



**ACCREDITATION CONDITIONS
LABORATORIES
CERTIFICATION BODIES**

Purpose

This document describes the conditions, which have to be fulfilled by accredited laboratories and by laboratories applying for accreditation as calibration- and/ or testing laboratories.

Contents

0. Introduction
1. Compliance With Requirements
2. Application And The Application Process
3. Proficiency Testing/ Interlaboratory Comparisons (ILC)
4. Surveillance And Renewal; Updating Of Quality Manuals And Related Documents
5. Application For Extension
6. Access To Premises And Availability Of Documents
7. General Information Obligation
8. Use Of The Pakistan National Accreditation Council Logo
9. Accreditation Fees
10. Sanction When Failing To Comply With The Conditions
11. Transferring Of Accreditation
12. Notice To Relinquish / Dissolvement
13. Financial Responsibility In Connection With Accreditation
14. The Right To Complain Against Decisions Made By PNAC
15. **References**



ACCREDITATION CONDITIONS FOR CABs

Doc G-02/04
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Rev No: 02

0. Introduction

Pakistan National Accreditation Council (PNAC) is an autonomous body working under the Ministry of Science and Technology. The Pakistan National Accreditation Council was established with the approval of the Cabinet in its meeting held on 7th January 1998. PNAC has the authority to accredit calibration laboratories testing laboratories, certification bodies, and inspection bodies. Further on, PNAC will extend its functions to other fields of accreditation.

This document gives an overview of the conditions, which an accredited laboratory must fulfil. Documents referred to are listed at the end of this document.

Accreditation will be declined to all laboratories, which are unable to document that they comply with the accreditation requirements. The accreditation does not replace any other necessary approval. Within the application process PNAC does not consider whether permissions etc. are necessary to perform the work. It is the laboratory's own responsibility to make sure that all other necessary permissions are obtained. If permission is necessary, we recommend that these are obtained or clarified before an application for accreditation is sent, (except if the accreditation is a condition for permission).

Further information regarding the accreditation scheme may be inquired from:

Pakistan National Accreditation Council
4th Floor, Evacuee Trust Complex
F-5/1, Islamabad.
Phone: 051 9222310-312
Fax: 051 9209510
www.pnac.org.pk

1. Compliance with requirements.

Accredited laboratories shall at all times comply with the requirements for accreditation. The laboratories shall adjust to new requirements or alterations in existing requirements within the time limits determined by PNAC. As a supplement to the requirements described in this document, the requirements are specified in the documents listed below:

General requirements:

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| ISO/IEC 17025 | General requirements for the competence of calibration and testing laboratories. |
| PNAC Doc. G-02/04 | Use of Pakistan National Accreditation Council's Logo and for Reference to PNAC's Accreditation |
| PNAC Doc. G-01 | Guidelines on accreditation Fees |

Specific requirements for testing laboratories

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| G-0205 | Requirements for calibration and control of weighing machines for accredited laboratories |
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ACCREDITATION CONDITIONS FOR CABs

Doc G-02/04
Issue Date: 04/10/06
Rev No: 02

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| G-0206 | Requirements for calibration and control of thermometers for accredited laboratories |
| <u>G-02/11</u> | <u>PNAC's Policy on Method Validation</u> |
| <u>G-02/12</u> | <u>PNAC Policy on Accommodation and Environment</u> |
| <u>G-02/13</u> | <u>PNAC Policy for Participation in Proficiency Testing</u> |
| <u>G-02/14</u> | <u>PNAC Policy on Assuring the Quality of Testing Procedures</u> |
| <u>G-02/15</u> | <u>PNAC Policy on Traceability of Measurement</u> |

ILAC (International cooperation for Laboratory Accreditation) have prepared guidelines which thoroughly mention the requirements above, where found appropriate.

Accredited laboratories must either follow the guidelines set out by PNAC, or otherwise as recommended by PNAC.

2. Application and the application process.

2.1 Application.

It can be applied for accreditation for sampling, testing and calibration in permanent premises and on site, and for interpretation/ evaluation of results. PNAC at the moment does not allow flexible accreditation.

When applying for accreditation, it is required that the organization (applicant) sends a complete application form with the necessary enclosures, before the handling of the application can be started. PNAC shall have an updated copy of the Quality-manual of the laboratory, appendixes, procedures and also descriptions of relevant education and work experience (CV) and job descriptions for key personnel. The results of Proficiency Testing/ Inter-laboratory Comparisons (ILC) and the laboratories own evaluation of these shall also be sent together with the application.

If the laboratory is applying for interpretation and evaluation of the results of testing, a description of this shall be enclosed the application, together with the documentation (e.g. regulations) which is the basis of the interpretation and the evaluation.

When the handling of the application is finished, all documentation received will be obliterated or returned to the applicant.

The extent of the application shall be described in an own appendix. The laboratory shall for every testing-parameter assign what measure range they want to issue accredited testing- and/or calibration results in. Regarding the qualitative testing-parameters, the lowest detection-limit shall be given. Once awarded accreditation for a certain scope, the laboratory shall display its scope in legible size, in a place where it can be seen by the customer.

By applying for accreditation the laboratory have to fill in PNAC's check list.

Applicants for accreditation or accredited laboratories shall inform PNAC if they are applying for accreditation within the same area, by an other accreditation body, or if their application have been approved or declined by such body.

If an applicant for accreditation state to have applied, or got an rejection for applications by an other body as described above, PNAC can request for the reason for this and if necessary request for the relevant assessors-report or other relevant information.

If the applicant does not wish to obey these requests, PNAC will immediately after an accreditation has been approved inform the bodies, which is considering the applications (or have refused the application) regarding the decision. This is done to give the bodies a possibility to complain against the decision, if they want to.

2.2 Methods

Preferably *standard-methods* shall be used. New versions of *standard-methods* shall be implemented within a year after the publication of them. *Modified standard-methods* are methods were laboratories have done smaller changes/modifying in a standard-method. These changes shall be written in the laboratory's own internal testing procedure.

The changes shall be validated and the validation shall document that the results (including the corresponding measurement uncertainty) stays the same as by the performing according to the standard-method.

The documentation of the validation shall be filed. It shall appear from testing-reports and calibration-certificates that the laboratory is using a modified standard-method. Simplified reporting shall be granted by the customer.

If an other principle of measurement is used and/or a matrix is changed compared to the standard-method, the method shall in any case be defined as an *internal-method*. Internal-methods based on standard-methods are methods were the laboratory have done changes/modifications in the standard-methods, and were the validation data show that the modified method do not give the same result (including the corresponding measurement uncertainty) as when performing according to the standard-method.

The documentation of the validation shall be filed and the modifications from the standard-method shall be described in the laboratories own testing procedure. A method based on a withdrawn standard-method is defined as an internal method based on the withdrawn standard.

If an earlier version of a standard-method is used longer that one year after it is revised, and this is acceptable for PNAC, the method shall be defined as an internal-method based on the earlier version.

2.3. Application process.

If PNAC makes use of external assessors during the handling of the application, PNAC shall get approval for the choice of assessor(s) by the applicant.

If the applicant wishes to refuse PNAC's proposal for assessor(s) this shall be substantiated.

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|  | ACCREDITATION CONDITIONS FOR CABs | Doc G-02/04 Issue Date: 04/10/06 Rev No: 02 |
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PNAC will evaluate if the reasons for refusing the proposed assessor(s) can be approved. Communication between the laboratory and assessors shall during the whole application process be done through the concerned Director in PNAC, in case nothing else is declined.

If PNAC shall be able to evaluate the functionality of the applicant's quality-system, it is a requirement that the system have been implemented before the accreditation is approved. To be able to decide if the accreditation-requirements are fulfilled, an examination of the laboratory's quality system, assessment of the implementation of the system, control of the participation in – and results from - ILC, and observations of the performance of selected tests/ calibrations and/or sampling.

In the standard of requirements for accreditation bodies there are requirements on the accreditation bodies to be impartial and avoid performing any consultancy towards applicants. If the applicant's cooperation with PNAC demands guidance activities from PNAC, which threaten PNAC's impartiality, PNAC has the right to terminate the application-/ assessment process.

If during the assessment, it is observed that the conditions, on which the visit was based on, are not fulfilled, the lead assessor can terminate the assessment-visit. e.g. if key personnel are not available as provided, the quality system/procedures are not implemented, the laboratory shows a lacking willingness to co-operate during the assessment or there are serious non-conformances so that an performance of the assessment-visit is not appropriate.

The management of the organization shall be present at the opening and closing meeting.

If the assessment-team fill in non-compliance-forms during the assessment, the applicant shall within the agreed deadline fill in and send all original observation-/ non-compliance-forms to the lead assessor, together with the documentation for the actions performed.

A copy of the observation-/ non-compliance-forms, together with the corresponding documentation, shall be sent at the same time directly from the applicant to the lead assessors, which have filled, in the observation-/ non-compliance-forms.

If requirements given by PNAC are not fulfilled within the time limit, or if the applicant during the next six months after the assessment has not reached any further regarding the application-process, PNAC can dismiss the application without refunding any charges. The applicant is bound to pay all accrued costs. The applicant will get a pre-warning to be able to give a statement before the process will be interrupted.

The applicant has to apply again after such interruption.

Reports prepared by PNAC, either during or after an assessment, shall not be reproduced in summary without a written approval from PNAC.

3. Proficiency Testing/Inter-laboratory Comparisons (ILC)



ACCREDITATION CONDITIONS FOR CABs

Doc G-02/04
Issue Date: 04/10/06
Rev No: 02

PNAC requires that all accredited calibration laboratories participate in inter-laboratory comparisons frequently. As a minimum each parameter shall be covered once during a period of renewal.

Calibration laboratories seeking accreditation, shall in agreement with PNAC participate in inter-laboratory comparisons with satisfactory results before accreditation is declined.

Before accreditation is approved the testing laboratories shall, for each parameter, document satisfactory results from inter-laboratory comparisons. PNAC requires all accredited testing laboratories shall participate in inter-laboratory comparisons frequently for each parameter, and at a frequency in accordance with accepted rules in each testing area. Testing laboratories shall participate in organized ILC programs if these exist for the specific testing area. If organized ILC programs only exist abroad, the laboratories shall either as a main rule participate at least in one of these programs.

PNAC is requesting the laboratories to use ILC organizers that comply with the requirement for ISO/IEC guide 43 or ILAC G13. For testing area where there do not exist any organized ILC, the laboratories shall perform other actions, which ensure satisfactory control of the test method's traceability such as comparison with other (accredited) testing laboratories and/or testing of (certified) reference material.

4. Surveillance and renewal; Updating of Quality Manuals and related Documents

To verify that the requirements for accreditations are met, PNAC will perform regular surveillance at the accredited laboratories preferably within 12 months after the first assessment.

The accreditation is renewed after three years, with normally two surveillances in between and the reassessment will then be as comprehensive as a first time assessment. In addition PNAC will, when it is needed, accomplish further surveillance activities as e.g. extraordinary visits or claim participation in ILC.

Accredited laboratories shall before an ordinary surveillance or renewal visit send in updated versions of relevant documents. The following documentation shall be sent directly to the assessors not later than 4 weeks before a surveillance and renewal visit, if nothing else is agreed on by PNAC.

Lead assessor shall as a minimum receive a copy of the quality manual including Appendixes, an index of other documents and forms in the quality system, a overview of the number of performed accredited tests and/or calibrations last year together with descriptions of relevant education and work experience (CV's) for new key personnel. If possible a copy of reports from internal audits and management's review performed last year, should be sent to the lead assessor. At renewal a description of relevant education and work experience (CV's) and job description for key personnel should be sent in, if relevant.

Technical Assessor/expert shall as a minimum receive the scope of accreditation, technical procedures, an overview of performed accredited tests and/or calibrations the previous year along with the relevant previous assessment report. Results of ILC performance since last visit will be evaluated during the visit. Any new technical personnel inducted will be interviewed

for their competence on ISO 17025, in particular and their CVs examined and authorizations checked. In addition at renewal a copy of the technical procedures including appendixes for technical personnel is required.

Regarding substantial changes in e.g. the quality system, or by renewal of accreditation, the laboratory shall fill in and send a checklist to PNAC.

During the assessment the laboratory's key personnel shall the whole time be available for the assessment team. The management of the organization shall be present at the closing meeting.

If the assessment team gives any non-compliances during a surveillance or renewal, the descriptions in section 2.3 in this document, (regarding observation / non-compliance forms together with documentation) must be followed.

Requirements for new appliers, as given in section 2 in this document, are also valid for already accredited laboratories.

5. Application for Extension.

Accredited laboratories can any time apply for extension of the accreditation.

When applying for an extension the laboratory has to send a completely filled application form together with the necessary appendixes, before the handling of the application can start. If the application for extension includes accreditation for interpretation/evaluation of the results, this shall be stated in the application form and be described in an appendix to the applications.

If the application of extension is sent PNAC not later than 2 months before an ordinary surveillance or renewal, the application for extension will normally be treated during the planned visit. In such cases fully documentation for evaluation of the application (procedures of methods and other relevant documents, results of ILC etc) shall be sent PNAC within 4 weeks before the date of the planned visit.

6. Access to Premises and Availability of Documents.

The laboratory has a duty to give PNAC the necessary access to their premises and to all relevant documentation.

Necessary access means access, which is necessary to be able to verify accordance to the requirements in the relevant requirement-standard.

Relevant documentation means documentation, which gives support in the evaluation according to relevant requirement-standards. Including is documents, concerning the work done by the laboratory. Relevant documentation shall on request be available for PNAC as soon as possible.

At the assessment the laboratory has a duty to adjust their normal activities so that the assessment team can perform an efficient assessment.

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|  | ACCREDITATION CONDITIONS FOR CABs | Doc G-02/04 Issue Date: 04/10/06 Rev No: 02 |
|--|--|---|

PNAC inform the organization about the visit in suitable time, but when it is required PNAC's assessment team shall be given assess without being informed in advance.

Documentation and premises shall be accessible for staff employed in PNAC as well as the assessors/ experts, which is engaged by PNAC and accepted by the laboratory.

7. General Information Obligation

Accredited laboratories shall at all times keep PNAC informed regarding changes in the organisation which may influence the organisation's ability to comply with the terms of accreditation. The organisation shall inform PNAC immediately if there are changes in:

- a) Legal status, ownership, name, E-mail address, phone, fax no, etc.
- b) The organization, management and key personnel, i.e. quality leader, the responsible for validation (for flexible accreditation), the responsible for interpretation (for accreditation, which includes interpretation and evaluation of results).
- c) The quality system if significant for the compliance with the terms of accreditation
- d) Essential calibration- and testing facilities, such as equipment, instruments and laboratory premises (e.g. moving of the laboratory), and other essential resources. PNAC shall approve such changes before they are effectuated.
- e) Substantial changes in national and international standard-methods which is used by the laboratory in tests/calibrations, or other substantial changes in methods.

The laboratory shall in the beginning of the year on request send a short annual report to PNAC with information regarding the activities last year. PNAC will send a form to be used for the annual report.

8. Use of the Pakistan National Accreditation Council Logo, and reference to the accreditation.

Accredited laboratories are requested to use PNAC's logo. Use of PNAC's logo and reference to accreditation shall be in accordance with PNAC's requirements G-02/02.

The laboratories shall have rules for how they refer to the accreditation in advertising materials and in other connections.

9. Accreditation Fees

Applicants and accredited laboratories are obliged to pay fees in accordance with the existing document regarding fees for the services performed by Pakistan National Accreditation Council.

10. Sanction when failing to comply with the conditions

If the accredited laboratory fails to comply with the requirements for accreditation, PNAC can put in effect one or more of the following sanctions, depending on how serious the non-compliances are:

- a) Instructions corrective actions (non-compliances)
- b) Suspend the accreditation or parts of it
- c) Withdraw the accreditation or parts of it

PNAC will evaluate which sanctions to be used. When it is necessary to do withdrawals, instructions of corrective actions and/or suspension shall be used first if PNAC finds that appropriate. The sanctions can be described as following:

I) Instructions of corrective actions (non-compliance).

PNAC can require that the laboratory correct the non-compliance within a specified date. If the laboratory wishes to keep the accreditation, it must prove that the non-compliance is satisfactory corrected within the time limit.

The instructions may include withdrawal of accredited calibration certificates and test reports. PNAC may also decide that an extraordinary visit to the laboratory is required to check that the corrections are satisfactory implemented.

II) Suspension:

If the non-compliance is not corrected within the agreed time, or if the non-compliance is substantial, the accreditation – or part of it- can be suspended for a limited time. A suspension is a blocking of the laboratory's accredited activity because of serious deficiency in fulfilling the requirements set by PNAC. Examples of serious deficiencies are:

- a) No traceability to standards of measurement.
- b) Unacceptable results from inter-laboratory comparisons (ILC) or qualified tests.
- c) Non-satisfactory competence because of changes in personnel/changes in the qualifications of key personnel.
- d) Lacking of performance of satisfactory corrections within the time limit.
- e) Big mistakes by performance of tests/calibrations, which show serious errors in the quality system.
- f) Misuse of the accreditation, or if the accreditation is not much used.

Changes of the laboratory's premises, regarding moving/rebuilding will normally lead to suspension. The same can in some cases be the result if where is changes in the organization.

A laboratory can ask to be **suspended** on voluntary base. An argument for this voluntary suspension can be i.e. that the laboratory itself register that the requirements for accreditation is not fulfilled, or by moving to new premises.

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|  | ACCREDITATION CONDITIONS FOR CABs | Doc G-02/04 Issue Date: 04/10/06 Rev No: 02 |
|--|--|---|

- When the accreditation or parts of this is suspended, the laboratory shall not offer or perform accredited services for the suspended activities as long as the suspension lasts.
- Accredited calibration-certificates/test reports shall not be issued within the area, which is included in the suspension.
- On request from PNAC the laboratory shall return the accreditation-certificate and accreditation-document.

- Suspensions are time limited to 3 months, but PNAC can prolong the limit up to 6 months.

The accreditation can be re-established by PNAC if the conditions which caused the suspension are improved in a satisfactory way within the time limit. In most of the cases this would be done by physical verification of the site.

However in certain cases where documentary evidence is sufficient, physical verification may not be needed. This would be decided by Director concerned either alone or if needed in consultation with the lead/technical assessor may decide to lift suspension without a visit.

III) **Withdrawal of accreditation:**

If the laboratory does not want to or is unable to correct the non-compliances, within the time limit, or the non-compliance is so serious that the laboratory no longer has the necessary qualifications to carry out accredited calibrations or tests, the accredited scope or parts of the scope will be withdrawn. In this case the laboratory's accreditation is terminated by the withdrawal. By termination of the accreditation the laboratory is required to return the accreditation certificate and the accreditation document to PNAC.

If parts of the accreditation are withdrawn the laboratory shall hand over to PNAC accreditation documents for destruction or alteration. The laboratory shall no longer offer to carry out accredited services within the areas withdrawn.

If the accreditation is fully or partially withdrawn the laboratory shall, in writing, inform clients concerned about the consequences. A copy of this information shall be sent to PNAC.

In the case of withdrawal or suspension, paid fees will not be refunded. The laboratory has a duty to pay all incurred costs. During a period of suspension the regular fees shall be paid as normal.

Before a decision to suspend or withdraw accreditation can be made, the laboratory must be given a notice and the possibility of a hearing, except in case of clause 5.2 of P-12/01, where immediate suspension is needed due to unsatisfactory performance.

Appeals on decisions concerning sanctions can be made.

11. **Transferring of accreditation.**

In cases where by purchase, merger, and changes of name etc. where accredited laboratories wish to transfer an accreditation from one organization to another. Transfer implies that an assigned accreditation is transferred from one organization to another. The accreditation-number will normally be kept.

Conditions for approval of transmission are as follows:

- a) The system of performance of the accredited tests/calibrations shall not in principal be changed, and the changes shall not be in conflict with the accreditation conditions.
- b) The changes do not lead to weakening of the quality of the work or the integrity of the organization.
- c) The changes have no influence on fulfilment of the requirements of accreditation.
- d) The transferring of accreditation does not mislead the market.
- e) The organization obliges the responsibility towards customers and PNAC.
(This implies that it at any time in the transmission process there have to be a clearly defined legal body which is responsible towards customers and PNAC).
- f) The changes are not in conflict with Pakistan's laws.

If transmission is requested the accredited laboratory has to send an application by letter for transmission of the accreditation. The application must include:

- g) Complete description of the background of the application.
- h) Clear and precise description of new legal status, when it is relevant.
- i) Description of possible changes in the quality system.
- j) Company-attestation
- k) Binding statement from the new owner/management that they will fulfil the requirements for accreditation.
- l) Binding statement from the new owner/management that possible relevant responsibility is taken over from the one the accreditation was transmitted from (e.g. abidance of offers which are already contracted make for delivery of accredited services).
- m) Plan for updating of the quality manual, procedures, catalogues, and other affected documents (e.g. change of name).
- n) Information regarding updating of necessary contract of employments, agreement with subcontractors etc. when relevant.

In accordance with the conditions of transmission, PNAC will decide whether verifications must be done at the location of the applicant or transmission can be declined on behalf of the received documentations.

In the cases where changes will lead to a new accreditation certificate and accreditation document the one who is accredited have a duty to return the earlier edition of these to PNAC when the transmission is declined.

12. Notice to relinquish / dissolution

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|  | ACCREDITATION CONDITIONS FOR CABs | Doc G-02/04 Issue Date: 04/10/06 Rev No: 02 |
|--|--|---|

An accredited organization may terminate its accreditation, without any argument, with a 2 months notice; the notice must be in writing. In special cases this period might be shortened.

If the organization is dissolved, it has a duty to immediately inform PNAC, which will withdraw the accreditation at once. The requirements, which are described in section 10 in this document regarding withdrawing are valid. The same requirements are valid if the laboratory for different reasons has to reduce the accreditation size.

13. Financial Responsibility in connection with accreditation

PNAC is not to be held responsible for the laboratories obligations towards their clients.

14. The Right to Appeal against Decisions made by PNAC.

Any appeal against PNAC's decisions must be presented to PNAC within 3 weeks after the laboratory received PNAC's decision. PNAC shall perform the necessary investigations and may annul or alter the decision, or reject the complaint if the terms to deal with it does not exist. If the decision is not altered, PNAC shall send all documents concerning the matter to the Appeal Committee. The Appeal committee recommends to DG for his decision.

The laboratories have at any time opportunity to appeal at PNAC's activities, as e.g. executive work and interpretation of the requirements for accreditation. Appeals have to be in writing. During the handling of appeals deadlines for closing of possible non-compliance be postponed.

15. References

- (1) ISO/IEC 17025 General requirements for calibration- and testing laboratories competence.
- (2) ISO/IEC17011 Calibration and testing laboratory accreditation Systems – General requirements for operation and recognition.
- (3) PNAC- G-02/04 Guidance to conditions for accreditation of laboratories.
- (4) PNAC- G-02/02 Regulations on the use of PNAC's logo and reference to accreditation
- (5) PNAC- F-01/02 Regulations on accreditation fees for PNAC's services.
- (6) PNAC- G-02/05 Requirements for calibration and control of weights for accredited laboratories.
- (7) PNAC- G-02/06 Requirements for calibration and control of thermometer for accredited laboratories.
- (8) ISO/IEC Guide 43 Proficiency testing by interlaboratory comparison
- (9) ILAC G13 Guidelines for the requirements for the competence of providers of proficiency testing schemes

Documents published by PNAC are available on Internet: www.pnac.org.pk

Documents published by ILAC are available on Internet: www.ilac.org/

Documents published by EA are available on Internet: www.european-accreditation.org/