CASE STUDY

Guidelines for Establishing Calibration Systems

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GUIDELINES FOR ESTABLISHING CALIBRATION SYSTEMS

by

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ABSTRACT:

The Inspection, Measuring, Test, Logging, Plotting and Process Control Equipment are the key tools to regulate, develop and approve the quality of the products of any industry. If the equipment itself is working within the specifications of permitted error limits, the measurement taken will be correct. The confidence on the measurement and competency of the equipment becomes internationally acceptable if the instruments are traceable to International or National Physical Standards.

Throughout the world, besides the government owned calibration laboratories, always there are a number of accredited calibration laboratories working for the measurement transfers in the private sectors. Some of the International Accreditation Systems for Calibration Laboratories like STP, Denmark / RNE, France / TELARC, New Zealand / NATA, Australia / NVLAP, U.S.A and NAMAS (UKAS), U.K etc. are discussed. The Accreditation Systems for Calibration Laboratories helps the government owned calibration laboratories as the load of calibration work is shared and time of industries is saved.

In the Accreditation Systems for Calibration Laboratories only approved calibration labs are allowed to undertake the calibration. The National / Primary and Secondary Standards Laboratories certify the Laboratory Reference Standards of accredited calibration laboratories and issue the essential documents. However the accreditation status and authorization of such calibration laboratories working in Pakistan is yet to be decided. Suggestion for running the PCSIR Accreditation Systems for Calibration Laboratories in Pakistan and fixing the authorization is given in the paper.

Key words: Calibration, Traceability, Accreditation of Calibration Laboratories, Authorization.
1. INTRODUCTION:

The inspection, measuring, test, logging, plotting and process control equipment are the key tools to regulate, develop and approve the quality of the products of any industry. If the equipment itself is working within the specifications of permitted error limits the measurement taken will be correct and production will comply with the specifications. The confidence on the measurement and competency of the equipment becomes internationally acceptable if the instruments are traceable to any international or national physical standards [1]. If these instruments are not functioning within their inbuilt limits of error claimed in specifications data or indicated in the certificate of calibration of compliance of accuracy, the production will not be satisfactory and there may be a great rejection ratio. Thus for all type of industries, the integrity of the instruments may always be questionable. After detailed implementation of quality standards ISO 9000 : 1994, it has been experienced that most powerful clauses are 4.9 (Process control), clause 4.10 (Inspection and Testing) and clause 4.11(Control of Inspection, Measuring and Test Equipment). The clause 4.11: ISO 9001 : 1994 itself is a strong check on the instrumentation and it should be implemented with its true requirements. The industries have to establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment to demonstrate the conformance of product to the specified requirements. The inspection, measuring and test equipment in any industry should be selected and used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability. Once the inspection, measuring and tests instruments are used there are six major causes for which the instruments need the periodic calibration at prescribed intervals against the certified equipment having a known valid relationship to internationally or nationally recognized physical standards [2], [3]. The calibration of all the critical instruments of any industry is carried out using the certified and traceable instruments. The certificate of compliance to the accuracy and traceability of these limited instruments may be received from any of the National Standards Laboratory or Secondary Standards Laboratory or some authorized calibration laboratory of private sector.

2. TRACEABILITY AND TRACEABLE MEASUREMENT SYSTEM:

The International Vocabulary of Basic and General Terms in Metrology (VIM; 1993) defines traceability as:

The property of the result of measurement or the value of a standards whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

Many government regulations and commercial contracts require regulated organizations or contractors to verify that the measurements they make are “traceable” and to support the claim of traceability by keeping records that their own measuring equipment has been calibrated by laboratories or testing facilities whose measurements are part of this “unbroken chain.” The purpose of requiring traceability is to ensure that measurements are accurate representations of the specific quantity subject to measurement, within the uncertainty of the measurement [4].
Industries/organizations may require traceability of their measurement to national physical standards in order to meet contractual obligations, to satisfy the requirements of ISO 9000 series standards or to establish the legal status of measurements [5]. In the developed and under developing countries National Measurement Systems (NMS) are effectively implemented using the National Physical Standards [6]. The existence of the NMS help in undertaking the coherent measurements and this is achieved through a government owned National Measurement Laboratory (like NPSL, Islamabad) housed with National Physical Standards. Besides the National Measurement Laboratory oftenly there are a few government owned Secondary Standards Calibration Laboratories (like PCSIR, Lahore and PCSIR, Karachi). However due to increased work load on the government owned calibration laboratories some additional calibration laboratories are accredited from the private sector. The calibration labs working in the private sector are accredited through a tough criteria.

2.1. Present Trends of Calibration: In Pakistan, regarding the calibration activities in most of the industries seeking the registration for ISO 9001/9002, a misunderstanding has been developed that each of the critical instrument must be calibrated from the out side calibration laboratory. A medium volume industry may have over 100 critical instruments declare for calibration. The ISO 9001/9002 require to arrange the calibration of all the critical instruments which effect the quality of the product against the certified instruments [2]. In fact a limited number of instruments, one for each parameter (an average of eight instruments) are selected or arranged and sent for calibration from outside calibration laboratory like NPLS, Islamabad or PCSIR Cal. Lab., Lahore or any other accredited / authorized calibration laboratory. This is the general practice being exercised in other developing and developed countries. Usually, these certified instruments are named as Laboratory Reference Standards and used for the in-house calibration. Besides the Quality Control Laboratory, a small in-house calibration set-up must be established in each industry (i) seeking the registration for ISO 9001/9002 and (ii) already certified for ISO 9001/9002 obtained the registration. This set-up proves a cost effective, time saving and self controlled solution for the implementation of clause 4.11 arranging a team from Q.C Laboratory and Maintenance persons. This additional job may be assigned to any responsible person who already arranges to complete the calibration job from the outside calibration laboratory after an interval of three to six months or due to immediate calibration requirement [2]. Throughout the country, the PCSIR Calibration Laboratories help to design and develop the in-house calibration set-up and over 200 national and multi-national ISO 9001/9002 certified industries. Our clients have established their own cost effective and time saving in-house calibration facilities.

Because the integrity of the instruments is the most important factor for the traceable measurements system, the selection of out side calibration laboratory is a still an issue to be resolved in Pakistan. Like other countries the accreditation systems for calibration laboratories have proven the effective solution and there is an immediate need of launching a similar accreditation system in Pakistan. Some of the international accreditation systems are discussed below.
3. INTERNATIONAL ACCREDITATION SYSTEMS:

The national measurement systems are supported by the national measurement laboratories and a parallel chain of accredited calibration laboratories. The permitted parameters (instruments) covered by the accredited labs are decided on their capabilities and resources. Some examples of calibration accreditation systems for the calibration laboratories are quoted for the interest of reader:

3.1. Tekniske Provenasvn (Scredited TP), Denmark

Organisation/Structure: Government, Ministry of Commerce


Evaluation Criteria: Highly trained and qualified head, trained staff, equipment, laboratory practice, accommodation and other technical aspects, the sub-topics for discussion are sampling & sample identification, supervision of staff, staff training, selection, maintenance of equipment, quality control, use of reference material, record systems and method of reporting.

Selection of Lab Assessors: Selected on the basis of (a) commercial impartiality and objective, and of the necessary knowledge; (b) their own personal experience and knowledge.

3.2 RESSEAU NATIONAL D’ESSAIS (ENE), FRANCE:

Organization/Structure: Private non-profit organization supported by Government.

Evaluation Criteria: The laboratory shall have a permanent policy for quality management including qualified and trained head and staff, details of test methods, proper testing equipment, access to reference standards of measurement and the suitable environment. The competent sectorial committee, in collaboration with the Permanent Secretariat visits at least once a year and carries out an inspection reporting whether to maintain, suspend or withdraw the authorization. The sectorial committees may furthermore, stipulate that accredited laboratories participate for inspection purposes in inter-comparison campaigns or in calibration of reference standards/amples.

SELECTION OF LAB ASSESSORS:
As per qualifications and expertise in relevant fields.

3.3 TESTING LABORATORY REGISTRATION COUNCIL (TELARC), NEW ZEALAND:

Organisation/Structure: Government

Apex Body: Testing Laboratory Registration Council (founded in 1972).
Evaluation Criteria: Highly trained and qualified Head/Staff, equipment, laboratory practice & accommodation, traceability of measurements test methods, records, systems, reporting of calibration/test results, retention of documents, instruments and samples, safety and environment, etc.

Selection of Lab Assessors: The reinstatement of a suspended registration will be consequent upon a satisfactory special reassessment. A special reassessment fee is levied.

3.4. NATIONAL ASSOCIATION OF TESTING AUTHORITIES (NATA), AUSTRALIA

Organization/Structure: Limited Company since 1946.

Evaluation Criteria: Trained/qualified staff, test equipment, accommodation space, lighting, ventilation, safety, cleanliness and storage facilities, laboratory practice-collection of samples, transport, handling and storage, receipt of calibration instruments/samples & identification, non-acceptance criteria for samples specification of tests, allocation of work, quality control programme, recording of test results, checking of calculation, reporting of calibration/test results, security of the system.

Selection of lab Assessors: Selected on the basis of: (a) commercial impartiality & objectivity, and (b) with knowledge & reputation in particular.

3.5. NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAMME (NVLAP), U.S.A :

Organization/Structure: Government, U.S. Department of Commerce

Apex Body: National Institute of Standards and Technology

Evaluation Criteria: The basic procedures and general accreditation requirements of NVLAP are described in NIST Handbook 150.

Selection of Lab Assessors: Whatever steps a participating laboratory may take to improve or assess its measurements process are taken voluntarily [7].

3.6. NATIONAL MEASUREMENT ACCREDITATION SERVICE (NAMAS), UK & UNITED KINGDOM ACCREDITATION SERVICE (UKAS), UK:

The British Calibration Services (BCS), U.K and National Testing Laboratory Accreditation Scheme (NATLAS), U.K were working under the umbrella of the National Physical Laboratory (NPL), U.K. During the late 80’s an average of 130 calibration laboratories were accredited by the BCS. The merger of BCS and NATLAS resulted in NAMAS and the number of accredited labs has been increased. Further, UKAS was formed by the merger of the National
Measurement Accreditation Service and the National Accreditation Council for Certification Bodies. A laboratory seeking accreditation has to meet stringent requirements set out in two key publications: NAMAS Accreditation Standard (M10) and NAMAS Regulations (M11). Both of these publications are available from UKAS. The M10 and M11 are consistent with internationally agreed documents (ISO/IEC Guide 25 and EN45001).

NAMAS/UKAS requirements for laboratories: NAMAS Accreditation Standard (M10) and NAMAS Regulations (M11) include requirements under the following headings:

UKAS provides publications to amplify and interpret M10 and M11 in specific areas of calibration and testing. These publication are listed in NAMAS Publications, M4.


Note: A parallel quality system like BS5750 / ISO9000 exists for complete activity of NAMAS/UKAS [8].

4. PCSIR ACCREDITATION SYSTEM FOR CALIBRATION LABORATORIES IN PAKISTAN:

There is essential need of an accreditation system for various calibration laboratories to arrange a uniform service of authenticated and traceable calibration of measuring instruments, gauges and reference standards to all those who make measurements. The PCSIR being the prime Research and Development organization already has completed a project of development of the National Physical and Standards Laboratory (NPSL), Islamabad. Now this highly technical project for the establishment of an accreditation system for calibration laboratories working in Pakistan may be floated by the PCSIR. Initial voluntary work has been started and two PCSIR Calibration Laboratories (one in Lahore and one in Karachi) are working in the PCSIR accreditation system of calibration laboratories. Two other calibration laboratories working in the private sectors (M/S Industrial Automations, Karachi and M/S Millat Tractors Gauge and Tools Division, Lahore) have approached the PCSIR for the accreditation. The same accreditation system is now extended to other calibration laboratories working in private sector.
4.1. **Who Can Seek Accreditation:** Any calibration laboratory that performs measurements, calibration or objective tests may seek accreditation, whether these activities are carried out in a permanent laboratory or on site. These laboratories may be from private sector, within industry, academic institutions, and government establishments and may provide the services on a commercial basis.

4.2. **Critical Aspects of Your Quality Arrangements:** Each calibration laboratory is required to operate with technical and commercial integrity, and be able to demonstrate that it can perform competently the calibration or tests for which it is accredited, to the required level of accuracy and with impartiality. Further, calibration laboratory must have the necessary equipment and facilities for the work that it has to carry out. It must operate calibration and measurement systems after the approval from the accrediting body. The calibration laboratory must operate in the accreditation system only for those inspection, measuring and testing equipment for which accreditation is awarded after the assessment of accuracy which may influence the accuracy or validity of the calibrations or tests for which the lab is accredited [9].

4.3. **Certified Laboratory Reference Standards:** This means that laboratory reference standards used must be calibrated, with calibrations traceable to national standards, where the concept is applicable in practice [2]. Applicant lab must hold certificates from the National Physical and Standards Laboratory (NPSL, Islamabad), PCSIR Calibration Laboratory Lahore, any foreign national laboratory like NPL, NRLM, ETL, NIM, NIST, PTB etc. or certificates of calibration bearing the NAMAS logo, NVLAP logo or any of the internationally recognizes logos are accepted by PCSIR accreditation system.

4.4. **Head and Staff:** The applicant laboratory must have a highly qualified and experienced Head/Technical Manager and a Quality Manager who are responsible for ensuring that accreditation requirements are met and that level of accreditation standards are maintained at all times. (In a small laboratory, the Head/Quality Manager may also be the Technical manager or Deputy Technical Manager.)

    The Head/Manager must be a Metrologist with minimum qualification of Masters Degree in Physics or Physical Chemistry, at least ten years experience in the field of calibration including two short term foreign technical trainings or one six months duration foreign technical training from a reputed calibration/standards laboratory. The staff may be trained by the head of calibration laboratory and must hold a necessary training certificate with sufficient experience in the field of metrology and calibration. Laboratories must be organized in such as way that all staff are aware of their responsibilities, and work within the framework to ensure that they operate with integrity and due regard for security and confidentiality.

    Note: The key to successful application of accreditation is your laboratory’s quality management system. The arrangements for maintaining quality in your laboratory need to be explained in your laboratory’s introductory brochure/quality manual, which must be available to all staff.
4.5. Calibration Procedures: The calibration laboratory must prepare separate calibration procedures for all the parameters/instruments for which it is applying and these procedures must be harmonized with the capabilities of the laboratory reference standards. The onus is on the Head to ensure that staff work at all adhere times to the procedures laid down in the approved manual. The Head must regularly audit the activities of the accredited calibration laboratory to see that this objective is being achieved.

4.6. Technical and Administrative Aspect: Presently this project has been launched from the PCSIR Laboratories Complex, Lahore. Besides other technical members, this body will also include one of the member (scientist of PCSIR) who already has been nominated by Ministry of Science and Technology and authorized to recommend the certified industries to receive the financial grant from the Govt. of Pakistan.

The PCSIR accreditation body will provide a limited technical support free of cost and a uniform lay out for writing the calibration procedures will be issued to the applicant laboratories, initially meeting the above requirement 4.3 and 4.4. The accreditation body will approve the labs for accreditation after passing through detailed assessments. Keeping in view all technical and administrative aspects, minimum two months and maximum six months time will be required to finalized the successful cases. An individual approval number for the accredited calibration laboratory will be issued. Further, keeping in view the facilities offered by other international accreditation programmes, additional facilities for the approved labs are being proposed.

4.7. Audits: Two audits per annum will necessarily be carried out by the PCSIR accreditation body’s approved auditors to assess the compliance of the programme. Any special audit may be carried out against the written complaint of the clients of the accredited calibration Laboratory. If necessary, a copy of each calibration certificate issued by the approved calibration laboratory will be maintained by the PCSIR accreditation body.

4.8. Financial Aspects: The fee will be charged with complete application form enclosed with necessary documents. A lump sum annual fee or nominal fee of registration and a nominal percentage of the approved calibration charges/rates will be payable to the PCSIR accreditation body. A uniform calibration charges/rates are being proposed for accredited calibration laboratories. Other financial aspects are yet to be proposed.

5. CONCLUSIONS:

The national measurement system regulates the traceability of measurements to all the levels right from calibration labs to the routine inspection, measuring and test equipment. Calibrated equipment are the basic tools which develop the quality in the products. As the calibration work has been increased due to the implementation of quality standards ISO 9000 in the industries, some private calibration laboratories have started the calibration work. To build the confidence on the calibration work carried out by the private labs and authorize these labs for such an important job, an accreditation system is essentially required in the country. The PCSIR has already been authorized to recommend the ISO 9001/9002 certified industries for the financial grant from the Government of Pakistan, may also be authorized to run a unified accreditation system for calibration laboratories in Pakistan.
5. REFERENCES:


5. Test and Measurements, National Measurement Laboratory, CSIRO, Australia, 1995


7. Report on Testing Facilities and Accreditation Programmes, Department of Science & Technology, India, 1984
