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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 Medical Lab:**  | **Name of PNAC’s assessor** |
| **Address:** | **Name of Management Rep of Lab** |
| **ISO 15189 Clause Ref.** | **Requirement** | **Reference in Labs Documents** | **For PNAC Assessors****Onsite verification & remarks** |
| **4** | **MANAGEMENT REQUIREMENTS** |
| **4.1** | **Organisation and Management Responsibility** |
| 4.1.1.2 | **Legal entity**The laboratory or the organisation of which the laboratory is a part shall be an entity that can be held legally responsible for its activities. |  |  |
| 4.1.1.3 | **Ethical Conduct**Laboratory management shall have arrangements in place to ensure that there is no involvement in any activities that would diminish confidence in the laboratory’s competence, impartiality, judgement or operational integrity; |  |  |
| 4.1.1.4 | **Laboratory Director**The laboratory shall be directed by a person or persons with the competence and delegated responsibility for the services provided.The duties and responsibilities of the laboratory director shall be documented. |  |  |
| 4.1.2.3 | Quality PolicyLaboratory management shall define the intent of its quality policy. includes a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of this International Standard, and continual improvement of the quality of laboratory services; |  |  |
| 4.1.2.4 | Quality Objectives and PlanningLaboratory management shall establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. |  |  |
| 4.1.2.6 | **Communication**Laboratory management shall have an effective means for communicating with staff. Records shall be kept of items discussed in communications and meetings. |  |  |
| 4.1.2.7 | **Quality Manager**Laboratory management shall appoint a quality manager who shall have, irrespective of other responsibilities, delegated responsibility and authority that includes: |  |  |
| **4.2** | **Quality Management System** |
| 4.2.1 | **General Requirements**The laboratory shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. |  |  |
| 4.2.2 | **Documentation Requirements** |  |  |
| 4.2.2.2 | **Quality Manual**The laboratory shall establish and maintain an quality manual that includes;a) the quality policy or makes reference to it;b) roles and responsibilities of laboratory management (including the laboratory director and quality manager) for ensuring compliance with this International Standard; |  |  |
| **4.3** | **DOCUMENT CONTROL** |
| 4.3.1 | The laboratory shall control documents required by the quality management system and shall ensure that unintended use of any obsolete document is prevented. |  |  |
| **4.4** | **Service Agreements** |
| 4.4.1 | **Establishment of Service Agreements**The laboratory shall have documented procedures for the establishment and review of agreements for providing medical laboratory services.Each request accepted by the laboratory for examination(s) shall be considered an agreement. |  |  |
| **4.5** | **Examination by Referral Laboratories** |
| 4.5.1 | The laboratory shall have a documented procedure for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretation for complex testing in any discipline |  |  |
| **4.6** | **External Services and Supplies** |
| 4.6.1 | The laboratory shall select and approve suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory’s requirements; however, it may be necessary to collaborate with other organizational departments or functions to fulfil this requirement. Criteria for selection shall be established.. |  |  |
| **4.7** | **Advisory Services** |
| 4.7.1 | The laboratory shall establish arrangements for communicating with users on the following:advising on choice of examinations and use of the services, including required type of sample, clinical indications and limitations of examination procedures and the frequency of requesting the examination; |  |  |
| **4.8** | **Resolution of Complaints** |
| 4.8 | The laboratory shall have a document procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties. Records shall be maintained of all complaints and their investigation and the action taken. |  |  |
| **4.9** | **Identification and Control of Nonconformities** |
| 4.9.1 | The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes. |  |  |
| **4.10**  | **Corrective Action** |
|  | The laboratory shall take corrective action to eliminate the cause(s) of nonconformities. Corrective actions shall be appropriate to the nonconformities encountered.1. determining the root causes of nonconformities;
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| **4.11** | **Preventive Action** |
| 4.11 | The laboratory shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. |  |  |
| **4.12** | **Continual Improvement** |
|  | The laboratory shall continually improve the effectiveness of the quality management system, including the pre-examination, examination and post-examination processes,  |  |  |
| **4.13** | **Control of Records** |
|  | The laboratory shall have a documented procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records.The laboratory shall define the time period that various records pertaining to the quality management system, including pre-examination, examination and post- examination processes, are to be retained.  |  |  |
| **4.14** | **Evaluation and Audits** |
| 4.14.2 | Authorized personnel shall periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received. |  |  |
| 4.14.3 | **Assessment of User Feedback**The laboratory shall seek information relating to user perception as to whether the service has met the needs and requirements of users.  |  |  |
| 4.14.4 | **Staff suggestions**Laboratory management shall encourage staff to make suggestions for the improvement of any aspects of the laboratory service.  |  |  |
| 4.14.5 | **Internal Audit**The laboratory shall conduct internal audits at planned intervals by personnel trained to assess the performance of managerial and technical processes of the quality management system.Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall, wherever resources permit, be independent of the activity to be audited. |  |  |
| 4.14.6 | **Risk management** The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken. |  |  |
| 4.14.7 | **Quality Indicators**The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes. |  |  |
| 4.14.8 | **Reviews by External Organizations**When reviews by external organizations indicate the laboratory has nonconformities or potential nonconformities, the laboratory shall take appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of this International Standard. Records shall be kept of the reviews and of the corrective actions and preventive actions taken. |  |  |
| **4.15** | **MANAGEMENT REVIEW** |
| 4.15.1 | Laboratory management shall review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care. |  |  |
| **5** | **TECHNICAL REQUIREMENTS** |
| **5.1** | **PERSONNEL** |
| 5.1.1 | **General**The laboratory shall have a documented procedure for personnel management and maintain records for all personnel to indicate compliance with requirements. |  |  |
| 5.1.2 | The personnel making judgments with reference to examinations shall have the applicable theoretical and practical background and experience. |  |  |
| 5.1.3 | **Job Descriptions**The laboratory shall have job descriptions that describe responsibilities, authorities and tasks for all personnel. |  |  |
| 5.1.5 | **Training**The laboratory shall provide training for all personnel Personnel that are undergoing training shall be supervised at all times.The effectiveness of the training programme shall be periodically reviewed. |  |  |
| 5.1.6 | **Competence Assessment**The laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to established criteria. |  |  |
| 5.1.8 | **Continuing Education and Professional Development**A continuing education programme shall be available to personnel who participate in managerial and technical processes. |  |  |
| **5.2** | **Accommodation and Environmental Conditions** |  |  |
| 5.2.1 | **General**The laboratory shall have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors.Where applicable, similar provisions shall be made for primary sample collection and examinations at sites other than the main laboratory premises, for example point-of- care testing (**POCT**) under the management of the laboratory. |  |  |
| 5.2.3 | **Storage Facilities**Storage space and conditions shall be provided that ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results.Clinical samples and materials used in examination processes shall be stored in a manner to prevent cross contamination.Storage and disposal facilities for dangerous materials shall be appropriate to the hazards of the materials and as specified by applicable requirements. |  |  |
| 5.2.5 | **Patient Sample Collection Facilities**Patient sample collection facilities shall have separate reception/waiting and collection areas. Consideration shall be given to the accommodation of patient privacy, comfort and needs (e.g. disable access, toilet facility) and accommodation of appropriate accompanying person (e.g. guardian or interpreter) during collection. |  |  |
| 5.2.6 | **Facility Maintenance and Environmental Conditions**The laboratory shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the sample, results and/or the health of staff.  |  |  |
| **5.3** | **Laboratory Equipment, Reagents, and Consumables** |
| **5.3.1** | **Equipment** |
| 5.3.1.2 | **Equipment Acceptance Testing**The laboratory shall verify upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concernedEach item of equipment shall be uniquely labelled, marked or otherwise identified. |  |  |
| 5.3.1.4 | **Equipment Calibration** The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects examination results. |  |  |
| **5.3.2** | **Reagents and Consumables** |  |  |
| 5.3.2.6 | **Reagents and consumables – Adverse Incident Reporting**Adverse incidents and accidents that can be attributed directly to specific reagents or consumables shall be investigated and reported to the manufacturer and appropriate authorities, as required. |  |  |
| **5.4** | **Pre-examination Processes** |
| 5.4.2 | **Information for Patients and Users**The laboratory shall have information available for patients and users of the laboratory services, timing and Location. c) opening hours of the laboratory; |  |  |
| 5.4.3 | **Request Form Information**The request form or an electronic equivalent shall allow space for the inclusion of, but not be limited to, the following:a) Patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier; |  |  |
| **5.4.4** | **Primary Sample Collection and Handling** |  |  |
| 5.4.4.1 | GeneralThe laboratory shall have documented procedures for the proper collection and handling of primary samples. The documented procedures shall be available to those responsible for primary sample collection whether or not the collectors are laboratory staff.In emergency situations, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient’s best interest. |  |  |
| 5.4.5 | **Sample Transportation**The laboratory shall have a documented procedure for monitoring the transportations of samples to ensure they are transported: |  |  |
| **5.4.7** | **Pre-examination Handling, Preparation and Storage** |
| **5.5** | **Examination Processes** |
| 5.5.1.1 | The laboratory shall select examination procedures which have been validated for their intended use. The identity of persons performing activities in examination processes shall be recorded. |  |  |
| 5.5.1.2 | **Verification of Examination Procedures**Validated examination procedures used without modification shall be subject to independent verification by the laboratory before being introduced into routine use. |  |  |
| 5.5.1.3 | **Validation of Examination Procedures**The laboratory shall validate, non-standard methods; laboratory designed or developed methods; standard methods used outside their intended scope; |  |  |
| 5.5.1.4 | **Measurement Uncertainty of Measured Quality Values**The laboratory shall determine measurement uncertainly for each measurement procedure in the examination phase used to report measured quantity values on the patients’ samples. |  |  |
| 5.5.2 | **Biological Reference Intervals or Clinical Decision Values**The laboratory shall define the biological reference intervals or clinical decision values, document the basis for the reference intervals or decision values and communicate this information to users. |  |  |
| **5.6** | **Ensuring Quality of Examination Results** |  |  |
| 5.6.1 | The laboratory shall ensure the quality of examinations by performing them under define conditions. |  |  |
| 5.6.2.1 | **Quality Control**The laboratory shall design quality control procedures that verify the attainment of the intended quality of results. |  |  |
| 5.6.2.2 | **Quality Control Materials**The laboratory shall use quality control materials that react to the examining system in a manner as close as possible to patient samples. |  |  |
| 5.6.2.3 | **Quality Control Data**The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure. |  |  |
| 5.6.3 | **Inter laboratory Comparisons** |  |  |
| 5.6.3.1 | The laboratory shall participate in an interlaboratory comparison programme(s) (such as an **external quality assessment programme or proficiency testing programme**) appropriate to the examination and interpretations of examination results.  |  |  |
| **5.7** | **Post-examination Processes** |  |  |
| 5.7.1 | **Review of Results**The laboratory shall have procedures to ensure that authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results. |  |  |
| 5.7.2 | **Storage, Retention and Disposal of Clinical Samples**The laboratory shall have a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples. |  |  |
| **5.8** | **Reporting of Results** |  |  |
| 5.8.1 | **General**The results of each examination shall be reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures. |  |  |
| 5.8.2 | **Report Attributes**The laboratory shall ensure that the following report attributes effectively communicate laboratory results and meet the users’ needs:a) comments on sample quality that might compromise examination results;b) comments regarding sample suitability with respect to acceptance/rejection criteria;c) critical results, where applicable;d) interpretive comments on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results (see 5.9.1) in the final report. |  |  |
| **5.9** | **Release of Results** |  |  |
| 5.9.1 | The laboratory shall establish documented procedures for the release of examination results, including details of who may release results and to whom.  |  |  |
| 5.9.3 | **Revised Reports**When an original report is revised there shall be written instructions regarding the revision. When reporting system cannot capture amendments, changes or alterations, a record of such shall be kept. |  |  |
| **5.10** | **Laboratory Information Management** |  |  |
| 5.10.1 | The laboratory shall have access to the data and information needed to provide a service which meets the needs and requirements of the user.The laboratory shall have a documented procedure to ensure that the confidentiality of patient information is maintained at all times. |  |  |
| 5.10.2 | **Authorities and Responsibilities**The laboratory shall ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification system(s) that may affect patient care. |  |  |
| 5.10.3 | **Information System Management**The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:a) validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation; |  |  |

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

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| **Brief history of the lab and its legal status** |
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| **Status of implementation of the standard w.r.t records** |
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| **Is the laboratory having sufficient and trained human resources to carry out its testing?** |
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| **Has the lab carried out testing for customer? If not, how does it ensure competence of its personnel?** |
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| **Which methods are being used for testing? Are they the updated international method?** |
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| **How is traceability to international standards maintained?** |
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| **Which type of internal and external quality controls are in practice? Where is the lab participating for PT/ILC and for which tests?** |
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| **Recommendation on its preparation for full assessment?**  |
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| **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** | **ML’s representative name & signature** |
| **Date** | **Date** |