



PAPUA NEW GUINEA LABORATORY ACCREDITATION SCHEME

GENERAL INFORMATION

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1.0 INTRODUCTION

Laboratory Accreditation and Its Objectives

Laboratory accreditation provides a means of determining the competence of laboratories to perform specific types of testing, measurement and calibration. It enables people who want a product, material or instrument to be checked or calibrated to find a reliable testing or calibration service able to meet their needs. It also allows the laboratory to determine whether it is performing its work correctly and to appropriate standards. Manufacturing organizations may also use laboratory accreditation to ensure the testing of their products by their own in-house laboratories is being done correctly.

Very importantly, laboratory accreditation provides formal recognition to competent laboratories, thus providing a ready means for customers to access reliable testing and calibration service.

In Papua New Guinea, the PNGLAS (Papua New Guinea Laboratory Accreditation Scheme) is the national accreditation body that assesses and accredits testing and calibration laboratories. The scheme is administered by the National Institute of Standards and Industrial Technology (NISIT).

The institute established an accreditation service, by accrediting laboratories operated by manufacturing industries, government departments, educational institutions and commercial consultants. The scheme is voluntary.

The PNGLAS just like any accreditation body in the world have adopted an international standard, called ISO/IEC 17025, as the basis for the accreditation of its testing and calibration laboratories. The adoption of these standards simply means that the PNGLAS approach to determining laboratory competence is uniform with other accreditation bodies that have also adopted the same standard.

Although the basic criteria for accreditation are the same for every laboratory, the manner in which these criteria are applied in any particular laboratory will vary depending on the nature of the laboratory. Some laboratories may have one or more functions and in each of these situations, may place their own demand on the nature of the organization, methodology, staffing, equipment, accommodation and operational procedures needed to fulfil their intended function.

The current laboratory accreditation system that the PNGLAS have in place and operational has two purposes:

- Examination

This is a thorough examination and evaluation of all the aspects of a laboratory's management, staff, equipment, records and operations that affects the reliability of test results. The question of whether the laboratories comply or not with the accreditation requirements, depends on the assessor's findings and recommendations to the Testing Laboratory Accreditation Board.

- Preliminary

During the assessment the assessment team may provide guidance and resources to testing facilities on means of

correcting deficiencies and suggests areas of improvements. Almost every initial assessment of an applicant laboratory will uncover some aspects of laboratory that does not meet the PNGLAS requirements. Even for a registered laboratory, it is not common to find one or more areas that have fallen below the required standard. For such situation the PNGLAS through its assessors will provide technical guidance on how to correct deficiencies, preventive means and improvements.

This document outlines the general information on laboratory accreditation mechanism and philosophy. For rules, mandatory documents, guidance documents, PNGLAS policies and procedures are made available on the NISIT-PNGLAS website: <https://www.nisit.gov.pg/95-accreditation> or can be obtained from the PNGLAS office in hard copy.

When a laboratory is accredited, its details including its scope of accreditation are published in the PNGLAS Directory ID3 and made available on the NISIT-PNGLAS website: <https://www.nisit.gov.pg/95-accreditation>

2.0 STRUCTURE AND GOVERNANCE

The PNGLAS was established in 1983 by the then National Standard Act - 1978. This was repealed in 1993 and replaced by NISIT Act – 1993. The National Institute of Standards and Industrial Technology (NISIT) is a non-profit Government agency, which administer PNGLAS.

The NISIT Act – 1993 established the NISIT Council which is responsible to the Minister responsible for NISIT and also for the administration of the standardization activities including laboratory accreditation. The Council members appointed by the Minister are representatives from industry, government and professional bodies. The Papua New Guinea Laboratory Accreditation Scheme (PNGLAS) is a national organization for conformity assessment for laboratories. Through NISIT Act – 1993, the Papua New Guinea government recognizes PNGLAS as the only national accreditation body for establishing competent laboratory practice in the country.

Testing Laboratory Accreditation Board (TLAB)

The Council established a Board called the Testing Laboratory Accreditation Board (TLAB) that is responsible for, assessing the impartiality and objectivity of the PNGLAS accreditation activities, their implementation and to ensure that accreditation activities are in the interest of all parties concerned.

Monitor the PNGLAS's activities and make proposals for improving the organization of its activities, taking part in the formation and development of the accreditation system, examining issues related to new areas of accreditation activities, preparation of normative documents and legislation regulating the accreditation process, activities of the PNGLAS and its accredited bodies. The Board also on behalf of the Council resolve queries relating to technical policies.

The Board's memberships are equally drawn from industries, government and professional bodies including scientific and research organizations. The members are appointed as individuals for their personal knowledge and expertise. They do not represent their employer or any other organization with which they may be associated.

The Accreditation Advisory Committees (AAC)

The Accreditation Advisory Committees (AAC) have the primary function of reviewing technical issues and advises the TLAB and the NISIT Council on accreditation criteria, guidance documents and procedures for the operation of the PNGLAS, determination of qualification requirements for technical assessors and offer suggestions, related to making the decisions on accreditation on concerning with complaints or on other accreditation activities.

The members of the committees are representatives from backgrounds with respect to the field of activities of the Committee such as; relevant government authorities, industry, research and academic institutions, as well as accredited laboratories. This composition aims to provide for a balanced representation of all parties having interest in accreditation.

The members are appointed based on their competence with respect to accreditation, general conformity assessment and experience with regard to specific field of testing. They are appointed by the NISIT Council upon recommendation by the PNGLAS/TLAB.

Assessors

The Scheme has a small pool of experts and technical assessors that have been volunteering to assist with the laboratory assessments. The assessors assist PNGLAS on a voluntary basis.

3.0 THE OBJECTIVES OF LABORATORY ACCREDITATION

The main objectives of the PNGLAS are:

- to provide, in the national interest, laboratory accreditation service which meets the needs of PNG stakeholders;
- facilitates the recognition and acceptance of test reports, products and services; and
- to promote science and practice of laboratory accreditation to enhance the acceptance of PNG reports or data and associated goods or services locally or on foreign markets.

4.0 ACCREDITATION PROCESS

The following information is provided to assist laboratories seeking accreditation or extensions to accreditation.

PRELIMINARY STEPS

The laboratory is encouraged to hold discussions with the PNGLAS Staff Officer before lodging a formal application for accreditation.

When seeking accreditation, laboratory staff should also familiarise themselves with the PNGLAS Accreditation Requirements. Following discussion with the PNGLAS Staff Officer, these accreditation requirements can be obtained from the Staff officer or from the NISIT-PNGLAS website: <https://www.nisit.gov.pg/95-accreditation>

ENQUIRY

It is the initial contact that the laboratories usually make with the PNGLAS. The PNGLAS Officer will outline to the laboratory what is required and may brief the laboratory on the accreditation process.

PRELIMINARY VISIT

The PNGLAS may conduct an informal review (Preliminary Visit) of the laboratory if requested to explain the significant requirements that relate to accreditation. Preliminary visit is not compulsory but applicant laboratories are encouraged to avail themselves to this service. Prior to a preliminary visit being conducted, the laboratory will be asked to provide a copy of the quality manual and associated documentation for review. The PNGLAS Officer will advise exactly what information is required for review.

APPLICATION

Applications for accreditation with the PNGLAS may be made by any legally identifiable organisation and must be made on the prescribed application form. This form will be provided at an appropriate time with regard to the intended time of application. The application must be accompanied by the current application fee, quality manual and associated documentations.

The PNGLAS Staff Officer may advice the laboratory of when to submit the application based on his evaluation of the laboratory during the preliminary visit.

DOCUMENT REVIEW

The document review is normally conducted by the PNGLAS Team leader and the assessment team who will be involved in the assessment of the laboratory. This involves a thorough review of the laboratory's quality manual and relevant document relating to the quality system. The purpose of document review is to confirm that policies and procedures, documented by the laboratory meets PNGLAS accreditation requirements. It also provides the team leader and the assessment team with both an understanding of the laboratory's operation and an opportunity to identify or make note of particular references within the laboratory's documented system that may require review during the on-site assessment or areas that appears to require further explanation or investigation.

ASSESSMENT

Compliance of an applicant laboratory with the accreditation requirements is determined primarily by an on-site assessment.

The objective of an assessment is to establish whether the laboratory can competently perform the tests, examinations, calibration and measurement for which accreditation has been sought. The PNGLAS assessment team is required to investigate the operation of the laboratory against the criteria detailed in ISO/IEC 17025 and the PNGLAS requirements. The assessment team reports their findings to both the

laboratory being assessed the Executive Manager and the committee and Board.

For the current practice, the assessment team is comprised of:

- Team leader (normally a PNGLAS staff)
- one or more specialist volunteer technical assessors/technical expert;
- an observer (if required).

The size of the assessment team is dependent upon the laboratory's scope of accreditation that must be covered in the course of the assessment.

Assessments will generally take at least two working days and may extend over a number of days depending on the range of activities to be covered.

Technical assessors/Experts are chosen according to their specialist knowledge and are matched as closely to the activities of the laboratory as is possible. Consideration is given to possible concerns about conflicts of interest in selecting assessors.

Laboratory staff will be called upon to discuss, with the technical assessors/Experts, technical issues relating to measurements and tests that are in progress or are carried out by the laboratory. Occasionally, such discussion may be hypothetical. The PNGLAS may also request prior to the assessment or in the course of the assessment that particular measurements or tests be demonstrated. Laboratories undergoing an assessment should expect all areas for which accreditation is sought to be covered in some way.

An exit interview or meeting is held at the conclusion of the assessment at which the assessment findings are presented by the Team leader. It is the prerogative of the laboratory to decide which of their staff should attend this meeting. Generally, the authorised representative would be expected to attend as well as relevant senior staff. The purpose of the exit meeting is to allow frank and open discussion about the findings of the assessment. Laboratories are strongly encouraged to clarify issues they consider may have been misunderstood by the assessment team and to seek clarification about assessment findings where this may be necessary.

A written or interim report is usually left on the day for laboratories to start the corrective action process. This report is subsequently reviewed by the assessment team. After peer review and confirmation, a final report is issued to the laboratory. Where necessary, the report will detail the action required by the laboratory to allow accreditation to be recommended. In these cases, the laboratory will be asked to provide the PNGLAS with the necessary evidence that action has been taken as claimed. Occasionally, the Executive Manager may direct that a further visit by a Team leader or another assessment be carried out. There are a number of reasons for this, including concerns about the competence of the laboratory, the inability to assess certain aspects of the laboratory during the scheduled visit because of lack of availability of key staff, or to review the effective implementation of the corrective action taken as a result of the assessment. The same procedures for assessment will be

followed but may concentrate on only the area(s) found to be deficient. Charges will be levied for such visits.

GRANTING ACCREDITATION

The Testing Laboratory Accreditation Board (TLAB) grants accreditation following a recommendation from the assessment team and Accreditation Advisory Committee (AAC. This recommendation is made when the laboratory has met all the requirements for accreditation. The TLAB may discuss any concerns raised with regards to the capability of the laboratory to meet the accreditation requirements with the relevant Accreditation Advisory Committee. The authorised representative is formally advised of the granting of the accreditation and issued with an electronic PNGLAS endorsement, certificate of accreditation and the scope of accreditation.

AFTER ACCREDITATION

The PNGLAS accredited laboratories must continue to comply with all accreditation requirements detailed in the PNGLAS Accreditation Requirements. In order to ensure continued compliance with these requirements, reassessments are generally carried out every three (3) years after accreditation. Surveillance visits 12 months after accreditation. Follow up assessments or extraordinary visits may require shorter intervals as specified. The reassessment follows the same processes and has the same broad objectives as the initial assessment. Accredited laboratories are also required to perform satisfactorily in relevant proficiency testing activities as designated by the PNGLAS. Re-assessments review action taken in response to proficiency testing results.

SCOPE OF ACCREDITATION

Accreditation is described by classes and sub-classes of test. The collective expression or scope of a laboratory's accreditation is known as its "scope of accreditation". These classes and sub-classes are fixed descriptors, free text being used to qualify or amplify the scope as necessary. Where the scope of testing of a laboratory cannot be adequately described by existing descriptors, the TLAB or relevant Accreditation Advisory Committee may from time to time establish new classes and/or sub-classes of test. A copy of the classes of test available in each field of testing is provided. Classes of test are however, revised from time to time, so for the most current version please contact the PNGLAS office.

Applications for accreditation may be made for one or more classes or sub-classes of test, or for one or more items or specific calibrations or tests within a class of test.

The scopes of accreditation of all the PNGLAS accredited laboratories are available on the NISIT-PNGLAS website: <https://www.nisit.gov.pg/95-accreditation>

VARIATIONS TO SCOPE OF ACCREDITATION

Accredited laboratories may request variations to their scope of accreditation. Significant variations will require an assessment. PNGLAS staff officer will provide direction on the information required, the process that will be followed, and the charges that will be levied.

ROLE OF AUTHORIZED REPRESENTATIVE

The authorised representative is a person nominated by the laboratory to be its representative in all matters relating to the application or accreditation. He/She is the laboratory's recognised official contact with PNGLAS. Nomination is made in the appropriate section on the application form or changes that are required thereafter, on the form available for this purpose.

The authorised representative's rights and obligations are detailed in the PNGLAS Rules. The authorised representative is normally a senior staff member who is in a position to make decision regarding laboratory accreditation and communicate with all laboratory staff. He/She may direct the PNGLAS to discuss relevant issues with other staff of the laboratory.

The authorised representative is required to notify PNGLAS within 14 days if:

- the name or ownership of the laboratory changes;
- changes in duties or departures of key staff occur; or
- significant changes occur to the functions or accommodation of the laboratory.

APPROVED SIGNATORIES

The Scheme no longer grants formal approval to laboratory staff to sign test reports or calibration certificates bearing the PNGLAS endorsement. The laboratories have been given this responsibility. The PNGLAS role will be to review the process and records during onsite assessments on how these approval are done by the laboratory. Approved signatories assume responsibility for the technical validity and accuracy of all information contained in an endorsed document. They must have and demonstrate a sound knowledge of:

- the principles of the calibrations, measurements and/or tests they perform or supervise;
- the standards or specifications for which accreditation is sought or held;
- the laboratory's quality system;
- ISO/IEC 17025, ISO 15189 (for medical laboratories), PNGLAS Rules and relevant General accreditation criteria;
- measurement ranges and the estimation of the uncertainties of measurement associated with the test or calibration results for which the laboratory is accredited or seeking accreditation (where relevant to the accreditation);
- the estimation of the actual uncertainties of measurement associated with the tests or calibration results.

Approved signatories should hold a position within the organisation which provides authority over the calibration and/or testing activities and, where necessary, results to be rejected when they consider them to be inadequate.

Individuals may be confirmed as signatories for all or part of the laboratory's scope of accreditation. Signatory approval is not a personal qualification and is not transferable from one laboratory to another without approval having been granted at each laboratory.

Signatory approval is available to consultants to the laboratory provided that the consultant has the knowledge necessary to allow him/her to be approved as a signatory, and have authority over the testing, as already defined. Consultants must also hold a written contract or agreement with the laboratory in which their role and authority in the laboratory is clearly defined, and that they agree to hold confidential information relating to clients of the laboratory and maintain impartiality in all their dealings. The agreement should further indicate that the laboratory is responsible for work performed by the consultant including acceptance of the indemnity responsibilities detailed in the PNGLAS Rules.

Laboratories must have approved signatories to cover the complete range of its scope of accreditation. The status of the accreditation may be changed for any parts of the scope for which approved signatories are no longer available.

PROFICIENCY TESTING OR INTERLABORATORY COMPARISONS

Participation in proficiency testing or interlaboratory comparisons is mandatory for an accredited laboratory. Each applicant or accredited laboratory is required to participate in appropriate proficiency testing or interlaboratory comparison activities nominated, approved or offered by PNGLAS, APAC or any other MRA recognised accredited under 17043 provider. Programs offered by industry or professional groups or other laboratories and other international accreditation bodies may also be suitable.

Participation in proficiency testing or interlaboratory comparisons may be required, as follows:

- a) prior to gaining accreditation with PNGLAS;
- b) at least once every two years for each major area of test/measurement, where available;
- c) when requesting significant extensions or variations to scope of accreditation;
- d) when confirming additional approved signatories.

Fees are charged for participation in proficiency testing programs offered by PNGLAS, APAC or any other ISO/IEC 17043 accredited or MRA recognized provider. Costs vary and will be advised prior to participation in the program. PNGLAS may nominate a laboratory without notifying the laboratory.

NON-COMPLIANCE WITH ACCREDITATION REQUIREMENTS

In accordance with the PNGLAS Rules, non-compliance with the accreditation requirements may lead to the accreditation status of a laboratory being changed. In these circumstances the laboratory is not able to issue endorsed reports or claim to be accredited for those services affected by the change in status. The PNGLAS Rules define the reasons, processes and the appeals mechanisms that may be followed.

PROVISION OF INFORMATION ON SCOPES OF ACCREDITATION AND APPROVED SIGNATORIES

Details of a laboratory's scope of accreditation are posted on the NISIT-PNGLAS website once accreditation has been granted and are also made available to inquirers. The names of approved signatories will also be provided on request.

CONFIDENTIALITY

All information provided by a laboratory in connection with an inquiry or an application for accreditation, and all information obtained in connection with an assessment, is treated as confidential by PNGLAS staff, technical assessors and committee, and Board members. All such personnel are made aware of this requirement and have signed confidentiality agreements.

PRIVACY

PNGLAS respects and upholds the rights of individuals. The PNGLAS Staff Officer is obliged to manage personnel information to ensure privacy protected. The following is a summary of the personal information collected from individuals in applicant and accredited facilities and the disclosure of that information or as set out in the PNGLAS PL9.

Authorized Representative

The authorised representative is an accredited laboratory's official contact with the PNGLAS. The personal information collected will include name; position; business address, business telephone, mobile phone and fax numbers; e-mail address.

This information may be used to:

- administer and manage your accreditation;
- seek feedback from you on ways to improve the PNGLAS services;
- provide you information on the PNGLAS activities and services.

The information may also be made available to enquirers requiring the services of the PNGLAS accredited laboratories.

Personal information may be disclosed to organisations outside the PNGLAS. Such organisations may include:

- government and regulatory authorities and other organisations, as required or authorised by law and/or with which the PNGLAS has a Memorandum of Understanding or similar formal agreement;
- professional advisers including accountants, auditors and lawyers;
- proficiency testing providers;

Laboratory Contact

Recognising that the authorised representative is not necessarily the most appropriate person to answer day to day and technical queries regarding an accredited laboratory's activities, PNGLAS provides laboratories the opportunity to nominate a person to deal with technical and other enquiries. (This person can, however, also be the authorised representative.)

The personal information collected will include name; position; business address, business telephone, mobile phone and fax numbers; e-mail address. This information may be given to enquirers and is included in the online directory.

Laboratory Personnel

The personal information collected on personnel of the applicant or accredited laboratory may include name, position, professional, technical or other relevant qualifications, membership of professional associations, employment history.

This information is used for the conduct of the assessment, reporting on the assessment and the process of granting/continuing accreditation. It may be disclosed to the PNGLAS staff members, assessors, assessment observers and PNGLAS committee members, all of whom have signed confidentiality agreements. It may also be disclosed to agencies to which the PNGLAS has a legal obligation or with which the PNGLAS has a formal agreement.

Disclosure of Personal Information by Applicant and Accredited Laboratories at Assessments

In order for PNGLAS to determine compliance with some accreditation criteria, it will be necessary to sight personal information at assessments. Examples might include personal information held in training records, complaint records, lists of approved suppliers etc. It is the responsibility of the laboratory to ensure that, it has appropriate arrangements in place to advise individuals that personal information collected may be disclosed to PNGLAS.

5.0 GENERAL REQUIREMENTS FOR ACCREDITATION

The general requirements for the competence of testing and calibration laboratories are described in PNGS ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories or ISO 15189 for medical laboratories. These requirements are designed to apply to all types of testing and calibration and therefore often need to be interpreted with respect to the type of calibration or testing concerned, and the techniques involved.

All testing or calibration laboratories must comply with all relevant clauses of PNGS ISO/IEC 17025, the PNGLAS Rules, and relevant statutory requirements. Additional information relating to specific areas of testing or changes or additions to accreditation requirements or policies may be issued from time to time in the form of PNGLAS Accreditation Requirements documents as well as normative documents. These shall supersede any previous requirements where indicated and should be filed in the relevant section of PNGLAS accreditation requirement (PAR) package. The contents of the PAR are:

1. PNGLAS General Information
2. PNGLAS Rules
3. Fee Schedule
4. ILAC Mandatory documents
5. International Guidance Documents
5. PNGLAS Policies & Procedures (where applicable)

Guidance documents are intended to provide guidance and therefore do not contain requirements for accreditation, unless specifically indicated in this document. A copy of the PNGLAS Accreditation Requirements must be readily available to staff working in a PNGLAS accredited or applicant laboratory.

6.0 FIELDS OF TESTING

The Papua New Guinea Laboratory Accreditation Scheme provides accreditation to the following fields of testing:

Construction Material Testing
Chemical Testing
Biological Testing

ANNEX 1: ACCREDITATION PROCESS FLOWCHART

The flowchart below shows the PNGLAS Accreditation Process

