MEDICAL AND DENTAL COUNCIL OF NIGERIA (MDCN)

Regulation of Laboratory Medicine (Clinical Laboratory)

Practice in Nigeria

2nd Edition

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Foreword to the Second Edition

In recognition of the critical role played by the clinical laboratory in both clinical care and public health activities, the Medical and Dental Practitioners' Act was amended in 1992 through Decree N 78 of 1992 (now incorporated into the Medical and Dental Practitioners' Act CAP 8 Laws of the Federation 2004), to clearly mandate the Medical and Dental Council of Nigeria (MDCN) to make regulations for the operation of clinical laboratory practice in Nigeria. The amendment also enlarged the membership of the Council to include two Pathologists.

Clinical laboratory practice is the major aspect and concern of Laboratory Medicine, and Laboratory Physicians who are the experts in this very important field of Medicine need to appreciate the central role of their specialty practice in both the training of medical doctors and some other health workers and in healthcare delivery. The fact that well over 60% of all diseases diagnoses rely on the report from clinical laboratories underscore the importance Laboratory Physicians should attach to issues of quality assurance in clinical Laboratory practice. Apart from the need to produce accurate, reliable and reproducible laboratory results and reports, timeliness is very critical. An excellent result that arrived late to be of use to the patient is not better than a poor result or report.

Laboratory Physicians must appreciate the important role of other professionals or persons in clinical laboratory practice and must ensure that competent and trusted hands are engaged to work in the clinical laboratories. The Laboratory Physician is the apex professional among clinical laboratory staff, and therefore takes responsibility and liability for the quality of results and reports from his/her clinical laboratory. Even when some responsibilities are delegated the Laboratory Physician remains responsible for the outcome.

Even though it is not usually necessary for the Laboratory Physician to perform the tests personally, it is very important for him/her to be current on all policies, processes, procedures, methods and techniques for all the tests performed in his/her clinical laboratory to be able to evaluate the results and troubleshoot challenges whenever necessary and consequently take liabilities for adverse outcomes. Whenever the need arises the Laboratory Physician should be prepared to defend or talk about the result/report from his/her clinical laboratory before a court, the Investigating Panel and the Tribunal of the Council.

As the leader in the multi-professional discipline, the Laboratory Physician must accord due recognition to others members of the Laboratory Medicine family in the practice – medical scientists, clinical scientists, medical laboratory scientists, scientific officers, research scientists etc. Cooperation and mutual respect are very essential for optimal results in the operation of the clinical laboratories.

Trainees of all categories must be given unimpeded access to learning materials, and also adequately exposed to practical experiences in fulfillment of their training curricular and guidelines in order to ensure the graduation of competent professionals. In general the laboratory performs three essential functions namely, pathology (clinical/medical laboratory) services, training and biomedical research.

Patient care lies at the centre of all doctor's training and practice; therefore the vision of the Laboratory Physicians should be "Customers' Satisfaction at all time". Core values should be emphasized and upheld in and outside the clinical laboratories in order to sustain users interest.

It is very important to remind Laboratory Physicians that they are first and foremost medical practitioners, and are therefore bound by the codes of conduct and ethical prescription for all medical practitioners in Nigeria, and are under the regulatory authority of the MDCN in all its ramifications.

Professor Roger Makanjuola
Chairman, Medical and Dental Council of Nigeria

1.1. The Medical and Dental Practitioners Act Cap M8 Laws of the Federation of Nigeria 2004 (as amended) empowers the Medical and Dental Council of Nigeria to make regulations for the operation of Clinical laboratory Practice in the field of Pathology and its subspecialties. In pursuance of the statutory provision, the Medical and Dental Council of Nigeria (MDCN), in plenary session, hereby approves the revised regulations (subsidiary legislations) in this document for all clinical laboratory practice in Nigeria. The provisions of this regulation are binding on all institutions, practitioners, persons and authorities wishing to operate or operating clinical laboratories in Nigeria.

1.2. The scope of clinical laboratory practice shall cover all the analysis of human specimens for all health seeking behaviours, the interpretation of all the results of all such analysis and the medical guidance on appropriate usage of such results in the clinical setting. The activities that constitute clinical laboratory practice shall normally occur in the clinical (medical) laboratory. The clinical (medical) laboratory refers to any place where human samples are sent to, submitted, received, processed and results generated for the purpose of making or assisting in making a disease diagnosis, preventing a disease, evaluating the extent and prognosis of a disease, monitoring the effect or outcome of therapy, medical investigation or clinical trial and for any medico-legal examination or evaluation that falls within the jurisdiction of medical practice.

1.3. The contents and the intents of this document shall apply to all Pathology (Laboratory Medicine) services in Nigeria. These will include all the main branches of Pathology, namely

1. Anatomic Pathology
2. Haematology and Blood Transfusion
3. Chemical Pathology and Immunology
4. Clinical/Medical Microbiology and Parasitology

It will also apply to the subspecialties of the these main branches, which include but are not limited to Histopathology, Forensic Pathology, Autopsy Pathology, Surgical Pathology, Cytology/Cytopathology, Immunohistochemistry, Clinical Cytogenetics, Haematology, Blood Transfusion Medicine, Clinical/Medical Microbiology, Clinical Mycology and Clinical/Medical Parasitology, Chemical Pathology, Clinical Chemistry/Biochemistry, Immunology, Genetics and Clinical/Medical Virology. In general every specialty of Medicine has its equivalent specialty in Pathology.

1.4. Given that the volume and types of tests to be carried out by a laboratory will differ according to the type of hospital being served, the staffing and the complexity of the layout of the laboratory, the extent of services desired to be rendered, clinical laboratories shall be categorized.

1.5. All point of care testing services shall be subject to the regulations of the Medical and Dental Council of Nigeria.

1.6. It is to be noted by all health care workers in a clinical laboratory that tests and investigations are conducted strictly in aid of the clinician involved in patients care and are in essence 'clinical consultations'. Thus, tests can only be done on receipt of specific requests made by clinicians in the process of patient care. The results of tests are returned to the requesting clinician in confidence, and he holds the professional authority to the confidentiality of such documents, while the Laboratory Medicine physician (Pathologist) in charge of the Laboratory ensures and takes ultimate responsibility for the confidentiality of all information supplied to clinical laboratory, as well as those of all results generated in the clinical laboratory.

2. PERSONNEL IN THE CLINICAL (MEDICAL) LABORATORY

2.1. The number and caliber of personnel within a clinical (medical) laboratory will vary with the kind and extent of clinical and preventive services it supports and the availability of finance and accommodation.

2.2. Any department which has a clinical (medical) laboratory shall be headed by a Medical Practitioner of the grade of Consultant with a minimum qualification of Fellow of the West African College of Physician (FWACP, Lab Medicine) or Fellow of the National Post Graduate Medical College, Faculty of Pathology (FMCPath) or their equivalent in the field of Laboratory Medicine as decided from time to time by the Faculty of Pathology, National Postgraduate Medical College of Nigeria.

2.3. Other staff complements should include

2.3.1 Other Consultants with the above stated minimum qualifications in the respective subspecialties,

2.3.2 Resident doctors (Consultant to Resident ratio being 1:4)– doctors training to become Laboratory Medicine physicians (Pathologists)

2.3.3 Medical Scientists – Holders of MBBS or equivalent and an MSc or PhD in any of the Laboratory Medicine related courses

2.3.3 Clinical Scientists – PhD holders who do not possess a fellowship of either colleges degrees and have passed or been exempted from an examination equivalent to Part I of Fellowship examination of the Faculty of Pathology conducted by the Faculty of Pathology, NPMCN

2.3.4 Scientific Officers or Research Scientists – Those with only academic qualifications such as MSc or PhD in Laboratory Medicine related courses

2.3.5 Medical Laboratory Technologists (Medical Laboratory Scientist - MLS) - usually constitute the largest group within the clinical laboratory- mainly bench or technical staff

2.3.6 Laboratory Assistants/Attendants, Medical Laboratory Technicians, Cleaners, Porters, Secretary/Typist, Receptionists, Nurses, Records officers and Drivers.

3. JOB DESCRIPTIONS AND QUALIFICATIONS OF THE VARIOUS CADRES OF STAFF IN THE CLINICAL (MEDICAL) LABORATORY

3.1. **Head of the Clinical (Medical) Laboratory** or the Laboratory Director

3.1.1. This role requires a person with capability for a balanced assessment of clinical usefulness, laboratory skills, scientific reliability and economy of resources and an assessment of continuing advances in medicine and science.

3.1.2. The person appointed shall be one qualified in both medicine and laboratory practice and trained in the methods and practice of scientific research.

3.1.3. Where the clinical laboratory is part of a department, he shall serve as the head of the department.

3.1.4. This office shall rotate (where applicable) among Consultant Laboratory Medicine physicians on terms to be determined by the authority of the institution.

3.2. Qualifications of the Head of the Laboratory

3.2.1. Consultant (by appointment)

3.2.2. FMCPath, FWACP (Laboratory Medicine) or equivalent qualifications (as determined by the Faculty of Pathology, NPMCN) registerable as a Category A Specialist by the Medical and Dental Council of Nigeria.

3.2.3. A post-graduate professional degree registerable in Category B specialist list by the Medical and Dental Council of Nigeria with a minimum of ten (10) years post qualification cognate experience in the specialty under a category A Consultant, and also satisfying other conditions set by the Faculty of Pathology, NPMCN.

3.3. Functions of the Head of the Laboratory

3.3.1. Take overall charge of the administration and management of the laboratory, and be responsible directly to the Chief Medical Director (CMD) or Medical Director (MD) through the Chairman Medical Advisory Committee (CMAC) or any other medical officer of equivalent status

3.3.2. Initiate, vet, sign and/or endorse all official correspondence or documents emanating from and leaving the laboratory for external destinations.

3.3.3. Take overall responsibility for the technical and clinical services of the laboratory.

3.3.4. Formulate and review, after due consultations, and publish all policies regarding the technical, clinical and administrative operations in the laboratory. This includes the development of new tests, techniques and methodologies.

3.3.5. Authorize the release and distribution of all rosters of duties for Consultants, Resident Doctors, Medical Laboratory Scientists (MLS) and other technical and general laboratory staff.

3.3.6. Endorse all requests from the laboratory, for the repair, servicing or purchase of equipment, materials, consumables and other services, or delegate such to a designated officer as he/she deems necessary.

3.3.7. Authorize all requisitions from Hospital stores into the laboratory and inspect and certify, with the assistance of the Laboratory Manager or any other competent staff, all deliveries to the Hospital stores, of materials destined for the department.

3.3.8. Carry out all other functions described under the job schedule for Consultants in the department or hospital.

3.3.9. Take overall responsibility for the training programmes in the laboratory. For the Residency programme, this will include the assignment of duties and rotational postings, arrangement of seminars and tutorials and supervision of dissertations.

3.3.10. Preside at all meetings of the clinical (medical) laboratory.

3.3.11. Represent the laboratory or send delegates, to all meetings where the presence of the laboratory is required.

3.3.12. shall design Strategy and Organisation of the service.

3.3.13. shall make decisions on how work is to be deployed among the different sections of the laboratory and staff

3.3.14. shall determine the kinds and sequences of examinations to be done on different categories of specimens.

3.3.15. shall make decisions on the arrangements for determining content and wording of reporting urgent results and proffering advice to Clinicians.

3.3.16. shall take decisions on when new methods are to be introduced and old ones discarded.

3.3.17. shall ensure quality of practice within the laboratory.

3.3.18. shall coordinate the preparation of the budget of the laboratory and ensure satisfactory control of same

3.3.19. shall coordinate all matters connected with the promotion of staff of the laboratory as well as the recruitment of staff into the laboratory.

3.3.20. shall in conjunction with key/senior staff of the laboratory determine established positions in the laboratory.

3.4. Qualification for Laboratory Physicians (Pathologists)

3.4.1. Consultant (by appointment)

3.4.2. FMCPath, FWACP (Laboratory Medicine) or equivalent qualifications (as determined by the Faculty of Pathology, NPMCN) registerable as a Category A Specialist by the Medical and Dental Council of Nigeria.

3.4.3. A post-graduate professional degree registerable in Category B specialist list by the Medical and Dental Council of Nigeria with a minimum of ten (10) years post qualification cognate experience in the specialty under a category A Consultant, and also satisfying other conditions set by the Faculty of Pathology, NPMCN

3.4.4. Possession of MBBS and M.Sc or Ph.D in a Pathology related course is not suitable or acceptable for appointment as a Consultant in Pathology. Holders of such purely academic degrees may, however be appointed as lecturers in the university or as a medical or clinical scientist or scientific officer or research scientists (see below) especially in research laboratories.

3.4.5. Consultant Special Grade II

A minimum of Four (4) years cognate experience after appointment as a Consultant

3.4.6. Consultant Special Grade I

A minimum of eight (8) years cognate experience after appointment as Consultant or four (4) years after attaining the rank of Consultant Special Grade II

3.5. Competences for the Consultant Laboratory Physician

3.5.1. Such a registered practitioner must

3.5.1.1.Maintain a knowledge base in the basic and clinical sciences necessary for effective consultation in laboratory medicine.

3.5.1.2.Versed in Clinical/Microbiology and Parasitology, or Histopathology, Cytopathology, Forensic Pathology or Haematology and Blood transfusion or Chemical Pathology, Immunology etc

3.5.1.3.Have special skill and knowledge in organizing the clinical laboratory in a way best adapted to service the needs of clinical and preventive medicine.

3.5.1.4.Be qualified to give advice in the interpretation of results and on problems of diagnosis, prevention and treatment of diseases.

3.5.1.5.Be qualified to appreciate the implications of advances in medicine for the kind of services the clinical laboratory should be prepared to undertake.

3.5.1.6.Be qualified to validate new tests and determine their usefulness in the clinical laboratory.

3.5.1.7.Be competent in carrying out any test in the laboratory when the need arises eg trouble-shooting and training

3.5.2. General Duties of Consultant Laboratory Physician

3.5.2.1.Receive and attend to patients referred to the department with any disorder suspected, provisionally diagnosed, confirmed or related to the areas of activity of the department.

3.5.2.2.Authorize the admission, investigation, management and discharge of department's patients where applicable.

3.5.2.3.Provide specialized care to all patients with relevant disorders in both the emergency, outpatient and in-patient categories as the case may be.

3.5.2.4.Receive and attend to consultations and referrals from doctors in other Units of the hospital and give expert opinions in such cases.

3.5.2.5.Examine all test results going out of the department's clinical laboratory and sign out completed ones with directives on actions necessary on results judged to require further attention. This task may be delegated under supervision to senior Registrars.

3.5.2.6.Provide Consultant cover for resident doctors on bench and clinical call duties as indicated on the duty roster approved by the H.O.D.

3.5.2.7.Participate in all the medical undergraduate and postgraduate professional and clinical training and continuing education programmes of the department. This includes clinic, ward rounds, clinical laboratory practice and autopsies, and the training of resident doctors and supervision of approved projects.

3.5.2.8.Carry out research projects in their particular areas of the specialty, the results of which may be used to increase knowledge and determine policy.

3.5.2.9.Represent the department on various committees and in other administrative capacities as may be advised by the H.O.D.

3.5.2.10.Be generally accountable to the CMD, CMAC and the Hospital Management through the H.O.D.

3.5.3. Specific Duties

3.5.3.1.These fall under four (4) broad categories namely

Administrative duties

Professional (service) duties

Research duties

Training duties

3.5.4. Administrative duties

Head of Department (with its Clinical Laboratory)

Head of a unit

Member, Medical Advisory Committee

Member/Chairman, Laboratory Revolving Fund Committee

Head of Infection Control Team (Medical Microbiology Department Only)

Chairman of Hospital Infections Control Committee (Nosocomial Infections) Medical Microbiology

Member, Hospital HIV/AIDS Control Committee

Organization of the haematology and Blood Transfusion Services – (Haematologists only)

Chairman, Hospital Blood Transfusion Committee – (Haematologists only)

Member or Chairman of any Hospital committee

Any other duties that may be assigned

3.5.5.-Professional (service) Duties

Blood banking services (H)

Clinical Autopsy services (AP)

Clinical Pathology Rounds (ALL)

Clinical Services and grand rounds in the areas of Infectious Diseases treatment and hospital Infection control (MM)

Haematology clinical service (H)

Clinical care for metabolic disorders (CP)

Bed side and out patient management of patients (MM,CP,H).

Consultation on all laboratory specimens analysis (ALL)

Cytopathology (AP)

Diagnostic procedures (ALL)

Forensic Pathology service (ALL)

General Supervision of Bench work (ALL)

Histopathology service AP)

Infection Control (MM)

Involvement in Journal Clubs (ALL)

Laboratory Organisation (ALL)

Laboratory Rounds(ALL)

Other Haematological Service (H)

Toxicology Services (CP)

Patient Treatment (CP,MM,H)

Ensure laboratory safety including post-exposure prophylaxis (ALL)

Quality Assurance (ALL)

Quality Control (ALL)

Reporting and authentication of all laboratory reports (ALL)

STD and Infectious disease Clinics (MM)

Supervision of purchase of laboratory equipment and

Consumables (ALL)

Key: MM= Medical Microbiology; CP= Chemical Pathology; AP= Anatomic Pathology; H= Haematology and Blood Transfusion

3.5.6. - Research/Training and Academic Duties

Clinicopathological Rounds

Journal Clubs

Training of undergraduate medical students and Resident doctors

Teaching of para-medical students and staff in the Department in form of continuing professional education and developmental programmes

Clinical-problem solving research

Supervision of Residents research work

Leadership in departmental research efforts

Membership of Ethical Review Committee

Sourcing Funding for Individual and Group Research

Active in health promotion programmes

3.6. Resident Doctors

3.6.1. These are fully registered medical practitioner who are specializing in Laboratory medicine. The minimum stay required for training is four (4) years.

3.6.2. They report directly to the Consultant Pathologist

3.6.3. They are involved in carrying out routine and specialized laboratory procedures including autopsies, microscopy, culture and sensitivity testing of pathogens in clinical samples, serology, chemical analyses of body fluids, oncology, blood grouping and cross-matching etc.

3.6.4. They are also involved directly or indirectly in the clinical management of patients.

3.6.5. They participate in clinicopathology rounds

3.6.6. They run clinics in their departments

3.6.7. They are involved in carrying out quality control and assurance in the laboratory.

3.6.8. They participate in and can initiate research.

3.6.9. Generally Resident Doctors shall

3.6.9.1. Acquire competences, appropriate to their residency level in carrying out routine and specialised tests as stipulated by the Nigerian and West African Postgraduate Colleges.

3.6.9.2. Acquire competence, appropriate to the residency level, in clinical and laboratory investigation of patients with suspected or confirmed disorders.

3.6.9.3.Carry out routine or special clinical laboratory tests as may be assigned by the HOD or a Consultant acting for the HOD.

3.6.9.4.Carry out emergency clinical as well as bench call duties as per duty rosters approved by the HOD.

3.6.9.5.Assist and learn from the Consultant in the investigation and management of departmental and referred cases.

3.6.9.6.Assist the Consultant in examining all test results going out of the laboratory, and sign out completed ones with appropriate comments. Results judged to require further attention may be referred to the MLS concerned or to a Consultant or the H.O.D.

3.6.9.7.Assist the Consultant to liaise with Clinicians to seek clarification or give suggestions concerning tests requested or results obtained in order to promote effective patient care.

3.6.9.8.Attend and participate at all departmental seminars, clinico-pathological meetings and other continuing education programmes.

3.6.9.9.Attend rotations in other laboratory and clinical disciplines as required by the postgraduate Colleges and assigned by the H.O.D.

3.6.9.10. Undertake, as stipulated by the Postgraduate Colleges, a dissertation project at Part II level under supervision by Consultants in the department.

3.6.9.11. Be accountable, through the Consultant, or directly, to the H.O.D. in all matters concerning their training and function in the laboratory.

3.6.9.12. Be qualified to supervise and carry out quality control and assurance.

3.6.9.13. Have some managerial/administrative skills to be able to assist the Head of Department in the administration of the clinical laboratory and the Department in general

3.7. Laboratory Supervisor (or Laboratory Manager) -most senior laboratory scientist or any person so appointed

3.7.1. Reports directly to the Consultant Laboratory Medicine Physician (Pathologist) in charge

3.7.2. Supervises subordinate technical staff on day to day basis

3.7.3. Advices on policy matters relating to clinical laboratory services.

3.7.4. Assists the head of department to prepare periodic and annual reports on clinical laboratory services.

3.7.5. May be designated as the Laboratory Supervisor or Manager

3.7.6. Specifically the =Laboratory Supervisor or Manager shall

3.7.7. Superintend the technical operations and supervise all technical staff in the department under the overall authority of the H.O.D.

3.7.8. Maintain efficiency, order and discipline in the laboratory and report any observed lapses to the H.O.D.

3.7.9. Prepare and submit to the HOD for review and approval Standard Operating Procedures (SOPs) for the various tests being performed in the clinical laboratory.

3.7.10.Set up, in collaboration with the Consultant or Chief Resident, Quality Assurance programmes and present periodically to the H.O.D. quality control reports.

3.7.11. Establish and maintain laboratory safety measures and recommend necessary improvements to the H.O.D.

3.7.12. Monitor stocks of materials and reagents and raise requisition for materials from Hospital Stores or raise requests for materials to be ordered, or purchased and submit to the HOD.

3.7.13. Prepare monthly routine and emergency duty rosters for senior and junior technical staff and schedule of deployment of staff and submit to H.O.D. for ratification and/or official release.

3.7.14. Prepare periodically, accounts of revenue generated from laboratory services for presentation at Laboratory Revolving Fund meetings through the H.O.D.

3.7.15. Prepare annual returns of tests performed and obtain periodic stock balance of regents and materials from the stores officer.

3.7.16. Prepare annual leave roster for senior and junior technical staff and submit to H.O.D. for adoption.

3.7.17. Assist the H.O.D. in drawing up annual performance evaluation reports on technical staff.

3.7.18. Assist the H.O.D. in recommending technical staff for promotion, and sponsorship to training courses or conferences.

3.7.19. Perform functions described in the job schedule for MLSs.

3.7.20. Be accountable directly to, and advice the H.O.D. in all matters regarding the smooth running of department's clinical laboratory services.

3.8. Other Medical Laboratory Scientist (MLS)

3.8.1. Carry out routine diagnostic testing on the benches as may be assigned by the HOD or Laboratory Supervisor/Manager and approved by the HOD.

3.8.2. Participating in the training and supervision of low cadre staff

3.8.3. Preparation of stains, reagents and media for bacterial propagation.

3.8.4. Caring for and breeding of laboratory animals

3.8.5. Assisting in documentation and preparation of periodic reports for supervising officer.

3.8.6. Carry out emergency and weekend and public holiday duties as per the duty rosters approved by the H.O.D.

3.8.7. Supervise junior technical staff and maintain efficiency, order and discipline in their respective areas of operation.

3.8.8. Carry out any other functions as may be assigned by the H.O.D. or the Hospital Management.

3.8.9. Be accountable, generally and specifically, through the Laboratory Supervisor or Manager or directly to the H.O.D. as the situation may warrant.

3.9. Medical Scientist

3.9.1. May temporarily take charge of the clinical laboratory in the absence of the Pathologist

3.9.2. shall assist in the evaluation and validation of new kits and test methodologies

3.9.3. may head the Department's research unit and be active in research activities

3.9.4. shall be actively involved in the training activities of the Department

3.9.5. shall take part in quality assurance/control activities

3.10. Clinical Scientist

3.10.1.shall assist in the evaluation and validation of new kits and test methodologies

3.10.2.may head the Department's research unit and be active in research activities

3.10.3.shall be actively involved in the training activities of the Department

3.10.4.shall take part in quality assurance/control activities

3.11. Medical laboratory Technician

3.11.1.This is the lowest cadre of clinical laboratory professionals

3.11.2.They perform similar duties as the Medical laboratory scientists leaving out a few of the critical steps to the senior professional/technical staff

3.11.3.Over time they become proficient on the critical aspects and may be used if certifies competent by the clinical laboratory authorities.

3.11.4.Specifically their duties shall be to

3.11.5.Assist the Medical Laboratory Scientists in performing routine tests and preparing reagents as may be assigned by the Laboratory Supervisor/Manager or other senior MLS or the HOD.

3.11.6.Carry out weekend and public holiday duties as per duty rosters drawn by the Laboratory Supervisor/Manager and approved by the H.O.D.

3.11.7.Carry out any other functions as may be assigned by the Chief MLS or the H.O.D.

3.11.8.Be accountable generally and specifically through the Laboratory Supervisor/Manager to the H.O.D.

3.12. Scientific Officer and Research Scientist

3.12.1.These are holder of B.Sc, M.Sc and Ph.D in Pathology related courses without either an MBBS or equivalent or passed the Part I Fellowship examination equivalent of the Faculty of Pathology, NPMCN

3.12.2.may take part in specimen processing provided they have been closely supervised to attain proficiency

3.12.3.shall take part in in-house training of junior cadre technical staff

3.12.4.shall take part in quality assurance/control activities

3.12.5.shall take part in research activities

3.13. Medical Laboratory Assistants and Attendants

3.13.1.Assist the MLSs and the Technicians in performing simple tests in the laboratory, and preparing reagents.

3.13.2.Maintain cleanliness and order, including disinfection of the working areas, and cleaning of Laboratory wares.

3.13.3.Perform clerical, receptionist, recording, and dispatch duties. General cleaning and messenger duties may also be required to be performed, especially in assistance of, or absence of messengers and cleaners deployed form administration.

3.13.4. Attend weekend and shift duties as may be assigned by the Laboratory Supervisor/Manager

3.13.5. Perform any other functions as may be assigned byLaboratory Supervisor/Manager.

3.13.6. Be generally and specifically accountable to the H.O.D through the Laboratory Supervisor/Manager the MLSs and Technicians.

4. ORGANOGRAM FOR PATHOLOGY DEPARTMENT

4.1. The organogram specified in Appendix 1 shall be strictly adhered to by all clinical and health related institutions operating clinical laboratories

4.2. No clinical laboratory shall operate in any secondary or tertiary hospital without a supervising Laboratory Medicine physician (Pathologist) in each of the Departments.

4.3. Where the institution is unable to secure the full time services of Laboratory Medicine physicians (Pathologists) after advertisements it shall engage the services of part-time or visiting supervisory Consultant Laboratory Medicine physicians (Pathologists) pending when it shall secure those on full time services, provided that no Anatomic Pathology clinical laboratory shall operate without the relevant Anatomic Pathologists on full time.

5. ACCREDITATION OF CLINICAL LABORATORIES

5.1. There shall be 2 forms of accreditation for the clinical laboratories. These will include

- Accreditation for undergraduate and postgraduate medical training.
- Accreditation for quality of service delivery

5.1.1. Accreditation for undergraduate and postgraduate medical training. This is done to ensure that minimum academic and professional/practice requirements for training are attained by clinical laboratories in which the doctors are to be or being trained. Whereas the MDCN shall directly carry out accreditation for undergraduate doctors training, the Faculty of Pathology, National Postgraduate Medical College of Nigeria (NPMCN) and the Faculty of Laboratory Medicine of the West African College of Physicians (WACP) shall carry out accreditation for postgraduate doctors training

5.1.2. Accreditation for quality of service delivery – This is an essential duty of the Council as part of its regulatory responsibilities and shall be carried out as stipulated in the MDCN guideline on clinical laboratory accreditation. It is important to state here that the ISO 15189 is the ultimate standard for the Council.

6. LEVELS OF CARE

6.1 Hospitals can be divided into Public health care and Private health care. Public health care is further subdivided into primary, secondary and tertiary level hospitals and these are served by their respective clinical laboratories. Clinical Laboratories are therefore divided into:

6.1.1 Public Health/Government Clinical Laboratory

a. Primary health clinical laboratory

b, Secondary health clinical laboratory

c. Tertiary health clinical laboratory

6.1.2 Private Clinical Laboratory

6.2 Primary Health Centre

6.2.1 This is the most peripheral and ought to be the first port of call by patients. It is basically an outpatient clinic which runs the well baby clinic, immunization programmes and serves patients with minor ailments.

6.2.2 The Primary Health Clinical Laboratory

6.2.2.1 One room is adequate.

6.2.2.2 It will only carry out simple procedures like gram stain, wet preparation on stool, determination of malaria parasites in thick and thin films, and Urinalysis

6.2.2.3 The laboratory will also carry out basic haemotological functions like packed cell volume (PCV) assessment, and haemoglobin estimation.

6.2.2.4 There shall be no histopathology services at the primary health care level.

6.2.3 Staff:

6.2.3.1 The minimum required is a medical laboratory technician with a cleaner. The number of ancillary staff will depend on the volume of work and the hours of duty.

6.3 The Secondary Health Hospital

This refers to the General Hospitals and state hospitals in the country. They are referral centers of the primary health centers and some private hospitals. The basic organization of the clinical laboratories is similar to that of the tertiary laboratories. The difference is mainly in the breadth and depth of the procedures carried out at the two levels.

6.3.1 The Secondary Health Clinical Laboratory

6.3.1.1 The Clinical Laboratory services should have four distinct departments:

a. Medical Microbiology and Parasitology

b. Haematology and Blood Transfusion

c. Anatomic Pathology (Morbid Anatomy)

d. Chemical Pathology and Immunology

6.3.2 Medical Microbiology Laboratory

6.3.2.1 Functions:

To serve the needs of Clinical and Preventive medicine by:

a. Examining specimens from patients for presence of potentially pathogenic organisms

d. Detecting antibodies and antigens

c. Determining sensitivity to drugs eg antibiotics

d. Assessing infectious potential of environmental material

e. Preventing and Controlling hospital acquired infections

f. Managing infectious diseases

6.3.2.2 Layout

a. The microbiology clinical laboratory should not be a thoroughfare and should ideally not be close to eating areas.

b. It must be well ventilated with air conditioners in all the laboratories to reduce the possibility of external contamination of culture plates. This is most critical in the mycology laboratory where some isolates need to be cultivated at room temperature which is 25°C and not 30-37°C that is most often used in bacteriology. Fans, whether ceiling, wall, table or standing are unacceptable health hazard and MUST NOT be used in the clinical laboratory.

c. There should be limited access to patients and visitors.

d. It should be divided into six main areas:

i. The Cloakroom

ii. The Common room

iii. The Laboratory area including the Media Kitchen and wash-up/autoclave room

iv. Offices

v. Call duty room

vi. Patient sample collection area

6.3.2.2.1 The Cloakroom/Changing room

a. Bags and personal effects are not allowed in the clinical laboratory.

b. There must be a designated room with lockers for staff to store their belongings safely till the end of office hours. There should be two - one for men and another for women- with lockers on one side and should have adjacent to it preferably two toilets and wash hand basin.

6.3.2.2.2 The Common Room

a. Food and drinks are not allowed in the clinical laboratory work areas and neither are visitors.

b. There must be a common room for staff to take a break, where they can eat.

c. This common room must have easy chairs and a sink. It is the only place that may be carpeted if it is so desired.

6.3.2.2.3 The Laboratory Area

a. This should be a minimum of 1000sq metres excluding corridors, circulation space, media kitchen, wash up/autoclave rooms and reception areas.

b. There should be about 2-3m of bench space and $10m^2$ of floor space available per person.

c. Each section must have a microscope and an autoclave except the Parasitology section that does not require an autoclave.

d. Every section must have a refrigerator.

e. There should be one deep freezer for storage of samples.

6.3.2.2.4 The reception and collection centre:

a. This is the area with the most patient interaction.

b. The room should have a table beneath a window through which patients submit their specimens. This should be accomplished without the patients having access into the main laboratory area.

c. There must be a wash hand basin just by the door that leads into a corridor in the laboratory.

6.3.2.2.5 The Bacteriology Laboratory

a. This is divided into five (5) sections namely, Urine, Enteric, Main bacteriology, CSF/Blood culture room.

b. These should preferably be in separate rooms but if it is not possible they can be accommodated in one large room with separate bays for each section

6.3.2.2.6 The Parasitology Laboratory

This is for the examination of faecal, blood and tissue specimens for parasites.

6.3.2.2.7 The Mycobacterium Laboratory:

a. This should be a highly restricted area and must be separated from all the other clinical laboratories.

b. It must have a Class 1 or 2 safety cabinet for processing of samples, which must have HEPA (High Efficiency Particulate Air) filters.

6.3.2.2.8 The Mycology Laboratory

This should be a separate room and requires a class 1 safety cabinet.

6.3.2.2.9 The Immunology or Serology Clinical Laboratory:

a. This is for the examination of serum samples for antigens and antibodies.

b In the absence of space it can be a convenient space in the available laboratory

6.3.2.2.10 The Media Kitchen:

a. This is where the sterile media are prepared and poured.

b. It must be a restricted area to prevent contamination of media.

c. This must be air conditioned and closed to outside air.

d. There should be a fridge for storage of media and a workbench.

6.3.2.2.11 The Wash-up/autoclave room:

a. The room must be large and well ventilated and should have an extractor fan.

b This is the room for washing up used materials (glass plate, tubes etc).

c. It should have two autoclaves (Downward Displacement Laboratory Autoclave), one for decontamination and the other for sterilizing.

d. There should be two large deep sinks for washing. There must also be a sink for washing hands.

e. There needs to be one hot air oven in the wash-up room.

6.3.2.2.12 The Store:

a. There must be a lockable store for keeping consumables.

b. This must have shelves on which items can be kept.

c. A common room for other members of staff

6.3.2.2.13 Offices:

a. There must be an office for each of the Consultant Medical Microbiologists, with adjoining secretaries offices, and theLaboratory Supervisor/Manager

b. There shall be at least one big room for junior resident doctors, one for senior residents and one for the Chief Resident doctor.

6.3.2.2.14 Call Duty Room

A well furnished room with toilet and shower for overnight calls should be situated adjacent to the laboratory.

6.3.2.2.15 Sample Collection Room:

Ideally there should be a room adjacent to the laboratory where special samples can be collected especially samples that are time-limited or require direct inoculation and which will not be practical for collection at clinic sites or at home.

6.3.2.2.16 Infection Control Rooms:

a. This is office for the infection control personnel.

b. These personnel should include the Nurse(s) and a secretarial staff.

c. There should be one room for the Infection Control doctor

6.3.2.2.17 Basic Equipment

- Microscopes
- Autoclaves
- Incubators
- Centrifuges
- Freezers (-20C and -70C)
- Bunsen burners
- Hot air ovens
- Inspissators
- Class 1 and 2 safety cabinets
- Water baths
- Wire loops
- Straight wires
- Media bottles
- flat bottom flasks
- beakers,
- Weighing balances,

- bijou bottles
- test tubes
- wire racks
- Steel baskets,
- ICT equipment
- Computer unit with UPS and printer for infection control

6.3.3 The Chemical Pathology and Immunology Laboratory Layout

6.3.3.1 A reception

6.3.3.2 A main Laboratory with the following in place

a. A phlebotomy room with comfortable chairs and at least a couch

b. A metabolic room for OGTT and other Dynamic function tests (should have a toilet attached, a bench and a couch)

c. Benches for assays

d. An automation unit

e. An Emergency Laboratory preferably centrally placed

f. Offices for the HoD and other consultant Chemical Pathologists and adjoining secretaries offices

g. Office of the Laboratory Supervisor

h. Rooms for Resident doctors – see 6.3.2.2.13b above

i. A well furnished call duty room for overnight calls

j. a common room for the laboratory staff

k Cloak room

l A reagent store

m. A wash room

n. A quality control unit

o. Appropriate spaces should be made available for special tests as the need arises.

The level of test carried out here will vary depending on the presence or absence of medical laboratory personnel.

6.3.3.3 Basic equipment

a. Centrifuges

b. Spectrophotometers (Visible and Ultraviolet)

c. Water distillers

d. Flame photometers and Ion selective electrode (ISE) electrolyte analyser

e. Automation equipment (autoanalysers)

f. Refrigerators and deep freezers (at least – 25°C)

g. Blood gas analyzer for the emergency unit

h. Computers and other ICT equipment plus software (LIS)

i. electrophoresis system with densitometer

j Atomic absorption spectrophotometer (AAS)

k. High Performance Liquid Chromatography system (HPLC)

l. Specialised laboratories should have additional equipment for molecular genetics (ie automated multi-purpose PCR machine) –this should be centralized for use by all the departments desiring its use.

6.3.4 The Haematology Laboratory

6.3.4.1 Function

a. The Clinical Laboratory is to serve as a referral centre for all hospitals in the State and to perform routine haematological tests. The various haematology laboratory units should therefore be adequately represented. These are:

a-i. Cell count and morphology unit

a-ii. Serology unit

a-iii. Haemolytic anaemia unit

a-iv. Coagulation unit

6.3.4.2 Layout

The following accommodations are required

a. Reception

b. General Office

c. Offices HoD and for the consultant haematologists

d. Offices for the resident doctors – see 6.3.2.2.13b above

e. One office for the Laboratory Supervisor

f. Automation room

g. Morphology unit

h. Coagulation room

i. Haemolytic anaemia room

j. A common room

All rooms should be well lit, well ventilated with good extractor systems for the laboratories.

6.3.4.3 Equipment

a. Automated cells counters

b. Haematocrit centrifuges

c. Haematocrit reader

d. Bunsen burner with gas cylinder and connecting pipe from outside

e. Microscopes – binocular with X100 objective lens

f. Fluorescent microscope

g. Coupling chambers

h. Coupling jars

i. Staining jars

j Staining racks

k. Electric mixers/rollers

l. Flow cytometer

m. Spectrophotometer

n.. Electrophoresis machine with densitometer for both agar and cellulose agar (Biosystem)

o.. Incubator

p.. Bucket type autoclave

q.. Water bath

r. Test tube racks

s.. Platelet aggregometer

t.. Centrifuges

u.. Refrigerators and deep freezers

v.. Mortar

w.. Chromatography column/Electrophoretic equipment

x. Coagulometer

y. Dryer

z.. Water distiller

a-2. Troughs for washing of glassware

b-2. Air conditioners

c-2. Computers for processing data

d-2. UPS and current stabilizer

6.3.4.4 The Blood Transfusion Section (BTS)

6.3.4.4.1 Introduction

a. The Blood Transfusion section should remain or be part of the centralized service of the State Blood Transfusion Service. This will ensure the maintenance of standard and quality as expected of a centre involved in blood collection, screening and processing.

b. The unit shall be headed by a Consultant Haematologist

6.3.4.4.2 Facility will comprise:

a. Blood Collection Area

i Reception area/waiting room

ii Registration room

iii Counselling room

iv Well ventilated large room for donor bleeding

v. One office room

b. Blood Storage Area/Blood Processing Area

i. One large room for storage of guaranteed blood

ii One large room for blood screening for TTI's

iii. One large room for blood processing into components

iv. One office room for the consultant haematologist

v. One office room for the Laboratory Supervisor/Manager

vi. One large room for storage of blood that is screened, labeled and ready for use.

vii. One large room for blood typing and antibody screening

c. Cross-matching Area

i. Reception area/waiting area

ii. Large, well ventilated area for cross matching

iii. One large room for storage of cross-matched ready to is sue blood

iv. One common room

6.3.4.4.3 Equipment

i. Three complete set of computer systems

ii. Four T-RAC Terumo recording automatic blood '

iii. Four T-RAC Terumo automatic blood component extractor

iv. Two cold centrifuges

v. Incubator

vi. Two plasmaphoresis machine

vii. Three 500 bag capacity blood bank for blood storage

viii. Two Binocular microscopes

ix. Automatic ELISA screening equipment, comprising

x Reader and Washer

xi Multi-channel automatic pipette

6.3.4.4.4 Personnel

a. Consultant haematologist with adjoining secretary's office

b. Medical Laboratory Scientists with Haematology and BTS bias

c. Nurses trained in phlebotomy to work in the blood collection section

d. Trained counselors

e. Laboratory Technicians

f. Laboratory Assistants

g. Receptionist

6.3.5 The Histopathology Laboratory

6.3.5.1 Introduction

a. In projecting for the expected increase in volume of work since the laboratory is to serve as a referral centre for hospitals in a State of the Federation, the following recommendations are being made.

b. Provision of adequate Laboratory space and offices as well as rooms for storage

c. Computerization of the laboratories

d. Establishment of a cancer registry to cover the whole of the State.

e. Establishment of a Fine Needle Aspiration Clinic.

6.3.5.2 Minimum recommended facilities for Histopathology laboratories

a. Reception area

b.. Fine Needle Aspiration Clinic Room

c.. Consultants' offices with adjoining secretaries offices

d.. Residents' rooms – see 6.3.2.2.13b above

e.. One well lit slide reporting room

f. laboratory Supervisor's Office

g. Staff common rooms for both senior and junior staff

h. Toilets with lockers

I. Secretary's room

6.3.5.3 Laboratories

a. Room for gross macroscopy with extractor fan

b. Main Laboratory with attached embedding room and equipped with fume cupboard.

c. Immunohistochemistry Laboratory or bench area

d. Cytopathology preparatory Laboratory

e. Other special techniques room(s)

6.3.5.4 Stores

a. For wet specimens (should be equipped with an extractor fan)

b. For paraffin blocks

c. For Slides

d. For consumable

e. Library for storage of Bound Reports

6.3.5.5 Mortuary: Recommended minimum accommodation for the mortuary (see Appendix 3 for private mortuary)

a.. Pathologist's office with attached toilet and shower

b. Changing room for resident doctors

c. Mortuary supervisors office

d. Common room for attendants

e. Reception and waiting room with attached public toilet

f. Dressing room/embalming room

g. Autopsy room

h. Demonstration room/theatre with an autopsy table

i. Museum pot preparatory room

j. Chapel/Viewing Room

6.3.5.6 List of Equipment

1. Surgical Pathology work Stations
2. Rotary microtome with accessories
3. Water bath
4. Embedding Centre
5. Cryostat machine and accessories
6. Automatic tissue processor
7. Weighing scale of various sizes
8. Thermometers
9. Staining dishes of various sizes
10. Coupling jars
11. Aspirator grip
12. Complete set of dissecting instruments
13. Full body weighing scale
14. Infant weighing scale
15. Metal rule
16. Cytospin
17. Cytology staining machine
18. Fluorescent Microscope
19. Embedding centre

20. Microscope with attachment for cameral and Video Monitor

21. Refrigerators

22. Linear Stainer which is preferably automated

6.3.6 Others

Other things to be put in place in the work areas include:

1. Running water

2. Emergency exit

3. Fire extinguishers

4. Telephone lines within the Hospital Complex for easy communication

5. Computers for proper record keeping and for Quality Control Programme.

6. An automatic generator and UPS should be provided for the laboratory to ensure correct ambient temperature and optimal functioning of the laboratory equipment.

7. TERTIARY LEVEL HOSPITAL

7.1 This is similar to the secondary hospital in many ways but also serves as a teaching institution and research facility;

7.2 It is under both State and Federal Governments.

7.3 It includes the teaching hospitals, specialist hospitals (e.g.National Orthopaedic Hospital, Igbobi) and Federal Medical Centres.

7.4 It will include some reference clinical laboratories and serves as a referral centre for the secondary health hospitals and private hospitals.

7.5 Tertiary Hospital Clinical Laboratory

7.5.1 The Clinical Laboratory services should also have four distinct departments:

a. Medical microbiology and Parasitology

b. Haematology and Blood Transfusion

c. Anatomic Pathology (Morbid Anatomy)

d. Chemical Pathology

7.5.2 The layout should be like the secondary health clinical laboratory, but shall in addition have

a. A virology unit in Med Microbiology

b. A Polymerase Chain Reaction unit in Med Microbiology

c. A Mycobacterium culture and sensitivity unit in Med Microbiology

d. A Research Laboratory – for each of the four Pathology Departments

e. A Public Health Laboratory – if desired- for monitoring outbreaks of infectious diseases in the community which will therefore involve it more in environmental and food specimens

f At least one seminar rooms that can sit up to 30 persons

7.5.3 Medical Microbiology Laboratory

7.5.3.1 Functions:

To serve the needs of Clinical and preventive medicine by

a. examining specimens from patients:

b. for presence of potentially pathogenic organisms

c. to detect antibodies and antigens

d. to determine sensitivity of organisms to drugs

e. to asses infectious potential of environmental material

f. and assessing new diagnostic tests and determine their cost effectiveness.

g. conducting research into different areas of the subject

h. serving as training place (wholly or partly) for doctors and other paramedical professions

7.5.4 The Chemical Pathology Laboratory

This is the same as the secondary hospital laboratory. The difference is in the range of specialized tests carried out and the likelihood that more cutting edge specialist tests will be carried out here. See section

6.3.3.3 for list of equipment

7.5.5 The Haematology Laboratory

7.5.5.1 The Laboratory is to serve as a referral centre for other hospitals and to perform routine haematological tests for the Teaching Hospital. The various haematology laboratory units should therefore be adequately represented as found in a secondary health laboratory. The main difference is that more specialised test are likely to be carried out here especially in the diagnosis of haematological malignancies.

7.5.5.2 The Blood Transfusion Section will be part of the centralized coordinated service of the Federal or State Ministry of Health. This will ensure the maintenance of standard and quality as expected of a centre involved in blood collection, screening and processing.

7.5.6 The Histopathology Laboratory and Mortuary

This is the same as the secondary health laboratory and will include the cancer registry, carry out research and more specialized tests such as specialized stains, karyotyping, frozen sections etc.

8. THE PRIVATE LABORATORY

This may be a general or specialist laboratory and, may be within a hospital or on its own premises. Most private laboratories will fall into the category of a secondary health laboratory but the more sophisticated ones may carry out investigations at the level of the tertiary health care system. The regulations guiding the setting up and the operation of private clinical laboratories shall be in the hands of the State Regulatory Board for Private Clinical Laboratories

(Appendix 2a), the composition of which shall include representatives of the various stake holders (Appendix 2b).

Where the private laboratory is part of a private hospital, the Medical Director of the hospital has the overall responsibility for the laboratory, if there is no Pathologist in the hospital.

9. International Standards Organisation and Quality Assurance

9.1 The standard of clinical laboratory practice at the tertiary health level shall not fall below the ISO 15189 standard

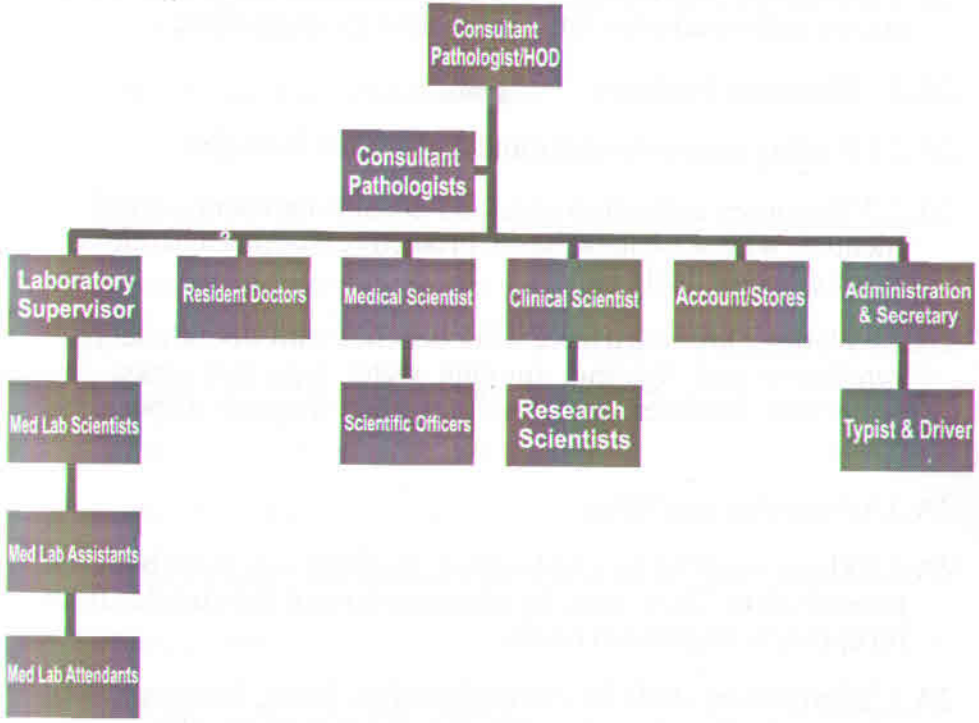
9.2 the standard at the secondary and other levels shall have substantial compliance with ISO 15189 at any point in time, but the ultimate is to attain ISO 1518 standard over a period of time not exceeding five years.

9.3 Every clinical laboratory shall ensure a very high level of quality assurance practices with proper and adequate documentation of all quality assurance activities.

9.4 External Quality Assurance (EQA) is mandatory for all clinical laboratories. Clinical laboratories at the tertiary level can serve as EQA partners for clinical laboratories at the lower levels if they have the capacity to do so.

Appendix 1

APPROVED ORGANOGRAM FOR THE PATHOLOGY (CLINICAL) LABORATORY



Appendix 2A

CRITERIA FOR THE REGISTRATION OF PRIVATE CLINICAL LABORATORY

2A.1 Definition: A privately owned clinical laboratory, which may or may not be part of a clinic, hospital or medical centre

2A.2 Minimum Facilities

2A.2.1 Waiting area with sitting and registration facilities

2A.2.2 Specimen collection area and consulting room – must be adequate with wash hand basin, protective clothing and relevant waste disposal facilities.

2A.2.3 Working area must have work benches with stools, adequate ventilation and lighting, running water taps and sinks; fire protection facilities, and facilities for adequate disposal of waste.

2A.3 Administrative Office

2A.3.1 There must be record keeping facilities e.g. workbook on patient's data. There must be adequate flow of the samples from reception to dispatch of result.

2A.3.2 Equipment shall be comprehensive, basic, functional and relevant to the disciplines(s) being covered by the private medical laboratory.

2A.4 General Equipment common to all the Laboratories

a. Binocular microscope with a minimum of three (3) objective lenses

b. Glasswares-pipettes, measuring cylinders, test-tubes and others.

c. Refrigerator/freezer

d. Water bath

e. Centrifuge

f. Timing devices

g Bunsen burner and tripod stand

h Gas cylinder

2A.5 Discipline

Minimum equipment requirement for each discipline in addition to the above listed is as follows

2A.5.1 Chemical Pathology (Clinical Chemistry)

a. Colorimeter and/ or spectorphotmeter

b. Flame photometer if electrolytes are offered

c. ISE analyzer if electrolytes are offered.

2A.5.2. Haematology

a. Counting chambers and counters

b. Haematrocrit centrifuge and reader

c. Western stand and tube

2A.5.3 Histopathology

a. Microtome and accessories

b Electric spatula, tissue processor

c. Hot plate,

d Wax dispenser

d. Weighing scale

2A.5.4 Microbiology

a. Incubator

b. Autoclave

c. Wire loops

d Safety hood

e. Weighing scale

2A.5.5 OPTIONAL EQUIPMENT

a. Water distiller,

b. De-ionizer

2A.6 SPECIAL LABORATORY OR SERVICE

These are clinical laboratories that have chosen to offer services outside the routine investigation lists e.g. Mortuary (refer to the mortuary registration criteria); Blood banking (refer to the criteria on private blood baking service) etc. Test(s) offered must be available, in addition to the General Laboratory equipment enumerated above.

2A.7 DISPOSAL OF WASTE

This includes office waste and Infective wastes (including all body fluids)

* Office wastes and packaging materials should be separated

from clinical and infective wastes and disposed off appropriately.

* Sharps must be collected in puncture-resistant or plastic containers before disposal

* Liquid wastes must be disposed into sanitary sewers

* Infective solid disposable wastes must be buried or autoclaved.

Wastes from specialized laboratories e.g radio-isotopes must be disposed according to existing regulation.

2A.8 The Person Qualified To Register a Clinical Laboratory Facility

a. A Pathologist – registered with the MDCN

b Medical Laboratory Scientist registered with the Medical Laboratory Science Council of Nigeria

c. Clinical Scientist – with the approval of the MDCN

d. Medical Scientist – registered with the MDCN

e. Any other person who the Council might permit

Irrespective of who registers a clinical laboratory the operation must comply with the provisions of this regulatory guidelines.

2A.9 Minimum staff complement

a Laboratory technician/Assistant

b Pathologist (if histopathology service is offered)

2A.10 Location

A laboratory should be located where:

* There is no danger to the population
* Public health regulations are fully observed and there is accessibility to the users.

APPENDIX 2B

State and FCT Regulatory Board for Private Clinical Laboratories

2B.1 Composition of the Regulatory Board: The Board shall consist of

1. The Chairman who shall be a Pathologist and shall be appointed by the State Commissioner for Health (the Secretary for Health of the FCT in the case of the FCT) on the recommendation of the Director of Medical Services and fourteen other persons, who shall include representatives of:
2. The State Ministry of Health (or FCT Department of Health) – the Director of Medical Services or representative
3. The State Hospital Management Board (or FCT Hospitals Management Board);
4. The Association of General and Private Medical Practitioners of Nigeria
5. Association of Pathologists of Nigeria
6. The Association of Medical Laboratory Scientists of Nigeria.
7. State or FCT Branch of the Nigerian Medical Association
8. An Anatomic Pathologist comprising a Histopathologist, a Medical Microbiologist, a Haematologist and a Chemical Pathologist
9. Association of Private Medical Laboratory Practitioners of Nigeria
10. Representative of the Ministry of Justice

11. A private citizen in the state who shall represent public interest.

12. A non-member Secretary who shall be a staff of the State (or FCT) Ministry of health, and who shall be a grade level 12 or above officer or equivalent

2B.2 Functions and powers of the State and FCT Regulatory Boards for Private Clinical Laboratories

The Board shall have the powers to:

1. Set up committees and bodies of experts to carry out specific functions or tasks on its behalf relating to Good Laboratory Practice, taking into consideration the provisions prescribed by the MDCN
2. Inspect and supervise all private clinical laboratories in the States and FCT in accordance with MDCN regulatory guidelines
3. Advise the State or FCT authorities on applications for registration received from a person who is eligible to set up a clinical laboratory.
4. Inspect the premises to be registered under this regulation
5. Collate all necessary information on registered private clinical laboratories
6. Ensure that all private clinical laboratories comply with the relevant prescriptions of the MDCN
6. Advise the commissioner on all matters relating to the registration, inspection, supervision and the need for the sealing off or withdrawal of operating licence of private laboratories in the State or FCT.
7. Collaborate with MDCN and other relevant agencies to coordinate the national external Quality assurance Programme (NEQAP)

APPENDIX 3

PRIVATE MORTUARY REGISTRATION CRITERIA

3.1 Types of Mortuary

a. Mortuary as a part of a hospital set-up

b. Mortuary as a funeral palour

3.2 The person qualified to register a mortuary:

a. Pathologist

1. Fellow of National Post Graduate Medical College (FMC Path)
2. Fellow of West Africa Post Graduate Medical College (FWACP in Laboratory Medicine)
3. Any other recognized Qualification registered with the Medical and Dental Council of Nigeria as a Pathologist.

b. Funeral Director

3.3 Premises:

3.3.1 Location:

a. Must be located in an entire Building or as part of a Hospital set up.

b. Must be well enclosed with parking space for a minimum of two cars.

3.3.2 Requirements for A Funeral Palour

a. Waiting room

b. Chapel/Mosque area

c. Resting chamber

d. Dressing room/Embalmment room

e. Administration office

f. Toilets and showers with running taps

g. Mortuary attendant's room (optional)

3.4 Requirements for a Hospital Mortuary

a. Resting chamber

b. Dressing/Embalming room

c. Mortuary attendant's room

3.5 Minimum Records

Register of incoming and outgoing corpses containing the following information:

a. Name

b. Sex

c. Age

d. Address

e. Next of Kin

f. Date and time of Death

g Name of person bringing Corpse in and his/her address, and time

h. Relationship to the Deceased.

i. Name and Address of Doctor who certified the death (a copy of the Death certificate must be taken)

j. Date of release and the Name and signature of person collecting the corpse

k. Destination of the corpse

l. Embalmment certificate

m. Autopsy register

n. Paraffin blocks, Slides and autopsy reports must be properly stored for recurrences and inspection

o. Coroner's record/exemption in cases of non-reportable deaths

3.6 Equipment:

a. Cooling chamber

b. Autopsy/Dressing table

c. Stand-by Generating set (One 10KVA unit)

d. Complete Autopsy sets

e. Embalming set

3.7 Personnel

a. Pathologist or Funeral Director

b. A minimum of two (2) attendants

3.8 Facilities for Disposal of Human Waste:

Burning of left over clothes and materials collected from the Corpses

3.9 Rules

a. No private Mortuary or funeral palour should accept a body without an accompanying death certificate or a duly filled Corona's ordinance paper from the Police.

b. A corpse may be accepted if the treating physician has requested for Hospital postmortem. Such a request should be in writing and duly signed by a registered and licensed Medical practitioner.

c. The above rules (3.9a and 3.9b) are only general and subject to any State rules relating to Coroners' law and disposal policies guiding the dead.

Review of this Document

This document shall be reviewed in the following manner

i. At the discretion of the Council any time it sees need to do so either in part or the whole document

ii. Whenever a proposal is made to the Council by any stakeholder in the teaching, or practice of Laboratory Medicine or by a recipient of Laboratory Medicine services. Council shall consider such proposal(s) and if found worthy shall effect the necessary changes.

iii. Intermittent or partial reviews and amendments shall not necessarily lead to immediate reprint of the entire document, but shall be released for use by Council through any medium and in any manner it may deem fit.

iv. A new edition shall be printed every five years to accommodate all amendments made after the printing of the previous edition.

Dr Abdulmumini A. Ibrahim
Registrar.

MEDICAL AND DENTAL COUNCIL OF NIGERIA