HOW TO ACHIEVE ISO 17025 CERTIFICATION IN 10 EASY STEPS

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Summary: ***The increasing popularity of ISO 17025 as a means of insuring product quality has spawned a flurry of demand for compliance. This paper presents an approach for achieving compliance through internal auditing and careful selection and application of process controls.***

THE 10 STEPS

1. Read the Standard for familiarity.
2. Create/Revise a checklist for compliance
3. Conduct an internal audit to the checklist.
4. If no non-conformities are found, skip to step 8.
5. Otherwise, list non-conformities and relate each to a specific clause of ISO 17025.
6. Change the process and /or documentation to eliminate the non-conformities.
7. Go to step 2.
8. Schedule and host an audit by a certified ISO 17025 registrar.
9. Change the process and /or documentation to eliminate the non-conformities.
10. Schedule a follow-up audit or communication to clear any non-conformities.

HAVE YOU READ THE STANDARD?

If you have not read the standard recently, or have never read it at all, you must do so before you embark on the path to compliance and/or certification. The standard will seem far less formidable once you have read it.

As a quick review, or as a preparation for reading the full standard, refer to the *Summary of ISO 17025* (see Appendix).

ISO 17025:1999, "*General Requirements for the Competence of Testing and Calibration Laboratories*", is essentially the application of ISO 9001 to a testing or calibration laboratory.

Whereas ISO 9001 is a general standard that can be applied to any organization, ISO 17025 is designed for testing and calibration laboratories. It includes all of the requirements of ISO 9001:1994. Future revisions will incorporate the requirements of ISO 9001:2000.

ISO 17025 (1999) is a process-control standard that contains all of the requirements that insure that testing and calibration laboratories have a quality system, are technically competent and are able to generate valid measurements. The Standard can be applied anywhere that testing and/or calibration is done.

Although ISO 17025 seems to be designed for accreditation of high-level calibration labs, nothing in the standard prevents its use in other organizations where the measurement discipline may be oriented toward manufacturing and the calibration of general purpose instrumentation. The American Association for Laboratory Accreditation (A2LA) instructs applicants for ISO 17025 certification to "…evaluate how the criteria [of ISO 17025] apply to your laboratory; identify clauses that do not apply, or apply only to a limited extent, and identify the reasons for their non-applicability."

THE CHECKLIST

An effective audit requires a clear, concise checklist that accurately reflects the requirements of the standard. Non-conformities generated by such a checklist will be unambiguous. Once the checklist is created, provide a copy to everyone in the organization so that they know exactly what is expected for compliance.

Sections 4.0 and 5.0 of the *Summary of ISO 17025* (Appendix) can be used as a first-draft checklist. Section 4.0 deals with management requirements and section 5.0 deals with technical requirements. Several paragraphs in those sections deserve special attention.

Section 4.0: Management Requirements

4.2.1 Documentation

Strive for just enough documentation supported by a lean, efficient retrieval system. Over-documenting leads to confusion and needless busy-work.

4.3 Document Control

Review and approval are essential to the credibility of your documentation. Authorization and control of revisions is necessary to prevent processes and documentation from diverging from one another. Auditors will expect to see proof that only the latest revisions of process documents are in use.

4.10 Corrective Action

Everyone makes mistakes. It is important to acknowledge this fact by having a system that identifies and analyzes mistakes and discrepancies, and changes the process to prevent recurrence. It is important to show that you never repeat a mistake.

4.13 Internal Audits

Periodic internal audits are required by the ISO 17025. They are the most effective way to fine-tune your quality system and they prepare your staff for audits by external agents. You should audit early and audit often. The results will show you exactly where to put your improvement effort. Have an experienced auditor show you how to use internal audits as a tool to uncover weaknesses in processes.

Section 5.0: Technical Requirements

5.2 Personnel

Selection and training of personnel for calibration lab work is a critical task. Expect a third-party auditor to look closely at your records for personnel.

Where a repetitive test process has been developed by engineers, it is not necessary to have skilled calibration personnel as operators. The test process itself can be certified, removing the technical interaction of the operator. Discrepancies are handled by the engineering staff.

5.4.2 Selection of Methods

A third-party auditor will understand measurement and will be interested in how and why you chose the measurement methods in your procedures. Be prepared; document the reasons for your choices.

5.4.5 Validation of Methods

Without validation, no process has credibility. It is important to validate your measurement processes *before* you begin to use them. The validation process must include a thorough analysis and statistical verification.

5.4.6 Estimation of uncertainty of measurement

At the very least, this process must follow the internationally-recognized ISO-GUM method. A third-party auditor will ask for examples of uncertainty analysis and ask for proof that the estimated uncertainty is being applied to measurement results.

5.5 Measurement Traceability

This is the bedrock upon which your entire measurement structure is built. State-of-the-art equipment and methods are lost-in-space without a solid, documented, traceability path to national or international standards.

CONDUCT AN INTERNAL AUDIT

Using the current checklist, audit every area within your walls that has a connection to your calibration activity. The same checklist can be used in each area, although certain items on the list may not be relevant in some areas. In the beginning, you may want to have an experienced auditor show you how it is done.

Do not postpone the audit until everyone “feels ready”. As soon as the first-pass checklist is finished, start auditing. You will obviously find many things wrong with both the checklist and the process on the first pass. That is to be expected. Internal audits are “free” (they do not count against compliance or certification) and are the best way to motivate people to prepare and/or repair their processes.

LIST THE NON-CONFORMITIES

List every deviation from the standard and cite the paragraph of ISO 17025 that applies to the non-conformity. The description of each non-conformity should be objective, descriptive and brief. It should be clear to the auditee exactly what must be done to clear the non-conformity.

Every audit should be documented with a report. This report is the basis for action and is an invaluable chronicle of your progress, as well as proof to an external auditor that internal audits have happened.

CHANGE THE PROCESS AND/OR DOCUMENTATION TO ELIMINATE NON-CONFORMITY

For each non-conformity, the offending area should submit a response that includes a plan to eliminate the non-conformity, along with a timetable for completion. Once the process has been changed, the area should do an internal audit of itself to verify that the change has been effective.

SCHEDULE AND HOST AN AUDIT BY A CERTIFIED ISO 17025 REGISTRAR

Nothing establishes your credibility for ISO 17025 compliance like a third-party audit by a certified registrar. Each registrar service has their own protocol for the audit and certification process. You will learn a lot by being audited. Be sure to involve all of your auditing staff so that they will have the experience of "shadowing" the professionals.

CHANGE THE PROCESS AND/OR DOCUMENTATION TO ELIMINATE NON-CONFORMITY

The certified auditor will most likely find non-conformities to ISO 17025 in your quality system. The auditor will provide a written report containing the non-conformities and the recommended action to clear them. In the exit briefing, you will receive an explanation of each non-conformity and will have an opportunity to question and clarify each one.

SCHEDULE THE FOLLOW-UP ACTION

Each non-conformity must be "cleared" to the satisfaction of the registrar. This may require a follow-up visit (for major nonconformities) or a simple exchange of communications, at the discretion of the auditor. Following this step, certification will be conferred on your calibration lab. Periodic re-certification will be necessary.

You made it!

Appendix

Summary of ISO Standard 17025 (1999)

General Requirements for the Competence of Testing and Calibration Laboratories

FOREWORD

This edition of ISO 17025 cancels and replaces ISO/IEC Guide 25: 1990.

INTRODUCTION

ISO 17025 applies to testing and calibration laboratories (not defined).

Accreditation bodies should use this standard to accredit the competence of testing and calibration laboratories.

Complying with ISO 17025 requires compliance with ISO 9001 or 9002 as well.

Certification to ISO 9000 does not remove the need for testing and calibration labs to comply with this standard. ISO 17025 covers several technical competence requirements that are not covered by ISO 9001/9002.

1. SCOPE

ISO17025 specifies the competence required to carry out tests and/or calibrations.

It applies to all organizations performing tests and/or calibrations, including testing or calibration that is part of inspection or product certification.

The NOTES given in the standard do not contain requirements and are not part of the standard. They provide clarification, examples, and guidance only.

2. NORMATIVE REFERENCES

(A list of documents whose provisions form part of the provisions of ISO 17025.)

3. TERMS AND DEFINITIONS

See ISO/IEC Guide 2.

4.0 MANAGEMENT REQUIREMENTS

4.1 Organization

Identify and eliminate potential conflicts of interest within the overall organization.

Identify and eliminate departures from the quality system.

Protect confidential and proprietary information.

Avoid activities that would diminish confidence in the lab.

Define the organization of the lab and the inter-relationships within the lab.

Have technically-competent management.

Appoint a quality manager for the lab.

Appoint deputies for key managerial personnel.

4.2 Quality System

Establish a quality system and document all policies, systems, procedures, and instructions.

Create a Quality Manual, to include:

a quality policy statement (management commitment, standards of service, objectives);

structure of documentation;

management roles and responsibilities.

4.3 Document Control

Control all procedures and identify and track all documents.

Create and maintain a Master List of Documents.

Insure that only authorized documents are in use.

Periodically review all documents and revise as necessary.

Remove invalid or obsolete documents from use immediately.

Uniquely identify each quality-system document.

Define and control the document revision process.

4.4 Review of Contracts

(Contains standard, common-sense requirements.)

4.5 Subcontracting of Tests and Calibrations

Choose only competent subcontractors who comply with ISO 17025.

Notify the client that subcontractors are being used.

Subcontractors must be approved by the client, whenever possible.

4.6 Purchasing Services and Supplies

Evaluate suppliers of goods and services that are critical to the quality of testing and calibration.

Inspect goods and services before use.

4.7 Service to the Client

Understand the client's needs and keep him informed of progress.

Seek feedback from the client.

4.8 Complaints

Have a procedure for resolving complaints.

Record all complaints and actions taken.

4.9 Control of non-conforming testing/calibration work

Assign responsibility and authority for handling nonconforming work.

Evaluate the significance of the non-conformity.

Take corrective action.

Notify the client.

4.10 Corrective Action

Find the "root cause" of all non-conforming work produced by the lab.

Select and implement the action most likely to eliminate the cause of the problem.

Corrective action should be appropriate to the magnitude and risk of the problem.

Monitor progress of the corrective action to insure effectiveness.

Document and implement any changes indicated by the corrective action.

If the nonconformity brings lab integrity into question, schedule an audit of the lab ASAP.

4.11 Preventive Action

Identify needed improvements and potential non-conformities.

Plan preventive action.

Ensure effectiveness of the preventive action.

4.12 Control of Records

Keep records of the quality system and of technical activity.

Store the records suitably.

Establish retention times.

Keep complete records of calibration results, made at the time of the tests.

Mistakes in recording results will be crossed out and initialed, but not erased.

4.13 Internal Audits

Audit the lab's activities at least annually.

Auditors should be independent of the audited facility.

If problems are found, take timely corrective action.

Follow up on corrective action to insure its effectiveness.

4.14 Management Reviews

Lab executive management will periodically review the lab's quality system and activity.

5.0 TECHNICAL REQUIREMENTS

5.1 General

(A list of factors that determine the correctness and reliability of the calibrations.)

5.2 Personnel

Only competent, qualified personnel can execute procedures.

Formulate goals for the education, training, and skills of personnel.

Identify training needs and provide training.

Keep records of authorization, competence, qualifications, training, and experience of personnel.

Maintain job descriptions for all personnel involved in tests or calibrations..

5.3 Accommodation and environmental conditions

Provide proper power, lighting, and environment to facilitate work.

Maintain the specified environment for testing.

Prevent cross-contamination by incompatible activities.

Control the access to testing areas.

Ensure good housekeeping.

5.4 Test and Calibration Methods and Method Validation

5.4.1 General

Use appropriate methods.

Where appropriate, estimate the measurement uncertainty.

Keep instructions for the use of all equipment up-to-date and readily available.

Deviation from established methods shall be documented and justified.

5.4.2 Selection of Methods

Use validated test methods that are suitable for the task and which meet the needs of and are approved by the client.

Methods published in international standards are preferred.

Lab-developed methods may be used if they are validated.

5.4.3 Laboratory-developed methods

The introduction of lab-developed methods will be planned and effective communication will be ensured.

5.4.4 Non-standard methods

Non-standard methods will be approved by the client and appropriately validated before use.

5.4.5 Validation of methods

Validation requires objective evidence that the selected method meets the requirements.

All test and calibration methods must be validated, regardless of origin.

Record the results of validation and the procedure used for validation.

The range and accuracy of values obtainable from validated methods shall be relevant to the client's needs.

5.4.6 Estimation of uncertainty of measurement

Calibration and testing labs will estimate the uncertainty of all measurements.

Where rigorous uncertainty analysis cannot be done, all relevant uncertainty components will be identified and a reasonable estimation of their magnitude will be made.

5.4.7 Control of data

Calculations and data transfers shall be systematically checked.

Validate and document all software written by lab personnel.

Protect the data generated in the lab.

Maintain the computers to insure the integrity of test and calibration data..

5.5 Equipment

Provide equipment that is capable of achieving the required accuracy.

Calibrate equipment before use.

Only authorized personnel will operate equipment.

Maintain a calibration record for each piece of equipment.

Protect and maintain equipment.

Remove defective or questionable equipment from use.

Examine the effect of having used defective or questionable equipment.

Update software to reflect changes in equipment parameters or correction factors.

Calibration status will be displayed on all equipment.

Prevent unauthorized adjustment of equipment.

5.6 Measurement Traceability

Calibrate equipment before use.

All equipment must have traceability (via unbroken chain) to national standards.

Reference standards shall be calibrated by a suitable agency.

5.7 Sampling

If sampling is employed, the sampling plan must be statistically justified.

Document requests by the client for deviations from the sampling plan.

Follow procedures for sampling and record the results.

5.8 Handling of Test and Calibration Items

Protect calibration/testing items.

Identify all items, to prevent confusion with similar items.

On receipt of an item, inspect it for damage, abnormality, and suitability for testing.

Provide safe storage facilities.

5.9 Assuring Quality of Test and Calibration Results

Monitor and ensure the validity of tests/calibrations.

Record data so that trends are obvious.

5.10 Reporting Results

Report the results of each test or calibration.

Include all information requested by the client.

Test reports and calibration certificates shall include a list of the items tested(see ISO 17025, page 20).

Test reports shall include measurement uncertainty and a statement of pass/fail with respect to requirements/specifications.

Calibration certificates shall include test conditions, measurement uncertainty and traceability.

Calibration certificates shall not recommend a calibration interval.

If possible, calibrate an instrument before and after an adjustment or repair.

Subcontractors doing calibrations will issue calibration certificates for their work.