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| --- | --- |
| Instructions on filling this document  The lab personnel should fill it completely and send it to PNAC while submitting the application form and quality system and give cross references to its clauses in the quality manual/ procedures/ forms etc. Please note that only giving reference to a particular procedure may not be sufficient in most of the cases.  PNAC’s Assessors Verification & remarks column will be filled in by the concerned officer in PNAC | |
| Name of the Certification Body (CB): | Name of PNAC’s assessor |
| Address |

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| **CLAUSE No. of ISO 17021-1: 2015**  **Requirements** | **CB’s Reference to its QSD** | **PNAC’s Assessor verification & remarks** |
| **5 General requirements**  **5.1 Legal and contractual matters** |  |  |
| 5.1.1 Legal responsibility  Is the certification body a legal entity, or a defined part of a legal entity, that can be held legally responsible for all its certification activities? (*A governmental certification body is deemed to be a legal entity on the basis of its governmental*  *status*) |  |  |
| 5.1.2 Certification agreement  Does the certification body have a legally enforceable agreement with **each client** for the provision of certification **activities in accordance with the relevant requirements of this part of *ISO/IEC 17021-1*?** |  |  |
| Where there are multiple offices of a certification body or multiple sites of a client, does the certification body ensure that there is a legally enforceable agreement between the certification body granting certification, and the client that covers all the sites within the scope of the  certification? Does the CB apply **IAF MD1:2007** &  **MD19:2016** requirements appropriately? |  |  |
| 5.1.3 Responsibility for certification decisions  Is the certification body responsible for, and does it retain authority for, its decisions relating to certification, including the granting, **refusing, maintaining of certification, expanding or reducing the scope of certification, renewing, suspending** or restoring following suspension, or  withdrawing of certification? |  |  |
| **5.2 Management of impartiality** |  |  |
| 5.2.1 Is the certification body responsible for the impartiality of its conformity assessment  activities? Does the certification body allow commercial, financial or other pressures to compromise impartiality or ensure that conformity assessment activities are undertaken impartially? |  |  |
| 5.2.2 Does the certification body have a policy demonstrating that it understands the importance of impartiality in carrying out its management system certification activities and managing conflicts of interest thus ensuring the objectivity of its management system certification activities? |  |  |
| 5.2.3 Does the certification body have a **process** to identify, analyse, **evaluate, treat, monitor** and document the risks related to conflict of interests arising from the provision of certification including any conflicts arising from its relationships on an **ongoing basis**? |  |  |
| In the event where any threats to impartiality are identified, does the certification body document and demonstrate how it eliminates such threats and document any residual risk |  |  |
| Does the demonstration cover all potential threats that are identified, whether they arise from within the certification body or from the activities of other persons, bodies or organisations? |  |  |
| Does the top management of the certification body review the residual risk to determine if the risk is within the level of acceptable risk? |  |  |
| Does the risk assessment process include the identification of and consultation with appropriate interested parties to advise on matters affecting  impartiality including openness and public perception? |  |  |
| Is the consultation comprised of appropriate interested parties which are balanced with no single interest predominating? |  |  |
| 5.2.4 Is there any evidence of the certification body certifying another certification body for its **quality** management system? |  |  |
| 5.2.5 Does the certification body or any part of the same legal entity and **any entity under the organizational control of the certification body**  **(*9.5.1.2b*)** offer or provide management system consultancy? This also applies to that part of government identified as the certification body? |  |  |
| 5.2.6 Does the certification body **or any part of the**  **same legal entity and any entity under the organisational control of the certification body (*9.5.1.2b*)** offer or provide internal audits to its certified clients? **The carrying out of internal audits by the certification body and any part of the same legal entity to its certified clients is a significant threat to impartially.** Does the certification body certify a management system on which the certification body completed the internal audits less than two years ago? |  |  |
| 5.2.7 Has the certification body certified a management system where there is a relationship between the consultancy organization engaged by the  management system and the certification body? In this case, does the certification body certify a management system less than two years following the end of the consultancy? |  |  |
| 5.2.8 Does the certification body outsource audits to a management system consultancy organization?  This clause does not apply to individuals contracted as auditors covered in 7.3 |  |  |
| 5.2.9 Is the certification body's activities marketed or offered as being linked with the activities of an organization that provides management system consultancy? |  |  |
| Does the certification body take action to correct inappropriate **links or statements** by any consultancy organization stating or implying that certification would be simpler, easier, faster or less expensive if the certification body were used? |  |  |
| Does the certification body state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy  organization were used? |  |  |
| 5.2.10 Does the certification body ensure personnel who have provided management system consultancy, including those acting in a managerial capacity, do not take part in an audit or other certification activities if they have been involved in management system consultancy towards the client **in order to ensure that there is no conflict of interest**?  A recognised mitigation of this threat is that personnel shall not be used for a minimum of two years following the end of the consultancy. |  |  |
| 5.2.11 Does the certification body take action to respond to any threats to its impartiality arising from the actions of other persons, bodies or organizations? |  |  |
| 5.2.12 How does the certification body ensure that all personnel, either internal or external, or committees, who could influence the certification activities, act impartially and not allow commercial, financial or other pressures to compromise impartiality? |  |  |
| 5.2.13 Does the certification body require personnel, both internal and external, to reveal any situation known to them that **can** present them or the certification body with a conflict of interests? |  |  |
| Does the certification body **record** and use this information as input to identifying threats to impartiality raised by the activities of such personnel or by the organizations that employ them? |  |  |
| Does the certification body use such personnel, either internal or external, that cannot demonstrate that there is no conflict of interests? |  |  |
| **5.3 Liability and financing** |  |  |
| 5.3.1 Can the certification body demonstrate that it has evaluated the risks arising from its certification activities? |  |  |
| Does the certification body have adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates? |  |  |
| 5.3.2 Does the certification body evaluate its finances and sources of income and demonstrate that initially, and on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality |  |  |
| **6 Structural requirements**  **6.1 Organisational structure and top management** |  |  |
| 6.1.1 Has the certification body documented its organizational structure, duties, responsibilities and authorities of management and other personnel **involved in certification** and any committees? |  |  |
| When the certification body is a defined part of a legal entity, does the structure include the line of authority and the relationship to other parts within  the same legal entity? |  |  |
| 6.1.2 Are the certification activities structured and managed so as to safeguard impartiality? |  |  |
| 6.1.3 Has the certification body identified the top management (board, group of persons, or  person) having overall authority and responsibility for each of the following: |  |  |
| a) development of policies and **establishment**  **of processes and procedures** relating to **its** operations; |  |  |
| b) supervision of the implementation of the policies, **processes** and procedures |  |  |
| c) **ensuring impartiality;** |  |  |
| d) supervision of the finances of the body; |  |  |
| e) development of management system certification services and schemes |  |  |
| f) performance of audits and certification, and responsiveness to complaints; |  |  |
| g) decisions on certification; |  |  |
| h) delegation of authority to committees or individuals, as required, to undertake defined  activities on its behalf; |  |  |
| i) contractual arrangements; |  |  |
| j) Provision of adequate resources for certification activities |  |  |
| 6.1.4 Does the certification body have formal rules for the appointment, terms of reference and operation of committees involved in the certification activities? |  |  |
| **6.2 Committee for safeguarding impartiality** |  |  |
| 6.2.1 Does the certification body have a process for effective control of certification activities delivered by branch offices, partnerships, agents, franchisees, etc., irrespective of their legal status, relationship or geographical location? |  |  |
| Does the certification body consider the risk that the certification activities pose to the competence, consistency and impartiality of the certification body? |  |  |
| 6.2.2 Does the certification body consider the appropriate level and method of control of activities undertaken including its processes,  technical areas of certification bodies’ operations, competence of personnel, lines of management control, reporting and remote access to operations including records? |  |  |
| **7 Resource requirements**  **7.1 Competence of management and personnel** |  |  |
| 7.1.1 Does the certification body have processes to ensure that personnel have appropriate knowledge **and skills** relevant to the types of management systems (**e.g. environmental management systems, quality management systems, information security management systems)** and geographic areas in which it operates? |  |  |
| 7.1.2 Does the certification body have a process for determining the competence criteria for personnel involved in the management and performance of audits **and other certification activities**? |  |  |
| Has the certification body determined the competence criteria for each type of management system standard or specification, for each technical area, and for each function in the certification process? |  |  |
| Is the output of the process ‘the documented criteria of required knowledge and skills necessary to effectively perform audit and certification tasks to be fulfilled to achieve the intended results? |  |  |
| Does the certification body apply the knowledge and skills for specific functions defined in AnnexA? |  |  |
| Does the certification body apply any additional specific competence criteria where they have been established for a specific standard or certification scheme? For example:  - ISO/IEC TS 17021-2 (EMS),  - ISO/IEC TS 17021-3 (QMS),  - ISO/TS 22003 (FSMS) |  |  |
| 7.1.3 **Evaluation processes**  Does the certification body have documented processes for the initial competence evaluation, and on-going monitoring of competence and performance of all personnel involved in the management and performance of audits **and other certification activities**, applying the determined competence criteria? |  |  |
| Is the certification body able to demonstrate that its evaluation methods are effective? |  |  |
| Is the output from these processes being to identify personnel who have demonstrated the  level of competence required for the different functions of the audit and certification process? |  |  |
| Is competence demonstrated by the individual prior to taking up the responsibility for the performance of their activities within the certification body? |  |  |
| **7.1.4 Other considerations**  Does the certification body have access to the necessary technical expertise for advice on matters directly relating to certification for technical areas, types of management system and geographic areas in which the certification body operates? |  |  |
| **7.2 Personnel involved in the certification**  **activities** |  |  |
| 7.2.1 Does the certification body have sufficient, **competent personnel** for managing and **supporting** the type and range of audit  programmes and other certification work performed? |  |  |
| 7.2.2 Does the certification body employ, or have access to, a sufficient number of auditors,  including audit team leaders, and technical  experts to cover all of its activities and to handle the volume of audit work performed? |  |  |
| 7.2.3 Does the certification body make clear to each person concerned their duties, responsibilities  and authorities? |  |  |
| 7.2.4 Does the certification body have processes for selecting, training, formally authorizing auditors  and for selecting and **familiarizing** technical  experts used in the certification activity? |  |  |
| Does the initial competence evaluation of an auditor include the ability to apply required knowledge and skills during audits, as determined  by a competent evaluator observing the auditor conducting an audit? |  |  |
| 7.2.5 Does the certification body have a process to achieve and demonstrate effective auditing,  including the use of auditors and audit team  leaders possessing generic auditing skills and knowledge, as well as skills and knowledge  appropriate for auditing in specific technical areas? |  |  |
| 7.2.6 Does the certification body ensure that auditors (and, where needed, technical experts) are knowledgeable of its audit processes, certification requirements and other relevant requirements? |  |  |
| Does the certification body give auditors and technical expert’s access to an up-to-date set of  documented procedures giving audit instructions  and all relevant information on the certification activities? |  |  |
| 7.2.7 Does the certification body identify training needs and offer or provide access to specific training to  ensure its auditors, technical experts and other personnel involved in certification activities are competent for the functions they perform? |  |  |
| 7.2.8 Does the group or individual that takes the decision on granting, **refusing**, maintaining, renewing, **suspending, restoring, or withdrawing certification, or on expanding or**  **reducing the scope of certification** shall understand the applicable standard and certification requirements, and have demonstrated competence to evaluate the  **outcomes** of the audit processes including  related **recommendations** of the audit team? |  |  |
| 7.2.9 Does the certification body ensure the satisfactory performance of all personnel involved in the audit  and **other** certification activities? |  |  |
| Is there a **documented process for monitoring**  **competence** and performance of all persons  involved, based on the frequency of their usage and the level of risk linked to their activities? |  |  |
| Does the certification body review **and record** the  competence of its personnel in the light of their performance in order to identify training needs? |  |  |
| 7.2.10 Does the certification body monitor each auditor considering each type of management system to which the auditor is deemed competent? |  |  |
| Is there a documented monitoring process for auditors? |  |  |
| Does the monitoring process include a combination of on-site observation, review of audit reports and feedback from clients or from the market? |  |  |
| Is the monitoring designed in such a way as to minimize disturbance to the normal processes of certification, especially from the client's viewpoint? |  |  |
| **7.2.11** Does the certification body periodically **evaluate**  the performance of each auditor on-site? |  |  |
| Is the frequency of on-site observations based on the need determined from all monitoring  information available? |  |  |
| **7.3 Use of individual external auditors and external technical experts** |  |  |
| Does the certification body require external auditors and external technical experts to have a  written agreement by which they commit  themselves to comply with applicable policies and implement processes as defined by the  certification body? |  |  |
| Does the agreement address aspects relating to confidentiality and **impartiality**? |  |  |
| Does the agreement require the external auditors and external technical experts to notify the certification body of any existing or prior relationship with any organization they may be assigned to audit? |  |  |
| **7.4 Personnel records** |  |  |
| Does the certification body maintain up-to-date personnel records, including relevant qualifications, training, experience, affiliations,  professional status and competence? |  |  |
| Does this include management and administrative personnel in addition to those performing  certification activities? |  |  |
| **7.5 Outsourcing** |  |  |
| 7.5.1 Does the certification body have a process in which it describes the conditions under which  outsourcing (which is subcontracting to another  organization to provide part of the certification activities on behalf of the certification body) may  take place? |  |  |
| Does the certification body have a legally enforceable agreement covering the  arrangements, including confidentiality and  conflict of interests, with each body that provides outsourced services? |  |  |
| 7.5.2 How does the certification body ensure that the decisions for granting, refusing, maintaining of certification, expanding or reducing the scope of  certification, renewing, suspending or restoring or withdrawing of certification are not outsourced? |  |  |
| 7.5.3 Does the CB: |  |  |
| a) Take responsibility for all activities outsourced to another body? |  |  |
| b) Ensure that the body that provides outsourced services, and the individuals that it uses, conform to requirements of the certification body and also to the applicable provisions of this part of ISO/IEC  17021, including competence, impartiality and confidentiality? |  |  |
| c) Ensure that the body that provides outsourced services, and the individuals that it uses, is not  involved, either directly or through any other employer, with an organization to be audited, in such a way that impartiality could be compromised? |  |  |
| 7.5.4 Does the certification body have a process for the approval and monitoring of all bodies that provide outsourced services used for certification  activities? |  |  |
| Does the certification body ensure that records of the competence of all personnel involved in  certification activities are maintained? |  |  |
| **8 Information requirements**  **8.1 Publicly information** |  |  |
| 8.1.1 Does the certification body maintain (**through**  **publications, electronic media or other means**), and make public, **without** request, **in all the geographical areas in which it operates**, information about? |  |  |
| a) audit processes; |  |  |
| b) processes for granting, refusing, maintaining, renewing, suspending, **restoring** or withdrawing certification, **or expanding or reducing the scope of certification;** |  |  |
| c) types of management systems and **certification**  **schemes in which it operates;** |  |  |
| d) the use of the certification body’s name and certification mark or logo; |  |  |
| e) processes for handling requests for information, complaints and appeals; |  |  |
| f) Policy on impartiality |  |  |
| 8.1.2 Does the certification body upon request provide information about? |  |  |
| a) geographical areas in which it operates; |  |  |
| b) the status of a given certification; |  |  |
| c) the name, related normative document, scope and geographical location (city and country) for a specific certified client. |  |  |
| 8.1.3 Does the certification body provide information to any client or to any marketplace, including advertising, which is accurate and not  misleading? |  |  |
| **8.2 Certification documents** |  |  |
| 8.2.1 How does the certification body provide **by any**  **means it chooses** certification documents to the certified client? |  |  |
| 8.2.2 Do the certification document(s) identify the following? |  |  |
| a) the name and geographic location of each  **certified** client whose management system is  certified (or the geographic location of the headquarters and any sites within the scope of a multi-site certification); |  |  |
| b) the effective dates of granting, expanding or reducing the scope of certification or renewing  certification which shall not be before the date of the relevant certification decision? |  |  |
| c) the expiry date or recertification due date consistent with the recertification cycle? |  |  |
| d) a unique identification code; |  |  |
| e) The **management system** standard and/or other  normative document, including **indication of issue status (e.g. revision date or number**) used for audit of the certified client; |  |  |
| f) The **management system** standard and/or other  normative document, including **indication of issue status (e.g. revision date or number**)  used for audit of the certified client; |  |  |
| g) the name, address and certification mark of the certification body; other marks (e.g. accreditation  symbol **client’s logo**) may be used provided they  are not misleading or ambiguous; |  |  |
| h) any other information required by the standard and/or other normative document used for certification; |  |  |
| i) in the event of issuing any revised certification documents, a means to distinguish the revised documents from any prior obsolete documents |  |  |
| **8.3 Directory of certified customers** |  |  |
| 8.3.1 Does the certification body have **rules** governing  any **management system certification** mark  that it authorizes certified clients to use? |  |  |
| Do these rules ensure, among other things, traceability back to the certification body? |  |  |
| Do these rules ensure, among other things, traceability back to the certification body? |  |  |
| Is there any ambiguity, in the mark or accompanying text, as to what has been certified and which certification body has granted the certification? |  |  |
| Is the mark used on a **product or product**  **packaging** or in any other way that may be  interpreted as denoting product conformity? |  |  |
| 8.3.2 Does the certification body permit its marks to be applied by certified clients to laboratory test,  calibration or inspection reports or certifications? |  |  |
| 8.3.3 Does the certification body have rules governing the use of any statement on product packaging or  in accompanying information that the certified client has a certified management system? |  |  |
| Product packaging is considered as that which can be removed without the product disintegrating  or being damaged. Accompanying information is considered as separately available or easily detachable. Type labels or identification plates are considered as part of the product |  |  |
| Does the statement imply that the product, process or service is certified by this means? |  |  |
| Does the statement include reference to: |  |  |
| - identification (e.g. brand or name) of the certified client; |  |  |
| - the type of management system (e.g. quality, environment) and the applicable standard; and |  |  |
| - the certification body issuing the certificate. |  |  |
| 8.3.4 Does the certification body require that the  **certified** client? |  |  |
| a) conforms to the requirements of the certification body when making reference to its certification  status in communication media such as the internet, brochures or advertising, or other documents; |  |  |
| b) does not make or permit any misleading statement regarding its certification; |  |  |
| c) does not use or permit the use of a certification document or any part thereof in a misleading manner; |  |  |
| d) upon withdrawal of its certification, discontinues its use of all advertising matter that contains a  reference to certification, as directed by the certification body (see 9.6.5); |  |  |
| e) amends all advertising matter when the scope of certification has been reduced; |  |  |
| f) does not allow reference to its management system certification to be used in such a way as  to imply that the certification body certifies a  product (including service)or process; |  |  |
| g) does not imply that the certification applies to activities that are outside the scope of certification; and |  |  |
| h) does not use its certification in such a manner that would bring the certification body and/or certification system into disrepute and lose public  trust. |  |  |
| 8.3.5 Does the certification body exercise proper control of ownership and take action to deal with  incorrect references to certification status or  misleading use of certification documents, marks or audit reports? |  |  |
| **8.4 Confidentiality** |  |  |
| 8.4.1 Does the certification body be responsible, through legally enforceable agreements, **for the**  **management of all** information obtained or  created during the performance of certification activities at all levels of its structure, including committees and external bodies or individuals acting on its behalf? |  |  |
| 8.4.2 Does the certification body inform the client, in advance, of the information it intends to place in  the public domain? |  |  |
| Is all other information, except for information that is made publicly accessible by the client,  considered confidential? |  |  |
| 8.4.3 Is information about a particular **certified** client or  individual disclosed to a third party without the written consent of the **certified** client or individual concerned? |  |  |
| 8.4.4 Where the certification body is required by law or **authorized by contractual arrangement** (such as with the accreditation body) to release confidential information to a third party, is the client or individual concerned, unless **prohibited** by law, notified of the information provided? |  |  |
| 8.4.5 Is information about the client from sources other than the client (e.g. complainant, regulators)  treated as confidential? |  |  |
| Is this treatment consistent with the certification body's policy? |  |  |
| 8.4.6 Do personnel, including any committee members, contractors, personnel of external bodies or individuals acting on the certification body's  behalf, keep all information obtained or created during the performance of the certification body's activities confidential **except as required by law**? |  |  |
| 8.4.7 Does the certification body have **processes and**  **where applicable** equipment and facilities that  ensure the secure handling of confidential information? |  |  |
| **8.5 Information exchange between a CB and its client** |  |  |
| **8.5.1 Information on the certification activity and**  **Requirements** |  |  |
| Does the certification body provide **information**  and update clients on the following: |  |  |
| a) a detailed description of the initial and continuing certification activity, including the application,  initial audits, surveillance audits, and the process for granting**, refusing**, maintaining of certification,  **expanding, or reducing the scope of**  **certification, renewing, suspending or restoring**, or withdrawing of certification and recertification; |  |  |
| b) the normative requirements for certification; |  |  |
| c) information about the fees for application, initial certification and continuing certification; |  |  |
| d) the certification body's requirements for prospective clients:  1) to comply with certification requirements; |  |  |
| 2) to make all necessary arrangements for the conduct of the audits, including provision for examining documentation and the access to all processes and areas, records and personnel for the purposes of initial certification, surveillance, recertification and resolution of complaints; and |  |  |
| 3) to make provisions, where applicable, to accommodate the presence of observers (e.g. accreditation auditors or trainee  auditors); |  |  |
| e) documents describing the rights and duties of certified clients, including requirements, when  making reference to its certification in  communication of any kind in line with the requirements in 8.3; |  |  |
| f) information on procedures for handling complaints and appeals. |  |  |
| 8.5.2 **Notice of changes by a certification body**?  Does the certification body give its certified clients due notice of any changes to its requirements for certification? |  |  |
| Does the certification body verify that each certified client complies with the new  requirements? |  |  |
| **8.5.3 Notice of changes by a certified client**  Does the certification body have legally enforceable arrangements to ensure that the certified client informs the certification body, without delay, of matters that may affect the capability of the management system to continue to fulfil the requirements of the standard used for certification? Do these include, for example, changes relating to: |  |  |
| a) the legal, commercial, organizational status or ownership; |  |  |
| b) organization and management (e.g. key managerial, decision-making or technical staff); |  |  |
| c) contact address and sites; |  |  |
| d) scope of operations under the certified management system; and |  |  |
| e) major changes to the management system and processes |  |  |
| **9 Process requirements**  **NB. Clauses 9.1.1 to 9.6.4 are covered in checklists, F146&F154** |  |  |
| **9.6.5 Suspending, withdrawing or reducing scope**  **of certification** |  |  |
| 9.6.5.1 Does the certification body have a policy and documented procedure(s) for suspension,  withdrawal or reduction of the scope of certification? |  |  |
| Does the certification body specify the subsequent actions by the certification body? |  |  |
| 9.6.5.2 Does the certification body suspend certification in cases when, for example: |  |  |
| - the client's certified management system has persistently or seriously failed to meet certification requirements, including  requirements for the effectiveness of the management system, |  |  |
| - the certified client does not allow surveillance or recertification audits to be conducted at  the required frequencies, or |  |  |
| - the certified client has voluntarily requested a suspension. |  |  |
| 9.6.5.3 Under suspension, is the client’s management system certification temporary invalid? |  |  |
| 9.6.5.4 Does the certification body restore the suspended certification if the issue that has resulted in the  suspension has been resolved? |  |  |
| Does failure to resolve the issues that have resulted in the suspension in a time established by the certification body result in withdrawal or  reduction of the scope of certification? |  |  |
| 9.6.5.5 Does the certification body reduce the client's scope of certification to exclude the parts not  meeting the requirements, when the client has  persistently or seriously failed to meet the certification requirements for those parts of the  scope of certification? |  |  |
| Is any such reduction in line with the requirements of the standard used for  certification? |  |  |
| **9.7 Appeals** |  |  |
| 9.7.1 Does the certification body have a documented process to receive, evaluate and make decisions  on appeals? |  |  |
| 9.7.2 Is the certification body responsible for all decisions at all levels of the appeals-handling  process? |  |  |
| Does the certification body ensure that the persons engaged in the appeals-handling process are different from those who carried out the audits and made the certification decisions? |  |  |
| 9.7.3 Does the certification body ensure submission, investigation and decision on appeals do not result in any discriminatory actions against the  appellant? |  |  |
| 9.7.4 Does the appeals-handling process include at least the following elements and methods: |  |  |
| a) an outline of the process for receiving, validating, investigating the appeal, and for deciding what  actions are to be taken in response to it, taking into account the results of previous similar appeals; |  |  |
| b) tracking and recording appeals, including actions undertaken to resolve them; |  |  |
| c) ensuring that any appropriate correction and corrective action is taken |  |  |
| 9.7.5 Does the certification body receiving the appeal responsible for gathering and verifying all necessary information to validate the appeal? |  |  |
| 9.7.6 Does the certification body acknowledge receipt of the appeal? |  |  |
| Does the certification body provide the appellant with progress reports and the result of the appeal? |  |  |
| 9.7.7 Is the decision to be communicated to the appellant made by, or reviewed and approved by, individual(s) not previously involved in the subject of the appeal? |  |  |
| 9.7.8 Does the certification body give formal notice to the appellant of the end of the appeals-handling process? |  |  |
| **9.8 Complaints** |  |  |
| 9.8.1 Is the certification body responsible for all decisions at all levels of the complaints-handling process? |  |  |
| 9.8.2 Do the submission, investigation and decision on complaints result in any discriminatory actions  against the complainant? |  |  |
| 9.8.3 Upon receipt of a complaint, does the certification body confirm whether the complaint relates to  certification activities that it is responsible for? |  |  |
| If so, does the certification body deal with it? |  |  |
| If the complaint relates to a certified client, does examination of the complaint consider the effectiveness of the certified management system? |  |  |
| 9.8.4 Is any complaint about a certified client referred by the certification body to the certified client in  question at an appropriate time? |  |  |
| 9.8.5 Does the certification body have a documented process to receive, evaluate and make decisions  on complaints? |  |  |
| Is this process subject to requirements for confidentiality, as it relates to the complainant and  to the subject of the complaint? |  |  |
| 9.8.6 Does the complaints-handling process include at least the following elements and methods?  a) an outline of the process for receiving, validating, investigating the complaint, and for deciding what actions are to be taken in response to it; |  |  |
| b) tracking and recording complaints, including actions undertaken in response to them; |  |  |
| c) Ensuring that any appropriate correction and corrective action are taken? |  |  |
| 9.8.7 Is the certification body receiving the complaint responsible for gathering and verifying all  necessary information to validate the complaint? |  |  |
| 9.8.8 Whenever possible, does the certification body acknowledge receipt of the complaint? |  |  |
| Does the certification body provide the complainant with progress reports and the  outcome? |  |  |
| 9.8.9 Is the decision to be communicated to the complainant made by, or reviewed and approved  by, individual(s) not previously involved in the  subject of the complaint? |  |  |
| 9.8.10 Whenever possible, does the certification body give formal notice of the end of the complaints-  handling process to the complainant? |  |  |
| 9.8.11 Does the certification body determine, together with the **certified** client and the complainant,  whether and, if so to what extent, the subject of the complaint and its resolution made public? |  |  |
| **9.9 Client Records** |  |  |
| 9.9.1 Does the certification body maintain records on the audit and other certification activities for all clients, including all organizations that submitted applications, and all organizations audited, certified, or with certification suspended or withdrawn? |  |  |
| 9.9.2 Do records on certified clients include the following? |  |  |
| a) application information and initial, surveillance and recertification audit reports; |  |  |
| b) certification agreement? |  |  |
| c) justification of the methodology used for sampling  **of sites, as appropriate**? |  |  |
| d) justification for auditor time determination (see  9.1.4)? |  |  |
| e) verification of correction and corrective actions; |  |  |
| f) records of complaints and appeals, and any subsequent correction or corrective actions; |  |  |
| g) committee deliberations and decisions, if applicable; |  |  |
| h) documentation of the certification decisions? |  |  |
| i) certification documents, including the scope of certification with respect to product, process or  service, as applicable; |  |  |
| j) Related records necessary to establish the credibility of the certification, such as evidence of  the competence of auditors and technical  experts? |  |  |
| k) Audit programmes? |  |  |
| 9.9.3 Does the certification body keep the records on applicants and clients secure to ensure that the  information is kept confidential? |  |  |
| Are records transported, transmitted or transferred, in a way that ensures that  confidentiality is maintained? |  |  |
| 9.9.4 Does the certification body have a documented policy and documented procedures on the retention of records? |  |  |
| Are records of **certified clients and previously**  **certified clients** retained for the duration of the  current cycle plus one full certification cycle? |  |  |
| **10 Management system requirements for**  **certification bodies**  **10.1 Options** |  |  |
| Does the certification body establish, **document,**  **implement** and maintain a management system  that is capable of supporting and demonstrating the consistent achievement of the requirements of this part of ISO/IEC 17021? |  |  |
| In addition to meeting the requirements of Clause  5 to 9, does the certification body implement a management system in accordance with either:  a) general management system requirements  (10.2) or |  |  |
| b) Management system requirements in accordance with ISO 9001 (see 10.3)? |  |  |
| **10.2 Option A: Management system requirements**  **10.2.1 General** |  |  |
| Has the certification body's top management established and documented policies and  objectives for its activities? |  |  |
| Does the top management provide evidence of its commitment to the development and  implementation of the management system in  accordance with the requirements of this  International Standard? |  |  |
| Does the top management ensure that the policies are understood, implemented and  maintained at all levels of the certification body's organization? |  |  |
| Has the certification body's top management, assigned responsibility and authority for: |  |  |
| a) ensuring that processes and procedures needed for the management system are  established, implemented and maintained,  and |  |  |
| b) Reporting to top management on the performance of the management system and any need for improvement? |  |  |
| **10.2.2 Management system manual** |  |  |
| Have all applicable requirements of this  International Standard been addressed either in a manual or in associated documents? |  |  |
| Does the certification body ensure that the manual and relevant associated documents are accessible to all relevant personnel? |  |  |
| **10.2.3 Control of documents** |  |  |
| Has the certification body established procedures to control the documents (internal and external)  that relate to the fulfilment of this International  Standard? |  |  |
| Do the procedures define the controls needed to: |  |  |
| a) approve documents for adequacy prior to issue, |  |  |
| b) review and update where necessary and re- approve documents, |  |  |
| c) ensure that changes and the current revision status of documents are identified, |  |  |
| d) ensure that relevant versions of applicable documents are available at points of use, |  |  |
| e) ensure that documents remain legible and readily identifiable, |  |  |
| f) ensure that documents of external origin are identified and their distribution controlled, and |  |  |
| g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose? |  |  |
| **10.2.4 Control of records** |  |  |
| Has the certification body established procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and  disposition of its records related to the fulfilment of this part of ISO/IEC 17021? |  |  |
| Has the certification body established procedures for retaining records for a period consistent with  its contractual and legal obligations? |  |  |
| Is access to these records consistent with the confidentiality arrangements? |  |  |
| **10.2.5 Management review** |  |  |
| **10.2.5.1 General** |  |  |
| Has the certification body's top management established procedures to review its management  system at planned intervals to ensure its  continuing suitability, adequacy and effectiveness, including the stated policies and  objectives related to the fulfilment of this  International Standard? |  |  |
| Are these reviews conducted at least once a year? |  |  |
| **10.2.5.2 Review inputs** |  |  |
| Does the input to the management review include information related to: |  |  |
| a) results of internal and external audits; |  |  |
| b) feedback from clients and interested parties; |  |  |
| c) safeguarding impartiality; |  |  |
| d) the status of preventive and corrective actions; |  |  |
| e) the status of actions to address risks; |  |  |
| f) follow-up actions from previous management reviews; |  |  |
| g) the fulfilment of objectives; |  |  |
| h) changes that could affect the management system; and |  |  |
| i) Appeals and complaints? |  |  |
| **10.2.5.3 Review outputs** |  |  |
| Does the input to the management review include information related to: |  |  |
| a) improvement of the effectiveness of the management system and its processes, |  |  |
| b) Improvement of the certification services related to the fulfilment of this part of ISO/IEC  17021; |  |  |
| c) resource needs, and |  |  |
| d) Revision of the organisation’s policy and objectives? |  |  |
| **10.2.6 Review outputs** |  |  |
| 10.2.6.1 Has the certification body established procedures for internal audits to verify that it fulfils the  requirements of this International Standard and that the management system is effectively implemented and maintained? |  |  |
| 10.2.6.2 Is the audit programme planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits? |  |  |
| 10.2.6.3 Are internal audits performed at least once every  12 months? |  |  |
| 10.2.6.4 Does the certification body ensure that: |  |  |
| a) internal audits are conducted by **competent personnel** knowledgeable in certification, auditing and the requirements of this International Standard, |  |  |
| b) auditors do not audit their own work, |  |  |
| c) personnel responsible for the area audited are informed of the outcome of the audit, |  |  |
| d) any actions resulting from internal audits are taken in a timely and appropriate manner, and |  |  |
| e) Any opportunities for improvement are identified? |  |  |
| **10.2.7 Corrective action** |  |  |
| Has the certification body established procedures for identification and management of nonconformities in its operations? |  |  |
| Does the certification body also, where necessary, take actions to eliminate the causes of  nonconformities in order to prevent recurrence? |  |  |
| Are corrective actions appropriate to the impact of the problems encountered? |  |  |
| Do the procedures define requirements for: |  |  |
| a) identifying nonconformities (e.g. from valid complaints and internal audits); |  |  |
| b) determining the causes of nonconformity; |  |  |
| c) correcting nonconformities; |  |  |
| d) evaluating the need for actions to ensure that nonconformities do not recur; |  |  |
| e) determining and implementing in a timely manner, the actions needed; |  |  |
| f) recording the results of actions taken; and |  |  |
| g) Reviewing the effectiveness of corrective actions? |  |  |
| **10.3 Option B: General management**  **system requirements**  **10.3.1 General** |  |  |
| Has the certification body established and maintained a management system, in accordance  with the requirements of ISO 9001 that is capable of supporting and demonstrating the consistent achievement of the requirements of this International Standard, amplified by 10.3.2 to  10.3.4? |  |  |
| **10.3.2 Scope** |  |  |
| Does the scope of the management system include the design and development requirements  for its certification services? |  |  |
| **10.3.3 Customer focus** |  |  |
| When developing its management system, has the certification body considered the credibility of  certification? |  |  |
| Has the certification body addressed the needs of all parties (as set out in 4.1.2) that rely upon its  audit and certification services, not just its clients? |  |  |
| **10.3.4 Management review** |  |  |
| Does the certification body include as input for management review, information on relevant appeals and complaints from users of certification activities and a review of impartiality for application of the requirements of ISO 9001? |  |  |

**To be filled in during pre-assessment (onsite visit) by PNAC Assessor**

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| --- | --- |
| **Brief history of the CB and its legal status** | |
|  | |
|  | |
| **Status of implementation of the standard w.r.t records** | |
|  | |
| **Is the CB having sufficient and trained human resources to carry out its activities?** | |
|  | |
| **Recommendation on its preparation for full assessment?** | |
|  | |
| **Are there any major gaps that need to be addressed before initial assessment?** | |
|  | |
| **Suggestion on no of man days/ type of team and scope to be assessed** | |
|  | |
| **PNAC’s Assessor name & signature** | **CB’s representative** |
| **Date** | **Date** |