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ACCREDITATION CONDITIONS

CERTIFICATION BODIES

Purpose

This document describes the conditions, which have to be fulfilled by accredited certification Bodies and by certification Bodies seeking accreditation with Pakistan National Accreditation Council (PNAC).

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/testing, medical laboratories, certification bodies and inspection bodies.

This document gives an overview of the conditions, which an accredited certification body (CB) must fulfil. Documents referred are listed at the end of this document.

Accreditation will be declined to certification bodies, which are unable to produce documented evidence that they comply with the accreditation requirements. Moreover, the CB is required to register as legal entity with the concerned Government authority before applying for accreditation with PNAC. The accreditation does not replace any other necessary approval required by any other authority of Government.

Further information regarding the accreditation scheme may be inquired from:

Pakistan National Accreditation Council
1-Constitution Avenue,
Opposite Prime Minister Office, G-5/2,
Islamabad, **Pakistan.**
Phone: 051 9222310-312
Fax: 051 9209510
www.pnac.org.pk



1.0 Definitions:

Accreditation

Third party attestation related to a conformity assessment body (e.g. certification body) conveying formal demonstration of its competence to carry out specific conformity assessment tasks

Accreditation Body

Authoritative body that performs accreditation (e.g. PNAC)

Accreditation Certificate (Certificate of Accreditation)

A formal document by PNAC to be used by accredited certification bodies to indicate their accredited status.

Assessment:

Process undertaken by PNAC to assess the competence of a certification body, based on particular standard(s) and/or guide(s) and/or other normative documents for a defined scope of accreditation

Assessor:

A person assigned by PNAC to perform, alone or as part of an assessment team, an assessment of a certification body.

Auditor:

A person assigned by CB to perform, alone or as part of an audit team, an audit of a certification body client.

PNAC	Pakistan National Accreditation Council
CAB	Conformity Assessment bodies
CB	Certification Body
ACB	Accredited Certification Bodies
IAF	International Accreditation Forum
PAC	Pacific Accreditation Cooperation
ISO	International Organization for Standardization
IEC	International Electrotechnical Committee
DG	Director General of PNAC

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2. Compliance with requirements.

Accredited certification bodies shall at all times comply with the requirements for accreditation. The certification bodies shall adjust to new requirements or alterations in existing requirements within the time limits determined by PNAC. All new applicants seeking PNAC's accreditation are required to meet & comply with the requirements for Accreditation given in this document and other referred documents. As a supplement to the requirements described in this document, the requirements are specified in the documents listed below:

2.1 General requirements:

- ISO/IEC 17021- *Conformity assessment — Requirements for bodies providing audit and certification of management systems*. This International Standard contains principles and requirements for the competence, consistency and impartiality of the audit and certification of management systems of all types (e.g. quality management systems or environmental management systems) and for bodies providing these activities. Certification bodies operating to this International Standard need not offer all types of management system certification.
- ISO/IEC 17065 - *Conformity assessment -- Requirements for bodies certifying products, processes and services*
- ISO/IEC 17024 - *Conformity assessment -- Requirements for bodies operating certification of persons*
- PNAC Doc. F-01/06 Fee Schedule for CBs
- PNAC Doc. F-0108 Agreement between PNAC & CB
- IAF and PAC policies

PNAC has the right to establish or amend the accreditation requirements of certification as and when needed.

3.0 Application for accreditation;

Certification bodies interested to get accredited by the PNAC for their certification system can obtain the application form, by sending a request to the CB section PNAC or may be downloaded from the website (www.pnac.org.pk). Applications on any other format are not acceptable.

The CBs info pack includes the latest copies of the following documents:

- a) Application form
- b) Fee Schedule
- c) Applicants Guide for CB
- d) Agreement between PNAC & CB
- f) Accreditation conditions for Certification Bodies and CABs
- g) Document Review Report/Checklist
- h) Guidance on use of Accreditation Mark

Any additional explanation needed by the applicant is provided by the concerned section on behalf of the PNAC, on receipt of a specific request for the same, including necessary explanations the specific schemes and scopes of accreditation that are covered under certification /registration system.

Before applying for accreditation, the applicant body must have met the following conditions:



- a. Operated the certification process for at least one year. This is necessary to assess the ability of the CB to carry out the certification process as per the documented system
- b. Carried out minimum one internal audit against the applicable criteria of accreditation and one management review for the documented Quality system prepared as per applicable standard.

The completed Application Form for accreditation has to be duly signed by the authorized representative/s of the organization seeking accreditation and forwarded to the PNAC along with the application fee given in the fee schedule. The PNAC reserves the right to seek information on the antecedents of the owners / those managing certification activities as and when required. The application fee is non refundable. Normally the receipt of the application would be communicated within a week of receipt to the CB.

The application is reviewed by the CB section for completeness, clarity of accreditation requirements and the capability of the PNAC to provide the services. Any mismatch is clarified and the outcome of the review is communicated to the applicant regarding acceptance of the application for further processing, or to complete any further requirements identified during the review.

Fee schedule along with boarding/logging expenses would be communicated to the CB. Further processing of application shall be taken up on receipt of acceptance of the fee schedule and confirmation that the agreement is acceptable.

Pre-assessment/assessment visit would be organized with the mutual consent of the applicant body and PNAC. Assessment fee would be charged usually after the visit. Logistic arrangements including the traveling and boarding would be the responsibility of the CB.

4.0 Criteria for Accreditation:

4.1 Adoption of Criteria;

The PNAC shall adopt and document the accreditation criteria for certification body based on international standards and guides, supported by the guidance documents released by the International Accreditation Forum (IAF). Definitions of various terms related to conformity assessment shall be as given in ISO/IEC 17000 and ISO/IEC 17011. The application package includes the documented criteria except for copyright of standards such as ISO/IEC 17021, ISO/IEC 17065 or ISO 9001 etc.

4.2 Amendment to the Criteria

The amendment to the Criteria shall be based on the nature of change required. The criteria of accreditation and the guidance documents shall be taken up for amendment based on following conditions individually or collectively if required,

- a) Any change in the International standards and guides
 - b) Any change in the IAF Guidance documents for implementation of international standards and guides
 - c) Feedback from the Peer Review assessment team that warrants amendment
 - d) Critical feedback from the implementation of the criteria
 - e) Any other reason as deemed fit by the PNAC
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4.3 Communication of changes to the Criteria

Any change in the criteria shall be notified to the accredited / applicant certification bodies by registered (AD) post / other means and a suitable time frame shall be given for implementing the modified criteria. The accredited certification bodies shall communicate their acceptance in writing by registered post / other means within 30 days of the receipt of the amended criteria. If the communication is not received within 30 days, it will be presumed that the accredited certification body has accepted the revised accreditation criteria. The implementation of the changed criteria shall be verified during the surveillance assessment of each certification body. In the event of any major change in the criteria, the PNAC reserves the right to carryout an additional assessment and the fee of such assessment visit shall be borne by certification body. In the event that an accredited certification body is not willing to adopt the changed criteria, it is allowed to opt out of the accreditation scheme and the accreditation is withdrawn with effect from the date of the implementation of revised criteria.

5.0 Conditions for Accreditation

5.1 Granting of Accreditation

The accreditation is granted to an applicant CB on completion of assessment and after the following conditions has been met by the applicant body

- a. The applicant has the certification system (activities including contracting for certification, audit planning and conduct of audit, decision making) in operation for at least one year before the office assessment is taken up.
- b. The applicant meets the criteria of accreditation and all non-conformities found against the criteria of accreditation during assessment have been closed to the satisfaction of the PNAC in accordance with the guidelines on the subject.
- c. There are no adverse reports / information / complaints with the PNAC about the applicant regarding the quality and effectiveness of implementation of certification system as per the criteria of the PNAC.
- d. The applicant body has paid all the outstanding dues.
- e. The Initial accreditation shall be for a period of 3 years. Subsequent renewals are for a period of 3 year subject to satisfactory operation of accredited certification scheme and reasonable number of PNAC accredited certificates being issued by the CB.

5.2 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 certification bodies preferably within 12 months after the first assessment, however an extension in accreditation status may be provided initially for 03 month and up to six months if the assessment could not be conducted within 12 months after previous assessment depending upon the previous record of the certification body.

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.

Accredited certification bodies shall before an ordinary surveillance or renewal visit send its updated versions of relevant documents. The following documentation shall be sent directly to the CB section PNAC before a surveillance and renewal visit, if nothing else is agreed on by PNAC.

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- a. Copy of the quality manual including Appendixes,
- b. An index of other documents and forms in the quality system,
- c. Scope of accreditation
- d. Education and work experience (CV's) for new auditors.
- e. List of technical experts (internal, external)
- f. Copy of reports from internal audits and management's review performed last year,

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

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

Requirements for new applicants, as given in section 3 in this document, are also valid for already accredited Certification bodies.

5.3 Application for Scope Extension.

Accredited certification bodies can any time apply for extension of the scope of accreditation. When applying for an extension the CB has to send a completely filled application form together with the necessary appendixes.

If the application or information of extension is sent to PNAC 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 and other relevant documents, list of auditors & technical experts) shall be sent PNAC within due date before the planned visit.

5.4 Access to Premises and Availability of Documents.

The CB 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 in 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 the documents, concerning the work done by the CB. Relevant documentation shall on request be available for PNAC as soon as possible.

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

PNAC inform the organization about the visit in suitable time, but when it is required PNAC's assessment team shall be given access 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 CB.

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5.5 General Information Obligation

Accredited certification bodies 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 manager, Lead auditors
- c) The quality system if significantly amend or changed.

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

No one except PNAC allowed to use PNAC logo.

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

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

5.7 Accreditation Fees

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

5.8 Sanction when failing to comply with the conditions

If the accredited certification bodies fail 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:

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

PNAC can require that the certification body (CB) correct the non-compliance within a specified date. If the CB wishes to keep the accreditation, it must prove that the

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non-compliance is satisfactory corrected within the time limit. PNAC may also decide that an extraordinary visit to the CB is required to check that the corrections are satisfactory implemented.

II) **Suspension:**

- a) If the corrective action is not taken by CB on the non-compliance 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 CB’s accredited activity because of serious deficiency in fulfilling the requirements set by PNAC.
- b) A CB can ask to be **suspended** on voluntary basis. An argument for this voluntary suspension can be i.e. that the CB itself register that the requirements for accreditation is not fulfilled.
- c) 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. This would be decided by Director CB 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 CB 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 CB no longer has the necessary auditors, technical experts to carry out accredited scope, the accredited scope or parts of the scope will be withdrawn. In this case the CB’s accreditation is terminated by the withdrawal. By termination of the accreditation the CB is required to return the accreditation certificate and the accreditation document to PNAC.

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

If the accreditation is fully or partially withdrawn the CB 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 CB 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 CB 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.

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5.9 Transferring of accreditation.

In cases where by purchase, merger, and changes of name etc. where accredited certification bodies 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 scope 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 CB 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.

5.10 Notice to relinquish / dissolve



An accredited certification bodies 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 this document regarding withdrawing, are valid. The same requirements are valid if the CB for different reasons has to reduce the accreditation size.

5.11 Financial Responsibility in connection with accreditation

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

5.12 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 CB 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 certification bodies 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.

6.0 Accreditation Scopes and norms for witness audits

This may not be applicable to all accreditation schemes mentioned at para 2.1 of this document.

6.1 Scope Classification

PNAC follows International Accreditation Forum guidelines where applicable.

6.2 Auditor competence

Relevant applicable technical specification described in ISO/IEC technical guides will be used by PNAC for its accreditation program which may serve as a starting point for determining auditor competence. However, it should be recognized that the technical areas in which a CB operates and where competence needs to be demonstrated, the CB is required to be more specific than the broad descriptors, given in this guide.

PNAC requires the CBs to define their auditor competence criteria in terms of knowledge and skills as identified in the initial competence analysis done by the CB. It is a requirement of PNAC that the knowledge would also include applicable regulations & statutory requirements, if any. In the absence of basic educational qualification relevant to the technical area, the CB is required to demonstrate how the knowledge requirements identified for the technical area have been met by the qualified auditor.

6.3 Restrictions in Scopes



Based on the available competence and / or the recommendation of the assessment team, the accreditation committee may decide to restrict grant of accreditation to a part of the broad scope sectors described at 6.6.

6.4 Witness audit plans for initial / reassessment

Office Assessment:

PNAC will conduct 2 man-day office assessment for initial, surveillance and re-assessment.

Witness of Scope

PNAC has classified the technical areas under the broad IAF Scopes for the purpose of witness audit planning. PNAC will conduct at least one witness audit for each management system during each surveillance or re-renewal. For initial assessment, PNAC will conduct witnessing of all EAC code of category A, whereas assessment team may decide for more witnessing, if required, in case of category code B & C based on the competence of the CB and number of certified clients for specific field / management system. PNAC will follow IAF MD 17 for witness assessment for ISO 9001 and ISO 14001 as per requirement.

In case there are no certified clients for a particular scope within the group, the scope may still be accredited but PNAC would reserve the option to review the reports of the first few clients in that scope sector. It would be the responsibility of the CB to keep PNAC informed of the issue of certificates in such scope sectors. In case of other accreditation schemes a sample of each category will be witnessed.

6.5 Witness audit plans for surveillance assessments.

Witnessing is a part of the surveillance program. The witness audit plans would depend on various factors including the number of clients issued with PNAC accredited certificates, the number of auditors employed / empaneled by the CB and inputs from any office assessment. PNAC may demand to witness a specific auditor or any organization issued with accredited certificate.

6.6 List of Scopes of accreditation

The list of scope of accreditation by PNAC is based on the IAF guideline.

Activities covered under Scope sectors 23, 35 and 39 would be on the basis of NACE classification against the respective scopes. Activities not covered under NACE classification would be dealt on a case-to-case basis.

6.7 Classification of scopes;

PNAC has categorized the broad IAF scopes into “technical areas” based on NACE Classification. Considering that within the broad IAF scopes the competence needed for auditing could vary significantly for various technical areas and some of these technical areas may require witnessing, the following classification has been made.

Class C – Does not require witnessing and accreditation can be granted to these technical areas based on a satisfactory demonstration of competencies during the office assessment.

Class B – Witnessing would not be required in case the auditor competence, basic qualification and experience requirements are based on ISO 19011. The assessment team would base their decision on

the above and demonstrated competence through certified client files or through the telephonic interview with the LA/TE.

Class A – Requires at least one witnessing and any other competence criteria other than basic qualification and experience shall have to be justified by the CB on the basis of knowledge and skills expected for the audit of the technical area.

Note 1: A successful witness audit under any NACE code specified with a “A” will gain accreditation for the full IAF Scope Category.

Note 2: The classification is based on health & safety considerations, regulations in the technical area and complexity of operations.

NACE	Description	Class
01	Agriculture, Hunting, Forestry & Fishing	B
02	Mining and Quarrying	A
03	Fo/d Products, Beverages and Tobacco	A
04	Textiles and Textile Products	B
05	Leather and Leather Products	B
06	Wood and Wood Products	B
07	Pulp, Paper and Paper Products	B
08	Publishing Companies	B
09	Printing Companies	B
10	Coke and Refined Petroleum Products	B
11	Nuclear Fuel	A
12	Chemicals, Chemical Products and Fibres	A
13	Pharmaceuticals	A
14	Rubber and Plastic Products	B
15	Non-metallic Mineral Products	B
16	Concrete, Cement, Lime, Plaster, etc.	B
17	Basic Metals and Fabricated Metal Products	B
18	Machinery and Equipment	B
19	Electrical and Optical Equipment	A

20	Ship Building	A
21	Aerospace	A
22	Other Transport Equipment	B
23	Manufacturing Not Elsewhere Classified	C
24	Recycling	B
25	Electricity Supply	A
26	Gas Supply	A
27	Water Supply	B
28	Construction	A
29	Wholesale and retail trade; repair of motor vehicles, motorcycles and personal G and household goods	C
30	Hotels and Restaurants	B
31	Transport, Storage and Communications	B
32	Financial Intermediation, Real Estate, Renting	C
33	Information Technology	B
34	Engineering Services	B
35	Other Services	B
36	Public Administration	C
37	Education	B
38	Health and Social Work	A
39	Other Social Services	C

7.0. References

- (1) ISO/IEC17011 Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies.
- (2) ISO/IEC17021- *Requirements for bodies providing audit and certification of management systems*
- (3) ISO/IEC 17065 - *Conformity assessment -- Requirements for bodies certifying products, processes and services*

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- (4) ISO/IEC 17024 - *Conformity assessment -- Requirements for bodies operating certification of persons*
- (5) IAF MD 17:2015 Witnessing Activities for the Accreditation of Management Systems Certification Bodies
- (6) IAF MD 5:2015 Determination of Audit Time of Quality and Environmental Management Systems (Issue 3, issued on 09 June 2015; Application from 09 June 2016)
- (7) PNAC- G-02/02 Regulations on the use of PNAC's logo and reference to accreditation

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

Documents published by IAF are available on Internet: www.iaf.nu/

Documents published by PAC are available on Internet: www.apec-pac.org