

	GENERAL CRITERIA FOR THE ACCREDITATION OF MEDICAL TESTING LABORATORIES	G-23/01 Issue Date: 28.04.06 Rev No: 00
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1. INTRODUCTION

- 1.1** This document describes the specific requirements for medical testing laboratories before they can be accredited.
- 1.2** This document shall be studied in conjunction with ISO 15189 Medical laboratories – Particular requirements for quality and competence and other Series of MEDICAL Technical Notes published by PNAC-MLAS.

2. PERSONNEL


2.1 LABORATORY DIRECTOR (LD)

- 2.1.1** The laboratory shall be directed by a person or persons having executive responsibility and the competence to assume responsibility for the services provided.
- 2.1.2** The LD (however named) shall be
- PMDC/PCP-certified pathologist or
 - registered medical practitioner with relevant laboratory experience of at least 5 years, or
 - scientist with professional certification

to direct the pathology or medical laboratory services. This individual shall be qualified and responsible for the professional, scientific, consultative, organizational, administrative and educational services provided. The LD shall have the authority to implement and maintain the quality standards of the services provided.

Note: When a non-pathologist or doctoral scientist serves as LD, such an individual must be qualified by training, expertise and experience in areas of analytical testing offered by the laboratory. These qualifications are to be documented. Where the functions of the laboratory require the services of a consulting pathologist than he/she shall be retained.

- 2.1.3** In all facilities where histopathology services are provided, a pathologist shall perform such services.
- 2.1.4** The LD shall delegate technical responsibility for each discipline within the laboratory or use the consultative services from SAB-certified pathologist or registered medical practitioner with relevant laboratory experience, or

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scientist with professional certification.

2.2 QUALIFICATIONS, RESPONSIBILITIES, AND ROLE OF THE LABORATORY DIRECTOR

2.2.1 The LD or designate shall possess a broad knowledge of clinical medicine and medical laboratory operations. The LD or designate shall have the appropriate training and background to be able to discharge the following responsibilities:

- a) provide advice to those requesting information about the choice of tests, the use of the laboratory service and the interpretation of laboratory data;
- b) serve as an active member(s) of the medical staff for those facilities served, if applicable and appropriate;
- c) Relate and function effectively (including contractual arrangements, if necessary), with
 - . applicable accrediting and regulatory agencies,
 - . appropriate administrative officials,
 - . the healthcare community, and
 - . the patient population served;
- d) define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services;
- e) implement the quality management system (the laboratory director and professional laboratory should participate as members of the various quality improvement committees of the institution, if applicable);
- f) monitor all work performed in the laboratory to determine that reliable data are being generated;
- g) ensure that there are sufficient qualified personnel with relevant documented training and experience to meet the needs of the laboratory.
- h) plan, set goals, develop and allocate resources appropriate to the medical environment;
- i) provide effective and efficient administration of the medical laboratory service, including budget planning and control with responsible financial management, in accordance with institutional assignment of such responsibilities;
- j) provide educational programs for the medical and laboratory staff and participate in educational programs of the institution;
- k) plan and direct research and development appropriate to the facility;
- l) select and monitor all referral laboratories for quality of service;
- m) implement a safe laboratory environment in compliance with good practice and applicable regulations;
- n) address any complaint, request or suggestion from users of laboratory services;
- o) ensure good staff morale.

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2.2.2 The laboratory director need not perform all responsibilities personally. However, it is the laboratory director who remains responsible for the overall operation and administration of the laboratory, for ensuring that quality services are provided for patients.

2.3 CONSULTING PATHOLOGIST

2.3.1 When the services of a qualified consulting pathologist are necessary, a close working relationship between the LD and the consulting pathologist shall be established.

2.3.2 The consulting pathologist shall play an active role in the programs established by the laboratory and the organization.

2.3.3 The services of the consulting pathologist shall be provided as often as required.

2.3.4 The consulting pathologist shall provide a written report for each consultative visit.

2.4 LABORATORY SUPERVISOR (LS)

2.4.1 The laboratory supervisor (however named) assists the LD and his/her role is to ensure that the daily operations of the laboratory are met. He/She is required to hold one of the following:-

- a) a Science Degree or above in a relevant discipline with a minimum of 3 years' medical laboratory experience,
- b) a Polytechnic Diploma in Medical Technology Sciences, or relevant discipline or other recognized qualification by the Ministry of Health Laboratory Board with at least 5 years medical laboratory experience or equivalent.

2.5 LABORATORY TECHNOLOGIST (LT)

- 2.5.1** a) The LT is an employee of the laboratory and he/she assists the LS in the daily operations.
- b) The LT may hold a Bachelor of Science Degree, a Polytechnic Diploma in Medical Technology Sciences or a relevant discipline, or other recognised qualification by the Ministry of Health with at least 3 years working experience in a facility recognised by PNAC-MLAS

3. PRE-EXAMINATION PROCEDURES

3.1 Request Forms.



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3.1.1 The request form shall contain information sufficient to identify the patient and the authorized requester, as well as providing pertinent clinical data. National, regional or local requirements shall be followed where necessary.

3.2 Sample Collection, Sample Transport & Sample Receipt

3.2.1 The laboratory management shall implement policies and procedures for specific instructions for the proper collection and handling of primary samples and this shall be made available to those responsible for primary collection. These instructions shall be contained in a primary sample collection manual.

3.2.2 The primary sample collection manual shall include or make references to

- a) lists of available laboratory examinations offered,
- b) consent forms, where applicable,
- c) information and instructions provided to patients in relation to their own preparation before primary sample collection, and
- d) information for users of laboratory services on medical indications and appropriate selection of available procedures

3.2.3 The primary sample collection manual shall include procedures for


- a) preparation of patient (e.g. instructions to caregivers and phlebotomists),
- b) identification of primary sample, and
- c) primary sample collection (e.g. phlebotomy, skin puncture, blood, urine and other body fluids), with description of the primary sample containers and any necessary additives.

3.2.4 The primary sample collection manual shall include instructions for

- a) completion of request form or electronic request,
- b) type and amount of the primary sample to be collected,
- c) special timing of collection, if required,
- d) any special handling needs between time of collection and time received by the laboratory (transport requirements, refrigeration, warming, immediate deliver, etc.),
- e) labeling of primary samples,
- f) clinical information (e.g. history of administration of drugs),
- g) positive identification, in detail, of the patient from whom a primary sample is collected,
- h) recording the identity of the person collecting the primary sample, and
- i) safe disposal of materials used in the collection
- j) storage of examined samples,
- k) time limits for requesting additional examinations,
- l) additional examinations, and
- m) repeat examination due to analytical failure or further examinations of same primary sample.

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- 3.2.5** The primary sample collection manual shall be part of the document control system.
- 3.2.6** Primary samples shall be traceable to an identified individual. Primary samples lacking proper identification shall not be accepted or processed by the laboratory.
- 3.2.7** The laboratory shall monitor the transportation of samples to the laboratory such that they are transported within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned, within a temperature interval specified in the primary sample collection manual and with the designated preservatives to ensure the integrity of the samples and in a manner that ensures safety for the carrier, the general public and the receiving laboratory, in compliance with regulatory requirements.
- 3.2.8** All primary samples received shall be recorded in an accession book, worksheet, computer or other comparable system, The date and time of receipt of samples, as well as the identity of the receiving officer, shall be recorded.
- 3.2.9** The laboratory shall develop and document criteria for acceptance or rejection of primary samples. If the laboratory accepts compromised samples for testing, the final report shall clearly indicate the nature of the problem and the required caution needed for interpreting the result.
- 3.2.10** The laboratory shall periodically review its sample volume requirements for phlebotomy (and other samples such as cerebrospinal fluid) to ensure that neither insufficient nor excessive amounts of sample are collected.
- 3.2.11** The laboratory's authorized personnel shall systematically review requests and samples and decide which examinations are to be performed and the methods to be used in performing them.
- 3.2.12** The laboratory shall have documented procedures for the receipt, labeling, processing and reporting of those primary samples received by the laboratory and specifically marked as urgent. The procedure shall include details of any special labeling of the request form and primary sample, the mechanism of transfer of the primary sample to the examination area of the laboratory, any rapid processing mode to be used and any special reporting criteria to be followed.
- 3.2.13** The sample portions shall also be traceable to the original primary sample.
- 3.2.14** The laboratory shall have a written policy concerning verbal requests for sample examinations.

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3.2.15 The samples shall be stored for a specified time, under conditions ensuring stability of sample properties, to enable repetition of the examination after reporting of the result or for additional examinations.

4 Examination procedures

4.1 The laboratory shall have work instructions/procedures on the handling and preparations of test items where the absence of such instructions could jeopardize the results of tests. All instructions, standards, manuals, and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel. Deviations from the test methods shall occur only if the deviation has been documented, technically justified, authorized and accepted by laboratory director or designate.

4.2 The laboratory shall use examination procedures, including those for selection/taking sample portions which meet the needs of the users of the laboratory services and are appropriate for examination. Preferred procedures are those that have been published in established/ authoritative textbooks, peer-reviewed texts or journals, or in international, national or regional guidelines. If in-house procedures are used, they shall be appropriately validated for their intended use and fully documented.

4.3 The work procedures shall comprise of the title, subject, purpose and scope, responsibility, definition and the appropriate method for the test item. The contents of the procedure manual must be relevant to the scope of testing activities of the laboratory and shall include principle, clinical significance, specimen type, required reagents, supplies and instrument/equipment, calibration, quality control, procedural steps, calculations, test results, and interpretation, as applicable.

4.4 The laboratory shall use only validated procedures for confirming that the examination procedures are suitable for the intended use. The validations shall be as extensive as are necessary to meet the needs in the given application or field of application. The laboratory shall record the results obtained and the procedure used for the validation.

Note: Such validation should include determination of systematic bias against reference materials or otherwise stated values, limit of detection, limits of determination, within- and between-run reproducibility, interfering substances, and robustness.

4.5 Method validation may also consist of analyzing the same sample material by different methods and comparing the recovery of known amount of reference standard.



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- 4.6** The methods and procedures selected for use shall be evaluated and found to give satisfactory results before being used for medical examination. A review of procedures by the laboratory director or designated person shall be undertaken initially and at defined intervals and any reviews shall be documented.
Note: Review is normally carried out annually.
- 4.7** All procedures shall be documented and be available at the workstation for relevant staff.
- 4.8** Card files or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a complete manual is available for reference. The card file or similar systems shall correspond to the complete manual. Any such abridged procedures shall be part of the document control system.
- 4.9** The procedure shall be based in whole or in part of the instructions for use (e.g. package insert) written by the manufacturer, provided that they are in accordance with 4.1 & 4.2 and that they describe the procedure as it is performed in the laboratory. Any deviation shall be reviewed and documented. Additional information that could be required to perform the examination shall also be documented. Each new version of examination kits with major changes in reagents or procedure shall be checked for performance and suitability for intended use. Any procedural changes shall be dated and authorized as for other procedures.
- 4.10** Test procedures should include start-up instructions, precautions, pre-treatment, analysis, detection limit, lower and higher limit, disposal of waste, remarks and trouble shooting and safety of the personnel and environmental aspects. The laboratory director or designate shall be responsible for ensuring that the contents of examination procedures are complete and have been thoroughly reviewed.
- 4.11** The appropriate test procedure should also address the reporting of results, units, calculation, interfering substances, report values, critical limits, reference limits for the appropriate tests.
- 4.12** Performance specifications for each procedure used in an examination shall related to the intended use of that procedure.
- 4.13** Biological reference interval shall be periodically reviewed. If the laboratory has reason to believe that a particular interval is no longer appropriate for the reference population, then an investigation shall be undertaken, followed if necessary, by corrective action. A review of biological reference intervals shall also take place when the laboratory changes an examination procedure or preexamination procedure, if appropriate.



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4.14 The laboratory shall make its list of current examination procedures, including primary sample requirements and relevant performance specifications and requirements, available to users of laboratory services upon request.

4.15 If the laboratory intends to change an examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services in writing, prior to the introduction of the change.

Note: This requirement can be accomplished in any of several different ways, depending on local circumstances. They include directed mailings, laboratory newsletters or part of the examination report itself.

4.16 Outdated procedures should be archived for at least two years.

5.0 PHYSICAL FACILITIES

5.1 The laboratory shall have adequate space so that its workload can be performed without compromising the quality of work, quality of control procedures, and safety of personnel or patient care services. The laboratory director shall determine the adequacy of this space. The resources shall be of a degree necessary to support the activities of the laboratory. Laboratory resources shall be maintained in a functional and reliable condition.

5.2 The laboratory shall have sufficient space for performance of work, storage of equipment, reagents, media and supplies. Ventilation, electrical supply, temperature and water shall be adequate as appropriate to the technical activities concerned. There shall be good housekeeping in the laboratory.

5.3 The laboratory shall be designed for the efficiency of its operation, to optimize the comfort of its occupants and to minimize the risk of injury and occupational hazards. Patients, employees and visitors shall be protected from recognized hazards.

5.4 When primary sample collection facilities are provided, consideration shall be given to the accommodation of patient disabilities, comfort and privacy, in addition to the optimization of collection conditions.

5.5 The laboratory design and environment shall be suitable for the tasks carried out therein. The environment in which the primary sample collection or examinations or both are undertaken shall not invalidate the results, or adversely affect the required quality, or any measurement.

5.6 Laboratory facilities for examination should allow correct performance of examination. There shall be sufficient resources, which include but not limited to




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space, instrumentation, appropriate furniture, communication systems, supplies, ventilation, piped gases, water, public utilities security, etc, to support the activities of the laboratory.

- 5.7** The laboratory shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results. It shall be a safe working place for its personnel and for the patients it serves. It shall comply with the safety regulatory requirements. The laboratory shall ensure that patients, employees, and visitors are protected from laboratory hazards. Employees shall be trained to prevent or contain the effects of possible accidents that may occur. Appropriate “Immunization program” should be administered for all laboratory personnel.
- 5.8** The environment within the laboratory shall be favorable for the effective performance of its scope of testing. It shall be able to demonstrate that the accommodation does not lead to contamination of the test samples. Work areas in which the analysis is done should preferably be separated from all other laboratory operations.
- 5.9** Separate work areas shall be available for the following operations:-
- a) cleaning of glassware, purification or reagents and solvents;
 - b) media preparation
 - c) analysis of highly infectious samples.
 - d) analytical instruments must be housed in a separate area provided with adequate airconditioning.
 - e) adequate and appropriate storage facilities must be available for
 - the storage of sample before and following analysis;
 - the storage of materials used in the course of analysis
 - the safe storage of hazardous and non-hazardous wastes prior to disposal
 - f) decontamination of persons and protective clothing.
- 5.10** Access to, and use of, areas affecting the quality of the examinations shall be controlled. Appropriate measures shall be taken to safeguard samples and resources from unauthorized access.
- 5.11** Communication systems within the laboratory shall be those appropriate to the size and complexity of the facility and the efficient transfer of messages.
- 5.12** Relevant storage space and conditions shall provided to ensure the continuing integrity of samples, slides, histology blocks, retained micro-organisms, documents, files, manuals, equipment, reagents, laboratory supplies, records and results,.

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5.13 Work areas shall be clean and well maintained. Storage and disposal of dangerous materials shall be those specified by relevant regulations.

5.14 Measures shall be taken to ensure good housekeeping in the laboratory.

6. REAGENTS

6.1 All laboratory personnel shall be made aware of their responsibilities on the use of suitable reagents, solvents, culture media, reference materials and laboratory ware in terms of the types of analysis they conduct.

6.2 Proper storage of all reagents and culture media shall be observed according to the requirements set up by the manufacturers.

6.3 Chemical reagents, solvents and gases shall be available in various grades and purity. The appropriate grade of materials as specified in the methods or procedures shall be used.

6.4 All reagent containers shall be labeled and tightly closed. They shall bear the original label or as minimum: reagent name, date of receipt, strength, solvent (if not water), any special precautions or hazards and date of expiry. The person responsible for the preparation of the reagent shall be identifiable either from the label or from records.


6.5 Laboratories shall establish written procedures for preparation of reagent solutions and culture media. Records of such preparations shall be maintained for later reference in case of doubtful test result. Records for reagent solutions shall include measured weights and volume, burette readings, pH readings, calculation of standardization factor and solution concentration. For culture media, they shall include medium name, batch number, amount prepared, pH before and after autoclaving, autoclave time and pressure.

6.6 For substances that are classified as scheduled poisons under the Poisons Act and its rules, they shall be kept separately from other reagents and held in locked cabinets. These substances shall be handled in accordance to the rules and guidelines set out in the Poisons Act.

7. REFERENCE MATERIALS

7.1 Certified Reference Materials

7.1.1 A certified reference material can be defined as a homogenous material with specific properties such as identifies purity and potency that has been measured and certified by a qualified and recognized organization.

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7.1.2 Certified reference materials are used to help calibrate instruments and measurement systems to ensure the long-term reliability and integrity of the measurement process.

7.1.3 Regardless of the source of certified reference materials, care shall be exercised to see that they are packaged, stored, and handled to prevent deterioration. This means that efforts shall be made to minimize exposure to moisture, air, heat, and light. They shall be kept under secure and appropriate storage conditions, and records shall be maintained of receipt and use.

7.1.4 It is preferable that records are kept in sign-in; sign-out logbooks located near the storage areas. Each analyst using a certified reference material shall be required to enter the name of the reference material in the log book, the date and time it is taken and returned, and his or her initials.

7.1.5 All analysts shall be instructed in the care of certified reference materials and procedures for handling them.

7.2 Working Reference Material

7.2.1 A working reference material can be defined as a substance other than a certified reference material that is used as a reference material in day-to-day analyses.

7.2.2 Laboratories may develop and perform tests and assays on a substance to establish it as suitable reference for an intended analysis especially when a certified reference material is not available. This substance is considered to be the laboratory's working reference material.

7.2.3 Working reference materials purchased shall be checked for integrity on receipt. For in-house prepared reference materials, the laboratory shall verify quality of materials used for the preparations.

7.2.3 A working reference material shall be assayed by the best method available, and the results shall be entered in a notebook for that purpose. The report shall include the analyst's name, date of analysis, source, lot number, all raw data, charts, and calculations.

7.2.4 A working reference material shall be handled in essentially the same manner as a certified reference material, and a record shall be made each time the standard is withdrawn for use. When the working reference material is used in the assay of a sample, a reference to it shall be made so that there can be no mistake as to the identity and purity of the material.

8. LABORATORY EQUIPMENT



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- 8.1** The laboratory shall be furnished with all items of equipment required for the provision of services (including primary sample collection, and sample preparation and processing, examination and storage). In those cases where the laboratory needs to use equipment outside its permanent control, laboratory management shall ensure that the same requirements are met.
- 8.2** Equipment shall be shown (upon installation and in routine use) to be capable of achieving the performance required and shall comply with specifications relevant to the examinations concerned.
- 8.3** The laboratory management shall establish a programme that regularly monitors and demonstrates proper calibration and function of instruments and analytical systems. (G-02/15)
- 8.4** **TABLE 1** in this document sets out the recommended frequencies for calibration and performance check of general equipment in the field of Medical Testing.
- 8.5** The frequencies of calibration stated in these documents are considered to be the minimum appropriate, provided that the other criteria specified below are met:
- a) the equipment must of good quality and proven stability and
 - b) the laboratory has both the equipment required, competent staff and expertise to perform adequate internal checks, and
 - c) if any suspicion or indication of overloading or mishandling arises, the equipment shall be checked immediately and thereafter at fairly frequent intervals until it can be shown that stability has not been impaired.
- 8.6** Where the above criteria cannot be met or the relevant registered methods have specified more stringent requirements, more appropriate frequencies shall be adopted.
- 8.7** Where the staff of a laboratory has performed calibrations, a full record of these measurements shall be maintained, including details of the numerical results, date of calibration and other relevant observations.
- 8.8** Where the accuracy of temperature measurement has a significant effect on the result of the analysis, temperature-measuring devices for equipment such as incubators, water baths, and ovens shall be calibrated. For such equipment, the stability of temperature and uniformity of temperature distribution shall be established initially and bi-annually. Daily records of temperature measurement when the equipment is in use for testing shall be maintained.
- 8.9** All equipment that comes under the control of the laboratory which requires calibration or verification shall be labeled or coded to indicate the status of calibration or verification and the date when recalibration or re-verification is due.



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- 8.10** Where calibrations give rise to a set of correction factors, the laboratory shall have procedures for ensuring that copies of prior correction factors are correctly updated.
- 8.11** The laboratory shall institute a preventive maintenance program (which, at a minimum, follows the manufacturer's recommendations) to prevent failure of equipment and ensure that the equipment is operating with the reliability required for quality results. The activities include specification checks, calibration, cleaning, lubricating, reconditioning and adjusting by competent personnel on a regular basis. Proper records shall be kept for such activities.
- 8.12** Each item of equipment shall be uniquely labeled, marked or otherwise identified.
- 8.13** Records shall be maintained for each items of equipment contributing to the performance of examination. These records include at least the following:
- a) identify of the equipment
 - b) manufacturer's name, type identification and serial number or other unique identification
 - c) manufacturer' contact person and telephone number, as appropriate
 - d) date of receiving and date of putting into service
 - e) current location, where appropriate
 - f) condition when received (e.g. new, used or reconditioned)
 - g) manufacturer's instructions,
 - h) equipment performance records that confirm the equipment's suitability for use
 - i) maintenance carried out and that planned for the future
 - j) damage to, or malfunction, modification or repair, of the equipment
 - k) predicted replacement date, if possible
- These records shall be maintained and shall be readily available for the life span of the equipment or for any time period required by law or regulation.
- 8.14** The equipment shall be operated by authorized personnel only. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals and directions for use provided by the manufacture of the equipment) shall be readily available to laboratory personnel.
- 8.15** The equipment shall be maintained in safe working condition. This shall include examination of electrical safety, emergency stop devices and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. Manufacturer's specifications or instructions or both shall be used, as appropriate.



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- 8.16** Whenever the laboratory equipment is found to be defective, it shall be taken out of service, clearly labeled and appropriately stored until it has been repaired and shown by calibration, verification or testing to meet specified acceptance criteria. The laboratory shall examine the effect of this defect on previous examinations and institute appropriate corrective and preventive actions. The laboratory shall take reasonable measures to decontaminate equipment prior to service, repair or decommissioning.
- 8.17** The lists of measures taken by the laboratory to reduce contamination shall be provided to the person working on the equipment. The laboratory shall provide suitable space for repairs and appropriate personal protective equipment.
- 8.18** When the laboratory equipment is removed from the direct control of the laboratory or is repaired or serviced, the laboratory shall ensure that it is checked and shown to be functioning satisfactorily before being returned to laboratory use.
- 8.19** The laboratory shall have procedures for safe handling, transport, storage and use of the equipment, to prevent its contamination or deterioration.
- 8.20** When computers or automated examination equipment are used for the collection, processing, recording, reporting, storage or retrieval of examination data, the laboratory shall ensure that
- Computer software, including that built into equipment, is documented and suitably validated as adequate for use in the facility,
 - Procedures are established and implemented for protecting the integrity of data at all times.
 - Computers and automated equipment are maintained to ensure proper functioning and provided with environmental and operating conditions necessary for maintaining the integrity of data, and
 - Computer programmes and routines are adequately protected to prevent access, alteration or destruction by casual or unauthorized persons.
- 8.21** The equipment including hardware, software, reference materials, consumables, reagents and analytical systems shall be safeguarded from adjustments or tampering that might invalidate examination results.

9. QUALITY CONTROL AND PROFICIENCY TESTING


- 9.1** The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results.
- 9.2** The effectiveness of the quality control programs shall be measured and be included in the management review of the laboratory.



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- 9.3** The quality control programs shall include tolerance limits and corrective action procedures to use when limits are exceeded.
- 9.4** All analytical procedures shall be validated against specified requirements and their limits defined.
- 9.5** Methods shall be validated by carrying out analyses of reference standards of known concentration, both in isolation and in the form of spiked samples to determine the recovery.
- 9.6** Where applicable, the method of quantification shall be evaluated using solutions of the analyte in a suitable solvent. An internal standard shall be included where possible.
- 9.7** Replicated analyses shall be carried out to ascertain the repeatability of analysis. Inclusion of a control sample in subsequent analyses will serve to check for deviations from the established method.
- 9.8** The stability of the analyte in the sample matrix during storage and throughout the analysis procedure shall be evaluated.
- 9.9** Method validation may also consist of analyzing the same sample material by different methods and comparing the recovery of known amount of reference standard. (G-02/12)
- 9.10** Participation in Proficiency Testing (PT) programs shall cover the extent and complexity of analytical procedures, including consultative services in histopathology. Where such PT programs are not available, the laboratory should embark on alternative means of ensuring proficiency (e.g., by a process of inter-laboratory comparison with laboratories doing similar work or the development of a mechanism of internal quality control). PT programs shall be in accordance with PNAC G-02/13.
- 9.11** The LD/LS or designate shall monitor the results of PT and participate in the documentation of corrective actions, where required.
- 9.12** The LD/LS or designate shall systematically monitor and evaluate the quality and appropriateness of the laboratory's contribution to patient care. When the program identifies systematic problems, the designated personnel shall take appropriate corrective actions.
- 9.13** The LS or designate shall establish a program that monitors and demonstrates the proper calibration, function and preventive maintenance of instruments and laboratory equipment.

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10. LABORATORY SAFETY

- 10.1** There shall be written safety policies and procedures. Procedures on safety practices of the laboratory shall be part of new employees' orientation program. This shall be documented when completed.
- 10.2** The laboratory shall report serious accidents and laboratory acquired illnesses to the relevant authorities.
- 10.3** All injuries that require medical treatment or time lost from work shall be reviewed as part of the laboratory's Quality Assurance program.
Note: This includes every sharp injury requiring appropriate treatment according to the documented protocol.
- 10.4** Injuries or occupational illnesses shall be documented and follow-up action recorded.
- 10.5** Laboratories shall ensure that its personnel wear protective clothing and safety equipment appropriate to the duties being performed.
- 10.6** There shall be a safety shower or other emergency source of water in all areas where quantities of concentrated caustics are handled. Piped eyewash fountains or the equivalent shall also be present. All of these and the protective equipment shall be easily accessible and shall not be obstructed by equipment, furniture, etc. Laboratories shall also provide fire extinguishers at appropriate places.
- 10.7** Chemical fume control devices such as hoods shall be checked annually and records shall be documented.
- 10.8** All laboratory instruments and appliances shall be grounded and checked for electrical leakage at least annually.
Note: Exceptions can be made for instruments and appliances that are doubly insulated.
- 10.9** All electrical receptacles in the laboratory technical work areas shall be checked annually for ground integrity and records of these shall be documented and maintained.
Note: Such tasks shall be delegated to trained biomedical and electrical engineers.
- 10.10** All dangerous and poisonous chemicals used in the laboratory must be contained, labeled and kept in a locked cabinet by a designated safety officer. The laboratory shall follow the guidelines from the relevant authorities.

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- 10.11** Material safety data sheets shall be documented for each hazardous chemical in the laboratory. The designated safety officer shall maintain the location of such documentation.
- 10.12** A chemical hygiene plan (CHP) shall be developed and shall define storage requirements, handling procedures (including requirements for personal protective equipment), location and the medical procedures that are to be followed should accidental contact or over-exposure occur. Monitoring of vapor levels of potentially toxic substances is required at a defined interval. The indications for these monitoring activities shall be defined in the CHP and records of monitoring shall be documented. All testing staff shall be provided appropriate training in safe handling procedures.
- 10.13** CHP shall specify the clinical symptoms or the environmental condition (such as spills) that occur during over-exposure. When such conditions exist, the CHP shall have procedure for the appropriate medical attention to be provided.
- 10.14** The CHP shall be reviewed annually and all employees shall be trained.
Note: Chemical carcinogens, reproductive toxins, and other severely toxic chemicals are special concerns. The laboratory shall be surveyed annually for the presence of carcinogenic and potentially carcinogenic chemicals. This includes any chemical, which has specific occupational regulations such as formaldehyde, ethylene oxide, and benzidine. The regulations also pertain to any other potentially carcinogenic chemicals. For practical purposes, this includes any substance so identified and because this list encompasses hundreds of substances and is constantly changing, no attempt will be made to itemize those substances here.
- 10.15** For Formaldehyde vapor the air contaminant shall not exceed the threshold of the regulatory requirement in the medical laboratory. The laboratory shall have documented evidence, that formaldehyde vapor levels have been measured.
- 10.16** Proper clothing and equipment shall be used when working with known hazardous gases e.g. formaldehyde.
- 10.17** Proper signs shall be placed at significant hazard areas. Reagent vessels containing hazardous substances shall be labeled appropriately with warnings.
- 10.18** The laboratory safety manual shall have a section outlining policies and procedures to be followed in the event of disaster.
Note: "Disasters" refer to events such as fire, flood, electrical outage or spillage of hazardous volatile substances, or any other mass casualty situation.

11. BIOLOGICAL HAZARDS AND CONTROL SAFETY



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11.1 The laboratory shall institute standard precautions against infectious hazards of blood and body fluids. Reference should be made to the following guidelines from the relevant regulatory bodies.

Note: Staff, whose work is likely to involve contact with body substances, shall use gloves and other appropriate personal protective devices. Gloves must fit properly; cleaning or disinfecting of disposable gloves for reuse is prohibited. Gloves, aprons, or laboratory coats and protective eyewear must be provided and are required for those activities likely to splash the skin.

11.2 Appropriate biohazard cabinet/s (BC) must be functioning in laboratories that culture mycobacteria, fungi and viruses. Each BC shall be certified annually and records shall be documented.

Note: This service is ordinarily performed by an outside vendor because of the specialized equipment required. Annual checks shall include filter checks, flow rate measurements and tests for seam integrity. Filters need not be replaced annually, only as needed but not exceeding every five years.

12 RETAINED SAMPLES

12.1 A retained sample refers to the tested sample or part of the original sample, which is preserved at the laboratory for future use in case of dispute over the findings.

12.2 Where applicable, a representative sample with sufficient quantity shall be retained for a specified period. It shall be properly sealed, appropriately identified and stored under appropriate conditions.

13. RADIOACTIVE SAFETY

13.1 Laboratories that use radionuclides shall manage them according to the procedures set up in the safety manual. The laboratory shall function under the general license of the regulatory authority if the facility uses only small amounts of radioactive materials e.g., if the only contact with radionuclides is from commercially prepared kits for radioligand analysis. If larger amounts are used, the laboratory shall hold a specific license.

14. WASTE DISPOSAL

14.1 The laboratory shall have policies and procedures for waste management for the disposal of all solid and liquid and gaseous waste. These methods shall be in compliance with applicable local regulations and reviewed annually.

14.2 Waste shall be disposed of at regular intervals not exceeding a week.

14.3 Mechanical pipette tips, sample cups, etc. should not be washed and reused.




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- 14.4** All sharps needles and razor blades should be placed into puncture-resistant containers.
- 14.5** Infectious waste shall be placed into biohazard disposal bags for appropriate disposal in a government-approved incinerator by licensed waste contractors.
- 14.6** Clinical infectious waste such as faeces, urine and body fluids from patients shall be flushed into the sewerage. However, if mercury is suspected or known to be present, it cannot be flushed into the sewerage.
Note : Infectious waste is defined as waste containing pathogens in sufficient concentration or quantity that exposure to it could result in disease
- 14.7** Infectious waste bagged in biohazard disposal bags shall be deposited at designated collection area/s to be transported to incinerators by licensed waste disposal contractors.

15. REPORTING OF RESULTS

- 15.1** There should be written procedures for reporting of results. Reporting of results should be complete with analytical authorization procedure, including authorization by laboratory supervisor or designate indicated.
- 15.2** Stat results, results obtained in out of hours service and results outside alarm limits should be reported as soon as possible, but only after verification by a competent technologist as approved by the laboratory.
- 15.3** Reporting of results by telephone should be documented, controlled and limited and it should be followed up by the hardcopy of the results.
- 15.4** Results should be archived and retained as determined by the laboratory complying with regulatory requirements.
- 15.5** Reported results should only be corrected by authorized technical / professional staff of the accredited laboratory. Correction of the results should be reported as soon as possible to the requesting physicians.
- 15.6** The turn-around-time of all tests must be made to known to all requesting physician and they should be familiar with the normal reporting time for assays.
- 15.7** The laboratory should regularly audit the turn-around time for stat and routine tests. The turn around time for assays sent to other laboratories should be known and checked.

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- 15.8** Reference values should be available for all assays, where relevant.
- 15.9** Consultation concerning interpretation of results and advice on further investigation should be available at all times.
- 15.10** There should be regular meetings of laboratory staff with the clinical staff regarding use of the laboratory and interpretation of results.
- 15.11** Professional staff should comment on reported results if necessary. E.g. warnings should be added to the report when pathological pitfalls or interfering substances are suspected.

REFERENCES:

1. PNAC 01/01: Procedure for Accreditation Application.
2. ISO/IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories
3. ISO 15189: Medical laboratories – Particular requirements for quality and competence
4. ISO 15190: Medical laboratories—Requirements for safety
5. G-02/11: PNAC’s policy on method validation
6. G-02/13: PNAC’s policy for participation in proficiency testing.
7. G-02/15: PNAC’s policy on Traceability of Measurement.



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**TABLE 1: RECOMMENDED CALIBRATION AND PERFORMANCE CHECK OF EQUIPMENT
COMMONLY USED IN THE MEDICAL TESTING LABORATORIES**

S. No.	Type of Instrument and Equipment	Maximum Period Between Successive Calibrations or Performance Checks
1	Anaerobic jars and cabinets	Each use: Check using indicators, vacuum gauge or control cultures
2	Analyzers <ul style="list-style-type: none"> ➤ Automated ➤ blood gas ➤ electrolyte ➤ glucose ➤ oxygen ➤ protein 	Check using appropriate controls and standard materials with frequency depending on the particular use of the equipment and manufacturer's recommendation
3	Atomic absorption Spectrophotometers	6 monthly: Check for sensitivity, baseline variation, background correction, and optimization parameters.
4	Autoclaves	(a) When used: Check for temperature and pressure on display. (b) Use autoclave tape to check performance; use biological indicator where appropriate. (c) Every 2 years: Calibrate gauges. (d) Register with the Ministry of Manpower.
5	Balances and scales	(a) When used: Zero point check. (b) Yearly: Calibration by accredited calibration laboratory for repeatability, linearity and accuracy. Use ten weighings of a mass having a value close to the maximum load of balance.
6	Biological Safety Cabinet & Laminar flow	Yearly: Certified to ensure filters are functioning properly and that airflow rate meet specifications.
7	Centrifuges	Yearly: (a) Check temperature using a calibrated thermistor, or more frequently if required, and (b) Check speed using a calibrated tachometer
8	Chromatography, Gas	Instrument must be routinely monitored during use with standard reference materials. System components (e. g. integrators, ovens, electronic amplifiers and detectors) must also be checked periodically, and records kept.
9	Chromatography, Liquid & (HPLC)	Liquid chromatography, including high performance (or high pressure) liquid chromatography (HPLC) and ion chromatography : The total system must be monitored during use with reference standards. Loss of efficiency may be detected by chronological comparison of reference material measurements. System components (e. g. pumping system and detectors) must be subject to periodic checks and details must be recorded.
10	Counter <ul style="list-style-type: none"> ➤ beta ➤ cell 	Each use: Check using appropriate controls and standard materials.



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- gamma
- particle size

- | | | |
|-----------|--------------------------|---|
| 11 | Deionizers | (a) Daily or when used: Check for conductivity using conductivity meter.
(b) 6 monthly: Check for sterility |
| 12 | Densitometers | 6 monthly: Check for linearity. |
| 13 | DNA- sizing equipment | Instrument performance must be routinely monitored during use with control samples. |
| 14 | Electrophoresis | Instrument performance must be routinely monitored using the appropriate controls. System components (e. g. electrodes, tank and power supply), must be checked periodically. |
| 15 | Flame photometers | Each use: Check using appropriate controls and standard materials. |
| 16 | Freezers | (a) Daily: Check temperature using a thermometer.
(b) Yearly: Check temperature with a reference thermometer. |
| 17 | Glassware | (a) Volumetric glassware (burettes, pipettes, and volumetric flasks).
Once – before first use.
(b) Volumetric glassware for general use. Need and extent of calibration to be appropriate for intended use. |
| 18 | Haematocrits | Yearly: Check speed using a calibrated tachometer. |
| 19 | Haemoglobinometers | Twice weekly: Check using the appropriate controls and standard materials. |
| 20 | Heating Baths | Daily or when used: Check temperature with a thermometer. |
| 21 | Heating Blocks | For use analytical measurement or critical procedure: each day of use - by thermometer. |
| 22 | Incubators | (a) Daily: check for temperature, using a calibrated thermometer. To maintain temperature to accuracy of +/- 2 °C or within a given range as stipulated in methods.
(b) Yearly: temperature checks, using a reference thermometer.
(c) Carbon dioxide incubator (microbiology): check carbon dioxide content daily using built- in gauge; 6 monthly using fyrite device or equivalent device. |
| 23 | Manometers | (a) Reference: Ten years (complete) and check fluid every three years.
(b) Working : Three years (Check against reference) |
| 24 | Masses | Reference: Three years initial, six years subsequent. |
| 25 | Microscopes | (a) Regular cleaning and maintenance. Clean stage and lenses after use.
(b) Yearly: Service maintenance. |
| 26 | Microscopes, Fluorescent | (a) Check for the used time of UV bulb. Bulb should be changed when time reaches 200- 300 hours or depending on life- span of bulb.
(c) Yearly: Service maintenance. |



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| 27 | Ovens | (a) Drying oven. By thermometer – frequency appropriate to use.
(b) Sterilizing oven (Hot air oven). Daily using thermometer. |
| 28 | pH Meters | Daily or when used: Check for accuracy. Bracket pH value expected as closely as possible with buffers. |
| 29 | Piston- operated volumetric apparatus
➤ Pipettes and Dispensers | Every 6 months: For gravimetric checks, volume delivery and weighing under specified conditions must be repeated at least ten (10) times. For adjustable devices check volume delivered at several settings. Delivery of volumes less than 100uL may be verified by spectrometry using a dye solution. |
| 30 | Refrigerators | (a) Daily: Temperature checks, using calibrated thermometer.
(b) Yearly: Temperature checks, using reference thermometer. |
| 31 | Spectrophotometers
➤ UV– visible Spectrophotometer / colorimeter | 6 monthly:
(a) Wavelength accuracy and reproducibility. Run two spectra.
(b) Photometric accuracy and reproducibility. |
| 32 | Sterilizers, gas | Each use: Using biological indicators. |
| 33 | Stop Watches | Yearly: Calibration by accredited calibration organization. |
| 34 | Tachometers | (a) Reference: Five years
(b) Working : Once a year |
| 35 | Thermocouples | Yearly: calibration by accredited calibration organization. |
| 36 | Thermometers | (a) Reference :
➤ 2 Yearly: Specific points check by accredited calibration organization.
(b) Working :
➤ Yearly: Temperature is checked at specific point using reference thermometer. |
| 37 | Timing Devices | Yearly: Verification. |
| 38 | Temperature- controlled equipment | The performance of water baths, incubators, ovens and refrigerators must be monitored continuously to ensure compliance with the temperature requirements of test methods. Accordingly, daily- recorded checks of the temperature within the load space of these items of equipment must be maintained. The thermometers used to monitor the performance of temperature- controlled equipment must be of sufficient accuracy to ensure that this equipment complies with the temperature tolerances specified in the test methods. The spatial distribution of temperature throughout the load space of temperature- controlled equipment may be checked following installation of equipment and at appropriate intervals thereafter. Temperature recording devices must be checked at yearly intervals against a reference thermometer and the results recorded. |



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- 39** Water Bath
Daily or when used: Check the temperature using a calibrated thermometer contained in water bath.
Maintain the accuracy of ± 1 C of the requirement. Record water bath thermometer correction factor and attach to water bath.
- 40** Water Purifiers
(a) Daily or when used: In- line check for conductivity. For instruments without in- line checks: weekly off- line check for conductivity.
(b) 6 monthly: Check for sterility.