

Key Insights on the New **ISO 17025/2017**

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With **Industry 4.0** constantly growing, automation has become essential to achieving previously utopian levels of efficiency and process control.

Among all the benefits achieved with automation, shorter response times for data collection and traceability stand out, making processes more efficient, higher quality, and, best of all, increasingly less expensive.

When we talk about laboratories and quality, it's impossible not to mention the new **ISO 17025/2017**, which aims to control and parameterize the laboratory quality system and is a key element for market competitiveness.

But what are the changes compared to the 2005 version?

Just a few years ago, the idea of a fully digital laboratory seemed out of reach—labs completely relied on paper records and overflowing filing cabinets to manage their data. However, with the **evolution of Industry 4.0**, the use of laboratory software is becoming a necessity rather than a desire.

With this in mind, the National Institute of Metrology, Standardization and Industrial Quality adapted the new generation of data computerization, adding item 7.11 – Data control and information management to the new version of the standard, the main objective of which is to regulate the use of software for laboratory management.



Requirements and Resources

Clarity in the definition and resource requirements, which requires that all parties involved in the laboratory processes, whether internal or external, work impartially and in accordance with the implemented management system.

The risk-based approach implemented in this new edition has allowed for a reduction in prescriptive requirements and a replacement with performance-based requirements, as well as greater flexibility in requirements for processes, procedures, documented information, and organizational responsibilities.



Personal Competence

The focus has shifted from a single post-training evaluation to ongoing monitoring of personal competence. Skills are now assessed continuously in the lab, and targeted training is provided as needed. The requirements for policies, training programs, and evaluation of the effectiveness of training activities no longer exist.

The new requirements require the registration and monitoring of skills, training, supervision, selection, and authorization of personnel.



Equipment Control

Section 6.4 emphasizes that the laboratory must verify laboratory equipment meets all specified requirements before it is put into service or replaced. This ensures the integrity of the results provided, providing greater reliability to the process.



Impartiality and Traceability

Demand for stronger management commitment to regularly review fairness and traceability, and take appropriate action when necessary.

Managing all these elements can be challenging, but process automation transforms complexity into efficiency. With **Confience myLIMS**, you can effortlessly monitor and ensure your processes—automatically, seamlessly, and entirely online.





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