Steps to ISO/IEC 17025 Accreditation

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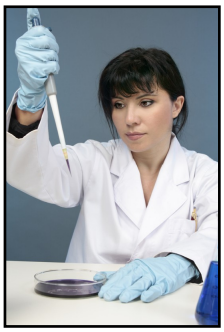
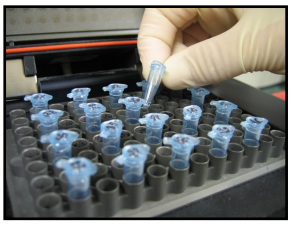


Implementing an ISO/IEC 17025 laboratory management system is a means to ensuring efficiency and technical competency in calibration and testing laboratories. A laboratory that establishes a laboratory management system compliant with ISO/IEC 17025 joins the growing world partnership of accredited laboratories.

An ISO/IEC 17025 accreditation certificate will show potential customers that your laboratory values quality and that you have taken steps to ensure that your calibration or testing results are accurate and reliable.

ISO/IEC 17025 accreditation is available for both freestanding laboratories and for laboratories which are part of larger facilities. If you want to solidify your laboratory's stance as a serious competitor, it is imperative that your laboratory management system comply with ISO/IEC 17025.



This booklet, ***Steps to ISO/IEC 17025 Accreditation*****,** was created by Perry Johnson Laboratory Accreditation, Inc., to give laboratories interested in seeking ISO/IEC 17025 accreditation a clear understanding of the complete process. We hope that this material will provide you insight and assist you with taking the necessary next steps towards achieving accreditation.

Tracy Szerszen – President/Operations Manager
Perry Johnson Laboratory Accreditation, Inc.

1.0 The Benefits of ISO/IEC 17025 Accreditation

ISO/IEC 17025:2005 – *General Requirements for the Competence of Testing and Calibration Laboratories*, is used to develop and implement laboratory management systems.

By having your laboratory management system accredited to ISO/IEC 17025, your company stands to gain a gold mine of benefits. One of the main advantages is that your laboratory will gain international recognition for its commitment to quality, competency and reliable results. In addition, ISO/IEC 17025 accreditation will signify that you comply with an internationally recognized standard, thus easing the global exchange of valuable information.

Benefits

- ✔ **International Recognition**
- ✔ **Sound Management System**
- ✔ **Prevents Defects**
- ✔ **Increased Accuracy**
- ✔ **Cost Savings**
- ✔ **Reduced Waste**
- ✔ **Access to Global Marketplace**

This is only one example of what ISO/IEC 17025 accreditation can do for your company. There are many other reasons to pursue accreditation.

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. This independent evaluation is important to the customer, because it is an unbiased guarantee that your laboratory is performing at its highest level.

Another benefit of achieving ISO/IEC 17025 accreditation is that it will set your laboratory apart from your competitors. ISO/IEC 17025 is an ideal management system model for laboratories because it aims to control quality costs, improve measurement accuracy and guarantee consistency of results. It is also customer-driven. When implemented correctly, the elements of ISO/IEC 17025 work meticulously together to ensure that required quality levels are met and that customers' needs are satisfied. This can be a powerful strategic tool.

Furthermore, when your company achieves ISO/IEC 17025 accreditation, you will be presented with a certificate of accreditation. This certificate can be used in advertising, promotional literature and stationary to show current and potential customers that your laboratory is committed to quality and has demonstrated technical competency to perform calibration or testing services.

As you can see, ISO/IEC 17025 accreditation can be a valuable tool. By becoming accredited, you can look forward to an efficient management system, improved calibration or testing, fewer customer complaints and a strong competitive edge.

2.0 Choosing an Accreditation Body

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.

As mentioned earlier, a key ingredient of the recipe for quality and competency is third-party accreditation. A company cannot achieve accreditation until it hires a well-recognized accreditation body to carry out a complete and thorough assessment of its laboratory management system.

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.

Knowing this, you should study the credentials of potential accreditation bodies carefully. To assist you in selecting an accreditation body that is best suited for your laboratory's needs, you'll want to examine the following areas:

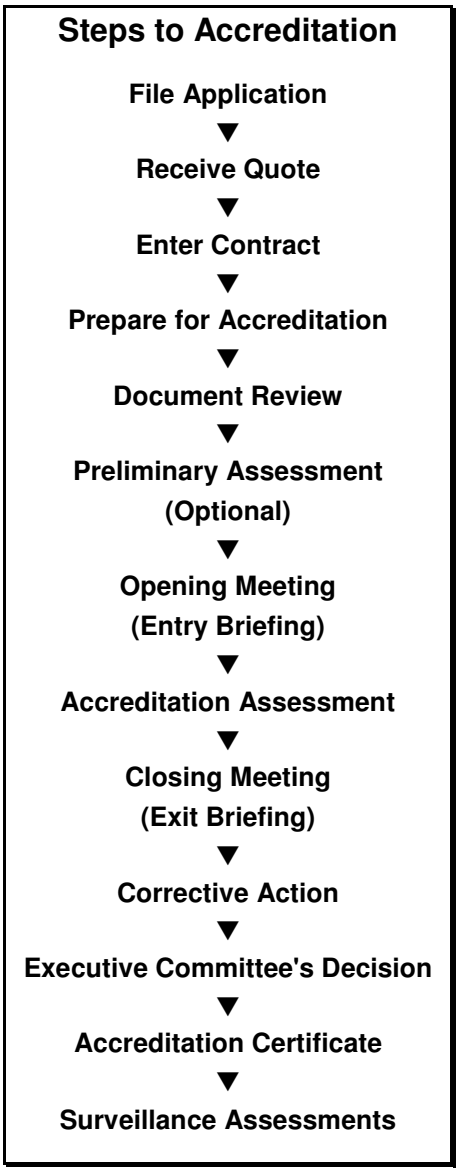
Key Questions to Ask:

- **Does the accreditation body have assessors qualified to conduct assessments in your particular scope of calibration or testing? Where are the assessors located?**
- **Is the accreditation body willing to provide you with a complete description of its accreditation process? Find out if there are any policies or contract restrictions that may affect you.**
- **Is the accreditation body recognized for its accreditation program? Check the credentials of the accreditation body. Refer to the International Laboratory Accreditation Cooperation (ILAC) listing of signatories at www.ilac.org.**
- **Is the company financially stable? Will the accreditation body still be in business during the period that your accreditation certificate is valid?**

3.0 ISO/IEC 17025 Accreditation

The graphic on the right illustrates each step of the ISO/IEC 17025 accreditation processes. We'll explain each procedure, in detail, on the following pages.

Let's begin our path toward accreditation by talking about the first step, filing an application for accreditation services.



Filing an Application

It's usually a good idea to establish a relationship with an accreditation body in the early stages of implementing your laboratory management system. In that way, you can familiarize yourself with its practices and establish a schedule for accreditation in advance, thereby avoiding possible delays.

PJLA will ask you to complete an application. Here are some standard questions you can expect to answer:

- **What is your desired time frame for accreditation?**
- **What is your laboratory's scope of testing and/or calibration?**
- **Is your laboratory freestanding or part of a larger facility?**
- **What is the status of your existing laboratory management system implementation?**
- **What is the state of your laboratory management system documentation?**

Receiving the Quote

It is important that you compare all quotes thoroughly to ensure you are getting the most for your money. Using your information from the application, PJLA will prepare a price quote and an estimate of time required for completing the accreditation assessment. All aspects of the accreditation process are offered up front during our quotation process.

Entering the Contract

After you've decided to enter into a contract with PJLA, the relationship is formalized. The contract will spell out the responsibilities of all parties involved including financial obligations and acceptance terms of adherence to the standard and PJLA policies.

Preparing for Accreditation

Your company is ready for accreditation after you've implemented an ISO/IEC 17025 management system and allowed ample time for laboratory employees to 1) become familiar with the system and 2) develop a sufficient evidentiary trail of documents that can be assessed.

Documentation should include the following:

Quality Manual: Outlining how your laboratory conforms to the standard;

Procedures: Describing how the system functions;

Work Instructions: Defining specific job activities affecting the quality of calibration or testing;

Quality Documentation: Documents, which explain how quality will be, managed for individual calibration or testing projects or contracts, as well as other types of specific documents;

Quality Records: Various records including charts, files, inspection and testing records, assessment results, and any other records of objective evidence.

Preliminary Assessments

In many cases, the laboratory may request a preliminary assessment, or dry-run assessment of its laboratory management system, prior to the accreditation assessment. This gives the accreditation body an opportunity to identify, in advance, any weaknesses that may exist in the laboratory management system.

During the preliminary assessment, PJLA will send an assessment team to your laboratory. The team, composed of competent assessors, will assess your laboratory, management system, records and other documentation, alerting you to any concerns that may interfere with a successful accreditation assessment.

Preliminary Assessment Perks

1) **Helps to determine a laboratory's preparedness for an accreditation assessment.**

2) **Can pinpoint major deficiencies in the management system, giving a laboratory sufficient lead time to correct any problems before the accreditation assessment.**

3) **Aids PJLA in planning for the accreditation assessment by determining the number of assessors needed, the length of time required to complete the assessment and other pertinent criteria.**

The main advantage of a preliminary assessment is that it allows you to correct any potential problems before the accreditation assessment begins. But you should remember that a preliminary assessment is not required for ISO/IEC 17025 accreditation. It is strictly optional, depending upon your own needs.

The extent of the preliminary assessment is also up to you. You may decide that you want a full preliminary assessment performed on every aspect of your laboratory's operations, or, to save on costs, you may decide that all you need is a sampling of your management system. It's your decision.

While a preliminary assessment is optional, it is recommended. In the long run, it can save you time and money by revealing deficiencies or nonconformities that, if corrected before the accreditation assessment, can save you the expense of follow-up actions.

Laboratory Management System Documentation Review

Once you're ready to begin the accreditation process, PJLA will request an uncontrolled copy of your laboratory management system documentation. It is recommended that you submit your documentation at least four to six weeks before your scheduled assessment so that if any deficiencies or nonconformances are uncovered, you'll have ample time to make corrections without delaying the process.

PJLA will review your documentation to determine whether it meets all of the requirements of ISO/IEC 17025. It will also be verified that the processes have been developed and implemented for management review, internal audits, interlaboratory comparisons, proficiency testing, and measurement uncertainty.

After your documentation has been reviewed, a report will be submitted to you by PJLA. If your documentation fails to meet all the criteria stipulated in ISO/IEC 17025, the deficiencies or nonconformances will be identified in the report and you will need to take corrective action.

A Documented Management System:

- **Defines the authority and responsibilities of personnel.**
- **Clearly communicates the objectives of the system, the laboratory's policies, procedures and work instructions.**
- **Promotes continuous improvement, which means the system, is monitored regularly and changes can be incorporated easily.**
- **Ensures consistent performance.**

Once PJLA has determined that your documented laboratory management system is satisfactory, arrangements will be made for the preliminary assessment, if wanted, or if not, the accreditation assessment at your laboratory. PJLA will appoint a qualified assessment team to carry out a full assessment of your laboratory management system. The team will consist of a Lead Assessor, who is responsible for coordinating assessment activities, and one or more assessors, depending on the size of your laboratory. At least one of those team members must be experienced in your particular area of calibration or testing.

The Lead Assessor will work with your Laboratory Management Representative in devising an assessment agenda for the on-site visit. Prior to arriving, the Lead Assessor will send you an agenda, confirming the daily schedule of events and any accommodation requests.

It is the assessment team's job to verify whether your laboratory management system is meeting all of the requirements of ISO/IEC 17025. The team determines this by assessing tests and/or calibrations performed by the laboratory including records, equipment and personnel.

The Accreditation Assessment

The Opening Meeting (Entry Briefing)

On the first day of your scheduled assessment, an opening meeting or entry briefing will be held with upper management and other parties directly involved with the laboratory management system. Under the direction of the Lead Assessor, the assessment team will present an overview of the assessment process, giving you a clear understanding of what can be expected in the days to follow.

The Accreditation Assessment Consists of:

- **An opening meeting (entry briefing)**
- **A detailed examination of your laboratory management system**
- **A closing meeting (exit briefing)**
- **Recommendation**

The team will review your assessment scope and objectives. They will confirm times, schedules and resources with you, and they will go over the procedures for identifying and reporting nonconformances or deficiencies.

At this time, you will be expected to introduce your selected guide(s) who will accompany the assessment team through the laboratory and its procedures.

The Assessment

Following the opening meeting, the assessment team will walk through your laboratory to observe and witness activities. Team members may conduct one-on-one interviews with employees, ask to inspect documents and records, witness selected calibrations or tests, and examine calibration or testing equipment.

Throughout the assessment, they will be seeking evidence of technical competency, such as statements, documented procedures, records and written policies, to support their observations.

If any deficiencies or nonconformances are found during the course of the assessment, the assessor will bring them to your attention, and record them on a nonconformance report. In the report, the assessor will specifically describe what the nonconformance or deficiency is and the related section of the standard the nonconformity or deficiency pertains to.

The Closing Meeting (Exit Briefing)

When the assessment team has completed its on-site assessment of your laboratory, a closing meeting or exit briefing will be held. This meeting is usually attended by the same people who sat in on the opening meeting.

At the closing meeting, the Lead Assessor will summarize the results of your assessment. The Lead Assessor will explain, in detail, any nonconformities or deficiencies that were found, and will provide you with an assessment report. In this report, the findings of your assessment will be reiterated in detail. If any nonconformities or deficiencies are identified, the assessment team will allow you a reasonable period of time, given the nature of the nonconformance, to take corrective action. The Lead Assessor will also provide a recommendation as to your laboratory's eligibility for accreditation.

Taking Corrective Action

If the assessment team indicates that your laboratory needs to take corrective action, it's nothing to become alarmed about. However, all nonconformances must be addressed and corrective action taken before accreditation can be granted.

Your corrective action response must include a copy of objective evidence, such as calibration certificates, laboratory procedures and training records, to indicate that corrective actions have been implemented and completed.

After you have corrected the nonconformance, PJLA may require a follow-up assessment, limited to the area of concern, to confirm that the problem has been resolved. The Lead Assessor cannot recommend accreditation until he or she has verified that all nonconformances or deficiencies have been corrected.

Accreditation

After all nonconformities have been corrected and verified by the Lead Assessor, your accreditation documents are forwarded to PJLA's Executive Committee, an independent decision-making body. The Executive Committee will review your assessment material and the Lead Assessor's recommendation and decide whether to grant accreditation to your company.

If the Executive Committee determines that you have met all of the requirements for accreditation, you will be notified immediately and your accreditation certificate will be prepared. The certificate will bear the accreditation body's logo.

Displaying Your Certificate of Accreditation

You can display your certificate of accreditation in advertising, promotional literature and stationery to show customers that your company has demonstrated technical competency to perform particular tests or calibration services.

Complaints, Disputes and Appeals

In the event that you think your laboratory has been unfairly denied accreditation, you can dispute the decision. PJLA is required to have a dispute board with an impartial panel. This board is independent of PJLA and will listen to your arguments and reevaluate your assessment material.

Maintaining Accreditation

Once you have attained accreditation status, your laboratory will be subjected to surveillance assessments by PJLA. This is a partial assessment of your laboratory management system particularly in the area of ILC (ILC = Inter Laboratory Comparisons) or PT (PT = Proficiency Testing) as well as traceability to look for objective evidence that you are still in compliance with the ISO/IEC 17025, and that your laboratory is continually working to improve and maintain the system.

4.0 How Much Does 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:

1. **Daily rate**
2. **Overhead expenses**
3. **Travel and accommodations**

Generally, most accrediting bodies will charge a daily rate. This part is straightforward. But when it comes to overhead costs and travel expenses, things can get somewhat clouded. Some companies will quote a daily rate, and then tack on extra charges for office preparation or other services. This creates confusion and presents an inaccurate picture of the total cost.

Cost Estimates Should Include:

- **Fees for document review**
- **Fees for preliminary assessment (optional)**
- **Fees for accreditation assessment**
- **Miscellaneous fees associated with accreditation, such as travel and accommodations**
- **Fees for surveillance**

During the accreditation process, it is PJLA's desire to provide assessors with the highest qualifications at the lowest total cost to your organization. Scheduling of assessments and assessors is based on qualifications and location of assessors. PJLA will always schedule the best-qualified assessor that is closest to your location to help minimize travel expenses associated with your accreditation process.

5.0 PJLA Advantages

- No mandatory preliminary site visit
- Awards ceremony option
- No penalty for changing schedule with reasonable notice
- No hidden costs in proposal
- No application fee
- No overtime charges
- Free press release assistance by PJLA technical writing staff
- Detailed preparation is done off-site
- Assessors' expenses minimized
- No travel mark-up; all expenses at cost

6.0 How Long Does it Take to Achieve Accreditation?

Just as cost estimates can vary, there is no set timeline for completing an accreditation assessment. The number of days required, will depend on several factors.

Generally, the length of time required to complete an accreditation assessment is determined by the desired scope of a laboratory, the number of employees and the complexity of a company's operations.

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 nonconformances 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.

The Number of Days Required to Complete an Accreditation Assessment Depends Upon:

1) **Size of laboratory.**
2) **Number of employees.**
3) **Complexity of calibration and/or testing operations.**

7.0 About Perry Johnson Laboratory Accreditation, Inc. (PJLA)

A company built upon a solid 15-year foundation in quality, PJLA knows the field of laboratory quality and thoroughly understands the assessment and accreditation process. PJLA was founded by **Perry L. Johnson**, one of the world's top experts and authors on ISO 9000 and a leading educator on the theories and practices of Total Quality Management. Based on its heritage, its vast experience in the field of laboratory accreditation, and the expertise of its assessment staff, PJLA is destined to become a prominent and respected accreditation body in the United States.

PJLA is a full-service accreditation body with technical experts and technical assessors on staff. PJLA's technical assessors have years of experience in testing and calibration fields. They have undergone training in ISO/IEC 17025:2005 and other relevant training sessions including Measurement Uncertainty. PJLA has selected our assessors to conduct ISO/IEC 17025 services due to their extensive work experience in testing or calibration and their years of experience in ISO/IEC 17025:2005 assessing practices.

PJLA is a MRA Signatory of the **International Laboratory Accreditation Cooperation (ILAC)** and of the **Asia Pacific Laboratory Cooperation (APLAC)**.

With the recognized support of international organizations, our firm will be able to provide tremendous marketing and business advantages to our accredited laboratories, especially those with foreign business interests.

For more information on PJLA's accreditation services, call: **(877) 369-LABS,** email: pjlabs@pjlab.com or write to: Perry Johnson Laboratory Accreditation, Inc., 755 W. Big Beaver Rd., Suite 1325, Troy, Michigan, 48084 USA.