

STANDARD OPERATING PROCEDURE FOR REGISTRATION/RE-REGISTRATION OF ANALYTICAL LABORATORIES



Revision No.: 002	Doc. No: IPAN/RED/SOP/LR/01	Issue No.: 003
Revision Date:	Copy No. (3)	Issue Date:
September 08, 2021		June 10, 2016

Signatures:		
Prepared by:	I indicate that I have prepared or updated this SOP according to applicable registration requirements and procedure: Preparing and Updating Standard Operating Procedures.	
	Name: GEORGIANNA ADDISON (PRINCIPAL SCIENTIFIC OFFICER)	
	Signature:	
	Date: SEPTEMBER 14, 2021	
Reviewed by:	I indicate that I have reviewed this SOP, and find it meets all applicable registration requirements and that it reflects the procedure described.	
	Name: OLUWATOYIN YAHAYA	
	(HEAD OF REGULATORY & ENFORCEMENT DEPARTMENT	
	Signature:	
	Date: SEPTEMBER 14, 2021	
Approved by:	I indicate that I have reviewed this SOP and find that it meets all applicable registration requirements and Institute's standards. I approve it for use.	
	Name: ALIYU A. ANGARA	
	(CHIEF EXECUTIVE OFFICER/ REGISTRAR)	
	Si mangan	
	Signature: Date: SEPTEMBER 14, 2021	
	Dutc. SEI LENIDER 17, 2021	



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1.0 PURPOSE

1.1 This procedure shall ensure that all Analytical Laboratories meet the general requirements for the competence of Testing and Calibration Laboratories.

2.0 SCOPE

- 2.1 Registration of Analytical Laboratories in Nigeria by the Institute of Public Analysts of Nigeria (IPAN).
- 2.1.1 This procedure shall apply to all Analytical Laboratories that want to be designated, registered and fully licensed by IPAN as prescribed by the Institute's Registration of Analytical Laboratory Regulations 2013 (IRALR 2013) for the analysis of Food, Drugs, Water, Cosmetics, Chemicals and Environment etc.

3.0 OBJECTIVE

3.1 This document shall ensure that every activity of the analytical laboratory for registration process is guided and complies with IRALR 2013.

4.0 RESPONSIBILITY

4.1 The Regulatory and Enforcement Department (RED) of the Institute shall be responsible for ensuring that the registration requirements herein are complied with by the laboratories seeking for registration before being registered.

5.0 PROCEDURE

- 5.1 For all Analytical Laboratories in Nigeria
- 5.1.1 A Laboratory shall apply to the Institute for registration by obtaining an Application Form after paying the prescribed non-refundable fee(s). See page 5.
- 5.1.2 Completed Application Form, Laboratory Quality Manual and other supporting documents shall be submitted to the Institute (RED) for processing. Unreturned application form becomes invalid after six (6) months of purchase or collection.



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- 5.1.3 Evaluation of returned application form, Laboratory's Quality Manual and other supporting documents by the Institute (RED) not more than four (4) weeks after receipt.
- 5.1.4 Outcome of evaluated Quality Manual and other supporting documents shall be forwarded to the laboratory by RED, so that the Non-Compliances (NCs) if any can be addressed by the concerned laboratory before the inspection date.
- 5.1.5 Notification of mutually agreed date for Laboratory inspection not later than six (6) weeks of submission of application form.
- 5.1.6. Once the application is judged to be completed, Laboratory inspection by a Team of IPAN Laboratory Inspectors consisting of the Lead Auditor, Auditor / Secretary and / or Observer shall be formed to inspect the laboratory.
- 5.1.7 The team shall inspect/review laboratory equipment, reagents, environment, documents / records, interview staff, and obtain copies of any document as objective evidence to prove that the laboratory meet IPAN Requirements for Registration of Analytical Laboratory Regulation 2013 (IRALR 2013; Section 3).
- 5.1.8 Preparation and submission of Laboratory Inspection Report by the Laboratory Inspectors to the appropriate committee of council not later than fourteen (14) days after inspection.
- 5.1.9 Consideration of report/recommendation of Laboratory inspection Team by the appropriate committee of council.
- 5.1.10. If any area(s) of non-compliance is/are identified by the team, corrective action request(s) shall be provided during the closing meeting of inspection to the laboratory to correct the non-compliance within the time frame of two (2) months.
- 5.1.11 One (1) month extension shall only be given to the laboratory that officially requests an extension, stating the reason(s) for inability to comply with the stipulated time.
- 5.1.12 Consideration of recommendations of the appropriate committee of council for Approval/Non-approval of Registration of Laboratory to the Governing Council for final approval. And Governing Council's position shall be communicated to RED within two (2) weeks.



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- 5.1.13 Where necessary, non-approved laboratory for registration shall require re-inspection with payment of the recommended non-refundable fee.
- 5.1.14 Approved Laboratory for Registration by the Governing Council shall be communicated through letter of Notification of Registration of the laboratory by RED.
- 5.1.15 Payment of prescribed Laboratory registration and Laboratory operation license fees by registered laboratories.
- 5.1.16 Issuance of Certificate of Laboratory Registration and any other authorizing materials.
- 5.1.17 Continuous monitoring and evaluation of registered laboratories to ensure compliance throughout t6e currency of the laboratory registration period, at least once every six (6) months by the RED (Deviation from compliance may lead to withdrawal of approval and license of the laboratory or any other sanction(s) deemed appropriate).
- 5.1.18 Renewal process to start six (6) months to expiration of the Certificate of Laboratory Registration issued to the laboratory and the laboratory should call for inspection three months (3) to the expiration so as to give the appropriate committee room for decision on approval processing.



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CURRENT APPROVED CHARGES FOR LABORATORY REGISTRATION

S/N	ACTIVITY	APPROVED FEE (N)
1.	Application Form	10,000.00
	(Invalid after 6-month)	
2.	Inspection Fees	
2a.	Pre-Inspection Advisory Audit	50,000.00
	(Optional)	
2b.	Laboratory Inspection	100,000.00
2c.	Re-Inspection	50,000.00
3.	Laboratory Registration for Three years	100,000.00
4.	Professional Postage Stamp	50.00 per unit
5.	Monitoring and Evaluation of Registered	0.00
	Laboratories	
6.	Re-evaluation of Quality Manual	0.00

From the table above, the fee for laboratory registration is either; Two Hundred and Ten Thousand Naira (N210,000.00) or Two Hundred and Sixty Thousand Naira (N260,000) only – inclusive of the optional pre-inspection advisory audit fee. Payment may be made in piecemeal at the commencement of every stage of the exercise.

The re-inspection fee of Fifty Thousand Naira (N50,000) is only applicable where the laboratory fails the first audit exercise.



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DOWNLOADING OF LABORATORY APPLICATION FORM AND OTHER RELATED DOCUMENT

Steps required accessing our website in order to download laboratory application form and other related document to serve as guidelines/requirements for registration of analytical laboratory with the Institute:

- 1. Login to www.ipan.gov.ng; click on 'departments' scroll to Regulatory and click on it.
- 2. The page will open and scroll to the bottom of the page. Click on Laboratory Application Form; Print the form and complete/provide the necessary information.
- 3. Scan and forward to the Institute evidence of payment (receipt), completed application form and other document for processing.
- 4. Cost of the application form is a sum of Ten Thousand (N10,000.00) naira only.

PAYMENT OF ITEMS USING GIFMIS CODE

S/N	DESCRIPTION OF ITEMS	GIFMIS CODE
1.	Practice License Fee	1000180958
2.	Laboratory Registration Fees	1000181054
3.	Laboratory Inspection Fee	1000181067
4.	Professional Laboratory Seal (Metallic Seal) Fee	1000181148
5.	Professional Plastic Stamp Fee	1000181151
6.	Professional Postage Stamp Fee	1000181135

Note: Do not hesitate to communicate the Regulatory and Enforcement Department (RED) of the Institute on issues that require clarification.