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Application of ISO 17025, a Quality Model for Laboratories

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APPLICATION OF ISO 17025, A QUALITY MODEL FOR LABORATORIES

by

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This standard is for confirming the performance of laboratories. The name of the international standard is

"GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES"

The requirements of this standard are beyond ISO 9000 certification

Accreditation to ISO 17025 requires that a laboratory has a quality system similar to ISO 9000. More importantly, the standard requires that a lab facility has adequate equipment to perform its testing or calibration tasks, as well as laboratory personnel have the competence to perform the testing.

Therefore we can rightly say

ISO 17025 is recognition of laboratory competence, while ISO 9000 alone is simply recognition of conformance to a Quality system.

ISO 17025 benefits the company professional who are clients of testing and calibration labs. Now companies, manufacturers and quality people requiring outside testing and calibration services can rely on the accreditation process for assurance that the lab they choose meets minimum standards of competence.

Good companies ensure that they get their work done from subcontractors who are ISO 9000 certified and labs, which are ISO 17025 certified. Many companies are getting certifications for their in-hours test or calibration laboratories also. This gives them an assurance that an international standard of competence exists in their working methodologies.

It is understood that any lab with ISO 17025 certification will have gone thru the standard section by section. Wherever the standard states that an activity SHALL be performed, the laboratory makes sure to perform the procedure or activity as recommended.

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A typical assessment audit could consist of:

Reviewing Quality system documents / records
Examining the laboratory facility and equipment
International lab personnel for procedural competency
Witnessing laboratory procedures in action

With this background on ISO 17025 lets build a Purpose Statement for the standard.

What are the objectives?

a) Labs to produce accurate measurements results
b) Labs to provide suitable calibration reports

How can these be achieved?

By ensuring that:
Labs should have operating procedures and good laboratory practices.
Hence the purpose statement:

"To provide calibration laboratories with operating procedures and good laboratory practices that, if followed, will help the laboratories to produce accurate measurement calibration reports".

Calibration is defined as

The set of operations that establishes, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

Calibration laboratory is a lab that performs calibration
There are three types segregated as their role and task as Type I, II, and III.

Type I: Labs primarily calibrate measurement standards. These have all reference standards, check standards, calibration system. They monitor the measurement processes continually Highest Level of environmental control is applicable. Calibration reports MUST specify Uncertainties.

Type II: Labs that calibrate and test adjust measurement and diagnostic equipment for use in product testing, manufacturing and servicing etc.

These labs have appropriate working standards and calibration systems to be able to calibrate to a specification or tolerance.

Appropriate environment is ensured usually referred to as test equipment calibration labs.

Type III: Lab providing a reference capability must have appropriate reference or working standards.

Environmental conditions are relaxed in house calibration monitoring of their masters in snot available hence Masters are calibrated by Type II, and then used for maintaining in-house quality levels.

Type III & II are not required to give uncertainties as in Type I.

Uncertainty is defined as the deviation from accuracy, which might affect the result.
The sources and magnitudes of the uncertainties that contribute to the total uncertainty attributed to any measurement result can include:

- Traceability to designated standard
- Measurement technique
- Ambient conditions
- Behaviour of the measured device during the measurement
- Any other uncertainty, which can be defined

ENVIRONMENTAL

Specific environmental conditions are laid down by the standard including Temperatures, Humidity, Air Particle count, and Light and Noise levels.

One of the ways to improve air cleanliness is to maintain a positive air pressure differential of at least 12 Pascals (0.05 inches of water) between the inside and outside of lab.

Soldering, smoking, eating, drinking is not allowed as there actions can contribute to the generation of airborne particles

LIGHT: Appropriate lighting conditions need to be present.
A lighting level of 700-1000 lux is generally suitable.

NOISE: To ensure a pleasant working environment, noise should be as less as possible. It should be kept below 65 dB.

DOCUMENTATION CONSIDERATIONS

As in ISO 9000, a Quality Manual is to be made giving details of the company working. In ISO 17025 does not leave much at the company's will. It specifies exactly what is the minimum requirement as in the Environmental Considerations. Instead of saying we do it like this now we shall say it has to be done like this refering to clear instructions in the ISO 17025 Manual.

The overall standard focuses on two concerns separately:
The Management Policy concern and the Technical Concern. There are 14 clauses in the Management Requirements and another 10 clauses in the Technical Requirements.

We shall talk about some which are the most critical, necessary and not covered earlier in ISO 9000.

A cross-reference chart of ISO 17025 and 9000, 14000 can be made Standard for a more detailed examination and comparison.

The Management Clauses are almost similar to ISO 9000, specially the 2000 version, like

So now let see some clauses.

Clause	4.10	Corrective Action
	4.10.2	Emphasis is on Root Cause Analysis
	4.10.3	Selection & Implementation of Corrective Actions
	4.10.4	Monitoring of Corrective Action

Technical Requirements are more important.
The technical know how is given due importance in the laboratories.

Only Personnel with certified Skill can work Outline of background knowledge is also specified. This is in Clause 5.2 of the standard.

Clause 5.4 Test & Calibration Methods & Method Validation, these procedures have to be written with clear objectivity.

These are to be validated by readings at various times and conditions. The procedure should specifically mention those conditions where applicable.

The beauty of the system is that you can use your knowledge and experience in designing and implementing a procedure.

As long as it can be validated the method is an accepted procedure. What is Validation?

This focuses on Continuous Improvement and Initiative.

The equipment as in clause 5.5 has to be properly identified. The necessary Records have been clearly spelled out as in 5.5.5 page 15.

Intervals of Calibration are the owner's responsibility. The lab shall not give a next due date unless specifically asked by the client.

Clause 5.6 Talks about Measurement Traceability. Here Traceability is to be established to the SI units by means of an unbroken chain of calibrations or comparisons linking the test equipment to relevant primary standards of the SI units of measurement.

National measurement standards can be referred to, or direct international Type I labs can be utilized which are linked to the International Standards.

Then there is Sampling Methodology where applicable.

Clause 5.8 Talks about the handling of Test and Calibration items. Adequate procedures and facilities are to be established for avoiding deterioration, loss or damage to the test or calibration item during storage, handling, preparation and transportation.

All items coming to the lab have to be uniquely identified.

Clause 5.9 Here the quality of test and calibration results is to be assured through Accuracy inspections and history.

Clause 5.10 Deals with the contents of the calibration certificates and Test Reports.

It gives in detail what and why any specific information should be part of the Reporting.

With this discussion on these Clauses we come to the end of the paper.

Before I leave, I would request all of you to visit PMCL (Preventive Maintenance Calibration Laboratory) established at PITAC (Pakistan Industrial Technical Assistance Centre) Lahore as we have made it as a working model for ISO 17025. We shall be going for the certification by end of this year. PMCL follows an open door policy and shall be pleased to share the system know how.

AUTHOR'S SYNOPSIS

Nouman Ali Khan is presently Executive Director of Alpha Plus Systems. He did BE Aerospace from PAF College of Aeronautical Engineering and MBA Marketing from The International University. He started his career as Maintenance Engineer in PAF in 1982. In 1998 he joined INSPECTEST as Head NDT and Industrial Safety and Training. In 1999 he took over the Quality Control of DESCON and remained there till 2001. In September 2001, Alpha Plus Systems was launched providing services to the industry in the fileds of Inspection, calibration, training and consultancy on ISO 9000, ISO 14000 & ISO 17025.

He has presented papers in many publications and national conferences, including ICQI (PIQC), Pak. Aeronautical Conference , Army Dte. Of Inspections, PWI (PAEC).

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