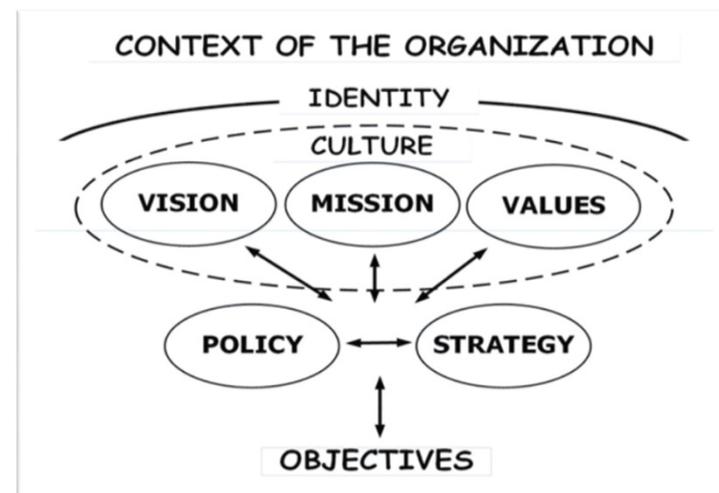
Il concetto di coinvolgimento **bilanciato** delle parti interessate viene a cadere.

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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); **perchè esistiamo**

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

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

✓ **Value -** value, value, value, value, value

Sono presenti numerosi richiami all'innovazione (ripetuta ben 77 volte nella norma!)

Professoressa Premio Nobel
Rita Levi Montalcini
"Ambassador Anno Europeo Creatività e Innovazione"
in occasione del compimento dei suoi **100** anni

946 **11.4 Innovation**

947 **11.4.1 General**

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

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

952 The organization should:

953 a) identify the need for innovation;

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

955 c) provide the related resources.

956 **11.4.2 Application**

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

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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);

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

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

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965
966 d) 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).

967 **11.4.3 Timing and risk**

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970 The organization should assess the risks and opportunities 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.

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

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

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

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

Non esiste invece NESSUN richiamo alla sustainibility (mentre il termine è richiamato addirittura nella costituzione di Francia e Svizzera) ma si usa il termine **SUISTAINED**.

Cioè, perché il successo sia duraturo, è (solo) implicito che debba essere anche sostenibile. Per motivi di politica normativa/burocratica (se si usa il termine sustainibility uscirebbe dalla competenze del CT 176), non si usa il termine sustainibility, ma si usa SUISTAINED success.

È una norma che si rivolge al Top Management. La ISO 9004 usa un linguaggio un po' troppo forbito/filosofico, poco fruibile dalle piccole e medie aziende italiane? È una norma poco pratica, troppo filosofica… non la leggerà nessuno!? È per una elite?

DRAFT INTERNATIONAL STANDARD
ISO/IEC DIS 17021-3

ISO/CASCO

Voting begins on:
2016-07-19

Secretariat: **ISO**

Voting terminates on:
2016-10-10

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

Nuove aree di attenzione per auditor, consulenti e aziende

✓ Elementi (interni ed esterni) che abbiano una influenza sulle scelte strategiche dell'organizzazione;

✓ Quali siano gli elementi, relativi al prodotto / servizio, ritenuti rilevanti dalle parti interessate;

✓ Come le infrastrutture e l'ambiente di lavoro influenzano/condizionano il prodotto/servizio offerto.

✓ Rimane l'attenzione sugli aspetti cogenti

Non è più una "semplice" 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;

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

La norma fornisce chiarimenti specifici... questo un esempio

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.

Figura professionale sul **Quality Manager** - novembre inchiesta pubblica del progetto, quindi entro l'anno dovrebbe essere avviato il progetto di norma

Entrerà a far parte delle professioni non regolamentate previste dalle legge 4/2013 (presunzione di competenza)

Mistery audit

✓ UNI TS 11312-1: Audit in incognito (mystery audit). Questa guida verrà portata all'ISO come contributo per la revisione della ISO 19011

✓ UNI 11312-2 Progettista, Coordinatore e Mystery Auditor

✓ Gli OdC inizieranno a fare verifiche ISO 9001 utilizzando anche tecniche di mistery audit (per la valutazione del processo, soprattutto in aziende di servizi)

Incontro GL 37 Revisione UNI 11312-1

Milano, UNI, 26 luglio 2016

Documento di facilitazione redatto dal gruppo ristretto:
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Documento redatto daL
Gruppo ristretto UNI GL37

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Riferimenti normativi per il Mistery auditing

✓ UNI EN ISO 9000:2015 - Sistemi di gestione per la qualità – Fondamenti

   e vocabolario

✓ UNI EN ISO 9001:2015 - Sistemi di gestione per la qualità – Requisiti

✓ UNI EN ISO 19011:2012 - Linea guida per audit di sistemi di gestione

Grazie per l'attenzione

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