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La nuova revisione della ISO/IEC 17025. Le novità

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Perché è necessario revisionare la norma ?

1. Aggiornare i riferimenti
2. Applicare i principi della norma alla ISO 9001 di nuova revisione
3. Aggiornare il linguaggio di alcuni requisiti rispetto allo stato dell'arte
4. Inserire per alcuni requisiti un linguaggio "obbligatorio" e mutuare una "struttura simile" per le norme della serie 17000

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Introduction

.... This International Standard requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. **The laboratory is responsible for deciding which risks and opportunities need to be addressed**....

……In this International Standard, the following verbal forms are used:
- "shall" indicates a requirement;
- "should" indicates a recommendation;
- "may" indicates a permission;
- "can" indicates a possibility or a capability.

DIS ISO/IEC 17025 : la STRUTTURA

1. Scope
2. Normative references
3. Terms and definition
4. General requirements
5. Structural requirements
6. Resource requirements
7. Process requirements
8. Management requirements

Annex A

Annex B

- Imparzialità Riservatezza
- Reclami
- Opzioni A / B
- Riferibilità metrologica
- Sistema di gestione

3. Terms and definitions

Non è necessario riportare tutte le definizioni in quanto ci si deve riferire a ISO/IEC 17000 e JCGM 200:2012.

ISO mette inoltre a disposizione le seguenti piattaforme :

http://www.electropedia.org
http://www.iso.org/obp

3. Terms and definition

3.3 interlaboratory comparison

3.4 intralaboratory comparison

3.5 proficiency testing

3.6 laboratory

body that performs one or more of th

- **calibration**
- testing
- sampling, associated with su ent calibration or testing

NUOVO CONCETTO !!!

3.7 decision rule

a rule that describes how measurement uncertainty will be accounted for when stating conformity with a specified requirement

4. General requirements

4.1 Impartiality

Il concetto di IMPARZIALITA' è già presente nella norma attuale sebbene non sia un requisito a se stante (4.1.4 e note)

...

4.1.4 **The laboratory shall identify risks to its impartiality on an on-going basis**. This shall include those risks that arise from its activities, or from i personnel. Howeve a laboratory with a ri

L'IMPARZIALITA' è l'unico requisito che espressamente richiede un' analisi dei rischi (vedi anche 8.5)

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

5. Structural requirements

5.4 The laboratory shall define and document the range of laboratory activities for which it conforms with this International Standard. **The laboratory shall only claim conformity with this International Standard for the range of laboratory activities**, ……..

Il Laboratorio deve definire le attività per le quali si può dichiarare conforme.

5. Structural requirements

*4.1.5 i) appoint a member of staff as **quality manager** (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority…*

Non viene più citato un referente della Qualità…
La Qualità viene interpretata come un lavoro di squadra!!!

5. Structural requirements

5.7 **Laboratory management** shall ensure that:

a) the integrity of the management system is maintained when changes to the management system are implemented;

b) communication takes place regarding the effectiveness of the management system and the importance of meeting customer and other requirements.

Sparisce il termine «alta direzione» (top manager).
Si parla di Laboratory management

5. Structural requirements

Non viene più prescritto di individuare dei "sostituti"

*4.1.6 j) appoint **deputies** for key managerial personnel*

6. Resource requirements

6.1 General

6.2 Personnel

6.3 Laboratory facilities and environmental conditions

6.4 Equipment

6.5 Metrological traceability

6.6 Externally provided products and services

6.2 Personnel

6.2.5 The laboratory **shall have procedure(s)** and maintain records for:

a) determining the competence requirements;
b) selection of personnel;
c) training of personnel;
d) supervision of personnel;
e) authorization of personnel;
f) monitoring of competence of personnel.

Imparzialità, supervisione, competenza, formazione

6.3 Laboratory facilities and environmental conditions

6.3.5 When the laboratory performs activities at facilities **outside its permanent control**, it shall ensure that the requirements related to facilities and environmental conditions of this International Standard are met.

Allo stato attuale è «sufficiente» quanto di seguito:

5.3.1 …The laboratory shall ensure that the environmental conditions ***do not invalidate the results or adversely affect the required quality of any measurement****. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility.*

6.4 Equipment

In questo paragrafo rientrano:

- **Definizione programma di taratura delle apparecchiature**
- **Manipolazione, trasporto, stoccaggio…**
- **Registrazioni (ad es. storico, manutenzione…)**
- **Gestione sovraccarichi o manovre errate**
- **Verifiche intermedie**
- **…**

l'attuale 5.5

6.4 Equipment

6.4.1 The laboratory shall have access to equipment required for the correct performance of the laboratory activities.
Equipment **includes** measuring instruments, software, measurement standards, reference materials, reference data, reagents and consumables or auxiliary apparatus or combination thereof necessary for laboratory activities and which can influence the result.

Il termine «Equipment» (Apparecchiature) assume un significato ampio e specifico

6.4 Equipment

6.4.6 When the measurement accuracy and measurement uncertainty affect the validity of the reported result, or **metrological traceability is a requirement**, measuring equipment shall be calibrated.

La necessità di taratura delle apparecchiature di misura si basa su:
-Incertezza
-Accuratezza
-Riferibilità metrologica

6.5 Metrological traceability

In questo paragrafo sono stati inseriti gli elementi essenziali già contemplati nell'attuale revisione.

E' stato aggiunto un Annex A, che riporta delle informazioni aggiuntive.

7. Process requirements

7.1 Review of request, tenders and contracts
7.2 Selection, verification and validation of methods
7.3 Sampling
7.4 Handling of test or calibration items
7.5 Technical records
7.6 Evaluation of measurement uncertainty
7.7 Assuring the quality of results
7.8 Reporting of results
7.9 Complaints
7.10 Management of non conforming work
7.11 Control of data – Information management

7.1 Review of requests, tenders and contracts

7.1.2 Externally provided laboratory activities

7.1.2.1 The laboratory's procedure for the review of requests, tenders and contracts **shall cover laboratory activities from external providers**. The laboratory shall, in particular, advise the customer of the specific laboratory activities to be performed by the external provider and gain the customer's approval.

Inseriti all'interno del riesame del contratto i requisiti dell'attuale subappalto che diventa «Externally provided laboratory activities»

7.2 Selection, verification and validation of methods

7.2.1.1 The laboratory shall use appropriate **methods** and procedures for all laboratory activities…

NOTE For calibration laboratories, "**method**" as used in this International Standard can be considered synonymous with the term "**measurement procedure**"

…

NOTE Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment are recommended

SELEZIONE dei metodi

Per i Laboratori di taratura, «metodo» è sinonimo di procedura di misura (-> tecnica)

Soddisfare richieste del cliente

7.2 Selection, verification and validation of methods

7.2.1.6 The laboratory shall **verify** that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. **Records of the verification shall be maintained**. If the method is revised, verification shall be repeated to the extent necessary.

VERIFICA del metodo

Il Laboratorio deve essere sicuro di poter utilizzare propriamente il metodo assicurando il raggiungimento dei risultati previsti.

7.2 Selection, verification and validation of methods

7.2.2.1 The laboratory **shall** validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope (modified standard methods)…

NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:

a) calibration and/or evaluation of bias and precision using reference standards or reference materials;
b) systematic assessment of the factors influencing the result;
c) testing method robustness through variation of controlled parameters such as incubator temperature, volume dispensed, etc.;
d) comparison of results achieved with other validated methods;
e) interlaboratory comparisons;
f) evaluation of measurement uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

VALIDAZIONE del metodo

7.7 Assuring the quality of results

7.7.2 The laboratory shall monitor the quality of the laboratory performance by comparing with output of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to a selection from the following list:

a) participation in proficiency testing;

NOTE 1 ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers.

NOTE 2 Proficiency test providers that meet the requirements of ISO/IEC 17043 are considered as competent

b) participation in interlaboratory comparisons other than proficiency testing.

La partecipazione a PT/ILC in conformità a RT-36 soddisfa questo requisito.

7.8 Reporting of results

Tarature, Prove e Campionamenti:
suddivisione tra requisiti comuni e requisiti specifici

Non viene inoltre più indicata esplicitamente la "firma" di chi autorizza il report ma viene richiesta "identification of the person authorizing the report"

7.8 Reporting of results

7.8.5.3 When reported information associated with a calibration includes a statement of **conformity with a specification**, omitting the measurement results and associated uncertainties, the reported information shall include a statement that the **data is not intended to be used in support of the further dissemination of metrological traceability** (e.g. to calibrate another device).

Al momento non prevista nell'attuale revisione, ma inserita in ILAC P-14

7.9 Complaints

7.9.6 The outcomes to be communicated to the complainant **shall** be made by, or reviewed and approved by, individual(s) **not involved** in the original laboratory activities in question.

Riesame e approvazione risultanze dei reclami fatti da persone non coinvolte nella gestione del reclamo

8. Management requirements

8.1 Options
8.2 Management system documentation (Option A)
8.3 Control of management system documents (Option A)
8.4 Control of records (Option A)
8.5 Actions to address risks and opportunities (Option A)
8.6 Improvement (Option A)
8.7 Corrective action (Option A)
8.8 Internal audits (Option A)
8.9 Management reviews (Option A)

8 Management requirements

Option A:
Ispirati alla ISO 9001 i requisiti di:
Controllo dei Documenti e delle Registrazioni, Miglioramento, Azioni correttive, audit interni, Riesame della Direzione.
Introdotto "Actions to address risks and opportunities"

Option B:
Sistema di Gestione conforme alla ISO 9001.
Se il Sistema è in grado di supportare i requisiti dal 4 al 7 ,allora si può dire che almeno soddisfa i requisiti da 8.2 a 8.9 (Option A)

8 Management requirements (opt. A)

8.5.1 The laboratory shall consider the **risks and opportunities** associated with the laboratory activities in order to:

a) give assurance that the management system can achieve its intended results;

b) enhance opportunities to achieve the purpose and objectives of the laboratory;

c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities; and

d) achieve improvement.

Option A:
inserite le "opportunità" al posto delle azioni preventive. Il Lab. dovrà pianificare le azioni e le modalità di gestione/ trattamento di rischi e opportunità.

8 Management requirements (opz. B)

Il Laboratorio, nell'implementare il proprio sistema in conformità ai requisiti della norma ISO 9001, deve garantire la sua copertura rispetto a tutti requisiti di norma ISO 17025.

Il sistema di gestione deve contenere i riferimenti necessari per descrivere completamente come le attività taratura siano conformi a tutti i paragrafi della ISO 17025.

applicazione SGQ: registrazioni

Grazie per l'attenzione

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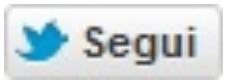


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