Catlab Informa

Butlletí Nº152

News of the UNE-EN ISO 15189:2023 standard: A paradigm shift for clinical laboratories.

1. Introduction:

The UNE-EN ISO 15189 standard aims to ensure the technical competence and quality of clinical laboratories, in order to guarantee the reliability of results and patient safety. Since its inception, it has been a reference standard for clinical laboratories that, through accreditation, has helped them to provide confidence in the development of their activities.

The publication of the 4th edition of the standard in December 2022, 20 years after the first version, **UNE-EN ISO 15189:2022 "*Clinical laboratories: Requirements for quality and competence*"**, has marked a milestone for clinical laboratories, as it introduces a complete technical review of the previous version (2013). This update, which has been developed through international consensus, seeks to align laboratory processes with current best practices, placing special emphasis **on patient safety**, **risk management** and **operational flexibility**. The new version of the standard places the **PATIENT AT THE CENTER OF ATTENTION** during all sections of the document.

The elaboration of this new version of the standard has been carried out with the collaboration of professionals from all over the world and all specialties. The international standardization structure, ISO (International Standard Organization) includes standardization bodies of each country (in Spain, Spanish Association of Standardization, UNE www.une.org).

At the European level, the text of the EN ISO 15189:2022 Standard has been prepared by the ISO/TC 212 Clinical laboratory tests and in-vitro diagnostic analysis systems in collaboration with the CEN/TC Technical Committee 140 Health Products for in vitro diagnostics.

At the Spanish level, the ISO 15189 standard is developed through the National Technical Committee CTN-UNE 129 In Vitro and Laboratory Diagnostic Systems, with vowels from scientific societies such as the Spanish Society of Laboratory Medicine (SEMEDLAB). The participation of the various global entities gives this standard an additional value and international recognition.

2. Restructuring and harmonization of the standard:

It is important to stress that the changes incorporated into the new version do not represent any major changes in their requirements. This shows the maturity of the rule and the broad consensus that exists in its content. This fact implies that most of the management systems implemented in clinical laboratories under the ISO 15189 standard (version 2013) remain valid, since accredited laboratories will not have to make major changes to adapt to the new version.

One of the main novelties of the new version of the ISO 15189:2023 standard is the reorganization of its structure, which is now aligned with the **ISO/IEC 17025:2017 standard "*General requirements for the competence of testing and calibration laboratories*"**.

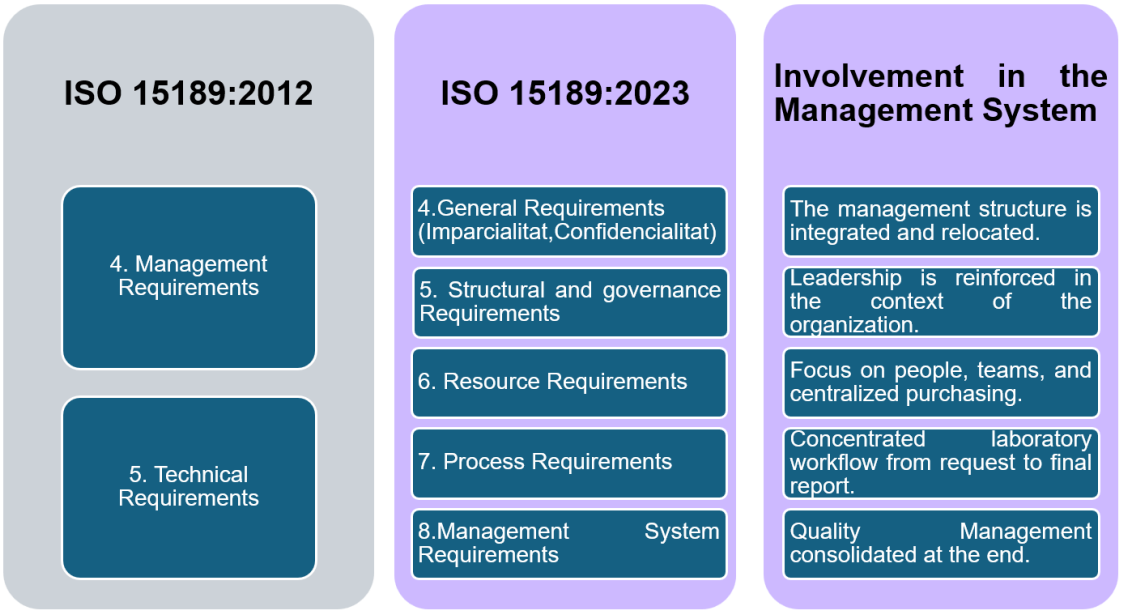
The new version is aligned with the High Level Structure (HLS), the universal template that shares all the standards of modern ISO management systems (such as ISO 9001:2015 or ISO/IEC

17025:2017). ISO 15189:2023 abandons the dual scheme of Management Requirements (Chapter 4) and Technical Requirements (Chapter 5) that characterized the 2012 version.

This change seeks greater coherence and a more uniform understanding between the different accreditation standards of clinical laboratories. The standard has an Annex with a cross table, which relates the sections of the previous standard with the current one.

In the **following figure** we can see the modifications of the general structure of the sections of the new version of the standard, as well as the implication that the different sections have had for the Quality Management System.

High-level structure (HLS) in the new ISO 15189:2023 standard



3. Greater flexibility in implementation:

The new standard offers greater flexibility, which makes it less rigid and more adaptable and flexible to the various realities of clinical laboratories. This provides laboratories with greater autonomy in adapting their management systems to the standard, while maintaining quality and patient safety as primary objectives.

- **Structure and delegation of responsibilities**: The 2023 version is less prescriptive in terms of the laboratory's organizational structure and its Quality Management System. The standard provides greater autonomy for the delegation of tasks and configuration of the management structure. The director of the laboratory remains ultimately responsible for the overall operation and administration.

4. Integration of the analysis at the patient care point (POCT-Point of care testing):

The new version of the standard incorporates in a comprehensive way the requirements for the analyses carried out near the patient (POCT), which until now were regulated separately in the ISO 22870:2016 standard.

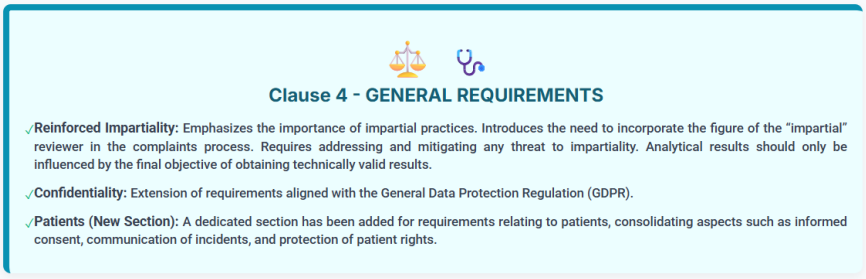
The inclusion of POCT in the standard supports the idea that POCT teams play a very important role for patient care, needing clear guidelines and standards for their implementation. This integration emphasises the responsibility of the laboratory to supervise these services, from the selection of equipment to the training of personnel and quality management.

As a support to ISO 15189:2023 in relation to the issue of POCT, the POCT user guide, EN ISO 22583:2024 "***Requirements and recommendations for supervisors and operators of POCT equipment***" continues to be in use.

5. List of the most important changes that ISO 15189:2023 has incorporated in each of its sections:

Ap.4:

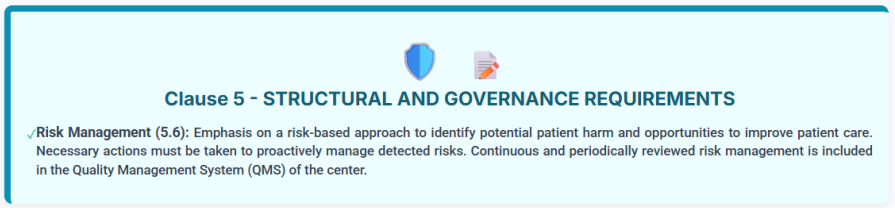
"*Strengthening ethical principles, impartiality and formalisation of the* ***PATIENT APPROACH***"



(**Major change** to 4.3 Patient requirements)

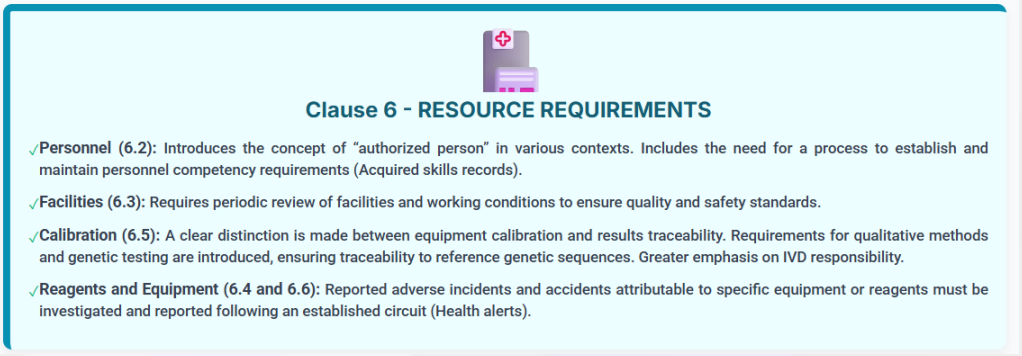
Ap.5:

"***RISK-based thinking*** *becomes a fundamental pillar of the Quality Management System (SGC)".*



Ap.6:

*"**New definitions** of competence and more detail in metrological control and reagents."*



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Ap.7: *"The main focus is on **RISK MANAGEMENT** to minimize potential harm to the patient."*

Clause 7 - PROCESS REQUIREMENTS (7.1 General)

✓**General Requirements (7.1):** Emphasis on the risk approach is increased across all processes, identifying risks that may cause patient harm. "Residual risks" must be communicated to users when necessary.

Ap.7.2: *"More control of RISK in the collection, handling, and transport of samples."*

Clause 7.2 - PRE-ANALYTICAL PROCESSES

✓**Sample Collection and Risk:** More extensive focus on sample collection (evaluating risks of sample collection, patient preparation, collection time, labeling, transport, and acceptance/rejection criteria).

✓**Integrity and Records:** Ensuring the integrity of samples and records in case of laboratory closure, acquisition, or merger.

✓**Stability Time:** Includes the need to record the time between sample collection and analysis when relevant to ensure sample stability.

✓**Transportation:** A periodic evaluation must be established to ensure that sample transport systems are adequate.

✓**Critical and Irreplaceable Samples:** Includes the need for the patient to know and accept the selection of critical and irreplaceable samples. Sample acceptance must prioritize the greatest benefit for the patient.

Ap.7.3: *"Emphasis on Genetics, Enhanced Quality Control, and Clinical Decisions".*

Clause 7.3 - ANALYTICAL PROCESSES

✓**Molecular Traceability:** Traceability with reference genetic sequences for molecular analysis.

✓**Alternative Methods:** Emphasis on the use of alternative methods when internal quality control (IQC) or external quality assessment (EQA) are unavailable. Justification is required in these cases.

✓**Intervals and Limits:** Biological reference intervals and clinical decision limits must be reviewed periodically. These values must represent the population of patients analyzed by the laboratory.

✓**Validity Assurance (Quality Control):** Quality Control reinforcing the validity of results based on IQC, EQA, and comparability of results. Alternative scenarios are included when these options are unavailable.

✓**Measurement Uncertainty (MU):** Measurement Uncertainty must be available to users upon request, considering biological variability in the response. Advice is included for calculating uncertainty in different situations.

✓**Verification by Modification:** If a method is modified by the manufacturer, the laboratory must repeat the verification and document it.

✓**Retention of Records (Validation/Verification):** For both verifications and validations, the method used, results obtained, specifications used, and the analysis of whether the specifications have been achieved must be retained.

Ap.7.4: *"Management of the final result, communication, and the fate of the samples"*

Clause 7.4 - POST-ANALYTICAL PROCESSES

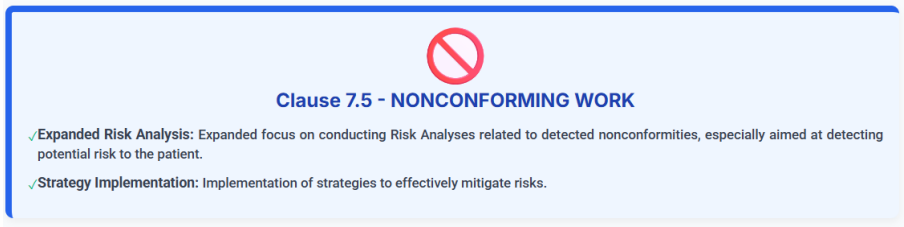
✓**Simplification and Traceability:** Includes simplification of processes for reporting results. Greater emphasis on demonstrating the traceability of the communication process, especially for critical values.

✓**Additional Reports:** Include additional information in reports such as the identification of analyses performed at referral laboratories, with the necessary information regarding the results obtained explaining the discrepancies between different locations.

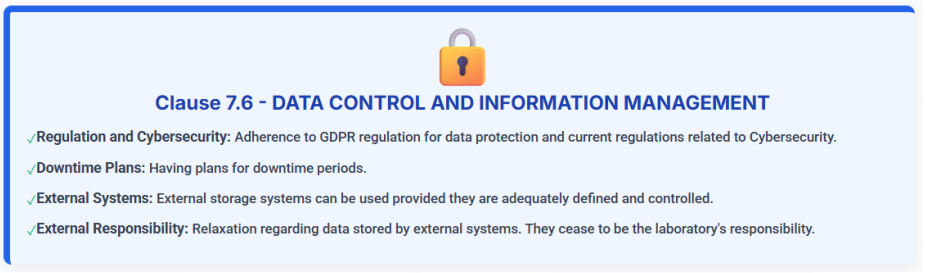
✓**Storage and Disposal:** Specific indications for the maintenance, storage, and disposal of samples after use.

✓**Escalation and Delay:** Emphasizes escalation procedures in case of delayed results, ensuring notification and rapid action to resolve the delay.

Ap.7.5: *"Broader approach to Non-Conformity to detect and mitigate **RISK** to the patient."*



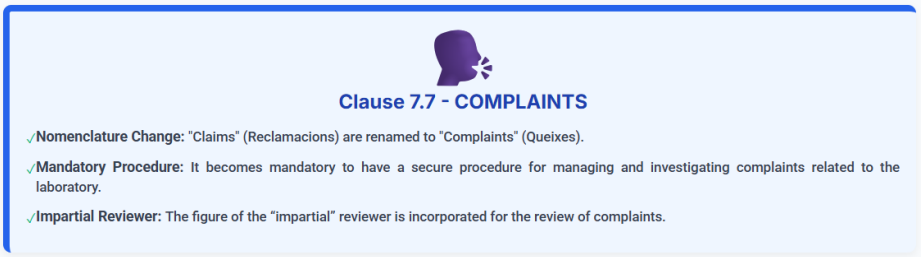
Ap.7.6: *"Compliance with the GDPR, cybersecurity, and management of external data responsibility."*



The 2023 version introduces us to **cybersecurity** (protection of the integrity and confidentiality of data), and acknowledges the limitations of laboratories in an ever-evolving digital environment. Unlike the previous version, laboratories are no longer required to verify the exact reproduction of their results in external information systems; it is assumed that the laboratory cannot control what is beyond its scope.

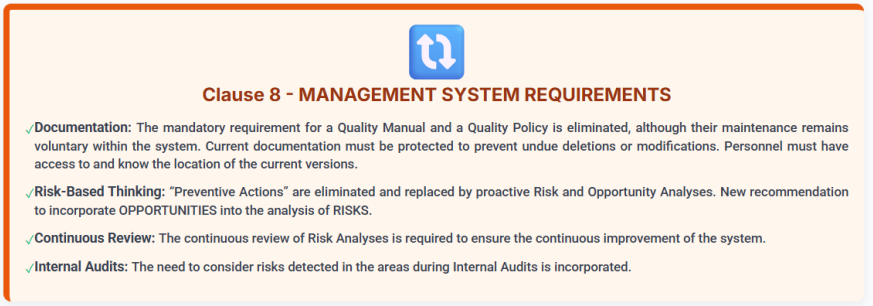
Ap.7.7:

"Mandatory procedure with the introduction of the figure of the impartial reviewer."



Ap.7.8: *"Strengthening laboratory resilience through tested Continuity Plans."*

Ap.8: *"Change of philosophy in the QMS from replacing Preventive Action with Proactivity." **The concept of "RISK" becomes transversal** to all points of the standard.*



6. **Integration with related documents:** References to other standards that are considered supplementary information for certain aspects are included in the standard**.**

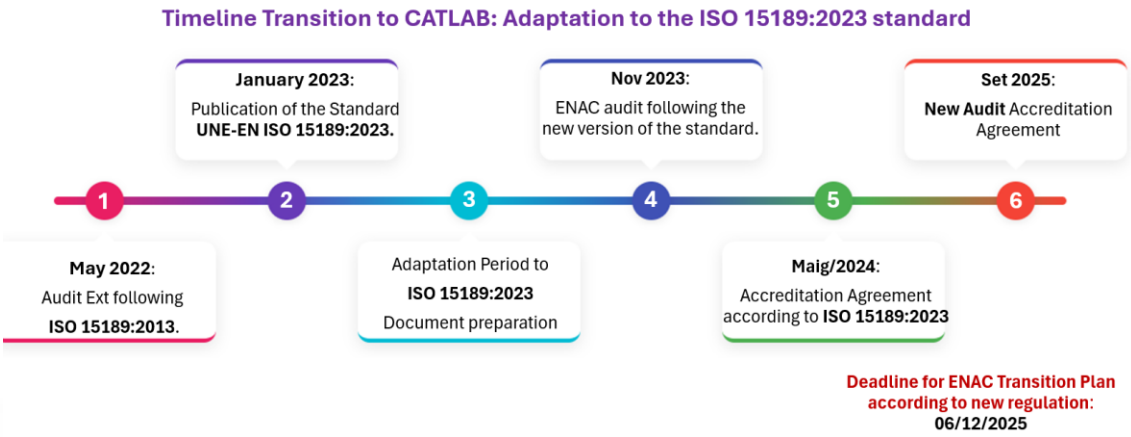
- ISO 22367:2020 Application of Risk Management for clinical laboratories..
- ISO 15190:2020 Safety requirements.
- ISO 35001:2019 Biological Risk Management in laboratories and other related organizations.
- ISO/TS 20914:2019 Practical guide for measuring uncertainty.
- ISO 20658:2023 Requirements for sampling, transport, receipt, and handling of samples.

7. Application of the standard and accreditation period: The publication of the new version of the standard has an impact on accredited laboratories and those applying for accreditation, as management systems must be adapted in compliance with the transition deadlines established by ENAC, following the guidelines of the International Laboratory Accreditation Cooperation (ILAC).

This three-year transition period for accredited laboratories to adapt to the new version ends on December 6, 2025. For this purpose, the National Accreditation Entity (ENAC), which is the national body in Spain and a member of ILAC, has been working in collaboration with scientific societies such as the Spanish Society of Laboratory Medicine (SEMEDLAB) to ensure a smooth and unified transition**.**

Catlab has undergone a process of adaptation to the new standard, which has included the modification of documentation and responses to corrective actions according to the new criteria specified in the Standard.

Since May 2024, Catlab has been carrying out its activities according to the new version of the standard, as demonstrated in the external audits conducted in 2024 and 2025.



CONCLUSION:

The ISO 15189:2023 standard emphasizes a more explicit and comprehensive approach toward the patient, through new aspects such as impartiality and confidentiality, always focused on the interests of the patient (especially in risk management), emergency planning, and documentation requirements. The changes incorporated aim to improve laboratory quality and patient safety, ensuring that laboratories not only meet the necessary requirements but also promote trust and transparency in their operations. In summary, UNE-EN ISO 15189:2023 not only updates the standard but also modernizes the way clinical laboratories manage quality, safety, and technology, consolidating their crucial role in healthcare.

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