

Controllo del processo [Q]

## **Q2 Requisiti per l'accreditamento: comparazione ISO 17025:2005 e 15189:2007**

### **Nota:**

all'indirizzo <http://snipurl.com/commqua> si trova il modulo telematico per la raccolta del consenso sui documenti

### **Introduzione**

EA, European Co-operation for Accreditation, è una associazione senza scopo di lucro istituita nel novembre 1997 e registrata in Olanda nel giugno 2000 ([www.european-accreditation.org](http://www.european-accreditation.org)).

EA risulta dalla fusione di EAC, European Accreditation of Certification, e di EAL, European co-operation for Accreditation of Laboratories ed è la rete europea degli organismi di accreditamento riconosciuti a livello nazionale con sede nella zona geografica europea.

EA multilateral agreement (MLA) fornisce un mezzo per consentire a beni e servizi di varcare i confini nazionali in Europa e nel resto del mondo.

Con MLA una prova o una relazione di controllo o un certificato rilasciato da un organismo accreditato in un paese è riconosciuto come equivalente ad una relazione o un certificato rilasciato da un organismo accreditato in uno qualsiasi dei paesi firmatari del MLA EA. Gli organismi di accreditamento ammettono di operare in un modo equivalente e che rilasciano equivalenti accreditamenti, fornendo lo stesso livello di competenza e di fiducia.

MLA trasforma l'accreditamento in un "passaporto" che facilita l'accesso alla UE ed ai mercati internazionali mediante la cooperazione con ILAC (International Laboratory Accreditation Co-operation) e IAF (International Accreditation Forum). Si veda anche il documento [http://www.european-accreditation.org/content/communication/EA\\_Brochures/Brochure\\_European%20co-operation\\_approved.pdf](http://www.european-accreditation.org/content/communication/EA_Brochures/Brochure_European%20co-operation_approved.pdf).

Un rapporto sull'estensione degli accordi internazionali che sostengono l'attività di EA MLA si trova all'indirizzo <http://www.european-accreditation.org/n1/doc/EA-1-08.pdf>.

Tra gli scopi di MLA si trova l'accreditamento dei laboratori con ISO 17025 e ISO 15189.

Si può vedere anche [http://www.european-accreditation.org/Docs//0001\\_General/0002\\_Procedural%20and%20Policy%20Documents%20Series%2002/01300\\_EA-2-11\\_rev01.pdf](http://www.european-accreditation.org/Docs//0001_General/0002_Procedural%20and%20Policy%20Documents%20Series%2002/01300_EA-2-11_rev01.pdf).

Nell'ambito del Laboratory Committee di EA, LC WG sta terminando la "Guidance on accreditation scopes for medical laboratories". The WG produced also a list of FAQ that is now available on the LC intranet.

In questo contesto possiamo prevedere un probabile e vicino scenario in cui si realizzano due situazioni. Da una parte organizzazioni cresciute e consolidate nell'attività di accreditamento di laboratori di prova e calibrazione con ISO 17025 si troveranno ad accreditare laboratori medici in riferimento a ISO 15189.

Dall'altra parte laboratori clinici maturati nell'esperienza con la certificazione del sistema qualità secondo

ISO 9001 e con l'accreditamento professionale secondo schemi diversi riceveranno visite da ispettori formati almeno in parte in ambiente ISO 17025 che applicheranno criteri e liste di riscontro basati su ISO 15189.

Si rende così opportuno affrontare un percorso di studio comparativo tra ISO 17025 e ISO 15189, al fine di evidenziare gli elementi comuni e quelli differenziali, che consentano di orientare sia l'attività di ispezione che quella di preparazione dei laboratori.

Il percorso comparativo comprenderà tutte le singole parti delle due norme.

Vengono confrontati due documenti:

- UNI CEI EN ISO/IEC 17025 september 2005
- EN ISO 15189:2007 may 2007

Il confronto non sarà pedissequamente sequenziale. Vengono prese in esame le singole parti individualmente, in base alla priorità di interesse. In questo documento si estraggono i punti riferiti alla qualità analitica.

## **ISO 17025 e 15189 sulla qualità analitica**

17025	15189
<p>5.9 Assuring the quality of test and calibration results</p> <p>5.9.1 The laboratory shall have <b>quality control procedures</b> for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following: a) regular use of certified reference materials and/or <b>internal quality control</b> using secondary reference materials; b) participation in interlaboratory comparison or proficiency-testing programmes; c) <b>replicate tests</b> or calibrations using the same or different methods; d) <b>retesting</b> or recalibration of retained items; e) correlation of results for different characteristics of an item.</p> <p>Note The selected methods should be appropriate for the type and volume of the work undertaken.</p>	<p>5.6 Assuring quality of examination procedures</p> <p>5.6.1 The laboratory shall design <b>internal quality control systems</b> that verify the attainment of the intended quality of results. It is important that the control system provide staff members with clear and easily understood information on which to base technical and medical decisions. Special attention should be paid to the elimination of mistakes in the process of handling samples, requests, examinations, reports, etc.</p>
<p>5.4.6 Estimation of <b>uncertainty</b> of measurement</p> <p>5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.</p> <p>5.4.6.2 Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of</p>	<p>5.6.2 The laboratory shall determine the <b>uncertainty</b> of results, where relevant and possible. Uncertainty components which are of importance shall be taken into account. Sources that contribute to uncertainty may include sampling, sample preparation, sample portion selection, calibrators, reference materials, input quantities, equipment used, environmental conditions, condition of the sample and changes of operator.</p>

uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.

Note 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as: - the requirements of the test method; - the requirements of the customer; - the existence of narrow limits on which decisions on conformity to a specification are based.

Note 2 In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).

5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

Note 1 Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

Note 2 The predicted long-term behaviour of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.

Note 3 For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement (see Bibliography).

## 5.6 Measurement **traceability**

### 5.6.1 General

All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of its equipment.

Note Such a programme should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.

5.6.3 A programme for **calibration** of measuring systems and verification of trueness shall be designed and performed so as to ensure that results are **traceable** to SI units or by reference to a natural constant or other stated reference.

Where none of these is possible or relevant, other means for providing confidence in the results shall be applied, including but not limited to the following:

- participation in a suitable programme of interlaboratory comparisons;
- use of suitable reference materials, certified to indicate the characterization of the material;
- examination or calibration by another procedure;
- ratio or reciprocity-type measurements;
- mutual consent standards or methods which are clearly

#### 5.6.2.2 Testing

5.6.2.2.1 For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

Note The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.

5.6.2.2.2 Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).

#### 5.6.3 Reference standards and reference materials

##### 5.6.3.1 Reference standards

The laboratory shall have a programme and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

##### 5.6.3.2 Reference materials

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

##### 5.6.3.3 Intermediate checks

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.

##### 5.6.3.4 Transport and storage

The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity. Note Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.

established, specified, characterized and mutually agreed upon by all parties concerned;  
f) documentation of statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer.

<p>5.9.1 ...This monitoring shall be planned and reviewed and may include, but not be limited to, the following: ... b) participation in <b>interlaboratory comparison or proficiency-testing programmes</b>; ....</p>	<p>5.6.4 The laboratory shall participate in <b>interlaboratory comparisons</b> such as those organized by external quality assessment schemes. Laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not fulfilled. Interlaboratory comparison programmes shall be in substantial agreement with ISO/IEC Guide 43-1. External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures.</p>
<p>5.9.1 ...: a) regular use of <b>certified reference materials</b> and/or internal quality control using <b>secondary reference materials</b>;</p>	<p>5.6.5 Whenever a formal interlaboratory comparison programme is not available, the laboratory shall develop a mechanism for determining the acceptability of procedures not otherwise evaluated. Whenever possible, this mechanism shall utilize externally derived <b>challenge materials</b> such as exchange of samples with other laboratories. Laboratory management shall monitor the results of this mechanism of interlaboratory comparison and participate in the implementation and recording of corrective actions.</p>
	<p>5.6.6 For those examinations performed using different procedures or equipment or at different sites, or all these, there shall be a defined mechanism for verifying the <b>comparability</b> of results throughout the clinically appropriate intervals. Such verification shall be performed at defined periods of time appropriate to the characteristics of the procedure or instrument.</p>
<p>5.9.2 Quality control data shall be analysed and, where they are found to be outside pre-defined criteria, <b>planned action</b> shall be taken to correct the problem and to prevent incorrect results from being reported.</p>	<p>5.6.7 The laboratory shall <b>document</b>, record and, as appropriate, expeditiously <b>act</b> upon results from these comparisons. Problems or deficiencies identified shall be acted upon and records of actions retained.</p>

*Commento*

*Molti punti di ISO 15189 hanno un corrispondente in ISO 17025.*

*Per la garanzia di qualità dei metodi nella fase analitica, troviamo un parallelo per 5.6.1 (internal quality control systems) in 5.9.1, nell'ambito di altre attività.*

*5.6.2 per l'incertezza è sviluppato in 17025 in una sezione completa (5.4.6, da 5.4.6.1 a 5.4.6.3), ma la principale differenza sta nell'affermazione di 15189 "where relevant and possible", laddove 17025 specifica "...for all calibrations and types of calibrations..." e "...Testing laboratories shall have and shall apply..."*

*15189 punto 5.6.3 della calibrazione trova un corrispondente in 17025 nell'intera sezione 5.6 (da 5.6.1 a 5.6.3.4). I concetti non sembrano diversi, ma in 17025 è sviluppata in dettaglio la parte di gestione dei materiali di riferimento. Si intuisce come nei laboratori clinici questa parte sia costruita mediante interazione tra il laboratorio ed i fornitori di metodi, reagenti, consumabili e sistemi.*

*Al contrario, il punto 5.6.4 dei confronti interlaboratorio è fortemente espresso in 15189, mentre viene solo toccato tangenzialmente da 17025 in 5.9.1. Lo stesso accade per il 5.6.5 dei materiali di riferimento mentre il 5.6.6 della comparabilità interna è del tutto assente in ISO 17025.*

*Infine, analisi dei risultati ed azioni sono uguali in 15189 5.6.7 e 17025 5.9.2.*

