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Skip to content Share by email Main image Click to view image in fullscreen ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories ISO/IEC 17025:2017 specifies the general requirements for the competence, impartiality and consistent operation of laboratories.ISO/IEC 17025:2017 is applicable to all organizations performing laboratory activities, regardless of the number of personnel.Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use ISO/IEC 17025:2017 in confirming or recognizing the competence of laboratories. Technical committee ISO/CASCO Committee on conformity assessment Publication typeInternational Standard Publication date2017-11-29 Edition3.0 ICS 03.120.20 Pages30 File size803.25 KB Under development EditionDatePublicationEditionStatus Custom Requests Interested in a custom solution? 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Unsourced material may be challenged and removed.Find sources:"ISO/IEC 17025"news newspapers books scholar JSTOR (January 2024) (Learn how and when to remove this message) (Learn how and when to remove this message)ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories is the main standard used by testing and calibration laboratories. In most countries, ISO/IEC 17025 is the standard for which most labs must hold accreditation in order to be deemed technically competent. In many cases, suppliers and regulatory authorities will not accept test or calibration results from a lab that is not accredited. Originally known as ISO/IEC Guide 25, ISO/IEC 17025 was initially issued by ISO/IEC in 1999. There are many commonalities with the ISO 9000 standard, but ISO/IEC 17025 is more specific in requirements for competence and applies directly to those organizations that produce testing and calibration results and is based on more technical principles.[1] Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results.[2] Material in the standard also forms the basis for accreditation from an accreditation body.There have been three releases; in 1999, 2005 and 2017. The most significant changes between the 1999 and 2005 release were a greater emphasis on the responsibilities of senior management, explicit requirements for continual improvement of the management system itself, and communication with the customer. The 2005 release also aligned more closely with the 2000 version of ISO 9001 with regards to implementing continuous improvement.[3]The 2005 version of the standard comprises four elements:Normative ReferencesTerms and DefinitionsManagement Requirements - related to the operation and effectiveness of the quality management system within the laboratoryTechnical Requirements - factors that determine the correctness and reliability of the tests and calibrations performed in the laboratory.The 2017 version comprises eight elements:ScopeNormative ReferencesTerms and DefinitionsGeneral Requirements - related to the organization of the laboratoryStructural Requirements -related to the organization of the laboratoryResource Requirements - cites issues related to the people, plant, and other organizations used by the laboratory to produce its technically valid resultsProcess Requirements - the heart of this version of the standard describes the activities to ensure that results are based on accepted science and aimed at technical validity.Management System Requirements -steps taken by the organization to give itself quality management system tools to support the work of its people in the production of technically valid resultsSome national systems (e.g. UKAS M10 in the UK) were the forerunners of ISO/IEC 17025:1999 but could also be exceedingly prescriptive. ISO/IEC 17025 allows laboratories to carry out procedures in their own ways, but require the laboratory to justify using a particular method.In common with other ISO quality standards, ISO/IEC 17025 requires continual improvement. Additionally, the laboratory will be expected to keep abreast of scientific and technological advances in relevant areas.In common with other accreditation standards of the ISO 17000 series (and unlike most ISO standards for management systems), assessment of the laboratory is normally carried out by the national organization responsible for accreditation. Laboratories are therefore "accredited" under ISO/IEC 17025, rather than "certified" or "registered" by a third party service as is the case with ISO 9000 quality standard.In short, accreditation differs from certification by adding the concept of a third party (Accreditation Body (AB)) attesting to technical competence within a laboratory in addition to its adherence and operation under a documented quality system, specific to a Scope of Accreditation.In order for accreditation bodies to recognize each other's accreditations, the International Laboratory Accreditation Cooperation (ILAC) worked to establish methods of evaluating accreditation bodies against another ISO/CASCO standard (ISO/IEC Guide 58 - which became ISO/IEC 17011). Around the world, regions such as the European Community, the Asia-Pacific, the Americas and others, established regional cooperations to manage the work needed for such mutual recognition. These regional bodies (all working within the ILAC umbrella) include European Accreditation Cooperation (EA), the Asia Pacific Laboratory Accreditation Cooperation (APLAC), Southern African Development Community Cooperation in Accreditation (SADCA) and the Inter-American Accreditation Cooperation (IAAC).The first laboratory accreditation bodies to be established were National Association of Testing Authorities (NATA) in Australia (1947) and TeLaRC in New Zealand (1973).[4][5] Most other bodies are based on the NATA/TELARC model include UKAS in the UK, FINAS in Finland and DANAK in Denmark to name a few.In the U.S. there are several, multidisciplinary accreditation bodies that serve the laboratory community. These bodies accredit testing and calibration labs, reference material producers, PT providers, product certifiers, inspection bodies, forensic institutions and others to a multitude of standards and programs. These ILAC MRA signatory accreditation bodies carry identical acceptance across the globe. It does not matter which AB is utilized for accreditation. The MRA arrangement was designed with equal weight across all economies. ABs include:The ANSI-ASQ National Accreditation Board (ANAB)|ANSI-ASQ National Accreditation Board[6]The American Association for Laboratory Accreditation (A2LA)[7]Perry Johnson Laboratory Accreditation (PJLA)[8]American Industrial Hygiene AssociationInternational Accreditation Service, Inc. (IAS)[9]National Voluntary Laboratory Accreditation Program (NVLAP) - technically part of the US government and only accredits a few narrow disciplinesAmerican Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD-LAB)[10] which is now ANAB (see above).In Canada, there are two accreditation bodies:Standards Council of CanadaThe Canadian Association for Laboratory Accreditation[11]The accreditation of calibration laboratories is the shared responsibility of the Standards Council of Canada (SCC) Program for the Accreditation of Laboratories-Canada (PALCAN), and the National Research Council of Canada (NRC) Calibration Laboratory Assessment Service (CLAS). The CLAS program provides quality system and technical assessment services and certification of specific measurement capabilities of calibration laboratories in support of the Canadian National Measurement System.In other countries there is often only one Accreditation Body. Typically these bodies encompass accreditation programs for management systems, product certification, laboratory, inspection, personnel and others:National Association of Testing Authorities (NATA) (Australia)Comit franais d'accrditation (COFRAC) (France)DAkkS (Germany)National Accreditation Board for Testing and Calibration Laboratories (NABL) (India)Komite Akreditasi Nasional (KAN) (Indonesia)Irish National Accreditation Board (INAB) (Ireland)Accredia - The Italian Accreditation Body (Italy)Dutch Accreditation Council (RVA) Archived 2021-07-24 at the Wayback Machine (The Netherlands)International Accreditation New Zealand (IANZ) (New Zealand)Korea Laboratory Accreditation Scheme (KOLAS) (South Korea)Bureau of Accreditation (BoA) (Vietnam)BiH Institute for Accreditation (BATA) (Bosnia & Hercegovina)Spanish Association for Standardization and Certification (AENOR) (Spain)Belac (Belgium)List of ISO standardsISO 17025 DocumentsQuality management systemMeasurement uncertainty^ "Principles behind ISO/IEC 17025" (PDF). Canadian Association for Laboratory Accreditation (CALA). Archived from the original (PDF) on 11 August 2019. Retrieved 27 March 2018.^ Honsa, Julie D.; Deborah A. McIntyre (2003). "ISO 17025: Practical Benefits of Implementing a Quality System". Journal of AOAC International. 86 (5): 10381044. doi:10.1093/jaoac/86.5.1038. PMID14632407. Retrieved 28 February 2012.^ "ISO/IEC 17025 Comparison - 1999 to 2005". SAI Global Limited ABN. Archived from the original on 2011-04-10. Retrieved 28 February 2012.^ "NATA - NATA Field and Program Accreditation Criteria - ISO-IEC 17025 Laboratory Accreditation (Applicable to all ISO/IEC 17025 fields)". www.nata.com.au. Retrieved 2017-04-28.^ "Testing Laboratory Registration Council Of New Zealand" (PDF). Archived from the original (PDF) on 2019-08-11. Retrieved 2017-04-28.^ "About ANAB". American Association for Laboratory Accreditation. Retrieved 30 August 2022.^ "About A2LA". American Association for Laboratory Accreditation. Retrieved 28 February 2012.^ "ISO/IEC 17025:2005 Laboratory Accreditation Program- PJLA". Retrieved 29 May 2015.^ "About IAS | The International Accreditation Service". Retrieved 29 May 2015.^ "ASCLD-LAB home page". American Society of Crime Laboratory Directors-Laboratory Accreditation Board. Retrieved 12 July 2012.^ "CALA". Retrieved 29 May 2015.ISO/IEC 17025:2017 Standard - General requirements for the competence of testing and calibration laboratories: ISO WebsiteRetrieved from " ISO 17025 is a crucial standard for laboratories to help them harmonise their procedures and methods. This harmonisation will facilitate the coordination between laboratories and other companies. In addition, the results of the laboratory sampling, testing and conformity assessment will be accepted between various countries all over the world. What is ISO 17025? What are its benefits?We will answer these questions and bring insights on the application of ISO 17025.ISO 17025:2017 is the most recent and revised standard of the ISO 17025 series. Historically it started with ISO/IEC Guide 25 that was published in 1990 which was the fruit of the collaboration between the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). In 1999, the first ISO 17025 was issued based on the ISO/IEC Guide 25. In 2005 the first revision of the ISO/IEC 17025 followed by a second revision 12 years later and published in 2017, making the ISO/IEC 17025 the third version of the standard which is adopted today. What is ISO 17025? ISO 17025 provides the General requirements for the competence of testing and calibration laboratories. This standard can be applied in all laboratories and it specifies the requirements of their practices to raise confidence in their ability to provide reliable and valid testing, calibration and sampling results. All this being possible thanks to a good quality system. The ISO 17025:2017 standard contains 5 main requirements for the accreditation of laboratories. The figure below shows the requirements of each criterion of the standard. The management system requirements of ISO 17025 are in line with the ISO 9001 standard. This was one of the main reasons of the previous revisions of the standard to include the management to the technical competence of the laboratory. A company or a laboratory can get ISO 9001 certification without having the ISO 17025 accreditation. To get accredited there are accreditation bodies that assess the laboratories and their conformities in meeting the requirements for the ISO 17025 standards. Among these accreditation bodies, we can mention the International Accreditation Service, UKAS the National Accreditation Body for the United Kingdom, ANAB the ANSI National Accreditation Board and many more exist in each country. Recommended for you :Discover the best Apps for Quality Management SystemWhat are the main benefits? First of all the ISO 17025 standard can be applied in all corporations that have laboratory activities regardless of their size. There are many benefits when the laboratory has ISO 17025 accreditation. They can vary from the brand image and promoting confidence, to the constant internal improvement of the processes and work quality. Here are some examples of the benefits: Better reputation and enhanced client confidence. The ISO 17025 standard is internationally recognised. It shows that a laboratory is operating successfully and providing valuable results, efficiently and effectively. And it shows that your laboratory operates with high levels of confidentiality and impartiality that attract a lot of clients and promote confidence in the brand image. Constant improvement of the activities and documentation. Constantly improving the system processes and protocols in place and adopting a risk based approach drives laboratories to always improve in a less costly way their activities. This will generate and increase operational efficiency and productivity. Hence the protocols in place are always updated and adaptable to all the new conditions and technologies that might be added to the activities. This will contribute to defining quality objectives and a more reliable and confident working environment. All these procedures, activities, protocols and objectives require proper documentation. It is in the ISO 17025 requirements and well conducted documentation provides stability and better results for the laboratory and the workers are more responsible. Gaining credibility and maintaining it. All the processes and procedures are reviewed and audited frequently. This is to ensure that the laboratory is well up to date with the new and evolving approaches. The auditing of the laboratory and the review of the protocols bring more credibility to the results, testing and calibration. This will also improve the reputation and reliability of the laboratory. The assessment (audit) is usually conducted by an accreditation body to make sure that everything is done correctly according to the ISO 17025 requirements and performed by well-trained personnel. Enhanced employees satisfaction. The standard underlines the necessity for a well-trained staff. This provides the opportunity for the employees to constantly improve and develop new skills. Thus, the personnel will be more responsible and provide good quality performance in their activities. Motivating the employees and giving them the opportunities and the means to evolve will greatly improve their satisfaction and the quality of their work life. Recommended for you :Discover the best Apps for Quality Management SystemHow can a digital tool help you get the ISO 17025 accreditation? The arrival of digital technology into our companies has reshaped the way the processes and protocols are implemented. It will allow an organisation to stand out from the competition and to be well prepared in the case of obtaining the ISO 17025 accreditation. The documentation of all the processes, protocols and procedures in the ISO 17025 requirements is highly important. A single digital platform with its Electronic Document Management (EDM) system can greatly reduce the paperwork and the dispersion of all the necessary documents. Everything is centralised on the platform and can be easily accessed from your computer, tablet or smartphone. The EDM can help you keep track of old versions of procedures and protocols, consult and modify them to have the newest version to comply with the requirements of the ISO17025. Accessibility can be adapted and limited to each department, depending on their needs and activities. A digital checklist can help you to successfully put in place all the necessary requirements and mandatory documents of the ISO 17025 standard. In addition, there are self-evaluation modules to make sure that all is correctly implemented before an accreditation audit. You can configure your evaluation in the form of customisable grids to answer all the basic criteria of the standard. You can easily add proofs to these grids by attaching photos, videos or related documents. The ISO/IEC 17025:2017 standard is applicable in all types of organisations regardless of their size and type of industry. It is an international standard allowing international recognition of laboratories when they are accredited. In addition to the ISO/IEC 17025:2017, there is the ISO 15189:2012 standard that is important for biomedical laboratories. So, are you well prepared to obtain the accreditation?Take the first step towards success by starting your certification preparation now, thanks to the QMS app. > Quality & EHS > ISO/IEC 17025:2017 Requirements, Benefits & Applications! In the realm of laboratory testing and calibration, ISO/IEC 17025 is a paramount standard that specifies the general requirements for the competence to carry out tests and calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods. ISO 17025 Method validation is a critical component of this standard, ensuring that laboratories can achieve consistent, reliable, and accurate test results. Method validation under ISO/IEC 17025 involves a series of procedures that laboratories must perform to confirm that a particular method is suitable for its intended use. This not only enhances the reliability of the results generated but also reinforces the laboratorys accreditation status. By validating methods, laboratories demonstrate that they can produce data that are precise, accurate, and repeatable, meeting the criteria established by the standard. ISO/IEC 17025 is essential for laboratory competence in testing and calibration. Method validation is key to reliable, consistent, and accurate laboratory results. Validating methods enhances a laboratorys credibility and accreditation status. Method validation under ISO/IEC 17025 ensures your laboratorys testing processes meet the required standards of quality and performance. Watch the video below from the very reputable ISO 17025 accreditation body, PJLA, to learn more about the ISO/IEC 17025 requirements concerning ISO 17025 method validation as detailed in section 7.2, Selection, Verification, and Validation of Methods of the ISO/IEC 17025:2017 standard. Accelerate your labs accreditation process with our comprehensive Quality Manual Template, designed to align with ISO/IEC 17025:2017 standards. Fully editable and customizable to fit your laboratorys needs. Includes all necessary procedures, forms, and policies. Structured to facilitate easy implementation and compliance. Developed by experts with extensive ISO/IEC 17025 experience. Access the Template Method Validation is a process documented by ISO/IEC 17025 that confirms your testing or calibration methods are suitable for their intended purpose. It requires examining and providing objective evidence that the specific requirements of your methods are fulfilled. Specificity: The method must unequivocally identify the analyte in the presence of other substances. Approval: The validated method should be approved and signed off by responsible personnel. Documentation: Proper validation requires maintaining comprehensive records as part of your method documentation. The purpose of method validation under ISO/IEC 17025 is to ensure consistent, reliable, and accurate testing outcomes in your laboratory. Objectives include: Quality Assurance: To ascertain the quality of the testing or calibration method, making sure it is fit for the intended use. Performance Verification: Confirming the method performs as expected over a range of conditions. Accreditation Compliance: Validated methods are a prerequisite for gaining and maintaining ISO/IEC 17025 accreditation, demonstrating your labs capability and competence. Method validation under ISO 17025 is a critical procedure that ensures your laboratorys testing methods meet the required standards for accuracy and reliability. This process verifies that methods are suitable for their intended analytical use. Definition of the Requirements: You initially need to identify the specific performance parameters and the scope of the methods to be validated, aligning them with your laboratorys needs. Preparation of a Validation Protocol: Prepare a document outlining how validation will be performed, including objectives, responsibilities, procedures, and acceptance criteria. Execution of Validation Plan: Carry out the validation according to the protocol, meticulously documenting all activities. Performance Parameters Assessment: Evaluate crucial performance parameters such as selectivity, accuracy, precision, linearity, range, detection limit, and robustness. Analysis of Data: Analyze the data generated and confirm that it meets pre-defined criteria. Preparation of the Validation Report: Compile all findings into a comprehensive report which will become part of your quality documentation. Implementation of the Method: Upon successful validation, implement the method as a standard procedure in your laboratory.Selection Based on Method Type: If you are using a standard method, your selection for validation depends on whether its already been validated by other organizations. If so, your focus will be on verification rather than full validation. Adjustments for Non-standard and Laboratory-developed Methods: For non-standard or in-house methods, choose a validation approach that comprehensively assesses whether the method fulfills all performance requirements and is fit for the intended purpose. Consideration of Method Modifications: Note that even minor modifications to an established method can necessitate a partial or full re-validation to ensure ongoing compliance with the ISO 17025 requirements. In method validation, the accuracy and reliability of your analytical methods are paramount. You need to ensure precision, specificity, and robustness meet the required standards. Accuracy: This is a measure of how close your test results come to the true value. Its crucial for ensuring your method yields true results. Precision: Reflects the repeatability of your measurements under unchanged conditions. Youre looking for consistent results, which instills confidence in your method. Specificity: Your method should exclusively measure the intended analyte without interference from other substances. This ensures the results are not compromised by the presence of other chemicals in the sample. Limit of Detection (LOD): Represents the smallest amount of substance that can be distinguished from the absence of that substance (a blank value). Its imperative for determining the lower end of your methods range. Measurement Uncertainty: Expresses the range of values within which the true value is confidently expected to lie. Understanding and calculating ISO 17025 measurement uncertainty is crucial for assessing the reliability of your results. Range: This is the interval between the upper and lower levels (including LOD and the highest measurable response) at which your method has a suitable level of precision, accuracy, and linearity. Calibration: The process of configuring your instrument to provide a result for a sample within an acceptable range. Its the groundwork to ensure your method can produce reliable results. Linearity: Your method should show that the results you obtain are directly proportional to the concentration of analyte in the sample within a given range. Robustness: Test your methods capacity to remain unaffected by small variations in method parameters, and to perform under a variety of conditions. This ensures the methods reliability under different operational settings. Repeatability: Refers to the methods ability to yield the same results over a short time frame when the operation is conducted in the same manner. Reproducibility: Unlike repeatability, this checks whether the method yields similar results under varied conditions different operators, instruments, and laboratories. It is essential for broader application of your method. Enhance your laboratorys accuracy by mastering the estimation of measurement uncertainty in material testing, calibration, and microbiological testing. Understand basic statistical concepts relevant to uncertainty. Apply ISO GUM and ISO 19036 methodologies. Develop effective quality control plans utilizing uncertainty measurements. Implement decision rules in compliance with ISO/IEC 17025 requirements. Enroll in the Course In this section, you will find practical examples illustrating how method validation is a critical component in achieving consistent quality in laboratories operating under ISO/IEC 17025 standards. In your laboratory, method validation is an integral process to ensure the reliability of the results you generate. For quantitative analysis, a lab might validate a method for measuring the concentration of a pharmaceutical compound in a drug by determining linearity, precision, and accuracy. This involves analyzing samples with known concentrationsusing certified reference materialsto create a calibration curve and assessing the methods ability to reproduce these values within acceptable limits. For qualitative testing, such as pathogen detection in food samples, you must demonstrate the methods specificity by confirming that it identifies the targeted pathogen and not similar non-target organisms. Proficiency testing can play a role here, providing external validation of your methods performance by comparing your results against those from a range of other laboratories. Consider a case study where a laboratory needed to validate a new analytical method for environmental testing. They followed ISO/IEC 17025 guidelines for method validation by first defining the methods purpose and ensuring it met the necessary criteria for fitness for purpose. After initial validation, regular quality checks like proficiency testing helped to maintain ongoing confidence in the methods performance. Another case involved a medical testing laboratory introducing a new diagnostic method. They validated the sensitivity and specificity of the method by testing known positive and negative samples. The methods ability to consistently identify the correct disease markers was then documented, forming part of the essential laboratory quality documentation required by ISO/IEC 17025. In pursuing ISO 17025:2017 compliance, youll face specific challenges related to method validation. This section delineates these challenges and provides practical strategies to address them, ensuring your laboratory maintains quality and confidence in its results. 1. Developing a Robust Validation Protocol: Crafting a comprehensive validation protocol is pivotal. You may struggle with defining parameters that accurately reflect performance characteristics such as selectivity, precision, and bias. These protocols are essential to demonstrate the methods ability to generate reliable results under stipulated conditions. 2. Managing Uncertainty of Measurement: Understanding and managing the uncertainty of measurement is a demanding aspect of ISO 17025:2017. You must be able to confidently quantify and report uncertainty, which requires a deep technical understanding and rigorous data analysis. 3. Technology Integration: Keeping pace with evolving technology poses a significant challenge. Your laboratory must integrate new technology without compromising method validation processes or quality standards. 4. Ensuring Competence: Ensuring that personnel are adequately trained and competent in performing validations and understanding ISO 17025 requirements can be an ongoing challenge, directly impacting the outcome of method validations. Developing a Robust Validation Protocol: Craft Detailed Plans: Begin with detailed protocols that outline each step of the validation process, including the specific performance characteristics to be tested. Emphasize Quality: Ensure your validation protocol prioritizes quality at every phase, from initial planning to final documentation, accounting for accuracy, precision, and bias. Managing Uncertainty of Measurement: Invest in Training: Equip your team with the necessary skills through targeted training in uncertainty evaluation. Use Reference Materials: Apply certified reference materials to calibrate instruments and validate methods, thus achieving more reliable measurements. Technology Integration: Stay Updated: Regularly review and adopt updated guidelines that pertain to the use of new technology in method validation. Validate Technology Adaptations: When introducing new technology, systematically validate any modifications to established methods to ensure compliance with ISO 17025 standards. Ensuring Competence: Ongoing Education: Implement continuous education programs to keep staff abreast of the latest ISO standards and validation techniques. Performance Evaluations: Regularly conduct performance evaluations to confirm the competence of your personnel in the execution of validated methods and in handling calibration tasks. In your method validation processes, technology plays a pivotal role in ensuring compliance with ISO/IEC 17025 standards. From software applications to advanced analytical instruments, technology transforms how you validate your methods to meet rigorous performance criteria. Technology and software are integral to robust method validation. You utilize computer systems and IT techniques to streamline method validation, enhancing accuracy and efficiency. Software can oversee and document the validation process, including: Data Collection: Automated systems ensure precise and consistent collection of validation data. Data Analysis: Advanced software evaluates method performance, ensuring it meets the defined criteria. Documentation: Information management systems securely store validation records, guaranteeing traceability and integrity. The correct implementation of technology ensures you are aligned with ISO/IEC 17025 that stipulates the use of suitable equipment, documented procedures, and continual method performance monitoring. As you look ahead, the future trends in validation technology are set to offer even more sophisticated tools. Heres what you can anticipate: Automation: Expanded automation of validation tasks reducing manual input and the possibility of human error. Integration: Seamless integration with other laboratory systems for comprehensive data management. Advanced Instruments: Cutting-edge instruments providing more precise measurements and quicker results, vital for method validation. Embrace these technological advancements, as they will serve to fortify your validation practices, ensuring accuracy, reliability, and compliance with international standards like ISO/IEC 17025. Your ability to fulfill the requirements of ISO/IEC 17025 is critical for method validation within your laboratory. It ensures a mark of quality and reliability that stakeholders can trust. By integrating the principles outlined in ISO/IEC 17025, you reinforce the competence of your testing and calibration methods. Consistency and accuracy are non-negotiable in your laboratory operations. The successful accreditation to ISO/IEC 17025 not only reflects the technical proficiency but also the organizational commitment to a systematic approach that values quality. This, in turn, fosters confidence among your clientele and regulatory authorities. Remember, attaining and maintaining accreditation is an ongoing process. Your laboratory should regularly review and enhance its quality management system. This dedication to continuous improvement underpins the reliability of your results. Heres a summary of key takeaways for maintaining your ISO/IEC 17025 compliance: Assure Quality: Implement and adhere to stringent quality management systems. Ensure Reliability: Validate and verify methods rigorously, confirming that they are fit for their intended purpose. Build Confidence: Consistently produce accurate and dependable results that clients can trust. Gain Trust: Use the accreditation to demonstrate technical competency and build trust with clients and regulatory bodies. In ensuring compliance with ISO/IEC 17025, method validation is crucial for the integrity and reliability of a laboratorys analytical procedures. This section covers key aspects of the process to guide you through understanding and implementing method validation effectively. Method validation is a series of procedures you conduct to confirm that an analytical testing method is suitable for its intended purpose. Within ISO/IEC 17025 compliance, it demonstrates that your method is reliable, repeatable, and capable of producing accurate results. To meet ISO/IEC 17025:2017 requirements, your laboratory must ensure method validation adheres to established protocols that examine characteristics such as specificity, linearity, accuracy, precision, detection limit, quantitation limit, and robustness. This is mainly a requirement for in-house methods used by a laboratory. It should be noted that if the laboratory is utilizing a standard published method, such as an AOAC or USP method, a method validation is not required since it has already been validated. When you conduct method validation as per ISO/IEC 17025 standards, important steps include defining the scope and parameters of the method, conducting a series of experiments to test its performance characteristics, documenting each step, and analyzing the data to confirm method effectiveness. Method verification is performed to ensure that the laboratory can consistently implement an already established method correctly, whereas method validation is a more comprehensive assessment to establish the performance characteristics of a newly developed, modified, or adopted method. Under AOAC guidelines, a method must typically meet criteria for parameters such as accuracy, precision, specificity, sensitivity, reproducibility, and ruggedness to be considered validated. This ensures the method is fit for its intended analytical use. Have questions about ISO/IEC 17025 or ISO 9001 implementation or accreditation? Schedule a free 45-minute consultation with me to discuss your Company or laboratorys needs and how we can achieve compliance together. Schedule Your Consultation Share copy and redistribute the material in any medium or format for any purpose, even commercially. Adapt remix, transform, and build upon the material for any purpose, even commercially. The licensor cannot revoke these freedoms as long as you follow the license terms. Attribution You must give appropriate credit , provide a link to the license, and indicate if changes were made . You may do so in any reasonable manner, but not in any way that suggests the licensor endorses you or your use. ShareAlike If you remix, transform, or build upon the material, you must distribute your contributions under the same license as the original. 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