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ISO 17025 Certification For Laboratory Accreditation

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ISO 17025 Certification ISO/IEC 17025

- Global quality standard for testing and calibration laboratories.
- It is the basis for accreditation from an accreditation body.
- Two main clauses in ISO 17025
 - Management Requirements and
 - Technical Requirements.
- Management requirements are related to the operation and effectiveness of the quality management system within the laboratory, and this clause has similar requirements to ISO 9001.
- Technical requirements address the competence of staff; testing methodology; equipment and quality; and reporting of test and calibration results.

ISO 17025 Certification ISO/IEC 17025

- ISO 17025 Accreditation is an objective way to assure your customers that you have demonstrated technical competence to provide reliable and accurate test or calibration results.
- Accreditation is objective because an independent, third party accreditation body performs annual assessments to verify whether your system is meeting all of the requirements of ISO/IEC 17025.
- Independent evaluation is important to the customer, because it is an unbiased guarantee that your laboratory is performing at its highest level. Certificationconsultancy.com

ISO 17025 Certification ISO/IEC 17025

- ISO 17025 for Laboratory Quality System Quality has become an important issue to people all over the world.
- ISO/IEC 17025 accreditation provides the assurance that calibration and testing laboratories are delivering good services, and consistent data.
- The accreditation body is responsible for assessing the quality system and technical aspects of your system to determine your compliance to the requirements of ISO/IEC 17025.
- It is the accreditation body that ultimately decides whether or not a laboratory is complying with the standard.

ISO 17025 Certification ISO/IEC 17025

- ISO 17025 Certification Process As with other ISO certifications, companies can decide to complete the steps in-house or hire a consultant to manage the certification process.
- A brief understanding of the ISO 17025 standard is the first step.
- The company should then conduct a gap analysis to determine the laboratory's current stage of compliance with the ISO 17025 Standard requirements.
- While most laboratories have to meet stringent technical requirements, they may be lacking in the management quality system components such as documentation and document control.

Gap analysis for ISO 17025 Certification

- The results of the gap analysis are the basis for the quality plan and implementation strategy.
- Once the standard requirements are satisfied, an internal audit will determine if there are still gaps in the quality system.
- Once these are satisfied, it is time to contact an ISO 17025 registrar who will conduct an independent certification audit.
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Key steps for ISO 17025 accreditation

- Key steps For ISO 17025 Accreditation
- There are eight key steps towards laboratory accreditation: Management defines a project owner.
- The project owner studies details of the standard, supporting literature, and other relevant information.
- The project owner defines the preliminary scope of accreditation and works with laboratory professionals to prepare a list with requirements.
- The project owner and laboratory professionals perform a gap analysis to determine the difference between the requirements and what is currently implemented in the laboratory.

Outcom of the gap analysis for ISO 17025 Certification

- Based on the outcome of the gap analysis, the project owner, laboratory professionals, financing and documentation professionals, and external consultants estimate the costs for accreditation.
- Estimated costs are presented to management, along with incremental opportunities.
- Management decides to proceed with accreditation. The project owner leads implementation steps.

ISO 17025 accreditation costs

- How does ISO 17025 Accreditation Cost? When you enter the market for an accreditation body, you'll find there is a wide range of prices for accreditation services, depending on different factors.
- Each laboratory has its own unique characteristics, and these come into play in estimating costs.
- There are three key elements that make up the cost of accreditation:
Daily rate Overhead expenses Travel and accommodations

ISO 17025 documentation

- What to include in ISO/IEC 17025 Documentation?
- When organization, either testing or calibration laboratories going for ISO 17025 accreditation, there are specific documentation requirements that need to be fulfill.
- List of such requirements for better understanding and defining quality system in laboratory as per ISO/IEC 17025:2005 are as bellow.
- ISO 17025 Manual Mandatory procedures Quality policy, SOP, Work Instruction Forms for record keeping Audit Checklists to verify implemented QMS system.

Time required to achieve ISO 17025 A

- Time required achieving ISO 17025 Accreditation Typically, it takes a laboratory six months to one year to prepare for the accreditation assessment.
- The assessment itself, from the day of closure of any applicable non conformances to the issuance of a certificate, takes approximately 8 weeks to complete.
- This includes Executive Committee review and administrative time required for paperwork and approval.

Benefits of achieving ISO 17025 Accreditation

- Recognition in the testing and calibration laboratory industry as an ISO 17025 certified facility.
- A competitive edge over competitors who are not certified in a globally-accepted quality system.
- Clearly document processes and procedures within a quality management system.
- A system to continuously improve both the management and technical aspects of the business Improved customer service and higher customer satisfaction with laboratory testing and calibration services.
- An internal audit process to identify non-conformance to standards and a process for corrective action and updating the quality system to the new quality standards Certificationconsultancy.com