

## B. INTRODUCTION TO ISO/IEC 17025: AN OVERVIEW

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### 1. Introduction

In today's competitive market climate, good business demands that products and services be designed, produced, delivered, installed and serviced under controlled, consistent and safe conditions. Several quality standards were developed in various countries in the 1960's and 1970's. The MIL-Q-9858A in the United States in 1963 and the BS 5750 in the United Kingdom in 1979 are the most important ones. The ISO 9000 series of quality standards have been established in 1987 for implementing and maintaining a quality system, which is internationally accepted and can be used as a criterion for third party quality assessment. Many national and international regulations and standards are available to ensure that the conditions are met. Among those are the ISO 9000 and the ISO/IEC 17025.



Figure 4. Mr. Farid Ullah Khan giving his talk on ISO 17025.

**ISO/IEC 17025:** "Management system" refers to the organization's structure for managing its processes - or activities - that transform inputs of resources into a product or service which meet the organization's objectives, such as **satisfying the customer's quality requirements**, complying to regulations, or meeting environmental objectives.

ISO 9001 is a generic management standard that can be applied to any business enterprise, public administration, or government department.

Growth in the use of management systems generally has increased the need to ensure that laboratories can operate to a quality management system that is seen as compliant with ISO 9001 as well as demonstrate technical competency. Therefore, ISO 17025 was written to incorporate all the ISO 9001 requirements that are relevant to the scope of testing and calibration services as well as specifying the technical requirements for technical competence. ISO/IEC 17025, focuses on the laboratory competence. ISO/IEC 17025 provides guidance to owners and operators of laboratories on both quality management in a laboratory environment and technical requirements for the proper operation of a testing laboratory.

ISO/IEC 17025 is a recently introduced standard from the International Organization for Standardization and the International Electrochemical Commission. ISO/IEC 17025 replaces a number of old standards and guides including ISO/IEC

Guide 25, EN45001 and ANSI/NCSL-Z540. It is a global standard for the technical competence of calibration and testing laboratories in addition to establishing quality system, documentation and personnel requirements. ISO/IEC 17025 is the single most important metrology standard for test and measurement products. Nearly all standards bodies and accreditation agencies around the world have adopted it.

## 2. What does ISO/IEC 17025 Cover?

ISO 17025 covers every aspect of laboratory management. It involves everyone in the laboratory, including the laboratory manager, assistant laboratory manager, or quality manager. The standard also involves all laboratory staff whose functions relate to the quality of laboratory data generated. A laboratory's fulfilment of the requirements of ISO/IEC 17025:2005 means that the laboratory meets both the technical competence requirements and management system requirements necessary for it to consistently deliver technically valid test results and calibrations.

The standard was revised in 2005, the purpose of which was to align it with ISO 9001:2000. Unlike before, the two standards are now considered to be compatible rather than fully aligned. The revision makes it clear that meeting the requirements of ISO/IEC 17025 does not automatically mean that the requirements of ISO 9001 are met. The standard does however recognize that, by being accredited to ISO/IEC 17025, a laboratory will meet the principles of ISO-9001. Consequently, laboratories may choose to be accredited to ISO/IEC 17025, or be certified to ISO 9001, or both, but the

processes of accreditation and certification would be two separate actions.

## 3. The Need for Competent Laboratories

The lack of acceptance of laboratory test data across national borders has been identified as a significant barrier to trade. The World Trade Organization has adopted two major new agreements to ensure that technical requirements do not restrict trade: The agreement on Technical Barriers to Trade (TBT); and the Agreement on Sanitary and Phytosanitary Measures (SPS).

Asia Pacific Economic Cooperation (APEC) has given priority to conformity assessment issues. The Declaration on APEC Standards and Conformance Framework and Osaka Action Agenda confirm the intention of members to achieve mutual recognition of conformity assessment among the eighteen APEC economies in both the regulated and voluntary sectors. Activities are being coordinated through the APEC sub-committee on Standards and Conformance with direct involvement from the "specialist regional bodies", including the Asia Pacific laboratory Accreditation Cooperation (APLAC). Other regional trade groupings are also enhancing cooperation in standards and conforming in order to facilitate trade.

Regional and international mutual recognition agreements are in place to facilitate acceptance of conformity assessment results, which include test results. These include the International laboratory Accreditation Cooperation (ILAC) and the APLAC.

These agreements and policies aim to avoid expensive testing. If they are to be effective, regulators and customers must be

able to rely on test conducted in other countries. They need to know the status and competence of the testing laboratories supplying the data and to have independent assurance that the test results are valid.

When testing laboratory implements an internationally accepted standard for good laboratory practices such as the ISO/IEC 17025 standard, the laboratory demonstrates that it has the competence to perform the tests and the test results produced are valid. Test reports/data generated by these laboratories provide Government bodies and regulators with the confidence in order to make their decisions based on sound technical judgments. These decisions relate to industry efficiency and technological development, enforcement of regulations for safety, health, environment protection and assure consumer interests are protected.

ISO/IEC 17025 is a specification for calibration and testing laboratories, applicable to any type of organization regardless of size, location or the range of services they provide. The majority of information is contained in 2 of its sections:

- Management requirements and
- Technical requirements

#### **Management requirements include:**

- Organization and management
- Quality system
- Document control
- Review of request
- Subcontracting of tests and calibrations
- Purchasing services and supplies
- Service to the client
- Complaints
- Control of non-conformity testing
- Corrective action

- Preventive action
- Records
- Internal audits
- Management reviews

#### **Technical requirements include:**

- General
- Personnel
- Accommodation and environmental conditions
- Test and calibration methods including sampling (This includes requirements for method validation (laboratory developed, non-standardized, standardized but used outside of their intended range) and measurement uncertainty)
- Equipment
- Measurement traceability
- Sampling
- Handling and transportation of test and calibration items
- Assuring the quality of test and calibration results
- Reporting the results

#### **4. What are the Benefits of Accreditation?**

As with any well-constructed standard, ISO 17025 is not to be considered as an unnecessary imposition on your time and efforts. It is designed to help you to improve, and then maintain, your quality and standards. By following the procedures and methods specified, everyone can be assured of the accuracy and integrity of your laboratory. However, you will have to continually monitor your quality processes to ensure that they continue to meet the guidelines of this standard. This is of great use to everyone, because rigorous quality processes mean fewer failures and errors.

It is also important to remember that as more calibration laboratories become accredited; correlation between these accredited laboratories' measurements will improve, thereby improving the general quality of the measurement process everywhere.

The International Standard ISO/IEC 17025 provides a defined and ordered process for operating all facets of a laboratory. It is the basis for laboratory accreditation programmes today. In particular, it specifies the general requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a management system that is technically competent and able to generate technically valid test results and calibrations.

#### **5. ISO/IEC 17025 accredited laboratories in Pakistan:**

Manufacturing enterprises and testing laboratories in Pakistan need reliable and credible source to calibrate the instruments used to measure, produce and test export products. Hence, UNIDO under TRTA programme initiated, in cooperation with the Ministry of Science and Technology, Government of Pakistan, various activities to build the capacities of National Physical and Standards Laboratory (NPSL), which is the custodian of the national physical standards of measurement in Pakistan.

Realizing the requirements and urgency of the issue, the Cabinet approved the National Quality Policy & Plan (NQP&P) in November 2004, which envisages strengthening of the National Quality Infrastructure to meet international requirements that will achieve accelerated economic growth, export enhancement and ensure supply of safe and quality products in the local market at competitive prices.

Standards create common understanding and criteria on products and processes facilitating trade relations. In Pakistan, overall responsibility of standard setting and certification lies with the Pakistan Standards and Quality Control Authority (PSQCA).

Pakistani exporters had to test their products abroad for international recognition of compliance, which was costly and time consuming. Such foreign testing were not only expensive but contributed to delays in receipt of test results thereby affecting adversely delivery times for exports from Pakistan. To facilitate timely access to testing, calibration and certification services and upgrading local safety and product performance standards to bring them at par to international requirements, Pakistan National Accreditation Council (PNAC) was launched to accredit testing and calibration laboratories in accordance with ISO/IEC 17025, Quality and Environmental Management System

PNAC has been established under the administrative control of the Ministry of Science and Technology, Government of Pakistan as the national apex agency to accredit conformity assessment bodies such as laboratories and certification bodies. The accreditation services of PNAC were launched during the year 2001. The seminal role of PNAC, is of prime importance, which is could play in accreditation of laboratories and eventually producing quality culture in Pakistan.

PNAC represents Pakistan in the following regional and international forums:

- International Laboratory Accreditation Cooperation (ILAC)

- International Accreditation Forum (IAF)
- Asia Pacific Laboratory Accreditation Cooperation (APLAC)
- Pacific Accreditation Cooperation (PAC)

#### 6. Accredited laboratories:

- a) National Physical and Standards Laboratory (NPSL), Islamabad
- b) Pakistan Council of Scientific & Industrial Research (PCSIR), Karachi
- c) Pakistan Council of Scientific & Industrial Research (PCSIR), Peshawar
- d) Qureshi Research International (Pvt.) Limited, Hattar
- e) Platinum Pharmaceuticals (Pvt.) Limited, Karachi
- f) Leather Research Centre(LRC), PCSIR, Karachi
- g) SGS Pakistan Textile Laboratory, Karachi
- h) Metrological Centre, F6 Rebuild Factory, Kamra
- i) Explosives (Chemical) Laboratory (XL), POF Wah Cantt
- j) Dimensional Metrology Laboratory (DML), POF Wah Cantt
- k) Metallurgical Laboratory (ML), POF Wah Cantt
- l) Neutron Activation Analysis Laboratory, PINSTECH, Nilore
- m) Fuel Research Centre (FRC), PCSIR, Karachi
- n) Process Laboratories, Pakistan Steel, Karachi
- o) Pakistan Tobacco Company Ltd. Akora Khattak, Nowshera
- p) SGS Pakistan Textile Laboratory, Lahore
- q) Mirage Rebuild Factory (MRF), PAC Kamra
- r) Mineral Testing Laboratory, Exploration Promotion Division, Peshawar
- s) Efroze Chemical Industries (Pvt) Ltd, Karachi
- t) 1SGS Chemical & Environmental Laboratory, Karachi
- u) Pakistan Council of Scientific & Industrial Research, Lahore
- v) Sarena Industries & Embroidery Mills (Pvt), Lahore
- w) Shakarganj Mills Ltd, Jhang
- x) Attock Refinery Ltd, Rawalpindi
- y) Interloop Limited, Faisalabad.
- z) Shaigan Pharmaceuticals, Rawalpindi.
- aa)BV Consumer Products Services Pakistan (Pvt) Limited