INSTITUTE OF PUBLIC ANALYSTS OF NIGERIA

Established by IPAN Act CAP. I16 LFN 2004 (Formerly Decree 100 of 1992)

REGISTRATION OF ANALYTICAL LABORATORY REGULATIONS 2013

Commencement

In exercise of the powers conferred on the Governing Council of the Institute of Public Analysts of Nigeria (IPAN) by section 18 of IPAN Act CAP. I16 LFN 2004, the Governing Council of IPAN with approval of the Hon. Minister of Health makes the following regulations:

1. These regulations prescribe the minimum requirements for the registration of analytical laboratories for the purpose of being designated, registered and fully licensed by IPAN. Laboratories shall be registered as Independent, In-house Quality Control or Specialized (Research, Teaching and Reference) laboratories.

Scope

2. The provisions of these regulations shall apply to analytical laboratories and sub-contracted analytical laboratories which are functioning independently irrespective of being an in-house laboratory or linked directly or indirectly to the manufacturing/processing unit of any Organization or Institution.

Applicability to sub-contracted Analytical Laboratories

3. The Institute shall have power for the purpose of carrying out these regulations:

Inspection of a Laboratory Facility

   a. To enter a laboratory or premises.
   b. Examine any equipment or items in the laboratory or premises.
   c. Examine any book, documents or other records found in the laboratory.
   d. Obtain copies of any document or information as may be necessary.

   The laboratory shall give all reasonable assistance to the Institute including making available all such records or information as may be required.

4. The laboratory or organization to which it belongs shall be legally registered with the Corporate Affairs Commission of Nigeria or any other appropriate authority approved by the Institute and an entity that can be held legally responsible. The evidence of registration shall be submitted to the Institute on request.

Organization

5. The laboratory may be owned by a public/private organization, individual or group of individuals. However, if it is not owned by a Public Analyst, it shall be managed by a Public Analyst who shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources.

Ownership

6. The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programmes, procedures, instructions, etc. to the extent necessary to assure the quality of the test results.

Management system

7. A laboratory shall be registered to carry out analysis in any of the following areas based on its competence: Food, Drugs, Water, Cosmetics, Medical devices, etc.

Areas of Laboratory Operations

8. The accuracy and reliability of tests performed by any laboratory depends on many factors, some of which are personnel, accommodation & environmental conditions, methods of analysis, equipment, calibration methods and frequency of calibration, sampling, sample preparation, handling of samples/test items and test reports.

Technical Requirements

The laboratory shall take account of these factors in developing test methods and procedures, in training and qualification of personnel, in the selection and calibration of the equipment it uses.

9. The Laboratory shall maintain records of all technical staff, their competence, educational and professional qualifications, training, skills and experience. Organogram with names and qualifications of key staff shall be documented while the head of laboratory must be a licensed Public Analyst. The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in analysis.

Personnel

The management of the laboratory shall formulate policies with respect to the education, training and skills of the laboratory personnel. The effectiveness of personnel performance and training shall be evaluated and recorded.

10. Laboratory facilities shall be such as to facilitate correct performance of its operations. The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement.

Accommodation & Environment Conditions

11. The laboratory shall not be sited in a residential building to avoid the danger of exposing residents to chemical hazards from wastes of toxic chemicals used in the laboratory and possible fire outbreaks, which can cause explosion.

Laboratory Premises

The Laboratory shall be located in a separate building preferably in an industrial area with adequate space for safe movement of people and materials.

Laboratory Building

12. The laboratory building shall be designed and equipped with appropriate lighting; ventilation, water and gas supply facilities. Nets may be installed on the doors and windows to prevent the entrance of insects and rodents.

    There shall be effective separation between neighbouring areas with incompatible activities, i.e. the physico-chemical; microbiological and biological laboratories shall be separated from each other. Measures shall be taken to prevent cross-contamination.

    Adequate provision shall be made for staff convenience, i.e. cloakrooms, office/common rooms and toilets should be provided for staff.

    Access to and use of areas affecting the quality of tests shall be controlled while measures shall be taken to ensure that both the internal and external parts of laboratory premises are kept clean at all times. Cleaning procedure shall be adhered to strictly.

Laboratory Safety Measures

13. Laboratory personnel shall wear neat protective gear appropriate for the duties being performed.

    The management shall ensure that adequate safety measures are in place and all relevant personnel have adequate safety gadgets. Smoking and eating in the laboratory is prohibited.

    Medical examination of staff shall be conducted before employment and periodically, any staff that is found to be suffering from any communicable disease shall not be allowed to work in the laboratory until certified medically fit.

Safety Gadgets

14. Apart from personnel protective equipment, other safety equipment shall be provided in the laboratory, e.g. fire extinguisher, fume-cupboard, pipette filler, first aid kit, safety goggle, etc. Management shall ensure the use of appropriate safety gadgets at all times.

    Material Safety Data Sheets (MSDS) shall be made available and displayed. Management shall ensure that not less than two workers are on duty at any point in time.

Waste Disposal

15. Laboratory waste disposal shall be carried out according to appropriate standard procedure to prevent cross-contamination and environmental pollution.

Methods of Analysis

16. The laboratory shall use appropriate methods and procedures for all tests which are within its scope. The laboratory shall have instructions on the use and operation of all relevant equipment and on the handling and preparation of items for testing. All instructions, standards, manuals, manual of laboratory methods and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel.

Equipment

17. The laboratory shall be adequately furnished with all the basic equipment required for the correct performance of its tests, such equipment shall include but not limited to weighing balances, pH meter, hot plates, thermometers, fume cupboard, autoclaves, microscopes, incubators, glassware, oven, water distillation units, sterilization apparatus, water bath, refrigerators, etc.

    Each equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment and manufacturer's manual shall be readily available for use by the appropriate laboratory personnel.

    Records of maintenance plan, maintenance carried out to date, etc. for each equipment shall be kept. Each item of equipment shall be serviced and calibrated by a qualified professional according to manufacturer's specifications.

    Sensitive equipment, e.g. UV/Visible Spectrophotometer, Weighing Balance, pH Meter, High Performance Liquid Chromatography (HPLC), etc. are affected by vibrations, electrical interference, humidity, temperature, etc., and should be located in an instrument room and used in accordance with manufacturers' specifications.

Chemical Reagents, Media and Microbial Cultures

18. Reference standards, chemical reagents, media and microbial cultures shall be provided in line with the functions of the laboratory. The reference standards, chemical reagents, etc. shall be properly labelled and arranged in an orderly manner for easy identification.

    The quality (concentration and purity) of purchased chemicals shall be ascertained before use. All reagents shall be prepared and appropriately labelled by competent personnel indicating the name, date of preparation, concentration, standardization factor, shelf life, and storage condition as well as the name or initial of the person who prepared the reagent.

    Good storage facilities such as shelves, cabinets, refrigerators, freezers, etc. shall be provided. Reference standards, reagents, media and all microbial culture shall be stored at the conditions specified by the manufacturers.

Sampling & Sample Retention

19. There shall be procedures for receipt and storage of samples. Appropriate storage facilities shall be provided and maintained pending analysis. In addition, safe storage facilities for reference samples and waste materials awaiting disposal should be provided.

    A sample of each product or material analysed shall have a retention period of a maximum of two years and stored under recommended condition. The retention samples shall be securely kept. The amount of retention samples shall be such that will permit at least a full re-examination.

Standard Operating Procedures

20. Standard Operating Procedures (SOPs) for all the activities in the laboratory shall be available from receipt of samples to release of results. Results of analysis shall be kept for a maximum of two years.

21. In reporting the results of analysis of a product or material, the laboratory shall keep details of all work done, e.g. identification, assay, calculations, potency, microbial counts, etc. shall be recorded in a separate note book or stored in a computer with a backup in place.

Reporting of Results

Each note book shall be specific regarding the type of analysis, with pages numbered. All reported analyses in the notebook shall bear the name of the product, date of receipt of sample, quantity and source of material, sampling/Laboratory No., batch No., manufactured date, and expiry date, date of analysis and name and signature of the Analyst. All fully used notebooks shall be kept in the archives.

23. Certificate of Analysis must bear the signature and stamp of a Public Analyst together with the Seal of the laboratory where the analysis was carried out. Copies of Certificate of Analysis shall be properly kept and easily retrievable.

Certificate of Analysis

24. When a laboratory subcontracts work due to unforeseen reasons or on a continuous basis, the subcontracted laboratory shall be registered with the Institute and must be competent for the work in question. The ultimate responsibility for the certificate issued lies with the Public Analyst that signed the certificate.

Sub-contracting of Analysis

25. The registration granted to any laboratory shall be valid for a period of three (3) years from the date of registration. The renewal of laboratory registration shall be for three (3) years at a time. A registered laboratory shall comply with any directives/amendments in these Regulations as issued by the Institute from time to time. A registered laboratory shall apply to the Institute for renewal at least six (6) months to the expiry of its registration.

Validity and Renewal of Registration

26. A registered laboratory shall be monitored yearly for compliance, maintenance of competency and the implementation of quality system(s) established by the laboratory. A laboratory shall be subjected to investigation in case of any complaints.

Monitoring of Laboratory for Compliance

27. The registration of a laboratory shall be suspended or cancelled at any time if among others: the laboratory violates the terms and conditions of registration; the laboratory indulges in unethical practices. The Institute shall issue a show cause notice in case it intends to suspend or cancel the registration of a laboratory after due investigation. The concerned laboratory shall be given an opportunity to defend itself before any action is taken against it.

Suspension or Deregistration of Laboratory

28. In case of appeal against none/deregistration, The Institute shall consider the appeal on its merit. In case of appeal against the cancellation of registration, the original certificate of registration must be submitted along with the appeal. Any complaints received regarding laboratory registration shall be handled as per complaint handling procedure of the Institute.

Appeal against Non or Deregistration

29. A laboratory shall be guilty of an offence if: **Offence and Penalty**

A) for the purpose of procuring the registration -

i) it makes or any other person employed by it or on its behalf makes any falsification in any matter relating to the registration;

ii) in expectation of reward or takes or uses any name, title, addition or description falsely implying that it has been registered by the Institute;

iii) obstructs or resists the Institute or any its designated officers in the execution of their duties under these Regulations; and

iv) without the knowledge of the Institute or any of its designated officer removes, alters or interferes in any way with an item, instrument or equipment during the inspection conducted under these Regulations.

B) it operates after the expiration of its License/Registration.

C) contravenes any of the provisions of these Regulations and commits any other offence as may be determined by the Institute.

The laboratory shall upon conviction in accordance with the Institute's Act be liable to fines and/or other disciplinary actions.

30. This Regulation shall be subject to review every five (5) years.

Definition

31. In these regulations (unless the context otherwise requires), the following terms shall have the meanings specified:

Act: IPAN Act CAP. I16 LFN 2004

Institute: The Institute of Public Analysts of Nigeria (IPAN).

Governing Council: The governing body of the Institute.

Analytical Laboratory or Laboratory: A facility where analysis are carried out in line with the mandate of the Institute.

Registration of Analytical Laboratory: The process of designating, registering and licensing a laboratory by the Institute.

Deregistration: The suspension or cancellation of a laboratory license by the Institute.

Regulations: Sets of minimum standard prescribed by the Institute for the operations of a laboratory.

Independent Laboratory: A laboratory licenced to carry out analysis on a commercial basis.

In-house Quality Control Laboratory: A laboratory which is established to analyse the product (s) of the parent organisation or company.

Specialized (Research, Teaching and Reference) Laboratory: A laboratory which is established for educational/referral purpose to analyse specific parameter (s) that are related to the operations of its parent institution/body.

Inspection of Laboratory: The total examinations of the books and operations of a laboratory by the Institute to verify compliance with prescribed standards.

Organogram: Organizational chart of an analytical laboratory.

Public Analyst: A registered member of the Institute with a current practice license.

Personnel: Employees of a laboratory who are involved in the daily operations of the laboratory.

Equipment: Any mechanical device used by a laboratory for analysis or in connection with the certification of product quality.

Chemical Reagent: Chemical substance used by a laboratory for analysis or in connection with the certification of product quality.

Certificate of Analysis: A certificate issued under the hand of a Public Analyst as evidence that a laboratory analysis was carried out.

Standard Operating Procedure: A documented step by step instruction that should be routinely followed during a laboratory activity.

Sample: A representative of the bulk of material to be analysed in a laboratory.

Sub - contracted Laboratory: A laboratory that has been contracted by another laboratory to carry out a laboratory analysis on its behalf.

Citation

31. These Regulations may be cited as the Registration of Analytical Laboratory Regulations 2013.

MADE AT LAGOS THIS ….. 30TH ….. DAY OF …… JANUARY…… 2014

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