QUALITY MANUAL

Version 01

ROYAL CENTRE FOR DISEASE CONTROL

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Department of Public Health
Ministry of Health
BHUTAN

FOREWORD

This quality manual provides a guidance to implement quality management system in the Royal Centre for Disease Control (RCDC). It sets a quality standard upon which the RCDC must base its performance and therefore, the manual provides an avenue for quality evaluation in different aspects of quality management.

The manual is based on ISO 17025:2017 (Standard for Testing and Calibration laboratories) and ISO 15189:2012 (Standard for Medical laboratories) and also CLSI GP26-A4 (Quality Management System: A Model for Laboratory Services; Approved guideline 4th edition). This manual is intended for the quality management team to enable them to facilitate process for continual improvement of quality service delivery. The document also ensures that the RCDC complies with the Bhutan Healthcare Standards for Quality Assurance (BHSQA) ICS 11.020.10, 2018.

The manual is developed to improve and standardize the quality of the activities in the RCDC. However, the other laboratories within the ministry of health can also use this manual to improve the quality of their laboratory activities.Therefore, I would like to urge the RCDC and all the relevant health workers to uphold the essence of this document and implement best practices for quality service delivery.

Dr. Sonam Wangchuk

HEAD

Royal Centre for Disease Control

AMENDMENT SHEET

Sl. No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature of Quality Manager	Signature of HEAD, RCDC

ABBREVIATIONS AND ACRONYMS

BHSQA	Bhutan Healthcare Standard for Quality Assurance
BMED	Bio-Medical Engineering Division
BMHC	Bhutan Medical and Health Council
BSL	Biosafety Level
CAPA	Corrective and preventive actions
CDC	Centers for Disease Control and Prevention
CLSI	Clinical and Laboratory Standards Institute, Wayne, Pennsylvania, USA
DOMSHI	Department of Medical Supply and Health Infrastructure
EQAS	External Quality Assessment Scheme
HRD	Human Resource Division
ISO	International Organization for Standardization
IWP	Individual Work Plan
IEQAS	International External Quality Assessment Scheme
LIS	Laboratory Information System
LQMS	Laboratory Quality Management System
MOH	Ministry of Health
MSPD	Medical Supply and Procurement Division
MSDD	Medical Supply Distribution Division
NEQAS	National External Quality Assessment Scheme
QC	Quality Control
QM	Quality Manual
QMS	Quality Management System
QSE	Quality System Essential
RCDC	Royal Centre for Disease Control
SOP(s)	Standard Operating Procedure(s)
TWGP	Technical Working Group for Procurement
WHO	World Health Organization

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1. INTRODUCTION

1.1. Overview of the organization

The RCDC conducts disease surveillance, outbreak investigations and research as part of the public health services. The RCDC provides scientific and technical back up and advice on health policy issues ensuring evidence-based decision making for disease prevention and control. The centre also provides primary public health laboratory services such as drug and water quality testing services to the health care providers and public health programmes, manages disease surveillance reporting systems. Further, the centre also participates in IEQAS and conducts NEQAS for the laboratories in the country.

The centre has adopted a quality management system for the purpose of an effective and efficient use of its resources. All employees are committed to a culture of quality and share responsibilities for identifying nonconformities or opportunities for improvement, recording these instances so that corrective or preventive actions can be taken to ensure delivery of quality public health services.

1.2. Mission statement

Provide scientific information to facilitate evidence-based policy decision and intervention to prevent, control, eliminate and eradicate diseases of public health concern.

1.3. Vision statement

Centre of excellence for Disease Prevention and Control.

1.4. Objectives

1.4.1 To achieve and maintain an effective and efficient quality management system

1.4.2 To produce accurate, reliable, and timely analysis of results

1.4.3 To ensure compliance with relevant statutory and safety requirements

The Quality Assurance team ensures the implementation of the quality management system to achieve the defined objectives.

1.5. Scope

This quality manual describes the quality management system of the RCDC.

1.5.1. Internal use- to communicate to the staff, the laboratory's quality policies and objectives, to make the staff familiar with the processes used to achieve compliance with quality requirements. This should facilitate the implementation of the quality management system as well as ensure its maintenance and required updates during altering circumstances. This should also allow effective communication and control of quality related activities and documented base for quality system audits.

1.5.2. External use- to inform the external stakeholders about its quality policy as well as its implemented quality management system and measures of compliance with quality.

2. Quality Policy

The RCDC management is dedicated to providing the resources necessary to maintain the laboratory quality management system and to ensure the laboratory's participation in the institutional quality plan.

The laboratories in the RCDC are committed to continual improvement, meeting internal requirements and stakeholders' requirements, and providing a basis for the establishment and review of the quality objectives. Quality practices are communicated within the organization, understood, and adhered to by all employees.

The centre ensures competent workforce to deliver quality results in a timely manner according to the ISO 17025:2017 (Standard for Testing and Calibration laboratories), ISO 15189:2012 (Standard for Medical laboratories) and complies with Bhutan Healthcare Standard for Quality Assurance (BHSQA).

3. QSE-1: Organization

3.1 Organization policy

The Head of the Centre has the authority, competence and responsibility for the services provided.

Laboratory management ensures the following:

a) Laboratory performance is not compromised.

b) Ethical respect and confidentiality of patient, patient samples and product's information is upheld.

c) Duties and responsibilities of laboratory personnel are defined.

d) Appropriate communication is established within the laboratory.

e) QA focal person from each laboratory is designated.

f) QA manager and a biosafety officer are designated.

3.2 Conflict of interest

The centre is not engaged in any activity that might influence its technical judgment. The centre is 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.

The centre is committed towards maintaining impartiality. All staff of the RCDC declares conflict of interest annually. The management of the RCDC assesses the declaration to identify any risks to impartiality and conflict of interest. If any risk is identified, it is reviewed in the management review meeting for necessary intervention.

3.3 Organization chart

The centre consists of five broad category services and 17 sections. Highlighted sections are to be established as shown in the Figure 1.

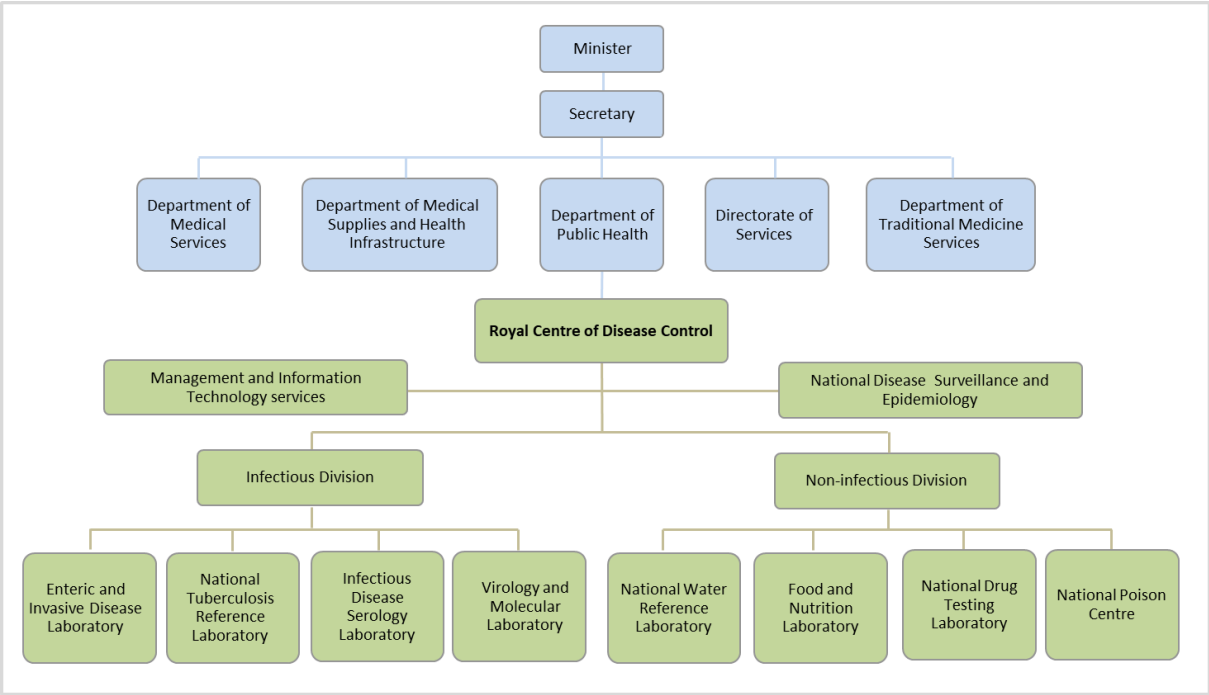

Figure 1 : RCDC organizational chart

3.4 Internal communication

The management ensures that appropriate communication takes place to keep staff members informed. Meetings are held fortnightly for Head RCDC and chief laboratory officer of infectious and non-infectious division; quarterly and annually for general staff (Table 1). During the meetings:

a) Laboratory activities of the week, month, quarter and annual are reviewed and activities to be performed are defined in annual work plan

b) All information on general organization are communicated

c) Minutes (notes) are taken of meeting discussions, followed by written reporting

Other meetings:

a) Quarterly Quality Assurance (QA) meetings

b) Technical Working Group (TWG) for procurement meeting is to be held as and when required.

3.5 Personnel responsibilities

3.5.1 Head of the Centre

a) approves, implements, and maintains quality management system

a) ensures the necessary human and material resources

b) ensures necessary information are available to enable effective operation and control of the processes of the quality management system

c) delegates tasks to qualified personnel

d) manages contracts

e) ensures adequate training

f) ensures internal and external communication

3.5.2 Quality Manager

a) assesses the facilities, procedures, practices, and training of personnel involved in the laboratory's activities, in regard to the quality management system

b) reviews the quality plan annually and recommends any revisions needed to the head of the centre

c) seeks advice from different relevant laboratories and experts and may require assistance from independent experts

d) establishes an internal audit program and informs the head of the centre of audit outcomes

e) establishes and monitors all processes and procedures for the quality management system

f) ensures the nonconformities are identified and resolved

g) ensures that action is taken in order to obtain continuous improvement of processes/activities

h) Ensures all staff has up-to-date Quality Management System (QMS) training.

3.5.3 Quality Assurance Team

a) QA Team assists the quality manager in executing the activities associated with the QMS

3.5.4 QA Focal Personnel

a) updates the QA manager on any recent QA associated developments in the unit

b) plans and coordinates the work schedule in respective Unit

c) ensures stock management/material management

d) ensures activities/processes included in the scope of the quality management system are identified and performed in compliance with this manual

e) applies the necessary techniques and criteria in order to verify that established processes/activities and their implemented controls are effective

f) liaise with the TWG for procurement in evaluating and identifying new products

g) In addition, oversees any biosafety related tasks

3.5.5 Technologist/ Sr. Technician

a) performs the tests

b) manages the section and updates the stock

c) manages and maintains logbooks for equipment

d) provides technical advice on laboratory quality procedures to personnel

e) reports to immediate supervisor on any significant problems of which he/she becomes aware in daily practice

3.5.6 Technician

a) performs the tests

b) controls and maintains equipment

c) reports to the supervisor any significant problems of which s/he becomes aware in daily practice

d) checks performance of internal quality controls to validate the tests

3.5.7 Biosafety Officer;

a) ensure biosafety measures are in place

b) ensure biosafety procedures are implemented and monitored

c) liaise with the QA Manager in areas where QA processes and biosafety activities are interfaced

d) Advise on risk assessment for all proposed work with biological agents and the development of codes of practice

e) Advise on waste disposal policy and arrangements.

3.5.8 Information Communication Technology (ICT) officer

a) Develops and maintains database system

b) Ensures data security and management

3.6 Supporting documents

Table 1: Supporting documents for QSE: Organization

Processes	**ID Code**
Communication	**QSE/SOP-1.2/Fig-1.1**
Conflict of interest	**QSE/SOP-1.3/Fig-1.2**
Procedures	
Meetings management	**RCDC/QMS/QSE/SOP-1.1**
Internal communication	**RCDC/QMS/QSE/SOP-1.2**
Conflict of interest	**RCDC/QMS/QSE/SOP-1.3**
Forms/Logs	
Meeting minutes	**QSE/SOP-1.1/Form-1.1**
Conflict of interest form	**QSE/SOP-1.3/Form-1.2**

4. QSE-2: Facilities and Safety

4.1 Policy

The laboratories in the centre are provided with sufficient space, reliable infrastructure and suitable environmental condition to perform its work, to ensure the quality, safety and efficacy of the services provided, and to meet national safety regulations. The laboratory design provides an efficient and safe environment for the laboratory staff, other health care personnel, patients, and the community. Personnel are trained in the basics of safety and biorisk management issues.

4.2 Facilities

The centre has two laboratory blocks, Block A and Block B.

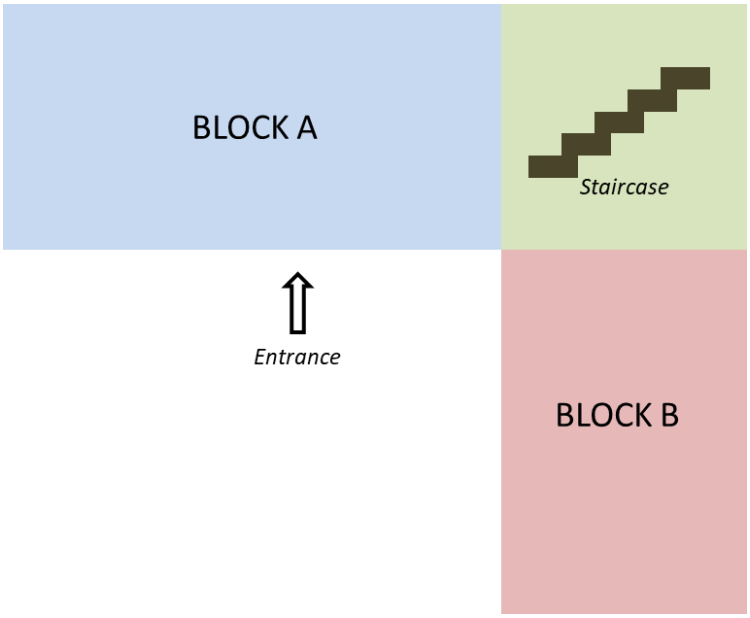

Figure 2 : The RCDC Buidling plan layout

4.2.1 Block A

The **Level 1** has information desk, sample reception counter, general offices and conference halls. The sample reception counter has designated infectious and non-infectious sample reception area and sample storage room (Figure 3). The general store is located at the basement.

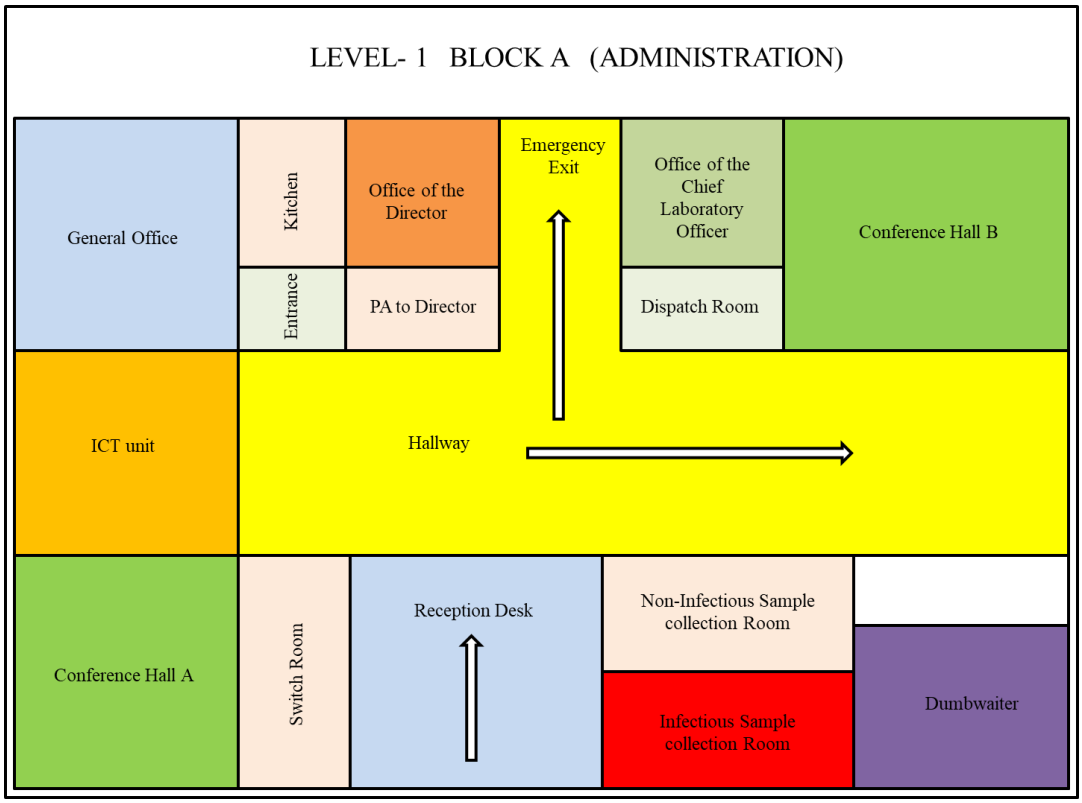

Figure 3: Level 1, Block A floor plan

The **Level 2** houses Food Microbiology Laboratory, Chemistry and Nutrition Laboratory, Quality Assessment unit and teaching laboratory. The Food Microbiology Laboratory has rooms for sample processing, media preparation, and sterilization/decontamination. The Nutrition Laboratory has rooms for sample processing and equipment. The Quality Assessment unit has one room and teaching has two rooms. The floor also has separate rooms for staff office, meeting room and a store (Figure 4).

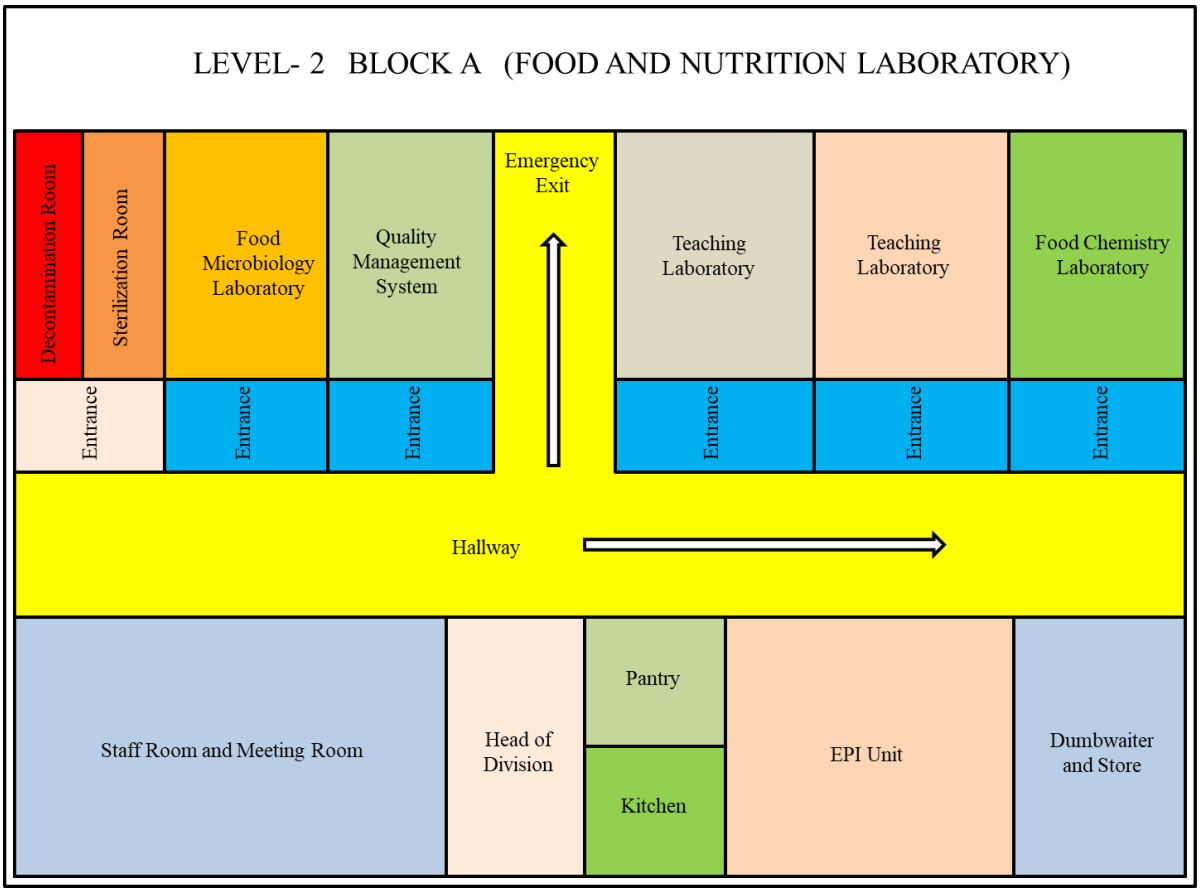

Figure 4: Level 2, Block A floor plan

The **Level 3** houses National Water Reference Laboratory (NWRL) and Immuno-Serology Laboratory. The NWRL has separate rooms designated for Water Chemistry, Water Microbiology and Environmental laboratories. The Immuno-Serology Laboratory has rooms for sample processing, washing room and a separate room designated as National Measles Laboratory. The floor also has separate rooms for staff, meeting, and a store (Figure 5).

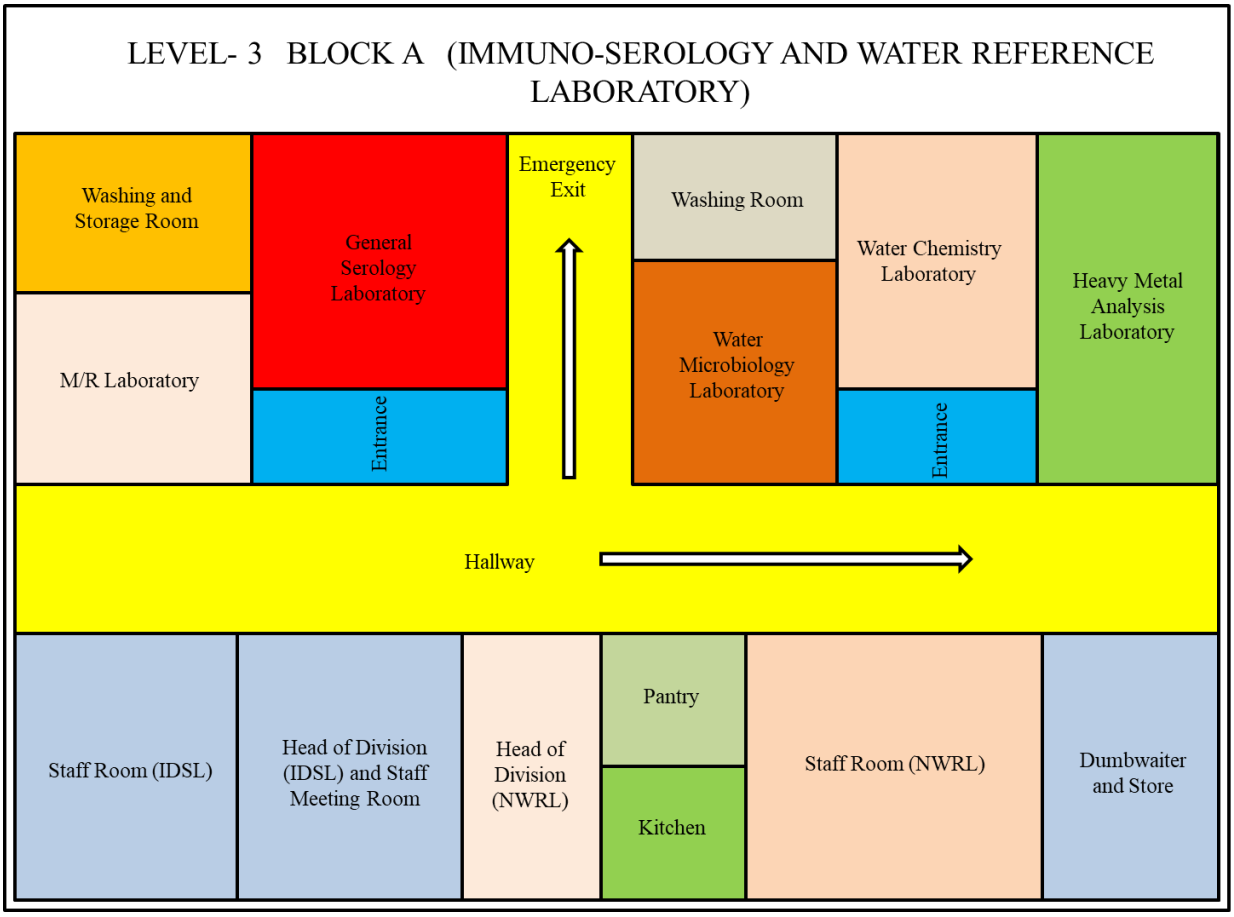

Figure 5: Level 3, Block A floor plan

The **Level 3** houses National Drug Testing Laboratory (NDTL). The floor also has separate rooms for analytical lab testing, staff offices, meeting halls and a store (Figure 6).

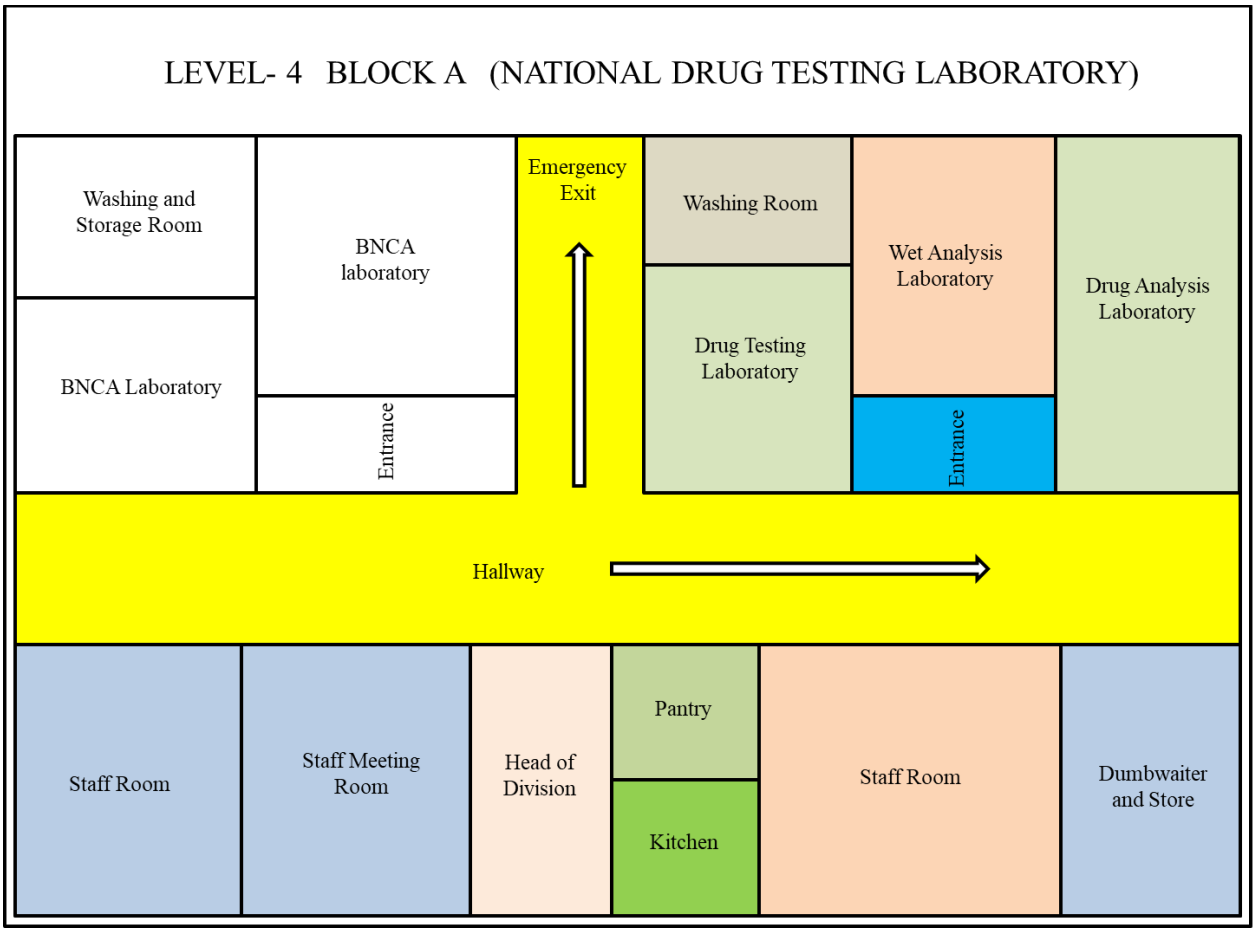

Figure 6: Level 4, Block A floor plan

4.2.2 Block B

The **Level 1** huses Enteric and Invasive Disease Laboratory (EIDL) which has separate rooms for Bacteriology and Parasitology labs with common ante-room, and Leptospirosis lab with ante-room furnished with hand washing sinks and emergency shower. Those rooms are provided with negative pressure and heat, ventilation and air circulation (HVAC) system. The floor has a separate room for media preparation, sterilization, decontamination and washing with entrance through common ante-room. The floor also has separate rooms for staff, meeting, and a store (Figure 7).

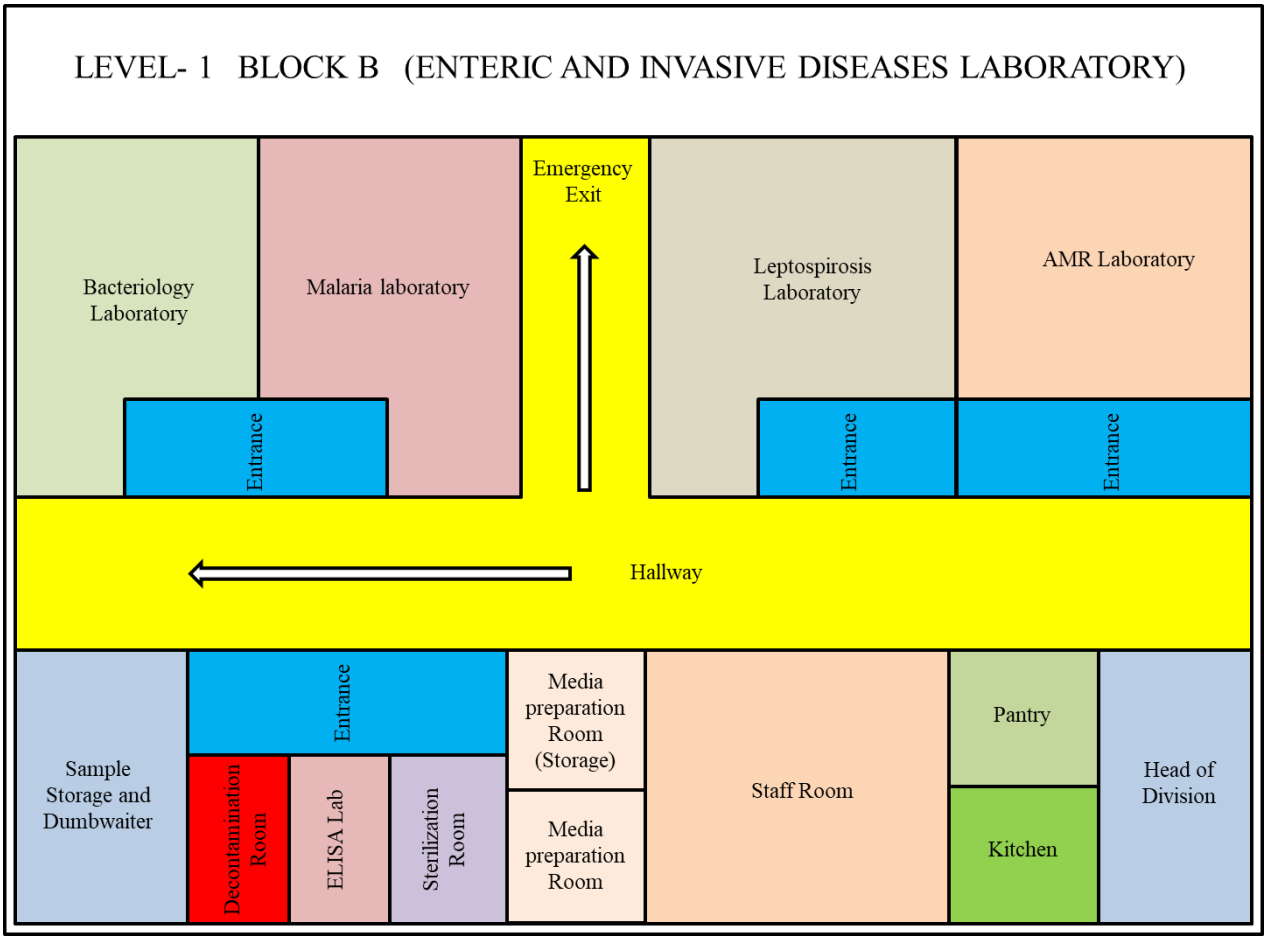

Figure 7: Level 1, Block B floor plan

The **Level 2** houses Virology and Molecular Laboratory (VML). The Virology Laboratory has separate rooms for tissue culture preparation and specimen processing with common ante room furnished with washing sinks. The Molecular Laboratory has separate rooms for DNA/RNA extraction, reagent preparation, gel documentation and PCR machines with common ante room furnished with washing sinks and emergency shower. The floor has a separate rooms for sterilization, decontamination and washing with entrance through common ante room. The floor also has separate rooms for staff, meeting, and a store (Figure 8).

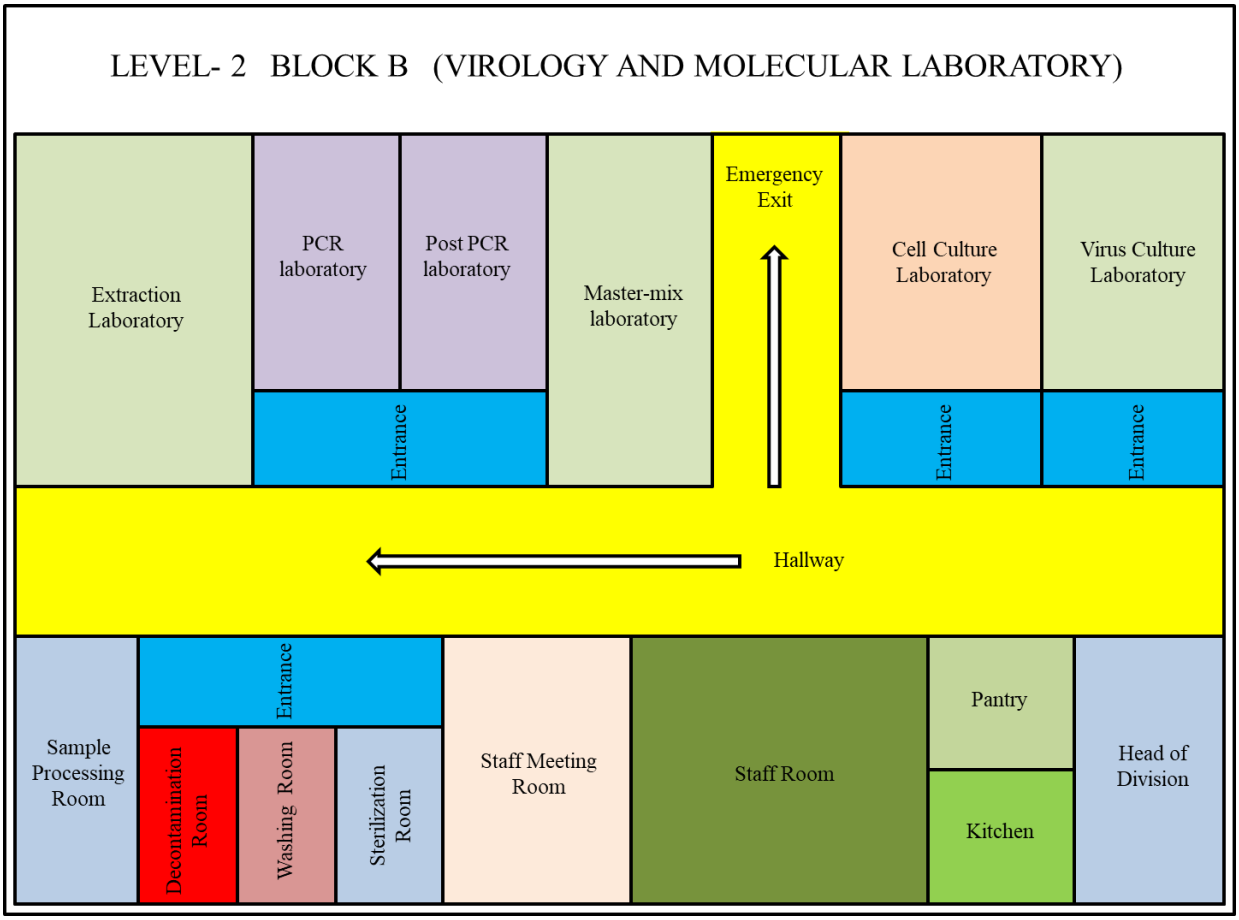

Figure 8: Level 2, Block B floor plan

The **Level 3** houses National Tuberculosis Reference Laboratory (NTRL) and Biosafety level 3 (BSL-3) Laboratory. The NTRL has separate rooms for sample processing and media preparation with common anteroom furnished with washing sinks and emergency shower. BSL-3 Laboratory has two main labs, three mini labs, PPE room, changing rooms, shower rooms, decontamination and anteroom. The lab rooms in both NTRL and BSL-3 have appropriate negative pressure and HVAC system. The floor also has separate Biosafety office, staff, and a store (Figure 9) and (Figure 10).

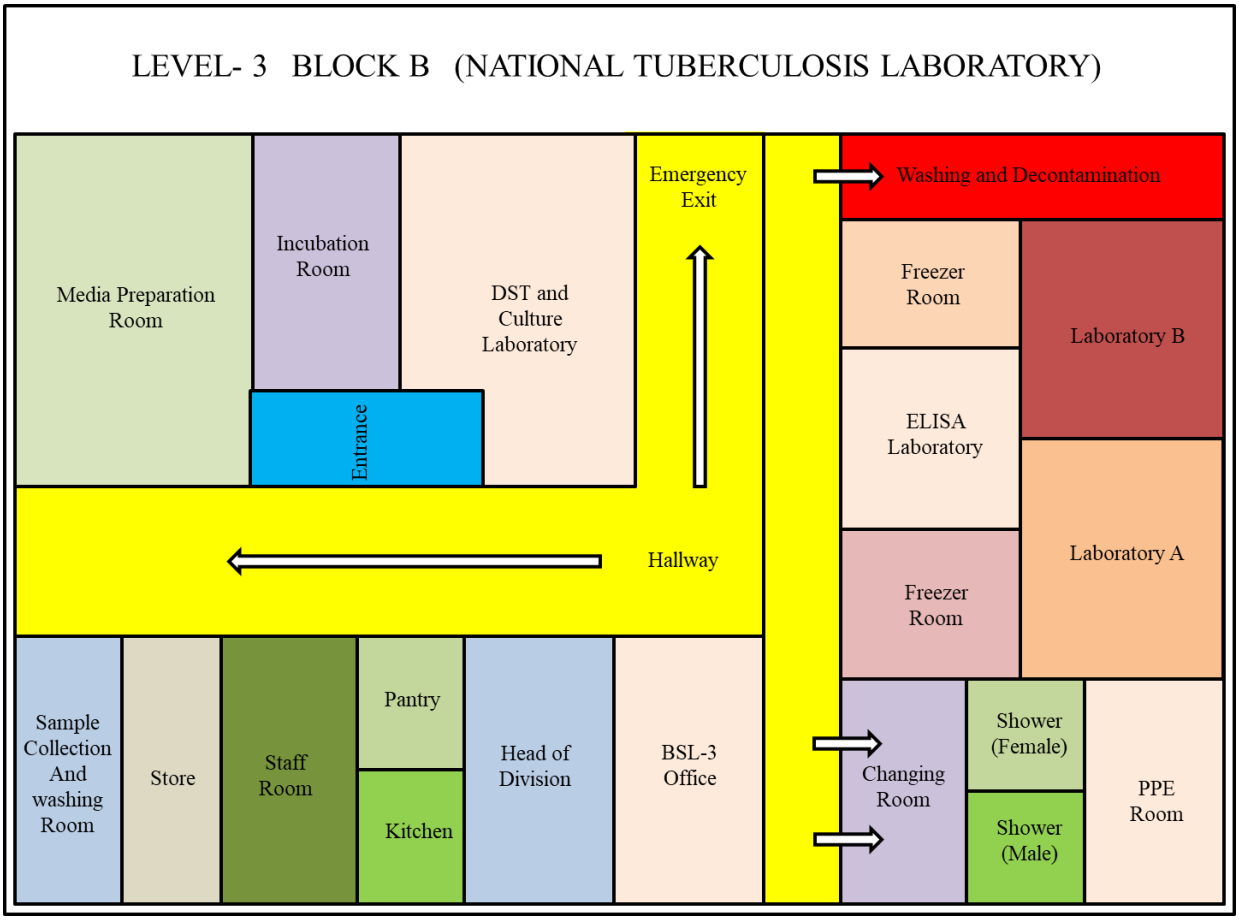

Figure 9: Level 3, Block B floor plan

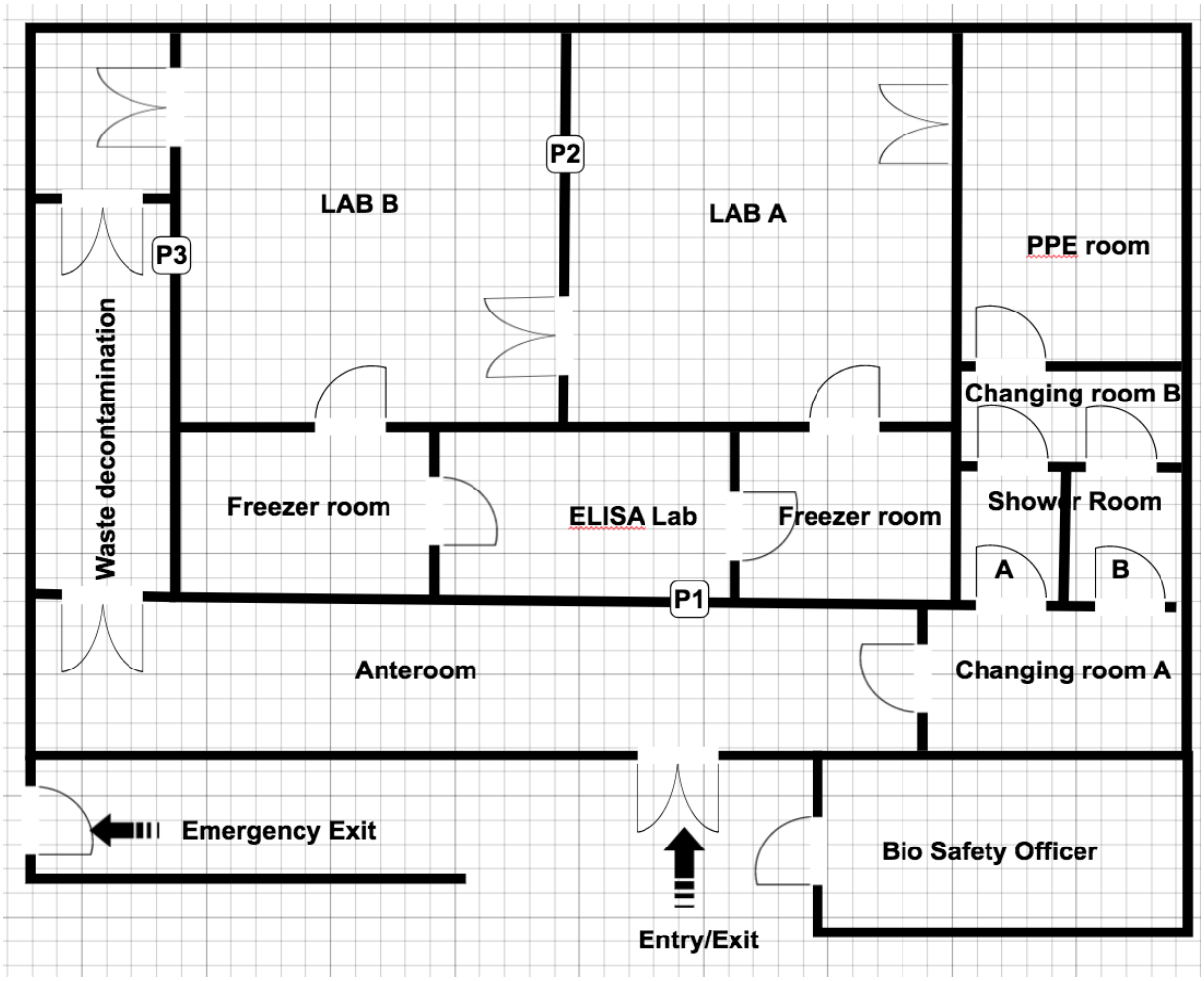

Figure 10: Biosafety Level 3 floor plan.

4.3 Security

The centre has three tiers of security. The first tier is at the main entrance, second at the respective entrance at each floor and third at respective designated laboratory. Access to all facilities other than reception is restricted to authorized personnel. Access is regulated by an access card (magnetic badge or code). The centre has CCTV surveillance system outside and inside the facilities for a 24-hour effective security service.

Access to the BSL-3 Laboratory requires:

a) general training on biosafety concerning BSL-3 level work

b) tutorial by the Biosafety Officer

c) specific clearance from Biosafety Officer

4.4 Working environment

The incoming specimens are received, recorded, segregated and distributed to the respective laboratory units following established Standard Operating Procedures (SOP) (Table 5: **RCDC/QMS/QSE/SOP-5.1**). All manipulation presenting a risk of contamination (for the samples, operators and environment) is isolated from other activities.

Environmental conditions that influence the validity of results are determined, monitored, controlled and are recorded.

Working areas are kept clean, dust free with disinfection of the work benches before and after performing procedures. A complete and thorough description of safety rules is available, and all personnel are trained in safety and biorisk management issues when working with chemicals and biohazardous specimens.

4.5 Waste disposal

Medical waste refers to all categories of waste generated from health facilities, clinics, animal husbandries, veterinary hospitals, clinical laboratories and home-based treatment of patients. Hazardous waste refers to any waste with properties which have the potential to cause harmful effects to human or environment when poorly managed.

All medical wastes are not hazardous; between 75% - 90% are comparable to unsoiled domestic wastes. The remaining 10% - 25% of it is hazardous which entails special treatment and management because of the potential to transmit infection, cause injury, and environmental pollution.

Sharps, pathological and infectious wastes are considered as infectious/hazardous waste. If infectious waste is mixed with general waste the entire waste must be considered as infectious and will require special handling, treatment and disposal practices.

The liquid hazardous waste after overnight treatment with 0.5% hypochlorite solution is run into the sink whereas all the solid hazardous wastes are disposed off as any other general wastes after autoclaving.

The non-hazardous/non-clinical wastes are packed into the biodegradable green plastic bags. This does not require any treatment and are disposed as any other domestic waste and sent to a recycling plant or into the landfill.

Waste (chemical, biological and other) segregation and disposal is in accordance with the *National guideline on infection control and medical waste management, 2014.*

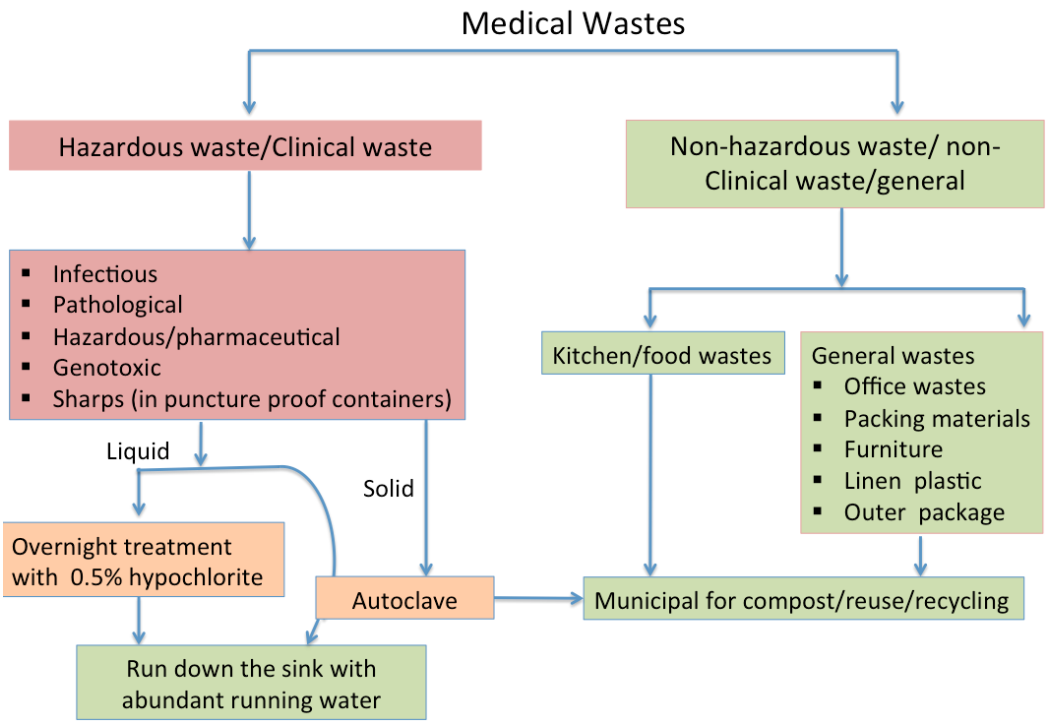

Figure 11: shows the different categories of medical waste
(Source; National guidelines on infection control and medical waste management, 2014)

All the laboratory staffs as well as the support staff are trained to handle all kinds of wastes generated from the laboratory in the most appropriate manner.

4.6 Supporting document

Table 2: Supporting documents for QSE: Facilities and Safety

Processes	**ID Code**
Facility maintenance	**QSE/SOP-2.2/Fig-2.1**
Security	**QSE/SOP-2.4/Fig-2.2**
Waste disposal	**QSE/SOP-2.5/Fig-2.3**
Procedures	
National Biosafety guideline	**RCDC/QMS/QSE/SOP-2.1**
Facility maintenance	**RCDC/QMS/QSE/SOP-2.2**
Safe manipulation	**RCDC/QMS/QSE/SOP-2.3**
Security	**RCDC/QMS/QSE/SOP-2.4**
Waste disposal	**RCDC/QMS/QSE/SOP-2.5**
Emergency Response Plan	**RCDC/QMS/QSE/SOP-2.6**
Spill management	**RCDC/QMS/QSE/SOP-2.7**
Safety Equipment SOP autoclaves	**RCDC/QMS/QSE/SOP-2.8**
Safety Equipment SOP biosafety cabinets	**RCDC/QMS/QSE/SOP-2.9**
Forms/Logs	
Incident report form	**QSE/SOP-2.2/Form-2.1**
Visitors log	**QSE/SOP-2.4/Log-2.2**
Housekeeping log	**QSE/SOP-2.2/Log-2.3**
Entry and exit log (BSL-3)	**QSE/SOP-2.4/Log-2.4**
Safety checklist (BSL-3)	**QSE/SOP-2.4/Form-2.5**
Off- Hour working record form	**QSE/SOP-2.4/Form-2.6**
Logs for earthquake and fire drills	**QSE/SOP-2.6/Form-2.7**
Safety equipment log	**Refer respective section (equipment specific safety log)**

5. QSE-3: Equipment

5.1 Policy

The centre ensures that equipment is properly selected, installed, validated, maintained and disposed of according to established procedures and manufacturer's instructions to meet the needs of the laboratory to perform quality testing.

5.2 Selection of equipment

Refer to QSE 6: Purchasing and Inventory.

5.3 Installation and acceptance Criteria

New instruments and equipment are installed and calibrated by the vendors and documented by the laboratory for assuring the satisfactory performance. Every new equipment is checked thoroughly upon receipt to confirm if the supply meets ordered specification placed by the laboratory.

The vendor or laboratory ensures space, ventilation; humidity and electricity meet specifications for satisfactory performance.

5.4 Equipment Inventory and master file

The store in-charge is responsible in maintaining the inventory and updating list of equipment and related documents in the laboratory.

All equipment is uniquely identified with Biomedical Engineering Division (BMED) instrument number, serial number, model number, manufacturer, funded by, and date of installation.

An inventory and master file are maintained for each piece of equipment in the laboratory.

The master file contains the following information (whenever possible):

a) name of the equipment

b) brand (manufacturer)

c) inventory number

d) BMED instrument number

e) serial number

f) model and year

g) software and firmware version

h) location

i) cost

j) Source of funding

k) date of purchase

l) date of installation

m) type of maintenance (contract with an external company, in house, etc.)

n) Manual from manufacturer (operational/user manual and service manual)

o) regular preventive maintenance to be performed, and frequency to perform these activities

p) calibration activities

q) record of preventive maintenance activities

r) record of repairs

s) Details of any damage, malfunction, modification or parts of the equipment that have been changed or repaired.

5.5 Equipment Validation/Verification

All equipment used for specific testing is the responsibility of the concerned division.

a) The laboratory validates/verifies each new piece of equipment.

b) The validation/verification process depends on the type of equipment and its use in the laboratory.

c) Reproducibility and accuracy tests are performed, documented, reviewed and approved before the instrument is used in the testing environment.

5.6 Equipment use and calibration

5.6.1 The responsible staff conducts or delegates the required calibrations of the equipment, affecting the validity of the test result, as per the calibration programme and labled to identify the status of calibration. The programme will be periodically reviewed and adjusted as necessery. The centre maintains unbroken chain of calibrations and, when possible, ensures traceable to the Interntional System of Units (SI). If the reference value or correction factor are obtained from calibration, this will be updated and implemented.

5.6.2 The records of all interventions on the equipment are maintained

5.6.3 Only assigned and trained staff can use the specific equipment. Use and maintenance of each equipment is based on the manufacturer's instructions.

5.6.4 A SOP on the use, maintenance and safety risks of the equipment is accessible at the bench.

5.6.5 The operating manual of each piece of the equipment is available and understood by the laboratory staff.

5.7 Intermediate check, Preventive maintenance and repair

5.7.1 Intermediate check and Preventive maintenance are performed and recorded on a scheduled basis.

5.7.2 Maintenance contracts and warranty service are documented and maintained by the concerned section/division.

5.7.3 Defective or malfunctioning equipment is identified with label until repair or surrender with the date (alerting that it is not in use) as per the process for equipment repair.

5.8 Decommissioning

Obsolete equipment is decontaminated and removed from the laboratory as per the decommissioning SOP.

5.9 Supporting documents

Table 3 : Supporting documents for QSE: Equipment

Processes	**ID Code**
Selection and acquisition of equipment	**QSE/SOP-3.1/Fig-3.1**
Equipment installation	**QSE/SOP-3.4/Fig-3.2**
Equipment repair	**QSE/SOP-3.4/Fig-3.3**
Decommissioning	**QSE/SOP-3.3/Fig-3.4**
Equipment identification	**QSE/SOP-3.1/Fig-3.5**
Procedures	
Equipment selection, validation and identification	**RCDC/QMS/QSE/SOP-3.1**
Decontamination of laboratory equipment	**RCDC/QMS/QSE/SOP-3.2**
Equipment decommission	**RCDC/QMS/QSE/SOP-3.3**
Equipment SOPs (calibration, operation and maintenance of each piece of equipment)	**RCDC/QMS/QSE/SOP-3.4**
Forms/Logs	
Laboratory equipment disposal form	**QSE/SOP-3.2/Form-3.1**
Checklist for decontamination	**QSE/SOP-3.2/Form-3.2**
Service certification	**QSE/SOP-3.4/Form-3.3 (company's form)**
Quality Inspection form for equipment	**Refer MSPD QI form 1**
Calibration form	**Refer respective sections' equipment calibration SOP**
Intermediate check and Preventive maintenance schedule	**Refer respective sections' form**
Form to record Intermediate check and Preventive maintenance schedule	**Refer respective sections' form**

6. QSE-4: Externally provided products/services and Inventory

6.1 Policy

6.1.1 The centre ensures an uninterrupted supply of consumables and/or services are available to perform all quality laboratory functions.

6.1.2 The laboratory maintains a list of vendors that meet the requirements for the product or service to be purchased. The laboratory in liaise with Medical Supply and Procurement Division (MSPD), MoH strives to purchase high quality reagents at a reasonable cost and without bias.

6.1.3 The Department of Medical Supply and Health Infrastructure (DoMSHI), MoH maintains documented procedures for ordering, receiving, documenting, evaluating and storing all consumables supplies.

6.1.4 The centre has an inventory management system.

6.2 Reagents and consumables management

The laboratory ensures that the procedures for the purchase, receipt and storage of all reagents guarantee that the quality of testing is not compromised. All new lot of reagents are crosschecked and documented with previous lots to ensure reproducibility. Environmental conditions for the storage of all reagents and consumables are monitored controlled and documented.

The laboratory maintains a record of all laboratory supplies, including reagents and consumables. This information includes:

a) identity of the reagent or consumable,

b) manufacturers name,

c) contact information for the supplier or the manufacturer,

d) date of receiving and date of commission,

e) condition when received (e.g. acceptable or damaged),

f) manufacturers' instructions,

g) Safety Data Sheets (SDS),

h) records that confirmed the reagent's or consumables initial acceptance for use,

i) performance records that confirm the reagents or consumables ongoing acceptance for use.

All reagents that are prepared within the laboratory, such as media, must contain all the above information as well as the following:

a) Name of the reagent

b) Name of the person who prepared it

c) Date of preparation.

d) Date of Expiry

e) Lot number

f) Batch number

g) Quantity prepared

6.3 Selection and evaluation of suppliers/service provinders

The centre liaise with the Medical Supply and Procurement Division (MSPD) to evaluate the suppliers for the reagents, consumables and equipment. The service provinders will be evaluated and selected by the centre. The evaluation should be conducted against defined criteria which may include:

a) value for money

b) end user's past experience with justification

c) specification

d) availability

e) in-country distribution

f) registration of the supplier

g) post-delivery support

h) the manufacturer/service provider has certification (ISO/GMP or international recognition)

i) Supplier/service provinders will be monitored and re-evaluated periodically

j) Detailed document of evaluation will be maintained by MSPD

6.4 Procurement of Equipment, reagents and consumables

The laboratory ensures that when purchasing, leasing or acquiring new equipment, reagents and consumables, it conforms to the established requirements.

6.4.1 Submission of requisitions

The list of equipment, reagents and consumables with specification is submitted to MSPD

6.4.2 Purchasing orders

The orders for purchase of supplies (reagents, consumables and equipment) are placed by MSPD.

6.4.3 Receipt of orders

The laboratory confirms receipt of the supplies from the Medical Supply Distribution Division (MSDD) and informs the MSPD along with a quality inspection form. The date of receipt is recorded.

6.5 Stock management and inventory

RCDC has a stock management system to ensure consumables are stored under correct environmental conditions and are used prior to their expiration dates.

A regular inventory monitoring is performed.

6.6 Supporting documents

Table 4: Supporting documents for QSE: Purchasing and Inventory

Processes	**ID Code**
Selection and acquisition of equipment, reagents, consumables and service providers (Refer chapter 5 Equipment)	**QSE/SOP-3.1/Fig-4.1**
Receipt of supplies	**QSE/SOP-4.1/Fig-4.2**
Stock and inventory management	**QSE/SOP-4.2/Fig-4.3**
Procedures	
Selection	**Refer RCDC/QMS/QSE/SOP-3.1**
Purchasing and Receipt	**RCDC/QMS/QSE/SOP-4.1**
Stock management and Inventory management	**RCDC/QMS/QSE/SOP-4.2**
Forms/Logs	
List of providers	**Refer to MSPD**
Stock log	**QSE/SOP-4.2/Form-4.2**
Inventory log	**QSE/SOP-4.2/Form-4.3**
Quality Inspection form for consumables	**Refer MSPD QI form VI**

7. QSE-5: Process Management

7.1 Policy

The centre has processes for each phase of the sample processing: pre-testing, testing and post-testing phases to ensure accurate and reliable testing.

The centre has quality control measures to monitor the examination phase of testing (qualitative, quantitative and semi-quantitative).

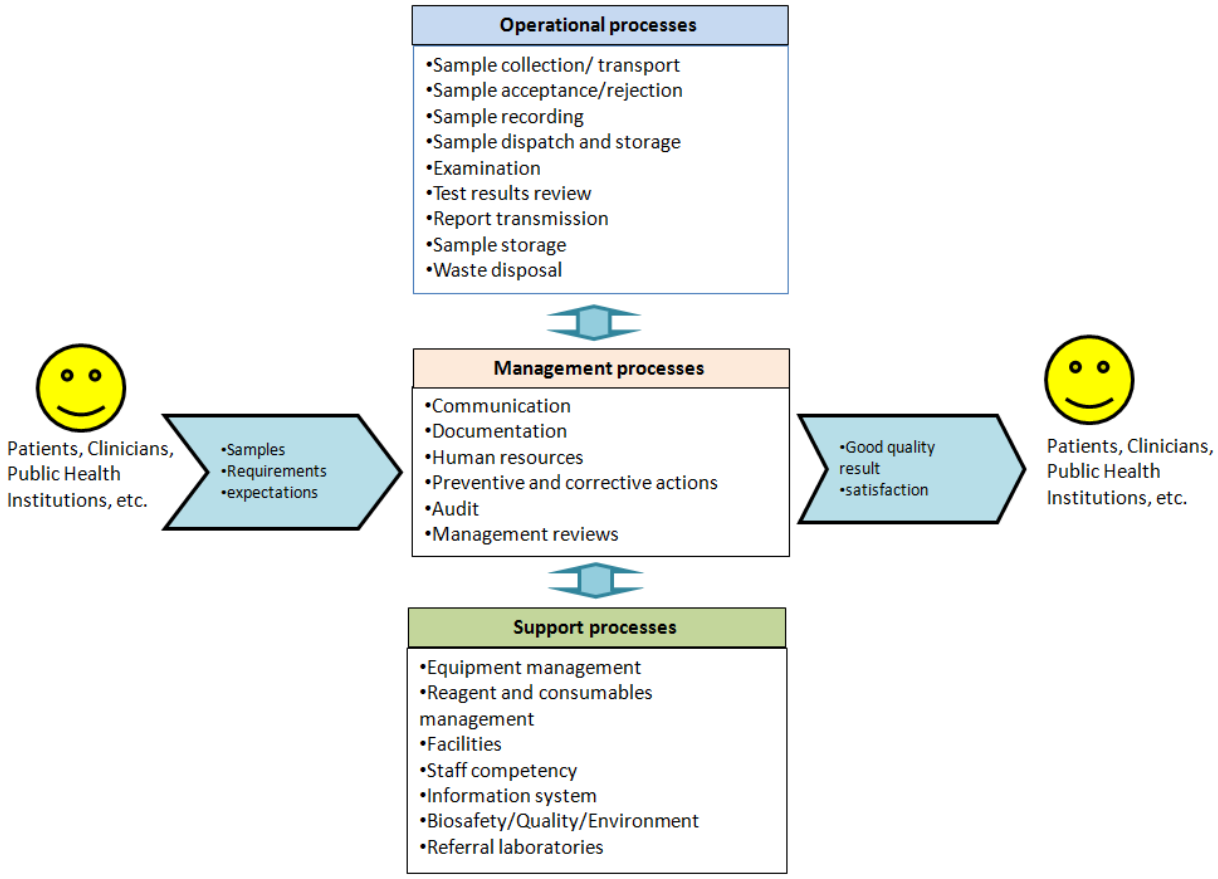

Figure 12 : Path of workflow

7.2 Sample management

7.2.1 Specimen collection and transport

The laboratory provides written instructions for specimen collection and transportation. The laboratory provides specimen collection containers, related forms, shipment boxes, transport medium and shipment forms. Specimen transport follows the sample shipment SOP or IATA regulations.

7.2.2 Specimen/ sample receiving

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

The laboratory rejects specimens/samples that are not suitable for processing. The requestor is notified of the reason for rejection by sending the rejection form detailing the reasons for rejection. In the case of critical specimens, such as one of limited volumes for laboratory testing, the respective laboratory consults with the requestor to prioritize testing/ resampling. If the specimen/sample is too critical to be rejected, the examination is performed and a notation is made on the report. A unique registration number is assigned to each specimen/sample to be analysed.

Data is recorded in the electronic database system and/or the laboratory register.

7.2.3. Specimen/sample handling, preparation and storage

Standard precautions are considered while handling the samples. All necessary measures are put in place to protect the product, person and the environment.

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

Samples are stored under proper temperature and safety conditions with proper sample inventory log.

7.3 Method validation/verification

The laboratory is responsible to assign personnel for method validation/verification of each test performed. All the methods in the laboratories are validated through a documented validation process.

The validated methods used in the laboratory, that have been published in scientific reviews or transmitted by national or international reference centres are validated/verified and documented under the laboratory's conditions and adapted when needed.

The methods and techniques used in the laboratory are described in the SOPs and associated documents.

7.4 List of examinations

The laboratories follow appropriate methods and techniques which are described in the SOPs and associated documents that are readily available to the laboratory personnel. Any deviation from written methods will be documented, technically justified, authorize and accepted by the customer. The technical records for laboratory activities shall be made on site and amendment will be done in traceable way. List of examinations performed in the laboratory and references to the corresponding SOPs (Annexure 1 and 2).

7.5 Measurement of uncertainty

When estimating the uncertainty of measurement, all uncertainty contributions that are of significance are taken into account using the applicable methods of analysis.

7.6 Quality Control

The laboratory has a Quality Control (QC) program with written policies and procedures.

Laboratory technical staff is trained to review and take appropriate action regarding quality control data.

Internal quality controls are required to ensure the results are valid.

The laboratory quality control monitoring system of the RCDC:

a) Provides immediate information for making the decision about the acceptability of laboratory test results,

b) Provides a method for evaluating data over time to help in making decisions about the overall performance of the test procedure. These controls are run on both qualitative (result is positive or negative) and quantitative (result is a number or value) tests. The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to the reviewing of the results.

Equipment calibration and servicing are monitored by concerned section head / user.

The test results are documented both in hard and soft copies by the authorised personnel to create a permanent traceable record.

If QC results are not validated, laboratory results are not reported.

When problems occur the laboratory investigates, corrects and repeats sample testing (QSE 11 Nonconforming Event Management).

7.7 Reporting

Laboratory results are reviewed by authorized personnel and in case of discrepancies occurred, the authorized personnel initiates corrective actions.

Reports are made available through paper based and/or RCDC web based system.

The authorized personnel contacts/notify the concerned programmes, policy makers, administrators, clinicians, public health service or relevant stakeholders for further information, if needed, or to transmit critical results to initiate necessary interventions.

Final reports are signed by the authorized personnel and released to the requestor.

Amendment to a report after issue is made only in the form of a clearly identified document.

7.8 Sample retention and disposal

The retention period of the samples are based on the objectives of testing; surveillance, diagnostics, environmental and pharmaceuticals.

For disposal of samples, (Refer QSE 4: Facilities and Safety).

7.9 Referral laboratories

The laboratory should select referral laboratories according to pre-defined criteria such as competency to perform the requested tests.

It will be the Laboratory management responsibility to designate the laboratories and/or companies with whom they will subcontract tests or calibration. These will be listed and kept in a folder with all documents referring to the subcontractors.

Subcontracting of samples may occur under any of the following circumstances:

7.9.1 test not performed routinely by the laboratory

7.9.2 instrument breakdown or reagents not available\

7.9.3 workload restrictions

7.9.4 client requested turnaround time cannot be met.

Where a laboratory subcontracts any part of the calibration of equipment, this work is contracted with a company complying with the requirements of this quality manual.

The laboratory ensures and demonstrates that its subcontractor is competent to perform the activities in question.

7.10 Supporting documents

Table 5: Supporting documents for QSE: Process Management

Processes	**ID Code**
Sample collection, transport, receipt, processing and storage	**QSE/SOP 5.1/Fig 5.1**
Reporting	**QSE/SOP 5.6/Fig 5.2**
Procedures	
Sample collection, labelling, storage, transportation and receipt at RCDC	**RCDC/QMS/QSE/SOP-5.1**
Sample rejection or acceptance	**RCDC/QMS/QSE/SOP-5.2**
Sample storage and disposal	**RCDC/QMS/QSE/SOP-5.3**
Analytical SOPs (procedure for each examination/test performed)	**Refer to respective section's SOPs**
Results validation	**RCDC/QMS/QSE/SOP-5.4**
Critical results reporting	**RCDC/QMS/QSE/SOP-5.5**
Result reporting and report amendment	**RCDC/QMS/QSE/SOP-5.6**
Forms/Logs	
Quality control logs	**Refer respective section**
Test result form	**Refer respective section**
Specific test request form	**Refer respective section**
RCDC sample shipment form	**QSE/SOP-5.1/Form-5.2**
Critical result reporting log Form	**QSE/SOP-5.5/Form-5.3**
Critical result reporting Assessment Form	**QSE/SOP-5.5/Form-5.4**
Result reporting log book	**QSE/SOP-5.6/Form-5.5**

8. QSE-6: Assessments

8.1 Policy

The Centre strives to continuously improve the quality of laboratory performance, the effectiveness of the quality management system and the reliability of test data to identify and resolve any nonconformity that may affect laboratory performance.

The centre performs following ongoing quality assessments to:

8.1.1 periodic review of examination requests, suitable methods and sampling requirements,

8.1.2 monitoring and evaluation of customer feedback, staff suggestions and impact of potential failures on examination results and customer expectations,

8.1.3 monitoring of determined quality indicators, corrective actions undertaken, and follow-up,

8.1.4 participation in proficiency testing program and review of the corresponding reports,

8.1.5 conduct internal and external audits.

8.2 Internal assessments

8.2.1 Internal Audits

During internal audits, information is gathered about:

a) processes and SOPs

b) staff competence and training

c) equipment

d) environment

e) handling of samples

f) quality control and validation of results

g) recording and reporting practices.

Once a year, the RCDC organizes an internal audit, led by the QA Manager. The findings are compared with the laboratory's internal policies and to BHSQA. The QA Manager submits a complete internal audit report with achievements, findings, recommendations and corrective actions to the technical committee of the RCDC for review and endorsement.

8.2.2 Review and follow up of corrective actions

All corrective actions undertaken by respective laboratories are evaluated by QA focals and reviewed during QA focal meeting.

The details of review is described in (QSE 11: Nonconforming Event Management).

8.2.3 Quality indicators

Quality indicators have been determined to monitor the quality objectives of the laboratory.

The quality indicators and monitoring is detailed in (QSE 12: Continual Improvement).

8.2.4 Staff suggestions

Staff suggestions for improvement of any aspect of the laboratory are recorded, evaluated and implemented if useful after discussion with laboratory staff and section head.

8.2.5 Review of requests, methods and sampling requirements

Requests are systematically reviewed to evaluate the appropriateness of the methods used for the test required.

The required sample volume and general sampling requirements are also reviewed every quarterly to ensure that samples are collected properly and in the correct volume needed for the best performance of the test.

8.3 External assessments

8.3.1 External Quality Assessment/ Proficiency testing

The centre participates in IEQAS for all the tests to ensure quality assured laboratory test results.

Following are the existing IEQAS in which the laboratories in the RCDC participate:

a) IEQAS in Bacteriology at National Institute of Health, Bangkok,Thailand.

b) IEQAS in Sputum microscopy with SAARC Tuberculosis and HIV/AIDS Center, Nepal

c) IEQAS in first line DST for Tuberculosis with Supra-national Tuberculosis Reference Laboratory, Bangkok, Thailand.

d) Proficiency testing in Pharmaceutical solid dosage form at Indian Pharmacopoeia Commission, Gaziabad, New Delhi, India.

e) IEQAS in Transfusion Transmissible Infections/STIs/ at NRL, Melbourne, Australia.

f) IEQAS in JE, Measles and Rubella with CDC, US.

g) IEQAS in Influenza with CDC, US

h) IEQAS in Influenza with H5 Reference Laboratory, Hongkong

i) IEQAS in Arbovirus with Royal College of Pathologists of Australasia, New Zealand

j) IEQAS in Lead and Multielement proficiency assessment, US, CDC

8.3.2 Customer feedback

Customer feedback is collected and reviewed on a regular basis. This is described in (QSE 10: Customer Focus).

8.3.3 External audits

The laboratories organize an external audit in order to be assessed according to a BHSQA and international standards. The RCDC organize annual external audit from WHO identified collaborating centers, based on ISO 15189:2012 and 17025:2017. A full assessment report is written with recommendations for improvements.

Assessment reports are shared with all staff and corrective actions are undertaken accordingly.

8.4 Supporting documents

Table 6 : Supporting documents for QSE: Assessments

Processes	**ID Code**
Internal audit	**QSE/SOP-6.1/Fig-6.1**
External audits	**QSE/SOP-6.2/Fig-6.2**
EQA programmes selection	**QSE/SOP-6.4/Fig-6.3**
Procedures	
Internal audit	**RCDC/QMS/QSE/SOP-6.1**
Preparing for external audit	**RCDC/QMS/QSE/SOP-6.2**
Follow up staff suggestion	**RCDC/QMS/QSE/SOP-6.3**
EQA review	**RCDC/QMS/QSE/SOP-6.4**
Forms/Logs	
Audit checklist	**QSE/SOP-6.1/Form-6.1**
Staff suggestion form	**QSE/SOP-6.3/Form-6.2**
List of EQA programmes	**QSE/SOP-6.4/Form-6.3**

9. QSE-7: Personnel

9.1 Policy

The centre defines staff educational requirements, competency qualifications, trainings necessary for conducting laboratory procedures.

The centre management strives to ensure recruitment is unbiased. The centre works with the Human Resources Division (HRD), Ministry of Health (MoH) to ensure education qualifications and references of job applicants are checked and to ensure legal contracts/agreements are signed by all parties prior to recruitment and within the set of period.

The Bhutan Medical and Health Council (BMHC) ensures that the competent and certified Laboratory personnel are deployed for the Laboratory Practices (Clause 6.8, National Health Policy).

All personnel (temporary, permanent, students, etc.) to sign a confidentiality agreement. All laboratory personnel respect the laboratory rules concerning health, safety and security. The laboratory provides training to its staff according to its needs.

9.2 Recruitment

The centre submits a completed HR recruitment form to the HRD, MOH that describes the appropriate education, training, experience, and skills needed for the available position. The date and the time for the interviews are arranged by the HRD.

9.3 Personnel file/ health file

An individual administrative file is established for each staff member (temporary, permanent, trainee) that contains documents concerning the staff qualifications (diplomas, CV, training certificate). Additional documents such as the orientation record, training records, continuing education, and job descriptions are maintained by HRD.

Individual file is also maintained in the Laboratory to keep the records for continued medical education such as workshops, seminars and trainings. It is mandatory to furnish medical

fitness certificate along with the list of required vaccinations prior to the recruitment of an individual to the centre. Documents of annual health screening are recorded.

9.4 Integration and clearance

Staff orientation of all new employees is completed within 21 days of joining the centre. Safety orientation occurs before an employee is assigned to duties. All newly recruited employees are trained comprehensively on all policies and procedures in the department that apply to their job description and assignments.

9.5 Training

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. The effectiveness of the training program is periodically reviewed.

9.6 Staff competency

Staff competencies cover technical and practical skills and general knowledge. Competency of each new employee is assessed and verified before permitting to perform test and reporting results.

One year of probation period is allotted for every new employee to assess competency prior to provision of regularity.

All employees are assessed for competency at least once in a year.

9.7 Personnel performance appraisal

Each staff member is given an opportunity for an annual interview with the section head. Every year each employee is required to develop Individual Work Plan (IWP) in consultation with section head as personnel performance appraisal. Any achievements besides the ones reflected in IWP is also appraised through IWP review process.

9.8 Continuous education

A continuing education program is available for the professional development of staff. Expectations for staff participation are communicated for those education sessions that are deemed mandatory.

A minimum of 30 Continuing Medical Education (CME) credits within five years is required for renewal of certification.

9.9 Non-regular personnel

Non-permanent personnel such as students, interns, contract staff, post doctorates and trainees follow the general laboratory orientation procedures for integration in the laboratory.

9.10 Supporting documents

Table 7 : Supporting documents for QSE:Personnel

Processes	**ID Code**
Orientation, training and competency	**QSE/SOP-7.1/Fig-7.1**
Performance appraisals	**QSE/SOP-7.3/Fig-7.2**
Recruitment	**QSE/SOP-7.4/Fig-7.3**
Procedures	
Orientation	**RCDC/QMS/QSE/SOP-7.1**
Internal training	**RCDC/QMS/QSE/SOP-7.2**
Competency assessment	**RCDC/QMS/QSE/SOP-7.3**
Recruitment	**RCDC/QMS/QSE/SOP-7.4**
Forms/Logs	
Orientation checklist	**QSE/SOP-7.1/Form-7.1**
Competency assessment checklist	**QSE/SOP-7.3/Form-7.2**
Competency assessment logbook	**QSE/SOP-7.3/Form-7.3**
Performance appraisal form	**Refer IWP**
Training logs	**QSE/SOP-7.2/Form-7.4**

10. QSE-8: Customer Focus

10.1 Policy

The Centre is dedicated in providing quality and timely services to all customers, both internal and external. The laboratory management is committed to providing adequate resources to meet customers' requirements and to provide an on-going program for continual improvement.

10.2 Review of requests and contracts

The laboratory has a procedure for the review of requests and contracts to ensure that:

10.1.1 the requirements are adequately defined, documented and understood.

10.1.2 the laboratory has the capability and resources to meet the requirements.

10.1.3 where external providers are used, the requirements of section QSE-4 are applied and the laboratory gains the customer's approval before referral.

10.1.4 the appropriate methods or procedures are selected which are capable of meeting the customers' requirements.

The laboratory informs the customer when the method requested may be considered inappropriate or out of date.

Any differences between the request and the contract is resolved before laboratory activities commence. Each contract is negotiated and agreed as applicable between both to the laboratory and the customer.

Customer request deviations do not influence the integrity of the laboratory or the validity of the results. The customer is informed of any deviation from the contract.

If a contract is amended, after work has commenced, the contract review is repeated, and amendments are communicated to all affected personnel.

The laboratory cooperates with customers or their representatives in clarifying the request and in monitoring the laboratory's performance in relation to the work performed.

Records of reviews, including any significant changes and concerning pertinent discussions with a customer relating to the requirements or the results of the laboratory activities are documented and retained.

10.3 Customers satisfaction measurement

Customer satisfaction survey is conducted and analysed by the Quality manager annually. The objective of the survey is to assess the satisfaction of the main customers: walk-in patients, clinicians, public health institutes and other relevant stakeholders.

The analysis of survey results will be disseminated to the technical committee and the corrective and preventive actions (CAPA) are implemented wherever necessary.

10.4 Claims management

The RCDC has complaint/suggestion box available at the reception desk at the entrance. All claims are reviewed at least quarterly.

Complaints are managed in order to correct or prevent actions for continuous improvement of the quality system by taking into account the customers' concerns (QSE 12: Continual Improvement).

10.5 Supporting documents

Table 8 : Supporting documents for QSE: Customer Focus

Processes	**ID Code**
Customer satisfaction	**QSE/SOP-8.1/Fig-8.1**
Nonconforming Event Management, and Continual Improvement	**Refer to QSE 11 & 12**
Procedures	
Customer survey	**RCDC/QMS/QSE/SOP-8.1**
Customer complaint	**RCDC/QMS/QSE/SOP-8.2**
Forms/Logs	
Customer survey form/questionnaire	**QSE/SOP-8.1/Form-8.1**
Customer complaint logbook	**QSE/SOP-8.2/Form-8.2**

11. QSE-9: Nonconforming Event Management

11.1 Policy

The centre is committed to the identification, documentation, correction, and prevention of nonconforming events in all aspects of the quality management system including pre-analytical, analytical and post-analytical processes.

Procedures are in place to:

11.1.1 designate the individuals who will be responsible and to take necessary actions for handling nonconformities,

11.1.2 ensure that each nonconforming event is documented, recorded, and reviewed at identified intervals, root cause analysis performed, and that CAPA is implemented and documented,

11.1.3 define when testing procedures and data reporting will be withheld due to nonconformities and when, and under what conditions, examination can resume,

11.1.4 define the steps taken when the test examination data resulting from a nonconforming event has already been released.

11.1.5 evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere in future.

11.2 Corrective Actions

All nonconforming events (from occurrence reports, claims, audit reports, patient/customer complaints, failed proficiency testing, etc.) are recorded, tracked, trends identified, root cause analysis and impact analysis performed by the QA Team. The appropriate CAPA are implemented in consultation with the technical committee. The effectiveness of implemented actions are reviewed and recorded.

11.3 Supporting documents

Table 9 : Supporting documents for QSE: Nonconforming Event Management

Processes	**ID Code**
Nonconforming events and corrective actions	**QSE/SOP-9.1/Fig-9.1**
Procedures	
Nonconforming event management	**RCDC/QMS/QSE/SOP-9.1**
Corrective actions and preventative actions (CAPA)	**RCDC/QMS/QSE/SOP-9.2**
Forms/Logs	
Incident report	**QSE/SOP-9.1/Form-9.1**
Corrective actions	**QSE/SOP-9.2/Form-9.2**
Noncomformance complaint form	**QSE/SOP-9.1/Form-9.3**
Noncomformance event management form	**QSE/SOP-9.1/Form-9.4**

12. QSE-10: Continual Improvement

12.1 Policy

The centre continuously improves the effectiveness of its quality management system and its processes, as stated in its quality policy and objectives.

A management review is performed annually to evaluate the laboratory's quality management system, evaluation activities and CAPA. The laboratory develops an action plan to address required improvements on an annual basis and also monitors the effectiveness of the actions undertaken.

12.2 Quality indicators

The laboratories establish quality indicators bi-annually to monitor and evaluate the performance of its processes.

List of quality indicators include:

a) the traceability of the sample from the reception to the storage after testing;

b) the turn-around time (TAT) from reception of the sample to the hand-out of the report;

c) the reliability of the competence of the technical staff (average of test competency assessments for determined tests).

These indicators are regularly monitored for their concordance with the defined objectives and activities established in the laboratory. These indicators are presented during the annual RCDC management review.

12.3 Annual management review

To ensure that the organization and the activities of the centre remain appropriate and efficient, annual management review is conducted. This allows for evaluation and continuous improvement of efficiency of the quality system of all the laboratories. The elements reviewed are related to the quality management system.

Elements of entry of the management review consists of the following agenda:

a) quality objectives of the past year

b) quality indicators

c) occurrences and nonconforming events recorded

d) customer complaints reports

e) customer satisfaction survey reports and personnel feedback

f) internal audit reports

g) proficiency testing reports

h) CAPA and follow up

i) changes in work load or type of work

j) changes in internal and external issues that are relevant to the laboratory

k) suitability of policies and procedures

l) status of actions from previous management reviews

m) assessments by external bodies

n) effectiveness of any implemented improvements

o) adequacy of resources

p) results of risk identification

q) outcomes of the assurance of the validity of results

r) all pertinent factors: monitoring activities and training, future activities, etc.

Elements of output of the management review:

a) actions for improvement

b) definition of the quality objectives for the next year

c) establishment of new quality indicators in concordance with the new quality objectives

d) improvement of the quality management system.

12.4 Preventive action

The QA Team of the centre reviews the data and implements preventive actions allowing the laboratory to anticipate eventual nonconforming events in its activities. Nonconformities are discussed during staff meetings or as and when required.

12.5 Supporting documents

Table 10 : Supporting documents for QSE: Continual Improvement

Processes	**ID Code**
Quality indicators	**QSE/SOP-10.1/Fig-10.1**
Management review	**QSE/SOP-10.2/Fig-10.2**
Procedures	
Quality indicators (including management and use)	**RCDC/QMS/QSE/SOP-10.1**
Management review	**RCDC/QMS/QSE/SOP-10.2**
Forms/Logs	
Review logs	**QSE/SOP-10.2/Form-10.1**
Corrective and Preventive actions	**QSE/SOP-10.2/Form-10.2**

13. QSE-11: Documents and Records

13.1 Policy

The center ensures that documents and records are managed from creation and receipt to archival and destruction, according to the Evidence Act of Bhutan (2005).

13.2 Documentation management

The four levels of documentation are represented in the pyramid below :

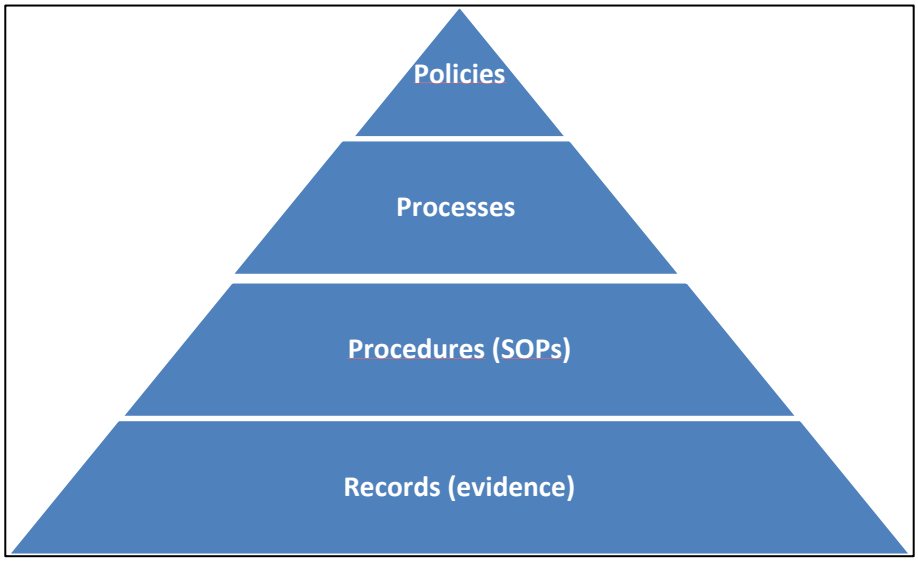

Figure 13 : Levels of document

a) The QA team reviews and Quality manager approves all requests for amendments to existing documents and the development of new procedures, processes and policies.

b) Staff is not permitted to make temporary amendments to documentation without the prior consent of the quality manager.

c) When new or modified policies, processes and procedures are instituted, staff requires re-training.

d) The quality manual and SOPs are reviewed every two years or as and when deemed necessary.

e) The QA focal person is responsible for reviewing, distribution of new documents, retrieval of old documents and maintenance of records of amendments.

13.3 Documents and records control

All documents are uniquely identified. Date of issue, revision, version, total number of pages and authorizing signatories are included in the document and are signed as a paper copy or authorized electronically.

A document control log is maintained identifying the current valid versions and their distribution. A secure master file is maintained of all documents to prevent unauthorized access, loss or damage.

13.4 Archiving

The QA focal person is responsible for the proper archiving of documents and records. The laboratory respects the Evidence Act of Bhutan (2005) concerning the retention time of all records. A copy of an obsolete document is kept to provide a means for review if the situation arises.

13.5 Supporting documents

Table 11 : Supporting documents for QSE: Documents and records

Processes	**ID Code**
Archive and retention of documents	**QSE/SOP-11.5/Fig-11.1**
Procedures	
SOP management	**RCDC/QMS/QSE/SOP-11.1**
Document management	**RCDC/QMS/QSE/SOP-11.2**
Short term archiving	**RCDC/QMS/QSE/SOP-11.3**
Long term archiving	**RCDC/QMS/QSE/SOP-11.4**
Document control	**RCDC/QMS/QSE/SOP-11.5**
Forms/Logs	
Document control log	**QSE/SOP-11.5/Form-11.1**

14. QSE-12: Information Management

14.1 Policy

The centre has access to the data and information needed to provide a service that meets the needs and requirements of internal and external customers. The Laboratory Information System (LIS) whether electronic or paper-based provides information for the collection, processing, recording, storage, and retrieval of data. The system has documented procedures in place to ensure the confidentiality of patient information and the security of the data during each step of the process.

14.2 Information system security

For computerized, the information management system used in the laboratory is managed by the Information Technology Division. This division is responsible for installing each computer with backup and antivirus system and has procedures in place to meet national and international requirements for data protection and to restrict unauthorized access.

For web based/online system, each user is provided with different access level and a unique user ID and password. For paper-based, appropriate measures should be put in place to ensure that all documents are protected from risk of damage by water, fire or animals. Procedures should be put in place to meet national and international requirements for data protection and to restrict unauthorized access.

14.3 Confidentiality

The personnel (temporary, permanent, student, etc.), whatever the duration of their contract signs a confidentiality agreement. The laboratory has a secure process for archiving and/or data disposal.

The laboratory is committed to maintaining confidentiality of technical record generated by the activities of the laboratory. The test report will be made available to relevant stakeholders only. The test reports for the samples received from private vendors shall be produced only to the respective customer and shall remain confidential. Worksheets/technical data shall be confidential to all stakeholders except for the accreditation and certification purpose.

The laboratory shall produce technical records to the court of law as and when required by informing the concerned customer.

Any information provided by the customer to the laboratory shall remain confidential. If the information is needed by another stakeholder, it shall be shared with prior approval from the customer.

All staff of the RCDC shall maintain confidentiality of any information obtained/created by the laboratory activities while acting on behalf of the laboratory except as required by the law.

14.4 Supporting documents

Table 12 : Supporting documents for QSE: Information Management

Processes	**ID Code**
Retrieval of data	**QSE/SOP-12.3/Fig-12.1**
Laboratory Information System (LIS)	**QSE/SOP-12.1/Fig-12.2**
Procedures	
LIS maintenance	**RCDC/QMS/QSE/SOP-12.1**
Back up	**RCDC/QMS/QSE/SOP-12.2**
Retrieval of data (manual or computerized)	**RCDC/QMS/QSE/SOP-12.3**
Forms/Logs	
LIS down-time log	**QSE/SOP-12.1/Form-12.1**
Backup log	**QSE/SOP-12.2/Form-12.2**

ANNEXURE 1: List of examinations performed in the laboratory

Table 13 : List of examinations performed in the laboratory

NON-INFECTIOUS DIVISION		
1. National Drug Testing Laboratory		
Sl. No.	**Test**	**Name**
1)	Physical	Uniformity of weight for tablets and capsules
2)		Disintegration test for tablets and capsules
3)		Friability test for uncoated tablets
4)		Identification by FTIR for tablets and capsules
5)		Identification by FTIR for Active pharmaceutical ingredients
6)		Sterility Test for parenterals
7)	Chemical	Dissolution test for tablets and capsules
8)		Assay by UV for tablets and capsules
9)		Assay by HPLC for tablets and capsules
10)		Assay by Titrimetry for tablets and capsules
11)		Content uniformity for tablets and capsules
2. National Water Reference Laboratory		
1)	Microbiology	Thermotolerant coliform
2)		Total Coliform
3)		E.Coli
4)		Biologiocal Oxygen Demand
5)	Physical	Conductivity
6)		Total Dissolved Solids
7)		pH
8)		Turbidity
9)	Chemical	Calcium hardness
10)		Magnesium hardness
11)		Alkalinity
12)		Available Chlorine
13)		Residual Chlorine
14)		Sulphate
15)		Nitrate

16)		Flouride
17)	Trace elements	Aluminium
18)		Selenium
19)		Cobalt
20)		Strontium
21)		Copper
22)		Chromium
23)		Iron
24)		Manganese
25)		Cadmium
26)		Arsenic
27)		Potassium
28)		Lead
29)		Zinc
30)		Molybdenum
31)		Magnesium
32)		Boron
33)		Nickle
34)		Barium
3.	**Food and Nutrition Laboratory**	
1)	Physical	Weight
2)		pH
3)		Water Content
4)	Indicator Organism	Total Plate Count
5)		Total Yeast/ Mould Count
6)		Environmental Listeria Count
7)		E. Coli Count
8)		Enterobacteriaceae Count
9)	Pathogenic Organism	Bacillus Species
10)		Staphylococcus Aureus
11)		Salmonella
12)		Shigella
13)		Aeromonas

14)		Plesiomonas
15)		Campylobacter
16)		Listeria monocytogenes
17)	PCR	E.Coli
18)	Anti-bacterial Sensitivity Test	
INFECTIOUS DIVISION		
4.	**Enteric Invasive Disease Laboratory**	
1)	Culture	Bacteriology Culture
2)	PCR	E.Coli
3)	Microscopic Agglutination Test	Leptospirosis
4)	ELISA	Rotavirus
5)		Astrovirus
6)		Adenovirus
7)		Norovirus
8)		Cryptosporidium
9)		Giardia landia
10)		Brucellosis
11)		Leptospirosis
12)		Dengue
13)		Chikungunya
14)		Japanese encephalitis
15)		Scrub typhus
16)		Leptospirosis
17)	Anti-bacterial Sensitivity Test	
18)	Microscopy	Malaria
5.	**Virology and Molecular Laboratory**	
1)	Molecular dectection and characterization of influenza virus	Influenza A, B
2)	Molecular detection and characterization of other respiratory virus	hMPV (Human metapeumovirus)

3)		RSV (Respiratory Syncytial Virus)
4)		Adenovirus
5)		Parainfluenzavirus 1 to 3
6)	Molecular dectection and characterization of infectious disease	MERS-CoV
7)		Zika virus
8)		Nipah virus
9)		KFD (Kyasanur Forest disease)
10)		SARS CoV-2
11)	Culture and identification	Influenza Virus
12)		
6.	**National Tuberculosis Reference Laboratory**	
1)	Culture	MTB
2)		1st line DST for MTB
3)		2nd line DST for MTB
4)		Microscopy
7.	**Infectious Disease and Serology Laboratory**	
1)	ELISA/RDT	Dengue
2)	ELISA/RDT	Chikungunya
3)	ELISA/RDT	Japanese encephalitis
4)	ELISA/RDT	Scrub typhus
5)	ELISA/RDT	Leptospirosis
6)	ELISA/RDT	HIV
7)	ELISA/RDT	Measles
8)	ELISA/RDT	Rubella
9)	ELISA/RDT	Bordetella pertussis
10)	ELISA/RDT	Human Anti-Herpes simplex virus Type 1 and 2
11)	ELISA/RDT	Hepatitis B
12)	ELISA/RDT	Hepatitis C

ANNEXURE 2: List of Standard Operating Procedures

A. NON-INFECTIOUS DIVISION

1. National Drug Testing Laboratory

Sl. No.	Name	SOP No.
1.	Analytical Balance	RCDC/NDTL/SOP- 01
2.	Careful Handling of Poisonous Chemicals	RCDC/NDTL/SOP- 02
3.	Centrifuge Kubota	RCDC/NDTL/SOP- 03
4.	Handling and Storage of Reagents/Chemicals	RCDC/NDTL/SOP- 04
5.	Cleaning of Quality Control Laboratory	RCDC/NDTL/SOP- 05
6.	Disintegration Test	RCDC/NDTL/SOP- 06
7.	Dissolution Apparatus	RCDC/NDTL/SOP- 07
8.	Friability Test of Uncoated Tablets	RCDC/NDTL/SOP- 08
9.	Good Laboratory Practice	RCDC/NDTL/SOP- 09
10.	Handling of Glass wares	RCDC/NDTL/SOP- 10
11.	Handling Spillages	RCDC/NDTL/SOP- 11
12.	Handling of Out of Specification(OOS) and Deviations	RCDC/NDTL/SOP- 12
13.	pH meter	RCDC/NDTL/SOP- 13
14.	Preparing Volumetric Solutions	RCDC/NDTL/SOP- 14
15.	Registration of Samples	RCDC/NDTL/SOP- 15
16.	Sonicator	RCDC/NDTL/SOP- 16
17.	Tablet Hardness Tester	RCDC/NDTL/SOP- 17
18.	Unusual Observation for Instrument during Calibration	RCDC/NDTL/SOP- 18
19.	UV-Visible Spectrophotometer(Perkin Elmer)	RCDC/NDTL/SOP- 19
20.	Washing of Glass wares	RCDC/NDTL/SOP- 20
21.	Water Bath	RCDC/NDTL/SOP- 21
22.	CAPA(corrective and Preventive Action)	RCDC/NDTL/SOP- 22
23.	Sample Collection	RCDC/NDTL/SOP- 23
24.	Sample Retention	RCDC/NDTL/SOP- 24
25.	Handling of Complaint	RCDC/NDTL/SOP- 25

Sl. No.	Name	SOP No.
26.	Change Control	RCDC/NDTL/SOP- 26
27.	Training of Staffs	RCDC/NDTL/SOP- 27
28.	Self Inspections/Internal Audit	RCDC/NDTL/SOP- 28
29.	Disposal of Used Reagent/Test Residue	RCDC/NDTL/SOP- 29
30.	Preparation of worksheet	RCDC/NDTL/SOP- 30
31.	Handling and Storage of References	RCDC/NDTL/SOP- 31

2. National Water Reference Laboratory

Sl. No.	Name	SOP No.
1.	Water sample collection for microbiological analysis	RCDC/NWRL/SOP/01
2.	Water sample collection for physiochemical analysis	RCDC/NWRL/SOP/02
3.	Water sample transportation	RCDC/NWRL/SOP/03
4.	Turbidity using HANNA turbidity meter	RCDC/NWRL/SOP/04
5.	Turbidity using LUTRAN turbidity meter	RCDC/NWRL/SOP/05
6.	pH using HANNA pH meter	RCDC/NWRL/SOP/06
7.	Delagua water testing kit	RCDC/NWRL/SOP/07
8.	Thermotolerant coliform	RCDC/NWRL/SOP/08
9.	Testing odor in drinking water	RCDC/NWRL/SOP/09
10.	Measuring residual chlorine using DPD-1 & color comparator	RCDC/NWRL/SOP/10
11.	Conductivity, TDS & Temperature of drinking water using HACH conductivity/TDS meter	RCDC/NWRL/SOP/11
12.	Acidity	RCDC/NWRL/SOP/12
13.	Alkalinity	RCDC/NWRL/SOP/13
14.	Arsenic using HACH low range arsenic test kit	RCDC/NWRL/SOP/14
15.	Digestion using DIGESDHALdigestion apparatus	RCDC/NWRL/SOP/15
16.	Fluoride using HACH DR 5000 spectrophotometer	RCDC/NWRL/SOP/16
17.	Sulfate using HACH DR 5000	RCDC/NWRL/SOP/17

Sl. No.	Name	SOP No.
	spectrophotometer	
18.	Total, CALCIUM & MAGNESIUM Hardness	RCDC/NWRL/SOP/18
19.	BIBBY STERILIN DIGITAL BURETTE	RCDC/NWRL/SOP/19
20.	GFL WATER DISTILLATION PLANT	RCDC/NWRL/SOP/20
21.	REFRIGERATOR SAMSUNG RT-26M	RCDC/NWRL/SOP/21
22.	TITRETTE BOTTLE TOP-BURETTE	RCDC/NWRL/SOP/22
23.	SHIMADZU WEIGHING BALANCE TXB 622L	RCDC/NWRL/SOP/23
24.	COLLECTION OF CHLORINE TREATED WATER USING SODIUM THIOSULFATE	RCDC/NWRL/SOP/24

3. Food and Nutrition Laboratory

Sl. No.	Name	SOP No.
1.	Standard Operating Procedure for Gram Straining	RCDC/FNL/SOP-02
2.	Standard Operating Procedure for Total Plate Count in Food Samples	RCDC/FNL/SOP-03
3.	Standard Operating Procedure for Counting of *Yeast&Mould* in Food Samples	RCDC/FNL/SOP-04
4.	Standard Operating Procedure for Detection and Identification of *Aeromonas spp.* and *Plesiomonas spp.*	RCDC/FNL/SOP-05
5.	Standard Operating Procedure for Detection and Identification of *Camphylobacter spp.* from Food Samples	RCDC/FNL/SOP-06
6.	Standard Operating Procedure for Detection and Enumeration of Coliforms by Most Probable Number Method	RCDC/FNL/SOP-08
7.	Standard Operating Procedure for Detection and Enumeration of *Listeria monocytogenes*	RCDC/FNL/SOP-10
8.	Standard Operating Procedure for Detection and Identification of *Salmonella spp.* from Food Samples	RCDC/FNL/SOP-11
9.	Standard Operating Procedure for Identification of *Shigella* species	RCDC/FNL/SOP-12

Sl. No.	Name	SOP No.
10.	Standard Operating Procedure for Detection and Identification of *Vibrio spp.* in Food Samples	RCDC/FNL/SOP-13
11.	Standard Operating Procedure for Detection and Identification of *Staphylococcus aureus* from Food Samples	RCDC/FNL/SOP-14
12.	Standard Operating Procedure for Detection and Identification of *Bacillus cereus*	RCDC/FNL/SOP-15
13.	Standard Operating Procedure for Air Sampler	RCDC/FNL/SOP-20
14.	Standard Operating Procedure for Use of Blender in Food	RCDC/FNL/SOP-21
15.	Standard Operating Procedure for Use of Refractometer in Food Laboratory	RCDC/FNL/SOP-22
16.	Standard Operating Procedure for Hot Plate	RCDC/FNL/SOP-23
17.	Standard Operating Procedure for Vortex	RCDC/FNL/SOP-24
18.	Standard Operating Procedure for Micropipettes	RCDC/FNL/SOP-25
19.	Standard Operating Procedure for Water Bath	RCDC/FNL/SOP-26
20.	Standard Operating Procedure for Double Door Refrigerator	RCDC/FNL/SOP-27
21.	Standard Operating Procedure for Analytical balance	RCDC/FNL/SOP-29
22.	Standard Operating Procedure for pH Meter	RCDC/FNL/SOP-31
23.	Standard Operating Procedure for Operation & Maintenance of STOMACHER® 400 Circulators	RCDC/FNL/SOP-32
24.	Standard Operating Procedure for Spectrophotometer	RCDC/FNL/SOP-33
25.	Standard Operating Procedure for Compound Light Microscope (Olympus)	RCDC/FNL/SOP-34
26.	Standard Operating Procedure for Biological Safety Cabinet Class II (ESCO)	RCDC/FNL/SOP-35
27.	Standard Operating Procedure for Autoclave (Tomy ES-215)	RCDC/FNL/SOP-36
28.	Standard Operating Procedure for Gel	RCDC/FNL/SOP-37

Sl. No.	Name	SOP No.
	Water Distiller	
29.	Standard Operating Procedure for Moisture Analyzer	RCDC/FNL/SOP-38

B. INFECTIOUS DIVISION

1. Enteric Invasive Disease Laboratory

Sl. No.	Name	SOP No.
1.	ABST	RCDC/EIDL/SOP/01
2.	Agarose Gel Electrophroesis	RCDC/EIDL/SOP/02
3.	API 20E	RCDC/EIDL/SOP/03
4.	Blood Culture	RCDC/EIDL/SOP/04
5.	Catalase Test	RCDC/EIDL/SOP/05
6.	Citrate Utilization test	RCDC/EIDL/SOP/06
7.	E.coli DNA extraction (Boiling Lysis)	RCDC/EIDL/SOP/07
8.	Gram Staining	RCDC/EIDL/SOP/08
9.	Hydrogen Sulphide Production Test	RCDC/EIDL/SOP/09
10.	Hippurate Test	RCDC/EIDL/SOP/10
11.	Indole Test	RCDC/EIDL/SOP/11
12.	Internal Quality Control	RCDC/EIDL/SOP/12
13.	Identification of Camphylobacter spp	RCDC/EIDL/SOP/13
14.	MR-VP test	RCDC/EIDL/SOP/14
15.	Oxidase Test	RCDC/EIDL/SOP/15
16.	Salmonella slide aggluting test	RCDC/EIDL/SOP/16
17.	Shigella Slide agglutining test	RCDC/EIDL/SOP/17
18.	Sterility Testing Autoclave Tomy (SX-700)	RCDC/EIDL/SOP/18
19.	Urease test	RCDC/EIDL/SOP/19
20.	Media & Reagent Preparation	RCDC/EIDL/SOP/20
21.	Leptospirosis Microscopy Agglutination Test	RCDC/EIDL/SOP/21
22.	Weighing Balance (Metler Toledo)	RCDC/EIDL/SOP/23
23.	Water Bath GRANT)	RCDC/EIDL/SOP/24
24.	GFL Water Distiller	RCDC/EIDL/SOP/25

Sl. No.	Name	SOP No.
25.	Operation, Care na d Maintenance of Pipette	RCDC/EIDL/SOP/26
26.	Uprite Freezer (Thermoscientific)	RCDC/EIDL/SOP/27
27.	Refrigerator (Snowland)	RCDC/EIDL/SOP/28
28.	Refrigerator (Sanden)	RCDC/EIDL/SOP/28
29.	Incubator(Memmert)	RCDC/EIDL/SOP/29
30.	Microwave Oven (Sanyo)	RCDC/EIDL/SOP/30
31.	Ultra violet PCR Cabinet (UVP)	RCDC/EIDL/SOP/33
32.	Thermal Cycler (T100) Bio-RAD	RCDC/EIDL/SOP/34
33.	Thermal Cycler Piko 24	RCDC/EIDL/SOP/35
34.	Microcentrifuge (Miko)	RCDC/EIDL/SOP/38
35.	Biosafety Cabinet Class II Type A (ESCO)	RCDC/EIDL/SOP/39
36.	pH Meter (Schott Lab 850)	RCDC/EIDL/SOP/40
37.	EMJH Media Preparation	RCDC/EIDL/SOP/41

2. Virology and Molecular Laboratory

Sl. No.	Name	SOP No.
1.	Respiratory specimen collection for Influenza testing	RCDC/VML/SOP/01
2.	SOP for sample Reception,verification, Rejection, Processing and storage	RCDC/VML/SOP/02
3.	RNA extraction using QIAmp viral RNA mini Kit	RCDC/VML/SOP/03
4.	Detection and characterization of Influenza virus by rRT-PCR	RCDC/VML/SOP/04
5.	Flu PCR result entry into the database and report dissemination.	RCDC/VML/SOP/05
6.	Storage, Packaging and transportation of Influenza specimen from sentinel sites to RCDC	RCDC/VML/SOP/06
7.	SOP sample shipment to reference lab (AFRIMS)	RCDC/VML/SOP/07
8.	Preparation of Reagents (cell culture)	RCDC/VML/SOP/08
9.	Propagation of MDCK cell lines	RCDC/VML/SOP/09
10.	Respiratory virus isolation using MDCK cell lines	RCDC/VML/SOP/10

Sl. No.	Name	SOP No.
11.	Hemaggutination test (HA)	RCDC/VML/SOP/11
12.	Hemagglutination inhibition (HAI) assay for viral antigen subtyping and serological testing of Influenza samples	RCDC/VML/SOP/12
13.	Dengue Nested PCR	RCDC/VML/SOP/13
14.	TrioPlex PCR	RCDC/VML/SOP/14
15.	Detection and characterization for Nipah virus by rRT-PCR	RCDC/VML/SOP/15
16.	Detection and characterization for KFD virus by rRT-PCR	RCDC/VML/SOP/16
17.	Detection and characterization for CCHF virus by rRT-PCR	RCDC/VML/SOP/17
18.	Detection and characterization for parecho virus by rRT-PCR	RCDC/VML/SOP/18
19.	Detection and characterization for Hanta virus by rRT-PCR	RCDC/VML/SOP/19
20.	MERS CoV PCR using ALTONA kit	RCDC/VML/SOP/20
21.	Auto extraction kit	RCDC/VML/SOP/21
22.	Equipment Calibration	RCDC/VML/SOP/22
23.	Operation and maintenance of Rotor-Gene™	RCDC/VML/SOP/23
24.	Operation and maintenance of ABI	RCDC/VML/SOP/24
25.	Operation and maintenance of Biosafety cabinet Nu Air	RCDC/VML/SOP/25
26.	Operation and maintenance of Biosafety cabinet Esco	RCDC/VML/SOP/26
27.	Operation and maintenance of Thermocycler	RCDC/VML/SOP/27
28.	Centrifuge (ALL)	RCDC/VML/SOP/28
29.	PCR hood	RCDC/VML/SOP/29
30.	water bath (All)	RCDC/VML/SOP/30

3. National Tuberculosis Reference Laboratory

Sl. No.	Name	SOP No.
1.	1st Line DST (solid)	PHL/NTRL/SOP-01
2.	MTB culture (solid)	PHL/NTRL/SOP-02
3.	Microscopy examination	PHL/NTRL/SOP-03
4.	Catalase test	PHL/NTRL/SOP-04

Sl. No.	Name	SOP No.
5.	Nitrate reduction test	PHL/NTRL/SOP-05
6.	Preparation of LJ media	PHL/NTRL/SOP-06
7.	LJ plain and drug media preparation	PHL/NTRL/SOP-07
8.	ZN reagent preparation	PHL/NTRL/SOP-08
9.	Preparation of panel sample for Gene-expert-MTB/RIF EQA	RCDC/NTRL/SOP-01
10.	Entry and Exit in BSL-3	RCDC/BSL-3/SOP-01
11.	TB sample flow in BSL 3	RCDC/BSL-3/SOP-02
12.	Waste flow inside BSL 3	RCDC/BSL-3/SOP-03
13.	DNA extraction of MTB	RCDC/NTRL/SOP-14
14.	Identification of MTB	RCDC/NTRL/SOP-06
15.	DST by MGIT 960	RCDC/NTRL/SOP-16

4. Infectious Disease and Serology Laboratory

Sl. No.	Name	SOP No.
1.	Dengue NS1-Panbio	RCDC/IDSL/SOP/01
2.	Centrifuge- Kubota 5200	RCDC/IDSL/SOP/02
3.	Dengue IgM capture ELISA Panbio	RCDC/IDSL/SOP/03
4.	Dengue IgM capture ELISA Inbios	RCDC/IDSL/SOP/04
5.	Chickungunya IgM ELSIA	RCDC/IDSL/SOP/05
6.	JE IgM ELISA-Inbios	RCDC/IDSL/SOP/6
7.	Vortex mixer	RCDC/IDSL/SOP/7
8.	Rotatest Shaker R100	RCDC/IDSL/SOP/8
9.	Waterbath- Memmert	RCDC/IDSL/SOP/09
10.	HIV Ag/Ab ELISA-Genscreen	RCDC/IDSL/SOP/10
11.	HIV Serodia-agglutination	RCDC/IDSL/SOP/11
12.	Leptospirosis IgM-SD ELISA	RCDC/IDSL/SOP/12
13.	Scrub typhus IgM-Inbios	RCDC/IDSL/SOP/13
14.	Bordetella pertussis- IgM-Novalisa	RCDC/IDSL/SOP/14
15.	HSV-IgM Human ELISA	RCDC/IDSL/SOP/15
16.	Varicella Zoster IgM-Human ELISA	RCDC/IDSL/SOP/16
17.	HBsAg-Murex	RCDC/IDSL/SOP/17
18.	Surface/ Equipment disinfection	RCDC/IDSL/SOP/18

Sl. No.	**Name**	**SOP No.**
19.	Innotest HCV AB	RCDC/IDSL/SOP/19
20.	Autoclave-Tomy ES-315	RCDC/IDSL/SOP/20
21.	Bio-safety cabinet class II (ESCO)	RCDC/IDSL/SOP/21
22.	Automated microplate reader	RCDC/IDSL/SOP/22
23.	HBsAg confirmatory- Murex	RCDC/IDSL/SOP/23
24.	DBS for Measles IgM antibody	RCDC/IDSL/SOP/24
25.	Anti measles-IgM-Euroimmune	RCDC/IDSL/SOP/25
26.	Anti rubella-IgM- Euroimmune	RCDC/IDSL/SOP/26