

Comparison of ISO 17025:2005 with ISO 17025:1999

| 2005 Clause | 1999 Clause | Revision | Impact |
|-------------------------|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Introduction | Introduction | Reference to the revisions necessary in light of ISO 9001:2000. Explains that a laboratory conforming to ISO17025 operates in accordance with 9001 but does not necessarily operate to all the requirements of 9001 | Can't claim to comply with ISO 9001. |
| 1.4 | 1.4 | This international standard is not to be used for the purpose of certification. The term management system means quality, administrative, and technical systems that govern the operations of the laboratory. | Highlights emphasis on technical competence. "Management system" replaces "quality system" throughout unless specified otherwise. |
| 1.6 | 1.6 | Laboratories that comply with this standard operate a quality management system that also meets the principles of ISO 9001 | "Principles" as in usual dictionary definition, "essentials, fundamentals". i.e., not the specific Principles of ISO 9000. |
| Management requirements | | | |
| 4.1.2 | 4.1.2 | "client" replaced with "customer" | Entire standard |
| 4.1.5 (a) | 4.1.5 (a) | ...including the implementation, maintenance and improvement of the management system,... | Managers and technical personnel need to be proactive in improving systems. |
| 4.1.5 (k) | N/A | Laboratory shall ensure that its personnel are aware of the relevance and importance of their activities to the achievement of the objectives of the management system. | Personnel need to understand their role in the lab operations and systems. |
| 4.1.6 | N/A | Top management shall ensure that appropriate communication processes are established within the laboratory and that communication | Effective communication and feedback regarding management system is needed. |

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| | | takes place regarding the effectiveness of the management system. | |
| 4.2.2 | 4.2.2 | The overall objectives of the management system policies shall be established and reviewed during management review | The laboratory will need to ensure its agenda for management review includes this. |
| 4.2.2 (e) | 4.2.2 (e) | Quality policy statement shall include the management's commitment...to continually improve the management system. | Emphasizes continual improvement of the systems. |
| 4.2.3 | N/A | Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness. | Puts responsibility for continual improvement of the systems at the highest level of management. |
| 4.2.4 | N/A | Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements. | Involves top management in the responsibility for communication of these aspects. |
| 4.2.5 | 4.2.3 | Change of clause numbering | |
| 4.2.6 | 4.2.4 | Change of clause numbering | |
| 4.2.7 | N/A | Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented. | Puts responsibility for integrity of the management system at top management level. |
| 4.7.1 | 4.7 | The laboratory shall be willing to cooperate with customers. | Gives some flexibility in difficult cases, e.g., where ensuring the confidentiality of other customers' work may be impractical. |
| 4.7.2 | 4.7 note | The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and | In essence, this raises the previous note on this topic to a requirement for the laboratory to seek customer feedback, analyze it and act on it to make improvements. Cannot rely on complaints for |

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| | | calibration activities and customer service. Note – examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers. | everything. |
| 4.10 | N/A | Improvement. The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. | Highlights and emphasizes continual improvement of the systems using all relevant information to measure this. |
| 4.11 | 4.10 | Change of clause numbering | |
| 4.12 | 4.11 | Change of clause numbering | |
| 4.12.1 | 4.11.1 | When improvement opportunities are identified or if preventive action is required... | Distinguishes between improvement and prevention. Improvements are actively sought even through a risk of non-conformity does not necessarily exist, whereas prevention is necessary when a risk of nonconformity has been identified. |
| 4.13 | 4.12 | Change of clause numbering | |
| 4.14 | 4.13 | Change of clause numbering | |
| 4.15 | 4.14 | Change of clause numbering | |
| 4.15.1 | 4.14.1 | The review shall take account of recommendations for improvement. | Closes the loop on identifying and acting on opportunities for improvement. |
| Technical requirements | | | |
| 5.2.2 | 5.2.2 | The effectiveness of the training actions taken shall be evaluated. | Need to ensure that laboratories are not only training personnel but also ensuring it is effective. Specific aspect of ISO 9001 related to improvement. |

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| 5.9.1 | 5.9 | Change of clause numbering | |
| 5.9.2 | N/A | Quality control data shall be analyzed and where they are found to be outside predefined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported. | Need to ensure that laboratories have an action plan in case of quality control data being outside limits and that action is taken. Specific aspect of ISO 9001 related to improvement. |
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