National Department of Health

Laboratory Quality Manual
G_10_QMAN_1_A

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G_10_QMAN_1_A	27/8/22	New document
G_10_QMAN_1_A	3/9/22	Additional document control requirements, Section 13.1 Equipment spares record to be maintained, section 6.5
G_10_QMAN_1_A	27/3/23	Addition of Dr Mabone, Chief Pathologist as a document authoriser Section 13 : Extensive changes – see tracked version Definition of Document Development and Review Groups within PMGH, CPHL and Blood transfusion service Definition of roles and responsibilities for document management across these organisations. Change to document numbering by discipline and organisation to include Biochem, Haem, AP/Cyto and Blood Tx service Clarification of amendment versus periodic revision terminology- version letter only to change at the time of review

Certification of printed copy:

Version	
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Date	

In memoriam Professor Evelyn Lavu, 1963 - 2021, Director of CPHL, a passionate leader who initiated the laboratory quality improvement journey in Papua New Guinea.

Distribution and Document Control

The online version of this manual is the controlled document. This is accessible from this location. All associated quality documents and templates are also accessible on that website.

All sites are responsible to ensure that any printed copy is certified by local management as reflecting the current online version. The copy is entered into the local Printed document log sheet (G_10_WS_5).

Reprinting of a new version leads to removal and destruction of old version copies by the Laboratory Quality Officer or the Document Control Officer.

A certification statement to be recorded on printed title page above.

Abbreviations and acronyms

BSL	Biosafety Level
CDC	Centers for Disease Control and Prevention, USA
EQA	External Quality Assessment
EUCAST	European Union Committee on Antimicrobial Susceptibility Testing
ISO	International Organization for Standardization
LIMS	Laboratory Information Management System
LQM	Laboratory Quality Manual (this document)
LQMS	Laboratory Quality Management System
NCR	Non-conformance report
QC	Quality Control
QM	Quality Manual
QSE	Quality System Essentials
OIC	Officer in charge
PC2	Physical containment level 2
PPTC	Pacific Pathology Training College
SOP(s)	Standard Operating Procedure(s)
WHO	World Health Organization

Contents

1. Introduction to the Quality Manual

This quality manual provides a roadmap of the laboratory quality management system (LQMS) in place for public laboratories in PNG including all the necessary policies and procedures that support a quality management system as specified by the ISO15189 Standard for Medical Laboratories. Refer here for a range of short LQMS information sheets.

The quality management system aims to provide the necessary support processes to enable the laboratory to perform accurate and reliable analytical work that meets customer requirements (refer to Figure below). The laboratory aims for continuous improvement of the system, and prevention of the occurrence of nonconformities (unexpected wrong results or significant deficiencies of practice).

PNG has legislated that all laboratories will eventually be accredited against this ISO standard. Implementation of ISO15189 LQMS is a complex process that takes several years. The WHO Laboratory Quality Stepwise Implementation tool provides a 4 phase roadmap with a staged approach to all of the Quality System Essentials (QSE) described in this manual. The development of the LQM is described in phase 3.

This manual is organized following the framework developed by the WHO. As most laboratories in PNG are just at the commencement of the LQMS journey, much of the content will not correspond to what is currently in place. The LQM provides detailed guidance for future action. Local laboratory management can steadily work through section by section, determining and giving priority/resources to action plans based on the required elements.

As a starting point, it is recommended that all Laboratory Managers read the LQMS Information sheet and enrol in the free WHO eLearning course on LQMS which focuses on the 5 very important initial challenges (approximately 30 minutes learning for each course): 1. Documents and records, 2. Personnel, 3. Purchasing and Inventory, 4. Equipment and 5. Facilities and Safety. Access is via this page and a certificate is provided upon completion of the 5 courses. Elements of these courses have been integrated into the text and the assistance of WHO is gratefully acknowledged.

1.1 Mission

Delivery of quality laboratory services essential both for providing clinical diagnosis for clinical decisions for patient care and as objective means to measure and monitor treatment of diseases.

1.2 Vision

To provide affordable, accessible, equitable, and quality medical laboratory services for the residents and non-residents of Papua New Guinea.

1.3 Scope

This quality manual describes the quality management system applicable to all PNG laboratories**.** The QMS is essentially a complete operational policy and procedures for management and staff. Its scope is for:

- **Internal use** - to communicate to staff the laboratory's quality policy and objectives, to make the staff familiar with the management structure and processes used to achieve

compliance with quality requirements. This can facilitate the implementation of the quality management system as well as ensure its maintenance and required updates during changing circumstances. This allows for effective communication and control of quality related activities and a documented base for quality system audits.

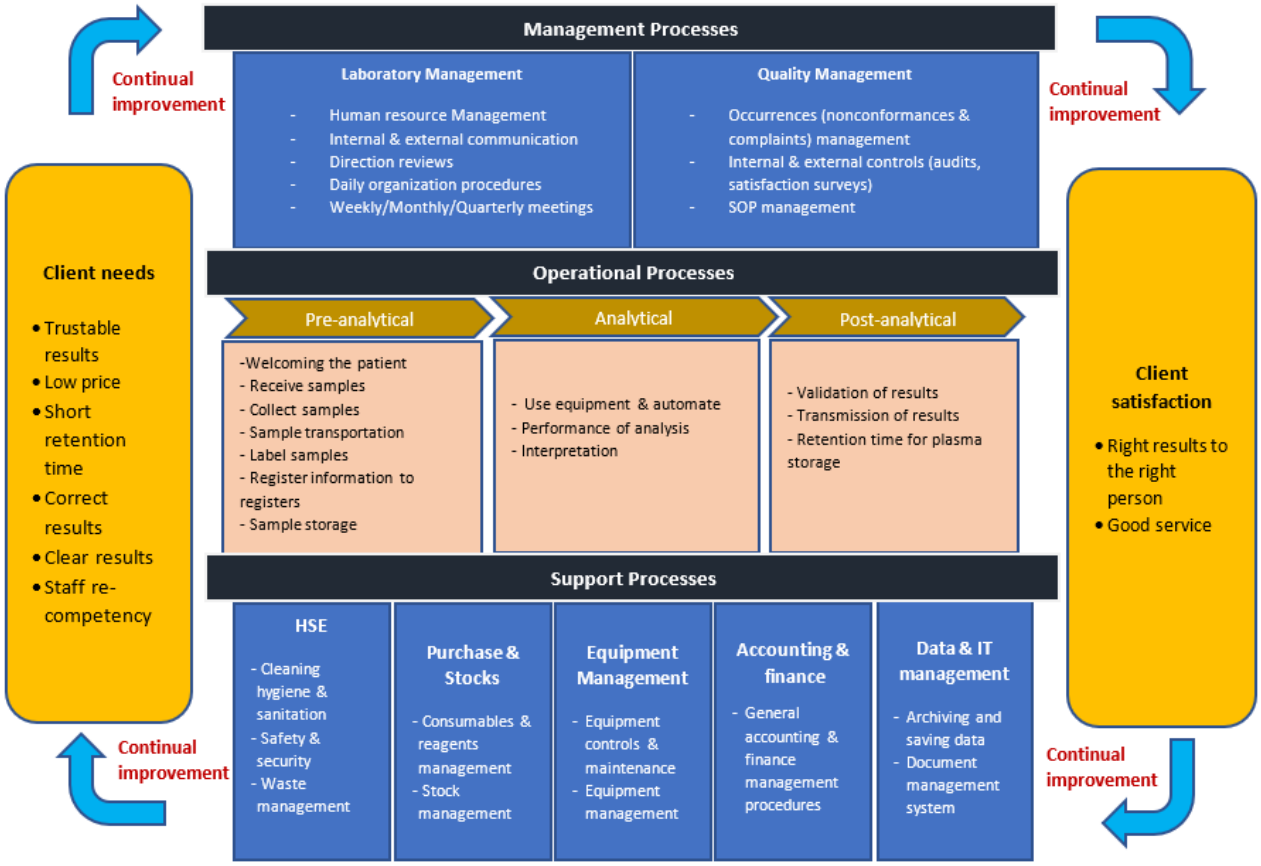
- **External use -** to inform the laboratory's external partners and customers about its scope of work, its quality policy as well as its implemented quality management system and measures of compliance with quality.

1.4 Information about individual public medical laboratories

Refer to https://path-png.org/laboratory-guides/ for location-specific information on available diagnostic services, pathology specialist consultation, laboratory organizational structure, managers, contact numbers, opening hours and specimen collection guide.

With the assistance of the Chief Pathologist's office, individual laboratories are required to complete and locally authorize descriptions of their officers, organizational structure and diagnostic services provided. The description is placed on the Pathology Laboratory Description template, G_10_TEMP_9 and forwarded to the office of the Chief Pathologist once completed. Note that if a locally authorized current list of diagnostic tests is available, then this should be provided and does not need to be duplicated within the template.

Figure: Laboratory workflow and key processes required for production of quality-assured patient results



2. QSE: Quality Policy

This laboratory is committed to the following principles:

Excellence • Compliance with ISO15189 2012 requirements for laboratory management and quality, as demonstrated by internal audit and external quality assurance • Compliance with the National Health Service Standards	**Service** • Timely, accurate and appropriate diagnostic services without interruption • Quality, accurate and reliable laboratory results • Laboratory staff who adhere to the vision and key objectives of the Pathology Laboratory • Good customer service
Teamwork and competence • A strong collaborative approach with clinicians • Provision of continuing education and support for staff professional development of all cadres • Provision of effective training and competency assessment for staff	**Integrity** • Management that avoids conflicts of interest and maintains transparency in all contracts and dealings • Management that follows proper staff recruitment processes • Staff who comply with the Laboratory Code of Ethics

Printed date:	
Authorised by:	
Date:	Signed:

The printed authorised copy is placed on the laboratory staff noticeboard.

3. QSE: Organization

3.1 Organization policy

The pathologist, coordinator of pathology services or laboratory manager has the authority, competence and responsibility for the services provided.

Laboratory management shall ensure the following:

- there are no activities that could compromise laboratory performance
- there are appropriate procedures to ensure ethical respect of patient samples and confidentiality of patient information
- duties and responsibilities of laboratory personnel are defined
- specific authorisations are documented in an authorisation chart (matrix) that is updated annually, authorised and displayed on the main laboratory noticeboard[1].
- appropriate communication is established within the laboratory
- staff are empowered to implement the quality management system
- quality and biosafety officers are designated

3.2 Conflict of interest and code of ethics

Medical laboratories do not engage in any activity that might influence its technical judgment. The laboratories are not committed to any commercial, financial or other pressure provided by any particular organization that could influence its technical judgment or affect its competencies and trust.

Every new staff member and every student on laboratory attachment are to read and endorse the laboratory code of ethics statement which is retained.

3.3 Organizational chart (structure)

Each laboratory specifies its organizational (management) structure that takes into consideration all key sections of the laboratory. This is reviewed annually. The new version is locally authorized and then provided to the Chief Pathologist to be made available on the PNG Laboratory website location (https://path-png.org/laboratory-guides/).

It is printed for display on the main laboratory noticeboard. Refer to the WHO template below as an example[2].

3.4 Internal communication

The laboratory management ensures appropriate communication takes place to keep staff members informed.

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[1] Authorisation matrix: refer to https://extranet.who.int/lqsi/content/make-authorization-matrix

[2] Making organisational charts – WHO Laboratory Quality Stepwise tool
https://extranet.who.int/lqsi/content/make-organizational-charts

Each laboratory defines its own internal communication strategy and section and management meetings schedule. This is placed into a location-specific SOP for communication.

All staff and management meetings require an agenda and minutes that contain '**SMART**' action points in the minutes.

Meeting actions:

Meetings are only valuable if they lead to efficient action to deal with issues arising.

When an agenda has an agreed action that is necessary to resolve an issue, then this action is translated into '**SMART**' action points in the minutes.

Example - A Clinician complaint regarding missing test results -

S—Specific Describe exactly the action that needs to be done eg Contact Clinician for complaint details

M—Measurable Formulate the action in a way that it can be checked (measured) whether it has been carried out eg record number of occasions Dr notifies laboratory of missing results over a defined time.

A—Agreed Mention the person(s) who will carry out the action eg name of staff member to contact the clinician, record the details, investigate the complaint, determine possible causes and liaise with the Lab Manager to discuss the investigation results.

R—Realistic Formulate a realistic action. An action which is not realistic will never be carried out eg achieve reduction of complaints from clinician within 4 weeks.

T—Time-bound Deadline of the action eg Contact Clinician by Friday this week with a view to Resolution within 4 weeks.

An example of an action plan to record in the meeting minutes for an item could be:

01.01.2020- Lab Technician, Joe Kangapu to contact Dr at PNG Clinic to obtain details, investigate complaint, notify Lab Manager of findings and suggest possible solutions before the next meeting date in 4 weeks.

3.5 Personnel responsibilities

The following roles are defined generically for all medical laboratories in this sequence of accountability:

1. Pathologist (Provincial Specialist Hospital Lab) or Laboratory Director (CPHL),
2. Laboratory Manager
3. Scientific Officer in charge of section
4. Scientist/technologist /technician
5. Medical laboratory assistants

All laboratories maintain current job descriptions for these cadres. These are subject to review at the annual staff performance appraisal meetings.

PMGH Pathologists report to the PMGH Laboratory Coordinator.

Pathologists employed by NDOH and attached at PMGH or PHA labs report both to the Chief Pathologist and the PMGH or PHA management.

The CPHL Manager is responsible to Deputy Secretary Public Health, NDOH.

The PMGH and PHA Lab managements report to the respective Senior Executive Management who are answerable to the respective PMGH and PHA Boards.

Note that generic job (position) descriptions are to be developed later in 2022 for use across all PNG diagnostic laboratories. These will be issued separately to this document.

Overview of tasks by role

Laboratory Manager

- ensure that the necessary human and material resources, as well as the necessary information, are available to enable effective operation and control of the processes of the quality management system
- ensure adequate training of staff
- manage staff contracts
- delegate tasks to qualified personnel
- ensure internal and external communication
- ensures laboratory facilities are maintained

Scientific Officer in Charge of section

- plan and co-ordinate the daily/weekly work schedule
- ensure stock management/material management
- ensure activities/processes included in the scope of the quality management system are identified and performed in compliance with this manual;
- apply the necessary techniques and criteria in order to verify that established processes/activities and their implemented controls are effective
- evaluate and identify new products and techniques
- ensures adequate training and supervision of trainees

Scientist/technologist

- manage, protect, and preserve uninterrupted availability of stock/consumables
- report, to the senior scientific officer in charge, any significant problems of which he/she becomes aware in daily practice
- perform the diagnostic procedures/tests in accordance with the standard operating procedures
- control and maintain equipment
- report to Scientific Officer in Charge any significant problems of which he/she becomes aware in daily practice
- check performance of internal QC to validate the tests
- ensures adequate training of trainees

Medical laboratory assistants (where applicable - district hospitals, level 4 and below)

- manage, protect, and preserve uninterrupted availability of stock/consumables
- report, to the senior scientific officer in charge, any significant problems of which he/she becomes aware in daily practice
- perform the diagnostic procedures/tests in accordance with the standard operating procedures
- control and maintain equipment

- check performance of internal QC to validate the tests

Several additional roles are defined as below – sectional/laboratory quality officer, biosafety officer, inventory officer and equipment officer. Existing staff are appointed to take on these additional responsibilities as required by the size of the laboratory.

It is recommended that larger laboratories specifically appoint a laboratory quality manager and a laboratory inventory officer.

3.6 Supporting documents

To access the currently approved versions of the numbered documents, navigate to this page.

Procedures	Document number
Management structure, meetings & internal communication SOP	Specific by lab site
Role descriptions	
Biosafety Officer - Role description	G_10_LQM_Ap_26
Quality Officer- Role description	G_10_LQM_Ap_27
Equipment Officer- Role description	G_10_LQM_Ap_33
Stock/Inventory Officer- Role description	G_10_LQM_Ap_33
Forms	
Code of ethics statement	G_10_WS_11
Orientation checklist for laboratory staff	G_10_LQM_Ap_14

4. QSE: Personnel

Graphic taken from WHO LQM eLearning module on Personnel management.

4.1 Policy

The laboratory recognizes that its most important resource is its staff (personnel).

The laboratory management shall define staff educational requirements and competency qualifications necessary for conducting laboratory procedures.

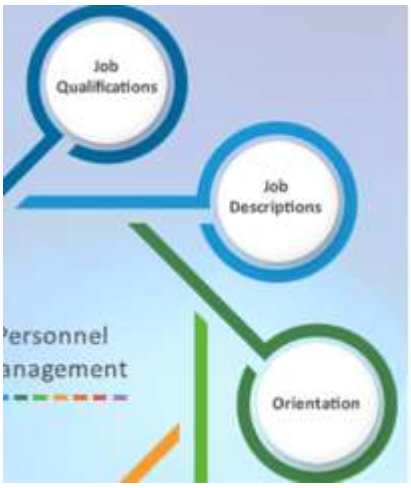
The laboratory shall ensure that all laboratory personnel including but not limited to students, temporary and permanent staff respect the confidentiality of personal laboratory data by reading and endorsing the Laboratory Code of Ethics statement G_10_WS_11.

The laboratory shall ensure that all staff respect the laboratory rules concerning health, safety and security. Regular discussion of rules and reminders are required at Staff Meetings (responsibility Biosafety Officer and Laboratory Manager). A prominent safety noticeboard is required to display relevant safety information and updates.

Staff shall be offered the opportunity to get vaccinated against COVID-19, influenza and hepatitis B. Staff shall also be kept up-to-date with tetanus vaccination.

Figure: Essential personnel management components (WHO LQMS Training Module: Personnel)[3]

4.2 Recruitment and orientation



Recruitment:

- laboratory management strives to ensure recruitment is unbiased and closely follows the requirements of the hospital/provincial health authority (employer) as relevant
- laboratory works with the Human Resources Department to ensure education qualifications and references of job applicants are checked and to ensure legal contracts/agreements are signed by all parties prior to employment or within a set period
- job description for each position includes the specific authorised responsibilities for the person and is made available to the staff member and filed in the personnel file

Orientation is completed within first week of employment/student term. Orientation and Safety Checklist is completed and filed in personnel file (responsibility of Lab Section Manager).

Safety orientation occurs before an employee or student is assigned duties as per orientation checklist above.

New staff are trained comprehensively on all policies and procedures in the department that apply to their job description and assignments (responsibility Lab Section Manager). Two checklists are completed – Orientation & Biosafety and Code of Ethics.

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[3] **Reference**: WHO LQMS training modules – module 2, Personnel: includes personnel management, competency and training – 30 minutes duration. [Register as external partner for free access to the 5 existing training modules] https://extranet.who.int/hslp/training/course/view.php?id=122

Role descriptions for Quality, Equipment, Stock/Inventory control and Biosafety Officers include additional authorised responsibilities.

Competency of each new staff member is assessed before permitting them to perform unsupervised testing or reporting. This initial competency assessment may reveal the need for specific training of the employee.

4.3 Staff member personnel files

A separate folder (e.g. ring folder) is maintained for each staff member (temporary, permanent or trainee) for laboratory reference (photo example right).

The staff folders are held in a controlled access area of the laboratory the lab manager's office to ensure confidentiality of personnel information.

The orientation checklist, training records, competency assessments, continuing education training record including certificates, job descriptions and annual performance development review (PDR) records are stored in the folder. Records of staff qualifications can also be included (diplomas, training certificates).

4.4 Training and competency assessment

The laboratory provides training for all personnel, which includes the quality management system, assigned work processes and procedures, the laboratory information system, health and safety, ethics and confidentiality.

Competency assessments that cover technical and practical skills and general knowledge necessary for performing specific job tasks schedules or programs for each staff member are to be established by the laboratory.

Training and competency records: the laboratory maintains a confidential individual record for each staff member in their personnel file that documents course attendance and other training and also contains competency assessment records (responsibility Lab. Section Manager).

Qualitative assessments of competency
As an interim until objective assessments are done, competency levels of staff against their work tasks can be assessed qualitatively and documented by the section/lab. manager annually, assigning these levels of competence: C0- minimal experience, C1- requires supervision, C9 – qualitatively assessed as competent.

Objective competency assessments
These measure staff competency against an SOP by a range of reading, observation, demonstration and problem-solving tasks. They aim to identify problems with staff

performance and to correct these issues before they affect patient care. Two additional categories are added: C2 – assessed as competent, C3- sufficiently competent to train other staff.

4.5 Continuing education and professional development

A continuing education program is organised for the professional development of staff by the lab manager, assisted where possible by external educators. **A program is displayed and updated at least monthly**.

Staff are encouraged to participate in continuing education and regular professional development.

Records are kept for all training events, listing the presenter, date, topic and the attendees (see Continuing Education event attendance record).

4.6 Personnel performance appraisal

Each staff is given the opportunity for an annual appraisal conducted by the laboratory manager.

Issues to discuss can include:
- actions arising out of the previous year's appraisal
- review of the job description, education and support
- work achievements, what's working well, individuals to be recognised
- work challenges and concerns,
- service, operation and individual professional improvement areas
- work goals and priorities & potential challenges
- following discussion : agreed employee actions ; agreed manager actions

The completed signed appraisal is retained in the staff member's personnel file.

4.7 Non-permanent personnel

Students, post graduate trainees and those on attachment must follow the general laboratory and safety orientation procedures for induction into the laboratory (see checklist below) and complete the ethics statement.

A baseline assessment post orientation is offered to establish their understanding of basic laboratory safety.

4.8 Supporting documents

To access the currently approved versions of the numbered documents, navigate to this page.

Information sheets	ID Code
Human Resources (personnel) requirements	G_10_Info_9
Procedures	
Personnel training and competency assessment SOP	Undefined
Recruitment – refer to local (PHA/Hospital) procedures	Local documents
Forms/Logs	
Staff Continuing Education attendance record	G_10_WS_2
Public Service Staff Appraisal form (PNG)	 Public Service Staff Appraisal document
Competency assessment checklists	
Disc AST Testing and QC Competency objective assessment example	G_90_COMP_1
References	
Cumitech 39 Competency Assessment	 Cumitech 39 Competency assessn
AIMS Competency Standards for Laboratory Scientists	 AIMS Competency-based S

5. QSE: Facilities and Safety

5.1 Policy

The laboratory management shall ensure that the laboratory facilities are adequate for performing tests under its scope and are able to meet national safety regulations.

The management shall ensure there is capacity to appropriately address and manage the risks associated with the biological agents being handled.

Laboratory personnel shall be trained on the basics of safety and risk management issues. New staff shall complete a biosafety training checklist that is part of the staff orientation checklist.

Annual fire safety training is recommended.

A monthly risk assessment (audit) shall be conducted by the biosafety officer to identify housekeeping, safety, waste and cleaning issues that require action. A quarterly biosafety administrative audit in conjunction with the Laboratory manager is also required.

Safety incidents/accidents shall be documented and actioned promptly by management. Incident records are retained for at least 7 years (refer to G_10_LQM_Ap_23).

A description of safety rules is available on the Laboratory Biosafety Information Sheet which is displayed on the biosafety noticeboard G_10_Info_3.

5.2 Facilities

Laboratory management ensures that a safe working environment for testing is available and sufficient personal protective equipment (PPE) is provided for the testing processes.

Safety shower and eye-wash stations are accessible within the laboratory and are tested monthly during the audit.

The laboratory shall have dedicated a biosafety noticeboard in a prominent location.

Fire extinguishers must be maintained and in-date.

A separate clean staff area is maintained for tea-room, bathroom facilities and the on-call room.

Sufficient clean laboratory gowns are provided and the hospital undertakes to clean gowns at least weekly.

Refer to G_10_Info_2 Physical Containment 2 (PC2) Standard Lab Requirements which specifies the required physical layout and structure of diagnostic laboratories. Note that microbiology sections (bacterial microscopy & culture, AFB detection, PCR including COVID19) should be placed in a separated laboratory room(s) that have a separate air handling unit that exhausts and filters air to the outside without recirculation to other non-microbiology sections of the laboratory.

5.3 Security

The laboratory reception is clearly marked with the appropriate signage. Access to all facilities other than reception is restricted to authorized personnel. Access is preferably regulated by a numerical entry coded lock – the PIN number is made known to all laboratory personnel and changed annually or with a closely controlled RFID tag lock system.

Access to the laboratory outside the opening hours is limited to laboratory management, technical staff and to on-call duty personnel.

5.4 Working environment

All manipulation presenting a risk of contamination (for the operator, environment and/or sample) is isolated from other activities.

Working areas are kept clean, dust free and are well maintained. Refer to Laboratory cleaning and disinfection SOP, G_10_SOP_16.

5.5 Staff biosafety educational resources

Laboratory biosafety officers complete these trainings where relevant (in accord with what level of lab and equipment).

Other staff are also encouraged to complete relevant modules.

Evidence of completion of specific courses is provided to the laboratory manager for addition to the personnel file.

CDC Lab Safety Courses Create an account for yourself first by following these instructions： https://idmic.net/2019/08/24/cdc-lab-training-videoclasses-easy-instructions-on-accessing/	1. Fundamentals of Chemical Fume Hood Safety 2. Fundamentals of Centrifuge Safety 3. Fundamentals of Working Safely in a Biological Safety Cabinet 4. Introduction to Laboratory Risk Management (LRM)
WHO Good Microbiological Practices and Procedures (Safeguarding biosafety and biosecurity in laboratories) 2.5 hrs. of training total; no logon required https://www.who.int/activities/safeguarding-biosafety-and-biosecurity-in-laboratories	1. Autoclaves 2. Transport 3. Sharps 4. Pipettes 5. Workflow 6. PPE 7. Surface decontamination
First aid (online course) – recommended for sectional biosafety officer role	First Aid Online with TCP (4-6 hour course) $40 AUD for each, todd@tcptraining.com https://www.tcptraining.com/online-courses/first-aid-online-courses

5.6 Waste disposal

Waste (chemical, biological and other) is segregated and disposed according to national regulations on waste disposal. Refer to the Waste decontamination and management SOP G_10_SOP_22.

People in charge of the waste disposal in the laboratory and hospital require training to handle biohazardous waste.

Chemical wastes require disposal via one of the two accredited waste management organisations in PNG.

5.7 Supporting documents

To access the currently approved versions of the numbered documents, navigate to this page.

Procedures (SOP)	Document number
Safety manual (WHO Biosafety Manual 4th Edition 2020) (all specific safety procedures including biosafety)	G_10_EX_001
Use and Maintenance of Biological Safety Cabinets	G_90_SOP_8
Waste decontamination and management	G_10_SOP_22
Laboratory cleaning and disinfection	G_10_SOP_16
Forms/Logs	
Quarterly Administrative Safety Audit	G_10_LQM_Ap_29
Monthly Laboratory Safety Audit	G_10_LQM_Ap_34
Safety incident report form	G_10_LQM_Ap_30
Visitors log	G_10_LQM_Ap_31
Job Aids and Information sheets	
How to use a Zeomed Biohazard Spill Kit	G_90_J_2
First aid kit	G_90_J_3
Safe handling of chemicals - obtain from https://www.safetypostershop.com/category/chemical-safety-posters/	Display this notice on the biosafety noticeboard
Safety rules : Laboratory Biosafety Information sheet	G_10_Info_3
Personal protective equipment	G_10_Info_8
Physical Containment 2 (PC2) Standard Lab Requirements	G_10_Info_2

6. QSE: Equipment

6.1 Introduction

An effective equipment management program:

Additional benefits include reduced interruption to services, increased safety and increased customer satisfaction[4].

6.2 Policy

The laboratory shall have processes for the selection, procurement, installation, acceptance criteria and testing, handling, transport, storage, use, maintenance, and decommissioning of equipment, in order to ensure proper functioning and to prevent contamination or deterioration[5].

Consultation with the Facilities Standards Branch of the NDOH must occur before the procurement of large items of equipment.

All new major equipment items are be included into the medical and dental catalogue to enable procurement of reagents and other items from NDOH.

Submit any new laboratory commodities required to the Procurement Standards Branch to be assigned temporary coding that allows for ease of procurement from NDOH.

In Level 5 and 6 laboratories, a laboratory/section equipment officer (EO) is appointed and familiarized with the role (see Role description). The EO reports to Lab/Section Manager who holds the EO accountable for ensuring that records on installation, qualification (validation[6]) and maintenance are kept up-to-date.

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[4] The graphic and text is drawn from the WHO LQMS training modules – module 4, Equipment management – 45 minutes duration. [Register as external partner for free access to the 5 existing training modules] https://extranet.who.int/hslp/training/course/view.php?id=122

[5] Laboratory equipment includes hardware and software of instruments, measuring systems, and laboratory information systems, or any equipment that influences the results of laboratory activities, including specimen transportation systems.

[6] Equipment validation: In performing a specific examination, or in using a specific piece of equipment, you assume that the data provided by the examination/equipment is valid, true, reliable and reproducible, and provide you with relevant information you expect. However, in quality management, the laboratory has to determine that what it assumes is indeed true. This is done through validation of the examinations and equipment. https://extranet.who.int/lqsi/node/184

Laboratory management defines and documents which staff are authorised to operate restricted equipment/instruments in a local authorisation chart (matrix)[7]. Such staff undergo training and competency assessment.

6.3 Equipment installation and acceptance

The laboratory ensures space, ventilation, humidity and electricity meets the vendor's specifications.

Prior to installation, confirm who can perform the installation and ask the following questions:

- Have safety checks been performed ?
- Is there an adequate power supply ?
- Is there sufficient space for the equipment ?
- Is there safe and adequate ventilation ?
- Does it require a water supply that is readily available ?
- Is the ambient temperature appropriate ?

Upon receipt of equipment, verify that the package contents include all items required before signing off on receipt. Do not attempt to use prior to proper installation.

The best way to ensure well-functioning equipment is to have it installed and, if required, validated by a service agent authorised by the sales company. In that case, the agent should provide a formal validation report for archiving.

The installation can include initial training of selected staff (including the equipment officer) in use, maintenance and troubleshooting.

6.4 Calibration, verification and validation of new equipment

Regular calibration is required to ensure stability of measurements. After determining the frequency of calibration, use commercially available calibrators or standards if available and follow the manufacturer's instructions. If not, prepare an SOP for the preparation of in-house standards.

The laboratory verifies that the equipment meets published performance specifications. For example: a pH meter is verified with standard certified buffer solutions.

Performance validation prior to use is required – for example: test known samples and compare results with existing assays or other methods; check the accuracy and precision of pipettes; check the stability of temperature controlled equipment.

Document all above in the equipment master file.

The quality officer and laboratory/section manager reviews these qualification results for completeness and verifies that adequate procedures for calibration and preventive maintenance are in place prior to releasing the equipment as approved for use.

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[7] Authorisation matrix: refer to https://extranet.who.int/lqsi/content/make-authorization-matrix

A competency assessment checklist is defined.

Once the new equipment is approved for use, authorised staff receive appropriate training in the operation, safety and maintenance of the equipment, referencing the equipment SOP and related documents. Competency is documented against the checklist.

6.5 Equipment inventory, records and master file

The Equipment Officer for the laboratory or section are responsible for working with the hospital facility management to ensure that their equipment assets register is updated at least annually. A copy of this register should then be retained in the laboratory/section.

The laboratory maintains a current register of equipment spare parts with their equipment numbers that are in stock.

Equipment is identified using this format: [lab initials]-[lab section code] (see QSE Documents and Records Section) -[sequential number] e.g. **GO-90-001** – Goroka microbiology equipment item 1.

Date of last service/calibration and Date of next service/calibration should also be specified on separate label where relevant.

This identity number is supplied back to facility management to be entered against the hospital fixed assets register.

Example lab initials in use:

C	CPHL	GO	Goroka
P	PMGH	N	Nonga
AN	ANGAU	M	Mt Hagen

All equipment records, manufacturer's instructions and the equipment SOP are to be kept in a single master folder for each instrument and located next to the equipment concerned[8]. The equipment SOP specifies operation, maintenance and safety risks of the equipment. ***It is not sufficient to rely only on the manufacturer's instructions.***

The staff responsible for particular equipment take responsibility for correct use of the equipment and the keeping of relevant records.

The following information is documented in the individual equipment master file:

- assigned internal identity number as above
- name of the equipment
- brand (manufacturer)
- manufacturer and vendor contact information
- laboratory inventory number (above)

[8] The equipment master file includes all types of relevant records and maintenance throughout the in-service period of the equipment. The performance records referred to in j) includes copies of reports/certificates of all calibrations and/or verifications including dates, times and results, adjustments.

- serial number
- model and year
- location in laboratory
- dates of purchase, received and entered into service
- warranty (note expiry date)
- calibration, verification and validation records
- instructions for use
- type of maintenance (contract with an external company, in house, etc.)
- record of preventive maintenance activities
- record of service and repairs - parts of the equipment that have been changed or repaired
- spare parts – details, price and ordering information

6.6 Preventive equipment maintenance and repair

All testing equipment have a documented program of preventive maintenance developed by EO, which, at a minimum, follows the manufacturer's instructions. This is documented in the specific equipment instructions SOP.

Equipment are maintained in a safe working condition and in working order. This includes examination of electrical safety; emergency stop devices where they exist and the safe handling and disposal of chemical and biological materials by authorized persons. At a minimum, manufacturer's schedules or instructions, or both, are followed.

Whenever equipment is found to be defective, it shall be taken out of service and clearly labelled 'OUT OF ORDER'. The out of service is recorded in the equipment inventory register and the quality officer or laboratory manager approves the notice.

The EO examines the effect of any equipment malfunction on previous diagnostic examinations and notifies the laboratory manager to discuss whether corrective action is required.

Before service or repair of any equipment, the equipment is decontaminated as per the manufacturers' instructions. For service or repair, the engineer for the equipment is informed either by email or phone call by the laboratory manager or quality officer and the service or repair is followed and supervised by the EO or by the assigned personnel until completed.

When equipment is removed from the direct control of the laboratory and repaired, its performance is confirmed and verified and results of controls and calibration filed before it is returned for use.

6.7 Decommissioning

The laboratory equipment is deemed obsolete and labelled "Out of Service" if it is faulty, unrepairable or the testing method is obsolete. The equipment is decontaminated following manufacturers' guidelines.

Disposal is to be approved by the Laboratory Manager Relevant disposal form to be completed (see example in 6.8).

Laboratory staff are responsible for decontaminating the decommissioned equipment before removal (see example checklist in 6.8).

All related document and records are retained for 4 years.

6.8 Supporting documents

To access the currently approved versions of the numbered documents, navigate to this page.

Procedures	Document number
Equipment SOPs (calibration, operation and maintenance); for Equipment SOP standardised template refer here.	Specific SOPs to be developed as required
Forms/Logs	
Equipment item front page registration, service and fault logs	G_10_WS_6
Temperature monitoring log sheet (all types of equipment)	G_10_WS_3
Equipment (asset) transfer and disposal form –local PHA process is followed.	Location specific
Checklist for decontamination – example for adaptation	 LABORATORY DECOMMISSIONING

7. QSE: Purchasing and Inventory

7.1 Overview from the WHO LQM stock management module[9]

Having an effective inventory (stock) management program means that supplies and reagents are always available, wastage is reduced and quality is maintained. Stock-outs interrupt testing and put at risk the health of patients and the population. They also affect the reputation of the laboratory.

Inventory management helps the laboratory to perform testing in a cost-effective way and with a minimum of waste. It prevents the laboratory from having to discard expired materials or procuring materials with the wrong specification. It helps to maintain quality services in the laboratory.

7.2 Policy

The laboratory shall have processes for the selection, procurement, reception, storage, acceptance testing and inventory management of reagents and consumables[10].

Level 6 and 7 laboratories shall appoint a stock management officer.

7.3 Procurement, reception and acceptance testing

7.3.1 Procurement of reagents, consumables and materials

The laboratory section head determines reagent/supply needs for the section by reviewing / conducting the periodic stock count and compiles the order for submission by the inventory officer (if there is such). The orders for purchase of supplies (reagents, consumables and materials) are requested using a specific form and submitted approval by the authorising procurement officer at NDoH or PHA.

7.3.2 Receipt and storage

The laboratory evaluates received supplies for quality and quantities and confirms receipt of the supplies with the assistance of the Financial & Accounts department.

The laboratory stock officer/Head of Section inspects the materials for acceptability, signs the delivery note and files the original copy in the "Laboratory stores received" folder.

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[9] **Reference**: WHO LQMS training modules – module 3, Stock management – 30 minutes duration – highly recommended for completion by all lab. managers and stock officers [Register as external partner for free access to 5 existing training modules]
https://extranet.who.int/hslp/training/course/view.php?id=122

[10] Reagents include substances which are commercially supplied or prepared in-house, reference materials, (calibrators and quality control materials); consumables include culture media, pipette tips, glass slides, POCT supplies, etc.

The lot numbers and date of receipt are recorded on the medical supplies stock card as part of the inventory management system (see below).

Laboratories that are supplying materials to lower tier laboratories, inspect and acceptance test (7.3.3) new materials prior to distribution.

7.3.3 Acceptance testing

Each reagent or new formulation of examination kits, or a new lot / shipment, is verified for performance before placing into use, or before release of results, as appropriate. Consumables that can affect the quality of examinations are verified for performance before placing into use[11].

Kits and new reagents lots have a date of first use recorded on the label. Where IQC is required prior to first use, then reagents awaiting QC are stored separately to prevent use.

Once IQC is passed, a small initialled green dot is placed on the reagent or kit box to indicate that the assay can be used. The assay is then placed on a shelf labelled 'Assays for use'.

7.4 Inventory management

The laboratory maintains a list of current providers of reagents, consumables, and equipment.

Stock officer records notes of the provider performance after receipt of materials in a logbook for future reference: e.g.
- Was everything in good order?
- Were the life spans and specifications as promised?
- Were the materials delivered without undue delay?
- Was the after sales service satisfactory?

The laboratory ensures that consumables are stored under correct environmental conditions as per the manufacturers' instructions and are used prior to their expiration dates.

Environmental conditions for the storage of all kits, reagents and consumables are monitored and documented.

As a minimum, the laboratory maintains manual stock cards for all unique laboratory supply items, including reagents and consumables.

The stock card records:
- identity of the reagent or consumable
- manufacturer's name and contact information for the supplier
- date of receiving and date of entering into service
- lot number
- expiry date
- condition when received (e.g. acceptable or damaged)

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[11] Comparative internal QC performance of new reagent lots and that of previous lots can be used as evidence for acceptance. Patient samples are preferred when comparing different reagent lots to avoid issues with commutability of IQC materials.

- manufacturers' instructions
- records that confirmed the reagents or consumables initial acceptance for use
- performance records that confirm the reagents or consumables ongoing acceptance for use.

The inventory officer has these responsibilities (see full role description):

- Doing a weekly, fortnightly or monthly stocktake to update the stock register
- Notifying the lab. manager when orders for new supplies and reagents are necessary
- Ensuring First-Expiry-First-Out (FEFO) is practiced
- Placing orders for new supplies and reagents when necessary and forwarding it to the Laboratory Manager
- Supervise checking and unpacking and documentation of newly arrived reagents and supplies
- Informing relevant staff members that goods have arrived

7.5 Supporting documents

Forms/Logs	
Medical Supplies Stock Card – PNG example	 Medical Supplies Stock card.pdf
Stock/Inventory Officer- Role description – *available on this page*	G_10_LQM_Ap_33

8. QSE: Process Management

8.1 Policy

The laboratory shall have documented processes for each phase of the sample processing: pre-examination, examination, and post-examination phases, to ensure accurate and reliable testing.

The laboratory shall have quality control measures to monitor the examination phase of testing.

All patient laboratory results shall be appropriately checked and authorised prior to issue.

8.2 Sample management

8.2.1 Specimen collection and transport

A national patient sample collection manual is in development. It provides written instructions for specimen collection, handling and transportation. Once issued, the document is to be made available in all sample collection sites and responsible staff will require relevant training.

Specimen or EQA sample transport by air or road between laboratories follows IATA transport regulations. Staff who prepare samples for transport require current IATA dangerous goods certification (DG registration number).

8.2.2 Specimen/sample receiving

The laboratory has established a written specimen/sample acceptance and rejection criteria for each test offered and provides this information to its customers, as applicable. All specimens/samples are inspected according to these acceptance/rejection criteria.

The laboratory rejects specimens/samples that are not suitable for processing as per the relevant laboratory section SOPs. The requestor is notified of the reason for rejection. If the specimen/sample is critical and cannot be rejected, the examination is performed, and a notation is made on the report.

In the case of critical specimens/samples, such as one of limited volume, the laboratory management consults with the requestor to agree which tests have highest priority.

Under ISO15189, each specimen/sample to be analysed is assigned a unique registration (laboratory) number that is recorded against all analyses, stored samples and the issued report. The current practice of sample/section specific laboratory numbers that reset to zero every year will eventually change to a LIMS computer-allocated unique number in this format:
PB22A001 (PMGH (P) Blood culture (B) A001 sample number)

8.2.3. Specimen/sample handling, preparation, and storage

If the specimen needs to be shared for different tests throughout the laboratory and/or additional referral, and storage purposes, each aliquot (sample) is labelled individually with the unique registration (lab) number, name and date.

Patient samples are stored at 2-6˚C for 7 days in buckets that are labelled by day of week.

8.3 Method validation (aspirational requirement)

The methods used in the laboratory, that have been published in scientific reviews, transmitted by national or international reference centres, or in accordance with testing kit procedures have been verified and documented under the laboratory's conditions and adapted when needed.

The laboratory will perform validation of examination procedures following the developed method verification and validation SOP in case non-standard methods are used, the laboratory has developed a new testing method, standardized methods outside the laboratory intended scope is used or validated methods are subsequently modified.

8.4 Quality Control

Internal quality control provides assurance that the results of testing are valid and consistent over a period of time.

Equipment calibration and servicing are monitored (responsibility Equipment Officer role). Laboratory technical staff are trained to review and take appropriate action regarding internal quality control data in accordance with the relevant Section QC SOP. All test procedures include a positive and negative control as per manufacturer's instructions.

The QC results are documented on relevant QC worksheets to create a permanent traceable record (all technical staff). At least monthly management review of QC data is required.

If internal QC results are not satisfactory (i.e. nonconforming), patients' diagnostic results may need to be withheld, dependent on how serious the issue is, and urgent management review required.

When such problems occur, a non-conformance report is required. The laboratory investigates, corrects, and repeats sample testing as indicated (refer to LQM Section on Nonconforming Event Management).

8.5 Result validation and reporting

The laboratory has procedures for review and evaluation of results before release.

Examination results are confirmed by the person who did the test and reviewed/verified by an authorized staff member and agreed upon before validation. If discrepancies occur the authorized staff member takes corrective action prior to issue.

Corrections following report issue are issued as an amended status report. The report indicates the prior incorrect result and how that was amended with date and authorisation details.

The authorized staff member contacts the clinician, ward, or public health service for further clinical details, if needed, or to communicate critical results.

Issued patient reports are signed by the authorized staff member and when possible, indicate the name and position of the staff member.

Critical results that require immediate reporting are defined and authorised by the individual laboratory. The list is shared with clinicians and displayed on the main noticeboard. The list is updated annually and publicised in the staff meeting.

8.6 Referral laboratories / subcontracting

Subcontracting of samples may occur under the following circumstances:

- test not performed routinely by the laboratory
- instrument breakdown or reagents not available
- workload restrictions
- client-requested turnaround time cannot be met.

The laboratory is responsible for tests performed by another laboratory on patient samples that are referred and ensure that, where possible, all referred work is done by a service that is accredited for the type of work or appears to be qualified.

8.7 Records, sample retention and disposal

The laboratory retains and disposes of records, documents, and specimens in compliance with G_10_LQM_Ap_23_A.

8.8 Supporting documents

To access the currently approved versions of the numbered documents, navigate to this page.

Procedures	ID Code
Required retention durations for records, documents, and specimens	G_10_LQM_Ap_23
Maintenance of cultures used for quality control testing	G_90_SOP_2
Disc diffusion AST quality control	G_90_SOP_3
Bacteriological media quality control	G_90_SOP_4
Forms/Logs	
Standard microbiology request form	G_10_LQM_Ap_8
Information sheet	
Specimen Collection Transport and Rejection (Microbiology)	G_90_Info_5

9. QSE: Assessments

9.1 Policy

The laboratory shall perform ongoing quality assessments such as:

- periodic review of examination requests, specimen registration errors, suitable methods, and sampling requirements
- monitoring and evaluation of customer feedback, staff suggestions and impact of potential failures on examination results and customer expectations (refer LQM section on Nonconforming Event Management)
- monitoring of agreed quality indicators[12], corrective actions undertaken, and follow-up
- participation in proficiency testing program (EQA) and management review of the corresponding reports
- participation in internal, (refer 9.2.1), and external audits (refer 9.3.3) of laboratory procedures.

The laboratory shall strive to continuously improve the quality of laboratory performance, the effectiveness of the quality management system and the reliability of test data.

The laboratory shall do its best to identify and resolve any nonconformity that may affect laboratory performance and patient outcome.

9.2 Internal assessments

Note: until a laboratory has implemented standard operating procedures for particular processes, it is not useful to conduct internal auditing of the same processes. The initial LQM focus is to develop the SOPs, training of staff and assessment/documentation of staff competency.

9.2.1 Internal Audits (aspirational requirements)

Section OICs will perform the internal audits for sections other than their own.

Each laboratory is to document its internal audit schedule in November for the following year and publicise this to staff and auditors. In general, a monthly audit examining the function of one section is recommended.

During internal audits, information is gathered about:

- processes and operating procedures
- staff competence and training
- equipment
- environment
- handling of samples
- quality control and validation of results
- recording and reporting practices.

The findings are compared with the laboratory's internal policies and to the chosen national or international standard. Any breakdown in the system or departure from procedures are

[12] There are no currently defined national laboratory quality indicators. A process to develop initial indicators is to commence in late 2022. Laboratories are encouraged to develop and monitor their own indicators as well.

identified. Any gap or nonconformity in performance identified, shows if the policies and procedures that the laboratory are not being followed.

All internal audit reports will be documented and presented at the Section Laboratory Meeting by presentation from the Auditor. The audit report includes an action plan and it is the responsibility of the OIC of the section audited to follow up on changes required.

The Quality officer and (or) Laboratory Manager is responsible for training of auditors.

9.2.2 Review and follow up of corrective actions

All corrective actions undertaken in the laboratory will be reviewed and their follow up evaluated (Refer to LQM Section, QSE: Nonconforming Event Management).

9.2.3 Staff suggestions

All members of staff are encouraged to offer suggestions for improvement of any aspect of the laboratory. These suggestions are recorded, evaluated, and implemented if useful. Feedback on the suggestions implemented is provided to the staff during scheduled laboratory meetings.

9.2.4 Review of requests, methods, and sampling requirements

Test requests are periodically reviewed to evaluate the appropriateness of the methods used for the test required. Errors with patient identification/registration also require detection.

Received sample types, sample volumes (where relevant), retention periods are reviewed at least annually to assess compliance with the National Specimen Collection reference document.

9.3 External assessments

9.3.1 External Quality Assessment/ Proficiency testing

Proficiency testing serves as a tool for quality improvement in the laboratory. One of the major benefits is identifying performance issues and correcting them.

National EQA programmes in PNG, administered by CPHL are currently limited to HIV, TB and malaria testing. A further CPHL-based EQA program for antimicrobial susceptibility testing is under development.

External EQA programs are available from the Pacific Pathology Training Centre (PPTC)[13] . Provincial and regional laboratories are encouraged to enrol in programs that are relevant to each laboratory section.

Each laboratory maintains a list of enrolled EQA programmes that is updated annually.

Microbiology sections that perform bacterial culture and antimicrobial susceptibility testing are enrolled in the PPTC microbiology EQA program.

9.3.3 External audits

Note. At the time of this edition, regular external laboratory auditing has not been implemented in PNG and pends a legislated national approach to laboratory accreditation and laboratory standards.

[13] https://pptc.org.nz/regional-external-quality-assurance-programme/

When third party international organisations conduct external audits, the scope of the audit is agreed to by local management review and any resulting audit reports require local management review and sharing with staff. Necessary corrective actions will be determined, implemented effectively, and documented

9.4 Supporting documents

To access the currently approved versions of the numbered documents, navigate to this page.

Procedures	ID code
Internal audit procedures	Undefined
Internal audit template	G_10_TEMP_11_A
Forms/Logs	
List of enrolled EQA programmes (annual update)	Local document
Internal audit schedule	Local document
External quality assurance assessment and management review	G_10_WS_10
Document control internal audit	G_10_Audit_1_A
Vertical specimen internal audit (microbiology)	G_10_Audit_2_A

10. QSE: Customer Service

10.1 Policy

The laboratory management shall be dedicated to providing quality and timely service to all customers, both internal and external.

The laboratory management shall commit to providing adequate resources to meet customers' requirements and to provide an on-going program for continual improvement.

10.2 Customers satisfaction measurement

Customer surveys are implemented. The objective is to assess the satisfaction of the main customers: patients, clinicians and public health institutes. The analysis of survey results leads to implementation of corrective actions where needed.

10.3 Complaints management

Complaints received from outside the laboratory (i.e.: doctors, pathologist, specialists, patients) are managed in order to lead to corrective or preventive actions (also refer to chapter 11 Nonconforming Event Management, and chapter 12 Continual Improvement).

The objective is to ensure continuous improvement of the quality system by taking into account the customers' concerns. The claim management will facilitate tracking and investigating potential non-satisfaction of customers.

10.4 Complaints from staff

Written complaints received from staff will be reviewed by the laboratory management to determine actions required.
These may include:

- Discussion of the complaint with the complainant to clarify or respond
- Notification of the complaint as a non-conformance report so that corrective actions if required can be documented and signed off by management
- Feedback to the complainant once the non-conformance report is closed

10.5 Supporting documents

To access the currently approved versions of the numbered documents, navigate to this page.

Forms/Logs	Document ID
Customer survey form/questionnaire	Undefined
Customer complaint logbook	Undefined
Customer complaint report and feedback	G_10_WS_1

11. QSE: Nonconforming Event Management (laboratory incidents/internal problems)

11.1 Policy (aspirational requirements)

The laboratory shall identify, document, correct, and strive to prevent non-conforming events that may arise across pre-examination, examination and post-examination processes.

All staff are empowered to make a non-conformance or safety incident report. These are submitted either to the Section/Laboratory manager or the Quality officer/manager. Blank printed report forms are made available in all laboratory sections.

The Quality Manager assigns the non-conformance or safety incident report a unique number.
- Quality non-conformances/incidents are denoted with Q#-year, for e.g: Q01-2022, for the first quality related incident for 2022.
- Safety-related incidents are denoted with S#-year, e.g.: S01-2022, for the first Safety related incident for 2022.

Laboratory requirements[14] :
- designate the individual(s) responsible for handling non-conformities, generally the responsibility of the appointed quality officer/manager
- ensures that **each non-conforming event is documented, recorded, and reviewed promptly** to consider an analysis of cause(s) performed and required corrective action(s)
- ensures that each non-conforming event is **tabled by the Section OIC or laboratory manager, at least once, at the relevant staff meeting** and staff input is invited and recorded on the non-conforming report
- ensures that **all individual open non-conforming event reports are tabled at each management meeting** to assess/document the status of actions and whether the event is ready for closure,
- define when testing procedures and data reporting will be withheld due to nonconformities and when, and under what conditions, examination can resume;
- defines the steps taken when examination data resulting from a non-conforming event has already been released.

Each laboratory / section maintains designated folders for non-conformance and safety reports. These folders are accessible and labelled for all staff to identify as per section.

11.2 Corrective Actions

All non-conforming events (from occurrence reports, claims, audit reports, patient/customer complaints, failed proficiency testing, etc.) are recorded, tracked, trends identified, and analysis to determine cause(s) performed by management. The appropriate corrective actions are taken.

[14] It is planned to develop a national nonconformance SOP that specifies procedures required by this QSE section.

The results of a non-conformance assessment are communicated to management (above) and become part of annual management review. The objective is to ensure continuous improvement of the quality system.

The Laboratory manager and or the quality officer/manager is responsible for maintaining a list of all incidents that occur within the laboratory – using the incident log.

Some examples of quality non-conformances are:

- Incorrect patient result issued
- If kits not available because not ordered in timely manner
- EQA proficiency sample failure
- SOP/worksheet/form not followed
- Internal QC not within range
- Negative control contamination
- Equipment/Machine breakdown (for example: Fridge/Freezer/cool room)
- Incorrect samples tested
- Samples lost in transit
- Samples not processed in the correct time frame
- Clinician incidents/complaints
- Patient complaints
- Staff disagreements/ allegations of bullying

Some examples of Safety Incident reports are:

- Chemical splash
- Chemical spill
- Sample containment failed (spill, dropped etc…)
- Needle stick injury
- Sharps injury
- Failure to wear appropriate PPE

11.4 Assay Validation and Non- conforming Work

OICs review all internal quality assurance measures (negative/positive controls,) and authorize the release of patient results. Similarly, to an incident report, a report details what happened, how, and how to prevent future occurrences.

11.5 Supporting documents

To access the currently approved versions of the numbered documents, navigate to this page.

Procedures	ID code
National NCR SOP to be developed	Undefined
Forms/Logs	
Non-conformance report form	G_10_WS_8
Non-conformance report logsheet	G_10_WS_9
Laboratory safety incident report form	G_10_LQM_Ap_30

12. QSE: Continual Improvement

12.1 Policy (aspirational requirements)

The laboratory shall strive to continuously improve the effectiveness of its quality management system and its processes, as stated in its quality policy and quality objectives.

A management review shall be performed annually to evaluate the laboratory's quality management system, evaluation activities, corrective actions, and preventive actions[15].

The laboratory shall develop an action plan according to improvement needs quarterly and monitors the effectiveness of the actions undertaken.

12.2 Quality indicators (aspirational goal)[16]

Standard quality indicators are used to monitor and evaluate performance of laboratory processes.

Example indicators:

- the traceability of the sample from the reception to the storage after testing
- the turnaround time from reception of the sample to the hand-out of the report
- contamination rate of blood cultures
- assessment of adequacy of blood culture fill

Agreed indicators are regularly monitored for compliance against the defined objectives and the activities established in the laboratory. These indicators are presented during the annual management review.

12.3 Management review

The Laboratory Senior staff management and OICs will meet at least annually to conduct the management review. This is to ensure that the organization and the activities of the laboratory remain appropriate and efficient. Therefore, it allows the evaluation and continuous improvement of the efficiency of the quality system of the laboratory. The elements reviewed are related to the quality system management.

Elements of entry of the management review (by section as appropriate):

- quality objectives of the past year
- quality indicators
- activity by section – number of tests
- occurrences and non-conforming events recorded
- customer complaints report
- customer satisfaction survey reports

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[15] For further information on management review, refer to https://extranet.who.int/lqsi/content/perform-management-review-end-quality-year

[16] There are no currently defined national laboratory quality indicators. A process to develop initial indicators is to commence in late 2022. Laboratories are encouraged to develop and monitor their own indicators as well.

- internal audit reports
- proficiency testing reports
- corrective/preventive actions and follow up
- changes in workload or type of work
- all pertinent factors: resources, budgeting, future activities, etc.

Elements of output of the management review:

- actions for improvement
- definition of the quality objectives for the next year
- establishment of new quality indicators in concordance with the new quality objectives
- improvement of the quality management system.

12.4 Preventive action

The laboratory reviews the data and implements preventive actions allowing the laboratory to anticipate eventual non-conforming events in its activities. A follow up of the actions implemented for improvement is ensured in the same way as described in chapter 11 Non-conforming Event Management.

12.5 Supporting documents

Procedures	ID code
Management review	Undefined
Evaluation activities (see chapter 8 Assessments)	Undefined
Forms/Logs	
Quality indicators	Undefined

13. QSE: Documents and Records[17]

13.1 Policy

The laboratory shall ensure that:

- documents are uniquely identified;
- documents are approved for adequacy before issue by authorized personnel who have the expertise and competence to determine adequacy;
- documents are periodically reviewed and updated as necessary;
- relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
- changes and the current revision status of documents are identified;
- documents are protected from unauthorized changes and any deletion or removal;
- the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose;
- obsolete controlled documents are retained for 4 years (electronic or paper form)

13.2 Document management

All approved documents are made available on the national laboratory quality management website which is maintained by the office of the Chief Pathologist.

All laboratory managers should subscribe their email address on the website (bottom left of home page) to enable automatic updates from periodic news items that are published there.

Issue of approved national documents or revisions are notified to Laboratory managers and quality officers/managers by the Chief Pathologist's office. The local quality officer/manager is responsible for tabling newly issued documents at the staff meeting, printing of documents that require it, updates of the printed document log and destruction of old printed versions.

Staff are not permitted to make temporary amendments to documentation without the prior consent of the Laboratory manager or quality officer. Handwritten temporary amendments, if made to printed documents are written in red, dated and initialled. Notify the Chief Pathologist chief.pathologistndoh@gmail.com of errors that require correction.

The laboratory quality manual and other controlled documents are reviewed every two years. This review leads to the document reissue with a new version letter (i.e. 'A' goes to 'B').

Minor amendments that are made do not prompt a version change. The amendment table is completed and the new issue date is recorded on that table and in the file name. However the document registry and header retains the original issue dates so that the version review can occur at the correct time. The second page of G_10_WS_4 (Printed SOP Acknowledgement Sheet)

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[17] For an introduction to this topic, please review Document Control and Records Management Information sheet G_10_Info_5.

Note that separate Document Control and Master SOPs are not currently defined under the national LQMS structure. This section serves as the reference document for both elements.

can be used by laboratory managers to document desired amendments, corrections or additions. These should be notified regularly to the relevant organisational Quality Manager for consideration.

Example of file name for an amended document:

G_10_WS_4_A Printed SOP Acknowledgement Sheet 7Apr22 amended 27Mar23 - Word

The responsibility for managing document development/review for national LQMS and safety documents lies with the Chief Pathologist office. For other documents relating to specific pathology disciplines (Microbiology, Haematology, Biochemistry and Anatomical Pathology), the Blood Transfusion Service and CPHL, separate Document Development and Review Groups are responsible (see table below).

Document Development & Control Overview

<table>
<tr><th>Roles</th><th colspan="3">Responsibilities</th></tr>
<tr><td>Discipline/Organisational Document Development and Review Groups (DDRG)</td><td colspan="3">• Monitors national document registry as required to learn of documents requiring review
• Manage SOP development using national templates
• Makes minor amendments and arranges periodic reviews when due
• Retain tracked changes WORD document of review changes (add a label in document name « tracked changes »)
• Complete amendment table on each document for amendments and changes arising out of periodic reviews
• Forward tracked changes WORD version to Laboratory Quality Manager</td></tr>
<tr><td>Disciplines and Organisations that require DDRGs</td><td>PMGH: AP/Cyto, Clin Chem, Haem and Micro disciplines</td><td>Blood Transfusion Service</td><td>CPHL</td></tr>
<tr><td>Organisational Lab Quality managers (PMGH, BTS and CPHL)</td><td colspan="3">• Check/completes document numbering, format and amendments table
• Updates national document registry
• Stores tracked WORD version on local drive
• Creates clean WORD version for management review and signoff</td></tr>
<tr><td rowspan="2">Management review with Lab. Coordinator/Directors Quality Managers</td><td>Dr Joseph
Coordinator, PMGH Lab</td><td>Dr Matthias
Director BTS</td><td>Mr Porau
CPHL Director</td></tr>
<tr><td colspan="3">• Makes document amendments as required to disciplines/sections +/- returns document to relevant DDRG for further work
• Regular considers amendment or correctio suggestions from laboratory sections or laboratories external to Port Moresby submitted on G_10_WS_4
• Participates in review/development of national LQMS documents as requested by the Chief Pathologist
• Stores clean WORD version of new versions/documents to the specific Google drive location associated with the document registry
• Notifies Chief Pathologist's office about document completion</td></tr>
<tr><td>Chief Pathologist

National Document Control Officer/ Quality Manager</td><td colspan="3">• Provides final authorisation for all documentation
• Manages review and development of level 1 national LQMS and Safety documents
• Records document approvals and issue dates on the national registry
• Stores new documents/versions to the specific Google drive location, usually as a PDF version
• Uploads the PDF to http://path-png.org website</td></tr>
</table>

	• Communicates to peripheral lab managers to inform them of new document issues and also creates a related news item on the website • Provides updates to National Laboratory TWG, INDOPAC-LAB and World Vision/CPHL LQMS leads

For local laboratory documents issued at other laboratories than above, the Quality Officer and/or the Laboratory or Section manager are responsible for document review and maintenance of a local document registry.

Printed controlled SOPs require certification on the front page by the lab manager or quality officer by completing the front page SOP template (enter version, date, name and sign). The document is placed in a document sleeve folder with the Printed SOP read acknowledgement sheet (G_10_WS_4) placed in front. Each printed document copy is entered onto the local Printed document log sheet (G_10_WS_5).

13.3 Control of documents and records

Controlled documents are to be uniquely identified with date of issue, document author, document number, document version, total number of pages and name of the authoriser. The period until the next review is to be specified (2 years).

The document number is made up of these components e,g "G_10_SOP_12_A" signifies:

Designation	Discipline	Document type	Sequential number	Version
G	**10**	**SOP**	**12**	**A**
G- general (national) B-reserved for Blood transfusion service documents C-reserved for CPHL documents P-PMGH specific documents	10 LQMS, Safety 20 BTS 30 AP/Cyto 40 Biochem 50 Haem 60-69 CPHL Sections 90 Microbiology	As below	Next number for that document type is allocated	

All approved document types have templates defined. The types include:

QMAN	Quality Manual	INFO	Information sheet
LQM_AP	Quality Manual appendix	J	Job Aid
Audit	Internal audit	WS	Worksheet/ Form
SOP	Standard operating procedure	TEMP	Template
T	Analytical Test	COMP	Competency assessment

A master document registry for nationally issued documents is maintained by the Chief Pathologist on a secure Google drive, assisted by the PMGH Laboratory, CPHL and Blood Transfusion Quality Managers. It records document type, description, number with version, stage of development, issue date and relevant notes (see snapshot below). Access to the

registry is available to Quality Officers and Lab. Managers by contacting the Chief Pathologist at chief.pathologistndoh@gmail.com

Screenshot of the registry:

			Stages: P roposed D raft R eview A pproved	As per date on issued PDF file name	
Type	**Document title**	**Document number_version**	**Stage**	**Effective date**	**Notes**
QMAN	**Laboratory Quality Manual (PNG)**	G_10_QMAN_1_A	A	27/8/22	
Info	Laboratory Quality Management	G_10_Info_1_A	A	12/2/21	
Info	Physical Containment 2 (PC2) Standard Lab Requirements	G_10_Info_2_A	A	12/2/21	
Info	Laboratory Biosafety	G_10_Info_3_A	A	8/10/20	

Separate registry spreadsheets are provided for General documents, Blood Transfusion Service, Anatomical Pathology/Cytopathology, Biochemistry, Haematology and Microbiology. A decision about registration of CPHL documents onto this registry has not been made to date.

Local laboratory documents that are necessary should be written on one of the relevant approved national document templates. All local documents should include the above document control elements and require local authorization. These documents are not tracked on the national document registry and can be branded with the PHA or hospital logo instead of the NDOH logo.

A regular internal audit (G_10_Audit_1) of printed controlled documents held in each laboratory is to be performed to check whether the Print document log sheet G_10_WS_5 has been kept current. A check on whether uncontrolled (unauthorised) documents or documents overdue for review are available or displayed in the laboratory.

13.4 Archiving (retaining records of superseded/old document versions)

The organisation quality managers are to retain / store the tracked changes WORD document of review changes for 4 years (refer to G_10_LQM_Ap_23).

The Chief Pathologist office retains old document versions for 4 years.

Superseded printed versions at each laboratory site are to be destroyed when replaced with a new version.

13.5 Supporting documents

To access the currently approved versions of the numbered documents, navigate to this page.

Procedures	ID Code
Required retention durations for records, documents and specimens	G_10_LQM_Ap_23
Document templates	
For access to all currently approved templates, access the Template list here.	
Forms	
Printed document log sheet	G_10_WS_5
Printed SOP Acknowledgement Sheet	G_10_WS_4
Information	
Document Control and Records Management Information sheet	G_10_Info_5

14. QSE: Information Management

14.1 Policy

The laboratory shall ensure that systems (paper-based or computerised) that record patient and test data are secure and kept confidential.

The laboratory shall ensure that appropriate access to patient test results by clinical staff and public health is facilitated by its systems.

14.2 Information systems

Hard cover registers are used for paper-based records. These records are restricted for within laboratory use only. Accessibility of information by non-laboratory staff is by request approved by hospital and laboratory management.

Computer-based information systems are managed locally under the authority of the respective Laboratory Manager or Section Head. Procedures are in place to meet data protection requirements and to restrict unauthorized access.

Computerised LIMS when implemented require documented procedures for staff and client usage and down-time periods.

14.3 Confidentiality

The personnel (temporary, permanent, student, etc.), whatever the duration of their contract, will sign a confidentiality agreement as per G_10_WS_11 Laboratory Code of Ethics statement.

The laboratory has a secure process for archiving and defines necessary retention periods for records – refer to G_10_LQM_Ap_23 Required retention durations for records, documents and specimens.

14.4 Supporting documents (undefined)

Procedures	ID Code
Informatics system maintenance and backup	
LIMS down-time procedures	
Forms/Logs	
LIMS down-time log	
Backup log	