ANNEXURE I

LABORATORY REGISTRATION PROCEDURE

1. A Laboratory shall apply to the Institute for registration by obtaining an Application Form after paying the prescribed non-refundable fees.

2. Completed Application Form, Laboratory Quality Manual and other relevant documents shall be submitted to the Institute for processing. All unreturned application will lapse after six months.

3. The Institute's Laboratory Audit Checklist shall be issued to the laboratory after satisfactory evaluation of submitted Form and other documents preparatory to inspection. If necessary, the Institute shall seek further information from the laboratory in order to facilitate the processing of the application.

5. Notification of mutually agreed date for Laboratory inspection.

6. Laboratory inspection by a team of IPAN Laboratory Auditors.

7. Preparation and submission of Laboratory Inspection Report and recommendation by the Laboratory Audit team.

8. Where necessary, Follow-up Action [Corrective Action(s)] on the Laboratory inspection by Laboratory Auditors.

9. Consideration/Approval of report/recommendation of Laboratory inspection by the Governing Council.

10. Notification of Approval/Non-approval of Registration of Laboratory.

11. Payment of prescribed Laboratory registration and Laboratory operation licence fees.

12 Issuance of Laboratory Licence and Seal

ANNEXURE II

TERMS AND CONDITIONS OF LABORATORY REGISTRATION

1. The registration shall be granted for a period of three (3) years, it shall be renewable every three years subject to satisfactory compliance with prescribed minimum standards which will be based on periodic monitoring/assessment of the laboratory operations/activities by the Institute. The laboratory shall apply for its renewal at least six months before expiry of registration.

2. The laboratory shall pay the prescribed administration charge of Fifty Thousand Naira prior to laboratory inspection and licence fees of Twenty Thousand Naira upon successful application. Fees are subject to review by Council without prior notice.

3. The laboratory shall perform only the tests in its approved premises as per the valid scope of registration. Sub-contracting is permitted with prior permission of the client(s) in only IPAN registered laboratory with appropriate scope of registration.

4. The laboratory shall keep records of any change in the Quality Management System on

which it has been registered and which may prevent it from complying with the minimum standards. It shall document all changes made to the Quality Management System and make records of such changes available to the Institute.

5. The laboratory shall maintain confidentiality of samples and information thereof. Its test report shall be treated as strictly confidential between it and the client. No information regarding any sample or analysis shall be divulged to any person other than that client or the Institute as may be required.

6. The laboratory shall participate in Proficiency Testing/Inter-Laboratory Test programmes on its own or as organized by the Institute and other recognized bodies.

7. The laboratory shall permit access to its facilities as may be required by the Institute for the purpose of inspection, monitoring or investigation. It shall give access to all relevant records, documents, equipment etc. for the purpose of verifying any details.

8. The laboratory shall not operate in such a manner as to bring the Institute and profession into disrepute/dispute or make any misleading statement about its registration.

9. The laboratory shall make public claim regarding its registration strictly based on the scope of its registration. Any advertisement of skill, competence or facilities by a laboratory is forbidden save as may be approved by the Institute in professional journals and similar media.

10. The Institute may cancel or suspend the registration of a laboratory, reduce its scope of operation or conduct a reassessment due to changes in personnel, equipment, and/or if a complaint or any other information is received which indicates and is proven to undermine the technical competence and satisfactory compliance of the laboratory.

11. The laboratory shall not operate after the expiration of its registration or during the suspension/cancellation of its registration.

12. Registration shall be accorded to a laboratory for single premise only.

ANNEXURE III

REVIEWED APPLICATION FORM FOR REGISTRATION OF LABORATORY

ANNEXURE IV

GUIDELINES FOR LABORATORY INSPECTION AND MONITORING

1. APPOINTMENT OF MEMBERS OF LABORATORY INSPECTION/AUDIT COMMITTE

a) The Council shall appoint members of the Institute and if necessary other stakeholders with similar functions as members of the Institute's Laboratory Inspection/Audit Committee for the purpose of inspecting, monitoring and ensuring full compliance with the provisions of IPAN Act and regulations.

b) Persons to be so appointed as per scope of the laboratory must have been trained on inspection procedures (certified laboratory Auditor/Lead Auditor), laboratory registration

standards and other regulatory matters and shall carry out their responsibilities in accordance with international best practice.

2. FUNCTIONS OF THE INSTITUTE'S LABORATORY AUDITORS/INSPECTORS

The Inspectors are authorised by the Institute to:

a. enter a laboratory or premises, which they believe, carry out laboratory analysis/consultancy services on consumer and health related products such as Food, Drugs, Cosmetics, Medical Devices, Water, Chemicals, Petroleum and Allied products, Environmental and Safety, etc. or any business in the field of laboratory practice/research.
b. examine any equipment or item in the laboratory or in any premises, which they reasonably believe, is used for the purpose of carrying out laboratory analysis, training, research or business in laboratory practices.
c. Open and examine while in the laboratory or premises any container, cubicle or cupboard which they reasonably believe may contain any equipment or things which are related to their inspection; and
d. Examine any book, documents or other records found in the laboratory or premises, which they reasonably believe, may contain information relevant to their assignment and make copies thereof.

The authorities, owners or persons in charge of laboratory or premises and every person found thereof shall give all reasonable assistance to the Laboratory Inspectors, including making available to the Inspectors all such information as they may require for the purpose of carrying out their assignments.

3. INSPECTION/MONITORING OF LABORATORY EXERCISE

The Laboratory Inspectors shall request for the current Laboratory Quality Manual which should among others contain the following information:

a. Name(s) of Public Analyst(s) in-charge of the laboratory.
b. Organogram of the Company.
c. Current Practice Licence of the managing director/operator and other personnel who are members of the Institute
d. Owner(s) of the Laboratory
e. Certificate of Incorporation of the company
f. Current Laboratory Registration Licence/certificate (where applicable)
g. List of staff with designation, qualifications and job description(s)
h. List of available instrument/equipment,
i. Documentation records which include: books – workbooks/logbooks, certificates of analysis, client's records, product records, receipts, protocols of analysis, etc.
j. Area(s) of specialization, type of product(s) analysed and nature of analysis (es) undertaken by the laboratory.

The Laboratory Inspectors shall among others ascertain the following using the Institute's approved Analytical Laboratory Inspection Score Sheet:

a. Type and make of the equipment
b. Adequacy of equipment/instrument, personnel and other facilities to carry out such analysis/research
c. Compliance of methods of analysis with standard procedure
d. Type and suitability of chemical reagents available
e. Adequacy of office/laboratory spaces
f. Suitability of location of premises and rooms
g. Availability of protective and safety devices, such as laboratory coats, head gear, nose mask, gloves, safety goggle, fume-cupboard, fire extinguisher, etc.
h. Compliance with standard specifications on documentation for SOPs, analytical results, reference standards, reference samples, work/log books, etc.
i. Compliance with waste disposal procedures for gaseous, liquid and solid wastes.
j. Compliance with Good Laboratory practices
k. Compliance with professional ethics

4. POWER TO ORDER CLOSURE THROUGH THE COUNCIL

From the report of the Inspectors/auditors, the Council may order the closure of any unregistered Laboratory premises where set standards are being compromised, seize and detain any equipment which it reasonably believes may have contravened any provision of the IPAN Act and Regulations.

5. REPORT OF INSPECTION

A report of every inspection or monitoring exercise shall be submitted within five (5) days to Council through the Registrar detailing findings and recommendations and any other measures that may be taken to ensure full compliance with IPAN Act and Regulations.

6. ASSISTANCE BY THE LAW ENFORCEMENT AGENTS AND OTHER PUBLIC ANALYSTS

The Laboratory Inspectors may be assisted in the discharge of their duties by such number of Law enforcement agents and members of the Institute as may be deemed necessary.

7. DECISION BY COUNCIL

The Council, after the consideration of the report of the Inspectors shall take the following decisions:

a. Approve the registration/non-registration of a Laboratory based on Inspectors' report.
b. Withdraw the Laboratory licence and/or practice licence of the operator.
c. Order the closure of a Laboratory premise by the Police
d. Order the owners or operators of premises to relocate or improve on the anomalies detected by the Inspectors.
e. Cause investigations to be conducted to ascertain persons involved in offences under IPAN Act or Regulations.

8. LABORATORY LICENCE

(i) The Council shall on the completion of an inspection, if it appears to it that the laboratory or premises inspected or monitored complied with the requirements of the IPAN Act and Regulations, direct the Registrar to issue a Laboratory Licence at the date of inspection under his hand to the laboratory or premises.

(ii) The Laboratory Licence shall be valid for threes year only and subject to annual renewal but may be withdrawn by the Council at any time, if it appears to the Council that there has been violation of any provision of IPAN Act or Regulation by the Laboratory.

ANNEXURE V

ANALYTICAL LABORATORY INSPECTION SCORE SHEET