

Contents

0.0 Introduction

1.0 Definitions

2.0 Compliance with Requirements

3.0 Application for Accreditation

4.0 Criteria for Accreditation

4.1 Adoption of criteria

4.2 Amendment in criteria

4.3 Communication of change in the criteria

5.0 Conditions for Accreditation

5.1 Granting of Accreditation

5.2 Surveillance and Renewal; Updating Quality Manuals and Related Documents

5.3 Application for Scope Extension

5.4 Access to Premises and Availability of Documents

5.5 General Information Obligation

5.6 Use of Logo/Mark/reference of Pakistan National Accreditation Council

5.7 Accreditation Fee

5.8 Sanctions When Failing to Comply With Conditions

5.9 Transferring of Accreditation

5.10 Notice to Relinquish / Dissolve

5.11 Financial Responsibility in Connection with Accreditation

5.12 Right to Appeal Against Decisions Made by PNAC

5.13 Audits of Integrated Management Systems (IMS).

5.14 Accreditation Assessment of CBs with Activities in Multiple Countries.

5.15 The Collection of Data to Provide Indicators of Management System Certification Bodies' Performance.

6.0 Accreditation Scopes and norms for witness audits

6.1 Scope of classification

6.2 Auditors competence

6.3 Restriction in scope

6.4 Witness audit plan for initial assessment

6.6 List of scope of accreditation

7.0 References

**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). Documents referred are listed at the end of this document.

**Introduction**

Pakistan National Accreditation Council (PNAC) is working as an autonomous body under Ministry of Science and Technology, Islamabad, Pakistan. PNAC established on 07th January 1998 with the approval of the Cabinet. PNAC has the authority to accredit Conformity Assessment Bodies (CABs) like Testing/Calibration, Medical Laboratories, Certification Bodies, Proficiency Testing Providers, Inspection Bodies etc.

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 (SECP in Pakistan) before applying for accreditation with PNAC. The accreditation does not replace any other necessary approval required by any other authority/department.

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 9214065

Fax: 051 9209510 [www.pnac.org.pk](http://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 issued 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 relevant

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 client of certification body.

PNAC Pakistan National Accreditation Council

CAB Conformity Assessment Body

CB Certification Body

ACB Accredited Certification Body

IAF International Accreditation Forum

APAC Asia Pacific Accreditation Cooperation

ISO International Organization for Standardization

IEC International Electrotechnical Commission

DG Director General of PNAC

**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 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 have been specified below:

**2.1 General requirements:**

**2.1.1** ISO/IEC 17021-1 *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 and for bodies providing these activities. Certification bodies operating to this International Standard need not offer all types of management system certification.

In addition to ISO/IEC 17021-1 and IAF Mandatory Documents (MD) series, PNAC also adopted specific requirements of IAF sub scope level 4 for accreditation of certification bodies, which includes;

1. ISO/IEC 17021-2 for Environmental Management System
2. ISO/IEC 17021-3 for Quality Management System
3. ISO/IEC 17021-10 for Occupational Health & Safety Management System
4. ISO 22003-1 for Food Safety Management System

These accreditation conditions outline the following IAF sub scope Level 5 requirements;

1. ISO 9001 Quality Management System (QMS)
2. ISO 14001 Environmental Management System (EMS)
3. ISO 45001 Occupational Health and Safety Management System (OH&SMS)
4. ISO 13485 Medical Devices Quality Management System (MDQMS)
5. ISO 22000 Food Safety Management System (FSMS)

**2.1.2** ISO/IEC 17065 - *Conformity assessment -- Requirements for bodies certifying products, processes and services*

**2.1.3** ISO/IEC 17024 - *Conformity assessment -- Requirements for bodies operating certification of persons*

**2.1.4** PNAC Doc. F-01/06 Fee Schedule for CBs

**2.1.5** PNAC Doc. F-0108 Agreement between PNAC & CB

**2.1.6** Adoption of IAF and APAC policies/procedures

**2.1.7** PNAC has adopted IAF Mandatory documents in addition to ISO/IEC 17021-1.

For example,

PNAC has adopted IAF MD series for the effective assessment of Certification Bodies (CBs);

|  |  |
| --- | --- |
| **Name of IAF Mandatory Document (MD)** | **Issue Date** |
| IAF MD 1:2023 IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization | 18-Oct-23 |
| IAF MD 2:2023 IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems | 14-Jun-23 |
| IAF MD 4:2023 IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes | 14-Jun-23 |
| IAF MD 5:2023 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems | 14-Jun-23 |
| IAF MD 7:2023 IAF Mandatory Document for the Harmonization of Sanctions and Dealing with Fraudulent Behaviour | 19-Jul-23 |
| IAF MD 8:2023 Application of ISO/IEC 17011:2017 in the Field of Medical Device Quality Management Systems (ISO 13485) | 20-Nov-23 |
| IAF MD 9:2023 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485) | 20-Nov-23 |
| IAF MD11:2023 IAF Mandatory Document for the Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems | 12-Sep-23 |
| IAF MD12:2023 Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries | 14-Jun-23 |
| IAF MD15:2023 IAF Mandatory Document for the Collection of Data to Provide Indicators of Management System Certification Bodies' Performance | 14-Jun-23 |
| IAF MD16:2023 Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies | 14-Jun-23 |
| IAF MD17:2023 Witnessing Activities for the Accreditation of Management Systems Certification Bodies | 14-Jun-23 |
| IAF MD22:2023 Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS) | 14-Jun-23 |
| IAF MD23:2023 Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies | 20-Dec-23 |
| IAF MD25:2023 Criteria for Evaluation of Conformity Assessment Schemes | 13-Jun-23 |
| IAF MD28:2023 IAF Mandatory Document for the Upload and Maintenance of Data on IAF Database | 26-Oct-23 |

**2.1.8** PNAC has the right to establish or amend the accreditation requirements for certification bodies as and when deem necessary.

**3.0 Application for accreditation;**

**3.1** Certification bodies interested to get accredited by PNAC for their certification system can obtain application form, by sending a request to the CB section PNAC or may download from website [(www.pnac.gov.pk).](http://www.pnac.gov.pk) Applications on any other format are not acceptable.

**3.2** CB info pack available on website of PNAC contain following documents:

a) Application form b) Fee Schedule

c) Applicant’s 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

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

**3.4** 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 and one management review against the applicable criteria of accreditation as documented Quality system prepared as per applicable standard.

**3.5** Completed Application Form has to be duly signed by the authorized representative/s of the organization seeking accreditation and be forwarded to PNAC along with application fee as described in fee schedule. PNAC reserves the right to seek information on the antecedents of the owners / those managing certification activities or any other information to fulfill the requirements of accreditation as and when required. The application fee is non-refundable. Normally the receipt of the application would be acknowledged within a week to the applicant CB.

**3.6** The application is reviewed by the CB section for completeness, clarity of accreditation requirements and the capability of 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.

**3.7** Fee schedule along with boarding, logging, travelling expenses may be communicated to the CB on request. Further processing of application shall be taken up on receipt of acceptance of the fee schedule and confirmation that the agreement is acceptable.

**3.8** Pre-assessment/assessment visit would be planned usually with mutual consent of the applicant and PNAC. Assessment fee would be charged usually before the visit. Logistic arrangements including Boarding/logging, travelling (Business Class) expenses of assessment team would be responsibility of CB and if incurred by PNAC, it would be communicated to the CB for compliance.

3.9 At any point in the application or initial assessment process, if there is evidence of fraudulent behaviour, if the CB intentionally provides false information or if the CB conceals information, PNAC has the right to reject the application or terminate the assessment process.

**4.0 Criteria for Accreditation:**

**4.1 Adoption of Criteria;**

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) or, Asia Pacific Accreditation Cooperation (APAC). Definitions of various terms related to conformity assessment shall be used as given in ISO/IEC 17000, ISO 17021 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**

Amendment to the Criteria shall be based on the nature of change required. The criteria of

accreditation and guidance documents shall be taken up for any 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 received from the implementation of the criteria

e) Any other reason as deemed fit by the PNAC

**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 / Website/ 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, PNAC reserves the right to carryout an additional assessment and the fee and related assessment expenses of team 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. Accredited and applicants Certification Bodies are advised to visit PNAC website regularly i.e., At least every 15 days to be aware of revised/updated related requirements/conditions/documents.

**5.0 Conditions for Accreditation**

**5.1 Granting of Accreditation**

The accreditation is granted to an applicant CB on completion of assessment process and following

conditions

a. The applicant has the certification system (activities including contracting for certification, application review, audit planning and conduct of audit, decision making) in operation for at least one year before the office assessment is carried out.

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 PNAC in accordance with the guidelines on accreditation.

c. There are no adverse reports / information / disrepute / complaints with PNAC about the applicant regarding the quality and effectiveness of implementation of certification system as per the criteria of 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 would be 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**

**5.2.1** To verify that the requirements for accreditations are met, PNAC will perform regular surveillance assessments of 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.

**5.2.2** The accreditation is renewed after three years, with normally two surveillances in between. Reassessment will be as comprehensive as initial (first time) assessment. In addition PNAC may conduct extra ordinary assessment beyond surveillance assessment when required.

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

a. Copy of the quality manual, procedures 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 of internal audit and management’s review performed last year,

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

**5.2.4** During assessment, CB’s key personnel shall be available whole time. The management of the organization will be present at opening and closing meetings.

**5.2.5** 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.**

**5.3.1** Accredited certification bodies can apply any time for extension of scope of accreditation. When applying for extension, the CB has to send duly filled application form along with necessary appendixes.

**5.3.2** If the application or information of extension is sent to PNAC before an ordinary surveillance or renewal, the application for extension will be treated normally, during the planned visit. In such cases CB shall have to send complete documentation for evaluation of the application (procedures and other relevant documents, list of auditors & technical experts) to PNAC within due date before the planned visit.

**5.4 Access to Premises and Availability of Documents.**

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

**5.4.1.1** *Necessary access* means access which is necessary to verify system (with information in hard or soft form, or physical access to any office of CB/certified client office and premises) in accordance to the requirements of the relevant standard.

**5.4.1.2** *Relevant documentation* means documentation, which gives support in the evaluation of system according to relevant requirement of standards, including the documents, concerning the work done by the CB. Relevant documentation shall be made available for PNAC on request as soon as possible.

**5.4.2** During period of assessment, it shall be the responsibility of the CB to manage its normal activities in a way so that the assessment team can perform assessment efficiently without distraction.

**5.4.3** PNAC will inform the CB about the required assessment visit and suitable time will be provided in routine cases. However PNAC may conduct surprise visit as and when required without prior intimation to the CB and it shall be the responsibility of CB to provide access to PNAC’s assessment team and bear the expenses as per routine assessment charges.

**5.4.4** Documentation and premises shall be accessible for staff employed in PNAC as well as the assessors/ experts, who are engaged by PNAC and accepted (in case of experts) by the CB.

**5.5 General Information Obligation**

**5.5.1** 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) Change of premises/office

c) The organization’s management and key personnel, e.g., Manager, Lead auditors d) If there is significant change/amendment in quality system.

e) Any action that can lead to disrepute of PNAC.

**5.5.2** The Certification Body shall be liable to,

i. pay all expenses incurred on account of Travelling directly to Team Leader / Technical Assessor/Expert through cross cheques (if personnel car is used by them for assessment purpose) and copy of acknowledgement will be sent to PNAC. Cash payment may be discouraged except under some unavoidable circumstances.

ii. provide at least four-star hotel accommodation to assessment team member(s) with all expenses on Bill to Company (BTC) basis.

iii. provide business class conveyance for pick and drop (back & forth from home/airport/hotel/office/premises etc to home) to all assessment team members.

**5.6 Use of Logo, Mark and reference of Pakistan National Accreditation Council.**

**5.6.1** No one except PNAC is allowed to use PNAC logo.

**5.6.2** Accredited certification bodies are advised to use Accreditation Mark. Use of Accreditation

Mark and reference to accreditation shall be in accordance with PNAC’s requirements G-02/02.

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

**5.7 Accreditation Fees**

Applicants and accredited certification bodies are advised to pay fee as soon as invoice is received in accordance with the existing document (available at website of PNAC) regarding fees against the services performed by Pakistan National Accreditation Council. If the fee is not received without one month after the issuance of invoice, PNAC may initiate action and suspend the accreditation status without further intimation to the CB.

**5.8 Sanction when failing to comply with the conditions**

**5.8.1** If the accredited certification bodies fail to comply with the requirements for accreditation, PNAC can put into effect one or more of the following sanctions, depending on intensity of non- compliances and response:

a) Instructions of corrective actions (taken against non-compliances/delay response)

b) Suspension of the whole accreditation scope or part of it c) Withdrawal of the whole accreditation scope or part of it

PNAC will evaluate and decide which sanctions should be applied. 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:

**5.8.1.1 Instructions of corrective actions (non-compliance/delay response).**

PNAC can require that the certification body (CB) correct the non-compliance or required compliance within a specified period. If the CB wishes to keep the accreditation, it has to prove that the non- compliance has been satisfactory corrected within the given time period. PNAC may also decide for an extraordinary visit of the CB for verification of implementation of the corrective actions.

**5.8.1.2 Suspension of Accreditation**

Suspension of accreditation is usually a temporary arrangement from which the CAB is expected to take measures to restore accreditation within time limit as defined by PNAC. Suspension of accreditation can be enforced by PNAC because of serious deficiency in fulfilling the requirements set by PNAC (forced Suspension) or can be requested by the CAB, whatsoever is the reason (Voluntary Suspension). In either case, PNAC shall ensure that appropriate steps have been taken to describe the new status of the CAB, which will be updated on PNAC website.

**5.8.1.2.1** Suspensions are done for 03 months, but PNAC can prolong the limit up to 6 months. CAB’s failure to reinstate its accreditation within the stipulated time-line shall lead to withdrawal of accreditation status.

**5.8.1.2.2** Suspension may apply to only part of the scope of accreditation or specific location or it may apply to the full scope depending on case. During a period of suspension, the regular fees shall be paid by the CAB.

**5.8.1.2.3 Forced Suspension**:

A forced suspension is blocking of the CAB’s accredited activity because of serious deficiency in fulfilling the requirements set by PNAC. Forced Suspension of Accreditation enforces the suspension of accreditation as a result that the CAB is not conforming to accreditation requirements or failure to

abide by the rules of accreditation. The CAB’s non-compliance with the requirements of the accreditation criteria can be determined during the assessment or even without an assessment e.g., random reviews, complaints, complete information – which shall be verified prior to enforcement of suspension.

**5.8.1.2.3.1** There may be following reasons of forced suspension, where, the accreditation or part of it can be suspended for a limited time or as the case may be;

a) If the corrective action is not taken by the CAB on the non-compliance within the agreed time, b) If CAB fails to close out the non-conformities within the stipulated timeframe,

c) PNAC can also enforce suspension of accreditation in case of CAB’s failure to undertake the due regular assessment or an additional assessment that has been decided by PNAC. (an additional assessment e.g. follow-up visit, extraordinary visit, additional surveillance, witness assessment, special assessment that could be decided during accreditation review and decision process or as a result of complaint or requirement.

d) Accreditation of a CAB can also be suspended in case of relocation of the CAB’s premises

where the scope activities are affected.

e) PNAC can also suspend an accreditation of the CAB for any outstanding financial dues &

fees, breach of accreditation agreement,

f) PNAC can also suspend an accreditation of the CAB for misuse of accreditation mark or

PNAC logo,

g) PNAC can also suspend an accreditation of the CAB for continued/unjustified rejection of nominated assessment team.

h) PNAC can also suspend an accreditation of the CAB if any action/activity of the CAB leads to disrepute of PNAC.

i) PNAC can also suspend an accreditation of the CAB if response is delayed.

j) PNAC can also suspend an accreditation of the CAB if it is found that CAB is concealing information or has provided fake/incomplete information.

k) PNAC can also suspend an accreditation of the CAB for not using mark of PNAC on client certificates of accredited scope.

**5.8.1.2.4 Voluntary Suspension**:

The accredited CAB can itself request for voluntary suspension of its accreditation status due to any reason sent to PNAC in-writing. Following are the examples of such reasons;

a) temporary loss of key personnel,

b) damage to essential equipment under accreditation scope, c) serious damage to CAB facilities

d) relocation of CAB,

e) temporary inability to meet the requirements of the standard.

**5.8.1.2.5 Lifting of Suspension:**

Accreditation can be restored after suspension time if the conditions which caused the suspension

have been complied in a satisfactory way within the defined time limit. Following options may be applied on case to case basis for lifting of suspension;

a) Special assessment (On-site Assessment office/site for Lifting of Suspension)

b) Suspension may be lifted on the basis of document review and review of evidences of the corrective actions taken by CAB depending on case to case as decided by PNAC.

c) In case the duration of suspension exceeds renewal timeline, PNAC can suspend accreditation for that remaining period or can determine to withdraw CAB’s accreditation or PNAC can also decide to extend the validity of accreditation as the case may be.

**5.8.2 Withdrawal or Reduction of Accreditation**

The accreditation of a CAB may be withdrawn or reduced for a number of reasons like;

a) the CAB itself may decide that accreditation is no longer required (voluntary withdrawal)

b) PNAC may judge that the CAB is no longer able to satisfy all or part of accreditation requirements

c) PNAC may judge that the CAB is no longer able to abide by the rules of accreditation (forced withdrawal).

d) PNAC may judge that the CAB is creating threat by any means to the credibility/repute of

PNAC.

e) In each case, PNAC will ensure that appropriate steps have been taken to suitably identify the new status of the CAB, which will be updated on PNAC website accordingly.

**5.8.2.1 Voluntary Withdrawal or Reduction of Accreditation**

A CAB may request to withdraw or reduce its accreditation at any time whatsoever reason, however,

the CAB is required to inform PNAC about its intent to withdraw or reduce accreditation at least 03 months before the next due assessment, failure to do so, the CAB shall have to pay the cost incurred by PNAC in relation to initiation of assessment preparations (such as, contracts with experts, logistical preparations, time spent on assessment preparations etc.).

**5.8.2.1.1** Voluntary withdrawal or reduction of accreditation may be due to some following reasons;

a) loss of key personnel,

b) damage to essential equipment under accreditation scope, c) serious damage to CAB facilities

d) relocation of CAB,

e) inability to meet the requirements of the standard. f) financial instability

**5.8.2.2 Forced Withdrawal or Reduction of Accreditation**

PNAC can enforce the withdrawal or reduction of accreditation if the CAB is not conforming to

accreditation requirements or CAB is not abiding by the rules of accreditation. In addition to withdrawal or reduction of accreditation, PNAC may take legal action(s) against the CAB.

**5.8.2.2.1** Forced withdrawal of accreditation may be due to some following reasons;

a) If the CAB is not able to resolve any problem to maintain its accreditation status within stipulated time-line.

b) Accreditation can also be withdrawn or reduced if the suspended CAB fails to address the issues which resulted in suspension of its accreditation adequately or in a timely manner.

c) Where there is evidence of fraudulent behaviour, or when the CAB intentionally provides false information or conceals information.

d) misuse of accreditation mark or PNAC logo e) non-payment of accreditation fee.

f) CAB is involved in an activity which is source of disrepute of PNAC. g) The reasons mentioned in case of suspensions

**5.8.2.2.2** The CAB shall no longer offer/carry out accredited services within the areas of withdrawn of accreditation. In case of withdrawal or suspension, PNAC will not refund paid fee, however the CAB shall have to pay all incurred costs by PNAC in this regard.

**5.8.2.2.3** The CAB upon withdrawal of its accreditation, shall discontinue its use of any reference to

PNAC accreditation;

**5.8.2.2.4** The CAB shall inform its affected clients about the suspension, reduction or withdrawal of its accreditation and the associated consequences without undue delay.

**5.8.2.2.5** Before decision of suspension or withdrawal of accreditation, PNAC may give a notice to the CAB and possibility of a hearing, except in cases, where immediate suspension or withdrawal is required due to unsatisfactory performance.

**5.8.3 Specific Harmonized Sanctions**

The following are situations requiring specific sanctions by PNAC:

Where there is proven evidence of fraudulent behavior, or the CAB intentionally provides false information, or the CAB deliberately violates accreditation rules, PNAC will initiate its process for withdrawal of accreditation.

Where a CAB is providing certification to any standard used as a basis for accrediting CABs (e.g. ISO/IEC 17021-1, ISO/IEC 17025, or ISO 15189), PNAC will initiate its process for suspension of accreditation.

**5.8.4** The CAB has right to appeal on decision made by PNAC as per procedure available on

PNAC website [www.pnac.gov.pk.](http://www.pnac.gov.pk)

**5.9 Transferring of accreditation.**

**5.9.1** In cases where accredited certification bodies wish to transfer an accreditation from one organization to another due to purchase, merger or change of name, transfer implies that an assigned accreditation will be transferred from one organization to another. Normally, the accreditation number will be same.

**5.9.2** Conditions for approval of transmission are as follows:

a) The system of performance of the accredited scope shall not be changed in principle and the changes, if any in system, 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.

The organization obliges the responsibility towards customers and PNAC. (This implies that at any time during the transmission process there have to be a clearly defined legal body which is responsible towards stake of customers and PNAC).

e) The changes are not in conflict with Pakistan’s laws.

**5.9.3** If transmission of accreditation is required, the accredited CAB has to send an application in writing to PNAC. The application must include:

a) Complete description of the background of the application.

b) Clear and precise description of new legal status, when it is relevant. c) Description of possible changes in the quality system.

d) Company-attestation of application

e) Binding statement from the new owner/management that they will fulfil the requirements of accreditation.

f) Binding statement from the new owner/management that possible relevant responsibility has been taken over for the accreditation which was transmitted from (e.g., abidance of offers which are already contracted for delivery of accredited services).

g) Plan for updating quality manual, procedures, catalogues, and other affected documents

(e.g., change of name).

h) Information regarding updating of necessary contract of employments, agreements with subcontractors etc. where relevant.

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

**5.9.5** In the cases where changes will lead to a new accreditation certificate and accreditation document, then the one which is accredited has responsibility to return the earlier edition of these documents to PNAC, if the transmission is declined.

**5.10 Notice to relinquish / dissolve**

**5.10.1** An accredited certification body may terminate its accreditation, without any argument, with a 02 month notice in writing to PNAC. In special cases this period might be shortened.

**5.10.2** If an organization is dissolved, then it is the responsibility of the organization to inform PNAC immediately. PNAC will withdraw accreditation at once. The requirements, described in this document regarding withdrawing, would be valid in such cases and the same requirements would be valid if the CB for any reasons like to reduce the accreditation scope.

**5.11 Financial Responsibility in connection with accreditation**

**5.11.1** PNAC would not be held responsible for any obligation of certification bodies or towards their clients.

**5.11.2** Neither PNAC nor any of its employees or any person on behalf PNAC shall be liable for any damage, loss of expenses whatever sustained by any person due to an act or error of whatsoever nature during assessment, training, on site-assessment or at the premises of CAB or its certified clients.

**5.11.3** PNAC shall not be held responsible due to any loss or damage whatsoever due to an act or error of whatsoever nature of accredited CABs or due to an act or error of whatsoever nature of certified clients of accredited CABs.

**5.12 The Right to Appeal against Decisions made by PNAC.**

CAB may appeal against decisions of PNAC in writing to PNAC within 03 weeks of being officially informed. PNAC shall perform the necessary investigations and may annul or alter the decision, or reject the appeal 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 for decision as per procedure of appeal handling, available at website of PNAC.

**5.13 Audits of Integrated Management Systems (IMS).**

PNAC adheres to IAF MD 11 guidelines for the assessment of Certification Bodies (CBs) conducting Integrated Management System audits for their clients.

**5.14 Accreditation Assessment of CBs with Activities in Multiple Countries.**

PNAC adheres to IAF MD 12 guidelines for the assessment of Certification Bodies (CBs) operating their offices in multi countries.

**5.15 The Collection of Data to Provide Indicators of Management System Certification Bodies' Performance.**

PNAC adheres to IAF MD 15 guidelines for the collection of data to provide indicators of management system certification bodies' performance.

**6.0 Accreditation Scopes and norms for witness assessment**

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 and Asia Pacific Accreditation Cooperation 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 description, given in this guide.

CB shall define auditor competence criteria in terms of knowledge and skills as identified in its initial competence analysis. 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 shall have 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/reviewer may decide to restrict grant of accreditation to the whole applied scope or part of the scope as described sector wise at 6.6.

Witnessing can also be initiated for other reasons, according to the AB’s procedures and/or policies/requirements e.g., upon the receipt of complaints, claims, disputes, market or regulator feedback, complaint of any CB or stakeholder.

**6.4 Witness audit plans for initial / reassessment**

***Office Assessment:***

**6.4.1** PNAC will normally conduct 02 man-day office assessment for initial, surveillance and re-

assessment or otherwise as per case.

***Witness of Scope***

**6.4.2** Witnessing of an audit is an activity performed by an AB whereby it observes, without

interfering and influencing, an audit performed by a CB audit team. The witnessing activities will be conducted as per the requirements of IAF MD 17. The witnessing activities would depend on various factors. The following factors will be take into account when deciding, how many and which audits are to be witnessed;

1. the CB's overall performance;
2. factors such as process complexity or legislation etc. which influence the ability of the certified organization to demonstrate its ability to meet the intended outcomes of the system;
3. feedback from interested parties including complaints about certified organizations;
4. the results of the CB's internal audits;
5. scheme owner requirements, etc.;
6. changes in CB work patterns – growth of work within a specific region or technical area;
7. number of clients within the CB’s scope of accreditation;
8. confidence in the CB’s auditor evaluation and approval process; and previous or other office or witnessing assessment results, etc.

The following additional factors may be taken into account to select witnessing activities:

1. number of certificates issued;
2. number of auditors;
3. different auditors for same scope/different regions;
4. whether auditors are internal staff or external resource;
5. different audits, initial audit (stage 1/stage 2), surveillance and recertification;
6. complex scope clients, combined and/or integrated audits, multi-site audits; countries where audits in the certification process are performed;
7. result of previous witnessing activities;
8. complaints, customer surveys;
9. interested parties and regulators requests;
10. the technical clusters already assessed;
11. experience from other types of accreditations of the CB;
12. previous history of the CB’s ability to manage its operations; level of controls exercised by a CB over its critical activities; specific scheme requirements; and
13. agreements with clients.

**6.4.3** In cases where there are no certified clients for a particular scope within the group, the scope may still be accredited depending on record of available competence of CB but PNAC would reserve the option to review the reports of the first few clients in that scope sector, however in line with IAF MD 17. 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 as per scope.

**6.4.4 Food Safety Management System (FSMS):**

In addition to the requirements mentioned in this accreditation condition (G-02/19), PNAC also follows the requirements of IAF MD-16 for the assessment of CBs accredited on Food Safety Management System FSMS.

**6.4.5 Occupational Health and Safety Management Systems (OH&SMS):**

In addition to the requirements mentioned in this accreditation condition (G-02/19), PNAC also follows the requirements of IAF MD-22 for the assessment of CBs accredited for the Certification of Occupational Health and Safety Management Systems (OH&SMS).

**6.4.6 Medical Device Quality Management Systems (MDMS):**

In addition to the requirements mentioned in this accreditation condition (G-02/19), PNAC also follows the requirements of IAF MD-09 for the assessment of CBs accredited for the Certification of Medical Device Quality Management Systems (ISO 13485).

**6.6 List of Scopes of accreditation**

The list of scope of accreditation by PNAC is based on ID1:2023.

**7.0. References**

1. ISO/IEC 17011 Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies.
2. ISO/IEC17021-1 Requirements for bodies providing audit and certification of management systems
3. ISO/IEC 17065 - Conformity assessment -- Requirements for bodies certifying products, processes and services
4. ISO/IEC 17024 - Conformity assessment -- Requirements for bodies operating certification of persons
5. PNAC- G-02/02 Regulations on the use of PNAC’s logo and reference to accreditation
6. IAF MD 1:2023 IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization
7. IAF MD 2:2023 IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems
8. IAF MD 4:2023 IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes
9. IAF MD 5:2023 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems
10. IAF MD 7:2023 IAF Mandatory Document for the Harmonization of Sanctions and Dealing with Fraudulent Behaviour
11. IAF MD 8:2023 Application of ISO/IEC 17011:2017 in the Field of Medical Device Quality Management Systems (ISO 13485)
12. IAF MD 9:2023 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)
13. IAF MD11:2023 IAF Mandatory Document for the Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems
14. IAF MD12:2023 Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries
15. IAF MD15:2023 IAF Mandatory Document for the Collection of Data to Provide Indicators of Management System Certification Bodies' Performance
16. IAF MD16:2023 Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies
17. IAF MD17:2023 Witnessing Activities for the Accreditation of Management Systems Certification Bodies
18. IAF MD22:2023 Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)
19. IAF MD23:2023 Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies
20. IAF MD25:2023 Criteria for Evaluation of Conformity Assessment Schemes
21. IAF MD28:2023 IAF Mandatory Document for the Upload and Maintenance of Data on IAF Database

Documents published by PNAC are available on Internet: [www.pnac.gov.pk](http://www.pnac.gov.pk/)

Documents published by IAF are available on Internet: [www.iaf.nu/](http://www.iaf.nu/)

Documents published by APAC are available on Internet: [www.apac-accreditation.org](http://www.apac-accreditation.org/)