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Establishment of an ISO/IEC 17025:2017 Accredited Electrical Testing Laboratory in Pakistan

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***Abstract*- Accreditation is a formal way to get a confirmation for technical competence, worldwide recognition and reporting technically valid results against internationally accepted testing methods. It also removes the technical barrier to trade (TBT) and enhances exports. The key factors are equipment, personnel, facilities/environmental conditions, testing methods, quality assurance and metrological traceability. This paper provides guidelines on the establishment of an "Accredited Testing Laboratory in Pakistan" based on ISO/IEC 17025:2017 standard, Pakistan National Accreditation Council (PNAC) policies, applicable IEC Testing methods and Quality Management System (QMS) developed at National Institute of Electronics (NIE) which forms the basis for accreditation. The Center for Quality Testing (CQT) at NIE has been established since 2008 and achieved remarkable achievements till date having implemented accreditation. The market share has been increased many folds. The suggested accreditation guideline shall also be exhibited for the betterment of the quality infrastructure for the newly established laboratories seeking accreditation. The same may be applicable for accreditation of calibration laboratories**.

***Index Terms*—Accreditation, Calibration, Competence, IEC, ISO/ IEC 17025, NIE, PNAC, QSD, QMS (Quality Management System), TBT**

I. INTRODUCTION

Accreditation is a process under which Conformity Assessment Bodies (CAB's) are assessed ensuring their compliance to ISO/IEC 17025:2017 standards and IEC testing methods. This has now become a global requirement for ensuring the quality of results in many areas including laboratories, industries, service organisations and hospitals etc. Accreditation is a handy tool for improvement of product/ service quality and provides information to the facility or program as well as to the users from general public [1-5].

Any agency, department, organisation, institute or laboratory that carries out testing or calibration, may seek accreditation of its activities irrespective of the fact whether these are undertaken in a permanent facility or on site through a mobile service [5-7].

The scope of accreditation is a document that defines the capability of laboratory for which the laboratory is accredited. The scope also defines the range of measurand (quantity to be measured) along with the associated uncertainty of measurement for each range.

A test certificate or report, as required by ISO/IEC 17025:2017, shall [1,4] demonstrate the metrological traceability to established National or International Standards of measurement, associated uncertainty of measurement and a statement of compliance [3,7] with identified metrology. Calibration Certificates of an accredited laboratory are considered enough to satisfy the requirement of metrological traceability. Where accredited calibration facility is not available, other tools may be considered to achieve metrological traceability as required by the standard "ensuring the validity of test results". Statement of metrological traceability will be an added advantage and provide confidence to customer [8-14].

Electrical testing laboratory with electrical safety testing includes at-least Hi-pot (Di-electric Withstand or Electric Strength Test), Ground Bond Test, Line Leakage Test (LLT) and insulation Resistance (IR) Test. These are generic electrical safety tests which are required for almost all consumer products in general that they comply with the specifications and safety standards before they are put in use [15-20].

Seeking accreditation to ISO/IEC 17025:2017 is an important step to achieve worldwide recognition. Accredited Electrical Testing laboratory plays a vital role in production of energy efficient products and energy management.

II. LITERATURE REVIEW AND METHODOLOGY

A. ACCREDITATION BODIES

International Laboratory Accreditation Corporation (ILAC) [15, 21] is the international organisation for accreditation bodies operating in accordance with ISO/ IEC 17011 and involved in the accreditation of CAB's in accordance with ISO/ IEC 17025:2017. Other than ILAC there are some established regional accreditation bodies such as European Cooperation for Accreditation (EA) [14] and the Asia Pacific Accreditation Cooperation (APAC) [13] etc. Almost every developed country of the world have their own national accreditation bodies such as United Kingdom Accreditation System (UKAS) [18], American Association for Laboratory Accreditation (A2LA) [12], Norwegian Accreditation Board (NAB) [16, 22] and Pakistan National Accreditation Council (PNAC) [17, 23] in Pakistan.

The PNAC operates under the administrative control of Ministry of Science and Technology, Government of Pakistan. PNAC is an apex national body working since 1996 for accreditation of CAB's undertaking Testing, Calibration, Certification, and Inspection activities etc. PNAC grants accreditation to those laboratories which demonstrates competency to ISO/ IEC 17025:2017, relevant testing methods (e.g. IEC 60335-1 etc.), PNAC policies, and ILAC relevant regulations and guidelines.

B. PRE-REQUISITES FOR ACCREDITATION

PNAC ensures that the laboratories have enough documentation to comply with Management, Structural, and Resource and Process requirements of ISO/ IEC 17025:2017 standard. Other important parameters for accreditation are technical competence, equipment, verification/ validation, and metrological traceability of testing equipment.

The significant requirements of PNAC are as follows:

- Laboratory Structured ensuring Impartiality and Confidentiality.
- Risks to impartiality and other laboratory activities identified.
- Developed Procedures both Management and Technical.
- Testing equipment available and metrological traceability demonstrated.
- Technical competence: e.g. trained and qualified staff, calibrated equipment, maintained environmental conditions etc.
- Uncertainty of measurement evaluated with identified contributions to it.

- Appropriate mechanism for root cause analysis of non-conformance/ problems and implemented Corrective Actions.

C. PARTICIPATION IN PT /ILC SCHEMES

Laboratories seeking accreditation are required to achieve good Z-score in PT/ ILC before getting accredited. In absence of relevant PT/ILC, the lab has to prove its competence through monitoring the validity of results by testing of CRM/ SRM, retesting/replicate testing, blind sample etc. All PT/ ILC activities recognised by APAC, ILAC, EA, members of ILAC and APLAC are acceptable by PNAC. The labs have to participate in same or similar type of PT/ ILC where it is not available as relevant to the scope of the lab to demonstrate its competency [2, 24-28].

If consistent outlier in Proficiency Testing/ Inter-Laboratory comparisons appears then PNAC may suspend the relevant tests from the laboratory's scope of accreditation during regular surveillance assessment.

D. REGULATIONS

To use the accreditation mark, an organisation shall:

- Be accredited with valid accreditation certificate.
- Comply with the PNAC policies.
- Accredited organisations can use the accreditation mark in promotional and publicity materials.
- Accredited organisations can use the accreditation mark for letters.
- Can be used on business cards held by the accredited body's staff.
- The accreditation mark shall not be used to demonstrate the accuracy of tested item covered under accreditation.
- More details are available in [17]

E. THE ACCREDITATION PROCESS

Any organisation seeking accreditation may follow the following steps:

- Finalise the scope of electrical testing with relevant IEC standard on which they want to get accredited e.g. IEC 60335, 60950 etc.
- Manpower training on ISO/IEC 17025: 2017, standard testing methods which can be gained through introductory courses.

- Laboratory can hire relevant professional for the development of QMS.
- Develop Quality Manual, Management and Technical Procedures Manual as per requirements of the standard.
  - The laboratory shall assign Quality Manager, Technical Manager, and deputies according to the scope and size of organisation.
  - Trainings of staff for the implementation and maintenance of the Quality System Documentation (QSD) shall be initiated.
  - Work instructions, Testing Procedures, PT/ ILC participation shall be planned and participated.
  - The process of accreditation with PNAC starts from enquiry through Phone/ Fax/ Letter/ Email/ Visit/ Info pack etc.
  - Submission of application to PNAC on prescribed form with all relevant prepared documents.
  - The application is processed by PNAC and assigned to the relevant Deputy/Director.
  - Preliminary review of documentation is conducted at PNAC by the relevant Director.
  - With the approval of Director General (PNAC), Pre-assessment of the Lab is planned to be conducted by a Lead Assessor along with relevant technical expert.
  - Any Gaps identified during the pre-assessment are reported on the report form F02/05 of PNAC.
  - Upon successful revision of identified gaps, a full assessment is carried out by PNAC assessment team comprising of Lead Assessor and Technical Assessor(s)/ Expert(s).
  - The result of the full assessment is recorded in the Lead Assessor's report accompanied with individual reports of Technical Assessor/ Expert having description of Observations and Nonconformities (NC's) identified during the assessment activity.
- The laboratory is required to take Corrective Actions and rectify the NC's within the stipulated time period (Normally 6 to 12 weeks). Upon successful root cause and correction of raised NC's concerned Deputy/Director submit the file to Accreditation Committee, comprising upon professional experts.
- Director General PNAC approves grant of accreditation status to the Lab, if the same has been recommended by the accreditation committee.
- Accreditation documents including the Accredited Scope and Accreditation Certificate are prepared and sent/ issued to the concerned laboratory. Fig -1 shows the standard flow chart diagram.

F. PNAC POLICIES

PNAC has formulated policies on the following to address relevant topics:

- Use of PNAC's Logo as Accreditation Mark; G-02/02
- Grading non-conformities; G-02/03
- Calibration of Weighing Machines and Weights of Testing Labs; G-02/05
- Calibration of Thermometers in Connection with Accreditation of Testing Labs; G-02/06
- Method Validation; G-02/11
- Accommodation and Environment; G-02/12
- Participation in Proficiency Testing; G-02/13
- Assuring the Quality of Testing/Calibration Results; G-02/14
- Traceability of Measurement; G-02/15
- Conflict of Interest, Confidentiality, Intellectual Property and Duty Loyalty; G-05/02

  [For details refer to PNAC's above mentioned guidelines such as G02/03, G-02/13 etc.]

A. OVERVIEW OF NIE/CQTC QUALITY MANUAL

The Quality Management System established at NIE; Pakistan has been established as follows:

The development of laboratory Quality Manual having stated policies on management requirements of the standard, including Quality Policy statement, Quality Objectives, laboratory and organisational structure, customer requests and services, control of Non-conforming work, Corrective/ Preventive Actions, Internal Audits and Management Reviews.

The second part deals with the technical operations, which includes training of Personnel, Facilities and Environmental Conditions, use of Validated and Verified Test Methods, Equipment Maintenance and Calibration, Metrological Traceability (Calibration from accredited laboratory or use of reference/ standard materials), evaluation of Uncertainty of Measurement, Handling of Test items, PT/ ILC plan and participation, assuring the Quality and Validity of results and reporting of Test results. The organogram developed in testing lab of NIE is referred in fig: 2

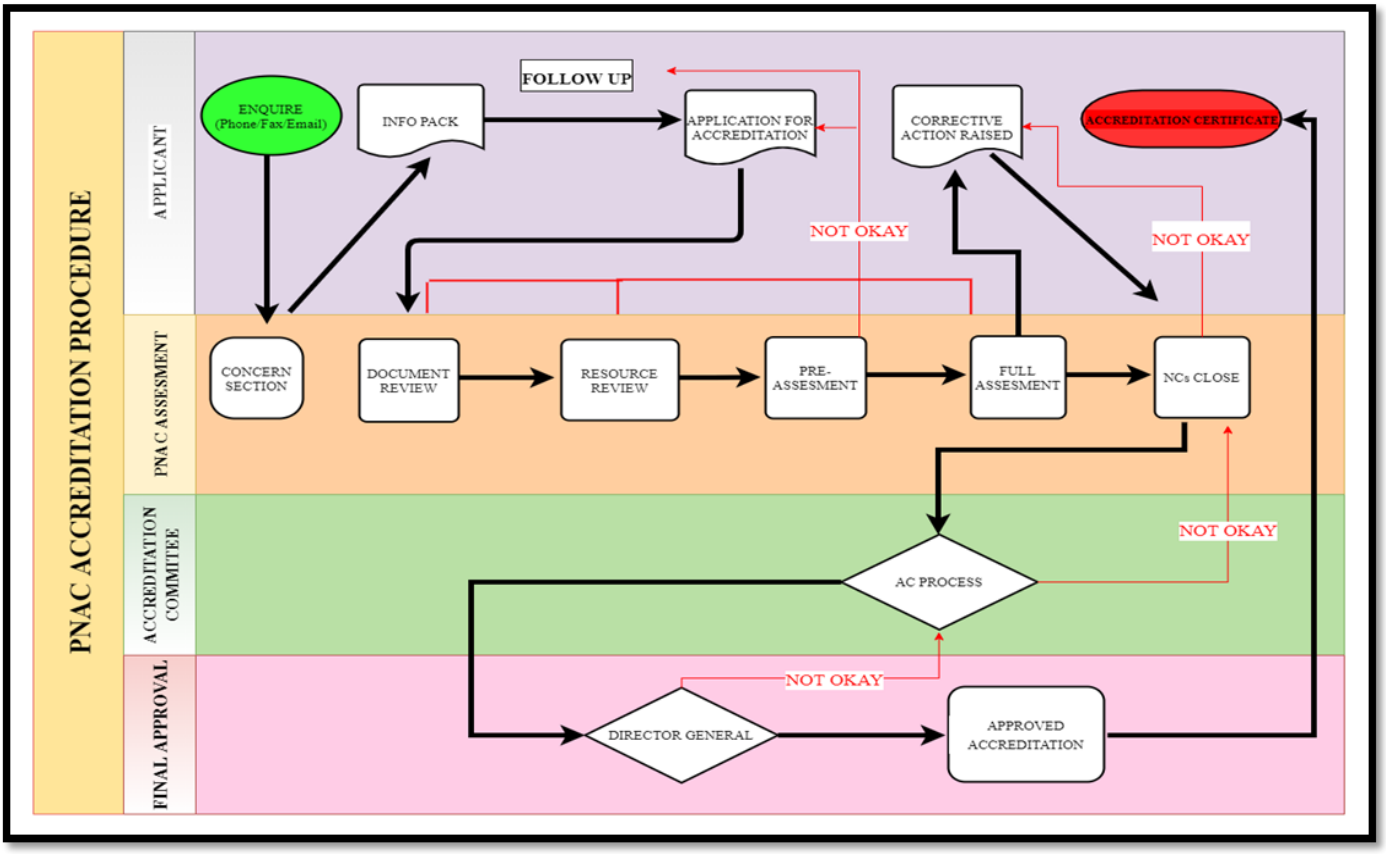

Fig-1: Flow Chart of Accreditation Process (PNAC);
Complete flow is depicted starting from customer inquiry to the grant of accreditation from PNAC

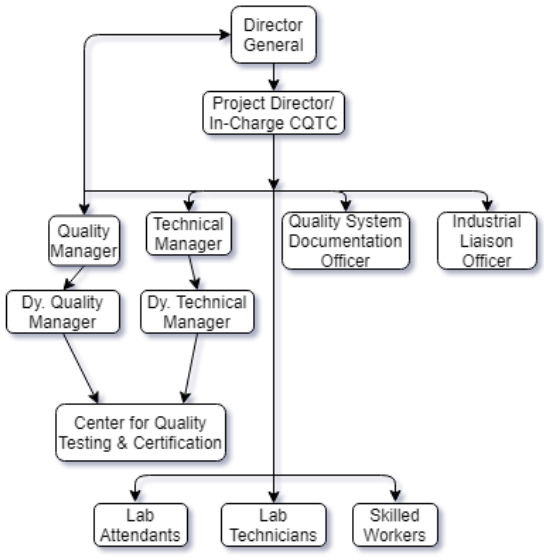

Fig-2: Organogram Implemented at NIE/CQTC
(Quality and Technical Manager are deputed to review and verify the testing operations and issuance of test results reports).

III. CONCLUSION

The establishment of an accredited Electrical testing laboratory in Pakistan has been comprehensively defined and structured in the paper. Literature study concludes that the revenue generated after accreditation for governmental owned and private laboratories is increased by about 10% [11]. Data analysis suggests that it is increased by 08~09 % after certification, which is very reasonable as there is proper no legislation in the country. Competition of accredited testing is not healthy so far in Pakistan. This paper will give a jump-start to already working laboratories seeking accreditation.

The benefits of accreditation that a Lab can gain are summarised below:

- Technical competence ensured.
- Reduce technical barriers to trade.
- Worldwide Testing/ Calibration acceptability.
- Provides a productive environment for continual improvement & increase customers confidence.
- Inculcate quality culture in the laboratories/organisations
- Meets regulatory/ procurement requirements

The procedural steps defined in this paper will help new electrical/ electronic testing labs of Pakistan to achieve accreditation status from PNAC and join the community of accredited laboratories.

The role of the NIE testing lab is also highlighted as a critical aspect for the growing industry. It can be reported as a demonstrated function to all testing facilities which are yet to be launched among Pakistan's industry.

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