LABORATORY QUALITY MANAGEMENT MANUAL

version 5 2026

LABORATORY SERVICES UNIT

NATIONAL CENTRE FOR ANIMAL HEALTH, BHUTAN

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Acknowledgment

The quality manual has been developed by the following AMR Technical Working Group (TWG) for Animal Health during June 2022 as follows:

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2. Dr. N. Dahal — Technical Working Group, Chair
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i. Abbreviation

BSL	Biosafety Level
CLSI	Clinical and Laboratory Standards Institute, Wayne, Pennsylvania, USA
EQA	External Quality Assurance
NEQAS	National External Quality Assurance System
IQAS	Internal Quality Assurance System
IATA	International Air Transport Authority
ISO	International Organization for Standardization
LIMS	Laboratory Information Management System
LQM	Laboratory Quality Manual
QC	Quality Control
SOP	Standard Operating Procedure
WHO	World Health Organization
NCAH	National Centre for Animal Health
LSU	Laboratory Services Unit
CLSI	Clinical and Laboratory Standard Institute
WOAH	World Organisation for Animal Health
BCSR	Bhutan Civil Service Rules and Regulations
BAFRA	Bhutan Agriculture and Food Regulatory Authority
BFDA	Bhutan Food & Drug Authroity
NCD	Nature Conservation Division
DoFPS	Department of Forest and Park Services
HRD	Human Resource Division

i. Approval

This Laboratory Quality Management System manual defines the policies and objectives with respect to implementation of the requirements of ISO/IEC 17025: 2017 Standard. This is being approved for implementation at the laboratory services unit (LSU) at National Centre for Animal Health (NCAH) and can be adopted at other veterinary laboratory in the country. All the personnel working at the veterinary laboratory have understood and implemented the policies as laid down in this manual.

After this initial approval, for any further amendments, the Program Director, NCAH and Head, LSU is authorized to approve required amendments.

Signature

ii. Amendment list

Sl no	Amendment	Clause	Reason	Date	Signature

iii. Quality policy

1. To comply with ISO/IEC 17025 standards at all times of laboratory testing
2. To achieve excellence in delivery of laboratory diagnostic services in the country.
3. The laboratory is committed to continual improvement, meeting internal requirements and client's requirements, and providing a basis for the establishment and review of the quality objectives.
4. Quality practices are communicated within the organization, understood and adhered to by all laboratory personnel.
5. Enhance and improve public service delivery as prescribed in BCSR 2018.

iv. Animal welfare

The laboratory activities shall comply with relevant sections of animal welfare prescribed in Livestock Act of Bhutan 2001, Livestock Rules and Regulations 2017 and relevant international regulations. It is also essential to fully understand the national legislation governing the ethical use of animals and put in place the processes to ensure compliance. An institutional animal ethics committee, with external representation, is recommended.

National Centre for Animal Health, Serbithang is also committed to conform to all the relevant National and International Standards while implementing the Laboratory Quality Management System as per ISO/IEC17025: 2017.

Signature

v. Quality objective

1. Provide accurate, consistent and efficient diagnostic and analytical results.
2. Maintain integrity and confidentiality of Analytical Reports.
3. Enhance technical knowledge and skills of the laboratory personnel to improve and enhance their competency.
4. Demonstrate the technical competence of the laboratory by participation in Proficiency Testing (PT) and Inter-laboratory Comparison (ILC) programs.
5. Continually upgrade & improve testing facilities with state-of-the-art equipment.

Signature

vi. Introduction

The National Centre for Animal Health (NCAH), Serbithang is the apex body for all animal health activities in the country and is responsible for animal disease diagnosis, disease surveillance, disease prevention and control programs, and providing technical backstopping to regional, districts and livestock commodity centers. The center also caters the diagnostic support services to other agencies such as Bhutan Food and Drug Authority (BFDA) and Nature Conservation Division (NCD) under the Department of Forest and Park Services (DoFPS). The Laboratory Services Unit (LSU) is one of the technical units under the NCAH and is mandated to provide routine and referral laboratory diagnostic services for detection of animal diseases including zoonotic diseases.

This quality manual is developed in compliance with the laboratory quality and accreditation standards of **ISO/IEC 17025: 2017- General requirements for the competence of testing and calibration laboratories.** This document is intended for implementing a quality management system for the purpose of an efficient use of its resources and to provide consistent and effective laboratory diagnostic services. It also aims primarily at achieving client's satisfaction through providing accurate, reliable and timely results. It involves continuous improvement of the system with identification of nonconformities and opportunities for improvement, recording these instances so that corrective and preventive actions can be taken to ensure quality service delivery.

vii. Quality policy

The NCAH 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 laboratory service unit at NCAH is committed to improvement, meeting internal requirements and stakeholder 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 a competent workforce to deliver quality results in a timely manner according to the ISO 17025:2017 (Standard for Testing and Calibration laboratories).

1. Scope

This quality manual elucidates the quality management system of the LSU at NCAH and other veterinary Laboratory in Bhutan. For internal use, the document is used to communicate to the staff about 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. For external use**,** it is used to inform the external stakeholders about its quality policy as well as its implemented quality management system and measures of compliance with quality.

2. Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document.

1. International standard, ISO/IEC 17025:2017 General competence for testing and calibration laboratories.
2. National Food Testing Laboratory, Bhutan Agriculture and Food Regulatory Authority, Quality Manual, 2023
3. Management of Veterinary Diagnostic Laboratories WOAH (OIE) Terrestrial Manual 2021 Chapter 1.1.1, 1.1.5.
4. Quality Management in Veterinary Testing Laboratories. In WOAH (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 2018.
5. Quality Manual, South Dakota State University, Animal Disease Research and Diagnostic Laboratory 2017.
6. Quality Management System, A model for laboratory services; approved guideline-fourth edition, Clinical and Laboratory Standard Institute (CLSI), 2011.
7. Livestock Act of Bhutan 2001 and Livestock Rules and Regulations 2017.
8. Accreditation Scheme for Laboratories, Technical Guide 4: A Guide on Measurement Uncertainty in Medical Testing. Technical Guide 4, 29 March 2019

9. Quality Manual, Royal Centre for Disease Control. 2020
10. WOAH (OIE) Terrestrial Manual . 2018. Chapter 1.1.2 Collection, submission and storage of diagnostic specimens,
11. Clinical Microbiology Laboratory Quality Manual. 1st Edition. As per ISO 15189: 2012. Jigme Dorji Wangchuk National Referral Hospital.

3. Terms and definitions

The following definitions are applicable for the purpose of the quality manual.

Client: An entity (e.g., person or animal owner, co-operative, agency, organization, etc.) receiving a report for the test performed as per the applicable requirements.

Specimen: A material collected or submitted by a client for testing, e.g., Serum

Sample: A material that is obtained from a specimen to be used for testing purposes.

Record: Written materials that provide proof of compliance with the quality system and evidence that a specified activity has been performed. Records may be in the form of a paper copy or electronic format and should be attributable to an individual.

Continuous improvement: A set of recurring activities carried out in order to enhance its ability to meet requirements. Some of these activities may include audits, management reviews, corrective and preventive actions, analyzing data and setting objectives.

Document: Any information or instruction, in any format or medium that has direct bearing on or effect on the quality of test results (e.g. quality manual, policy, test procedure, work instructions, forms, etc.

WOAH/OIE: Standard Quality Management in Veterinary Testing Laboratories. Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. OIE publication.

Policy: A written statement of overall intentions and directions defined and endorsed by DoL to achieve a specific goal.

Procedures: A specified way to perform a laboratory activity. NCAH test methods are written as Standard Operating Procedures (SOPs).

Process: One or more interrelated resources and/or activities that transform inputs (ex. policies, samples) into outputs (ex. procedures, reports).

Quality: Quality means fitness for purpose. The diagnostic service provided must be fit for its purpose. To be fit for purpose, the diagnostic service must meet client expectations and be efficient in terms of diagnostic performance.

Quality assurance: Planned and systematic activities to provide adequate confidence that test or testing activity conforms to established technical requirements.

Quality control: Operational techniques and activities that are used to ensure that quality standards are being met.

Quality management: An entity that determines quality policy, objectives, procedures and responsibilities of the lab personnel.

Quality policy: General statement of its beliefs about quality, how quality will come about and its expected result. It defines top management's commitment to quality and describes its basic intent.

Quality System (QS): The organizational structure, resources, policies, processes, and procedures needed to implement objectives of quality management.

4. General requirements

4.1 Impartiality

a. The NCAH management is committed to impartiality and ensures that the veterinary laboratory personnel and services provided are free from any commercial/financial or any other similar pressures.
b. The management ensures declaration of conflict-of-interest during procurement by the various levels of committees for purchase of goods and services e.g., calibration, consumables of laboratory media, reagents, equipment, etc. government procurement rules will apply.
d. The management ensures impartial recruitment of the laboratory personnel/officials through open competition and selection by the various committees for the vacant post. Management will support the Human Resource Division (HRD) of Ministry of Agriculture and Livestock and Royal Civil Service Commission (RCSC) for the selection as per the Chapter 5, Recruitment, Selection and Appointment of Civil Service Act 2010 of the RCSC.

4.2 Confidentiality

The details of the laboratory activities and the results are confidential and can be accessible in the Laboratory Information Management System (LIMS) database only by authorized laboratory officials with encrypted user defined roles.

5. Structural requirements

5.1 National Centre for Animal Health (NCAH)

NCAH is located at Serbithang, Thimphu, established in accordance with the Livestock Bill of Bhutan, 2023. It is the legally identifiable national apex body headed by the Program Director. The address to NCAH is:

Laboratory Service Unit
National Centre for Animal Health
Department of Livestock
Ministry of Agriculture and Livestock
Serbithang, Thimphu
PB: 155
Phone: +975-02-351083
Fax: +975-02-351095
Email: ncah@moal.gov.bt
https://ncah.gov.bt

5.2 Organogram

The organogram of the LSU at NCAH, the management and technical operating structure is provided below (fig 1):

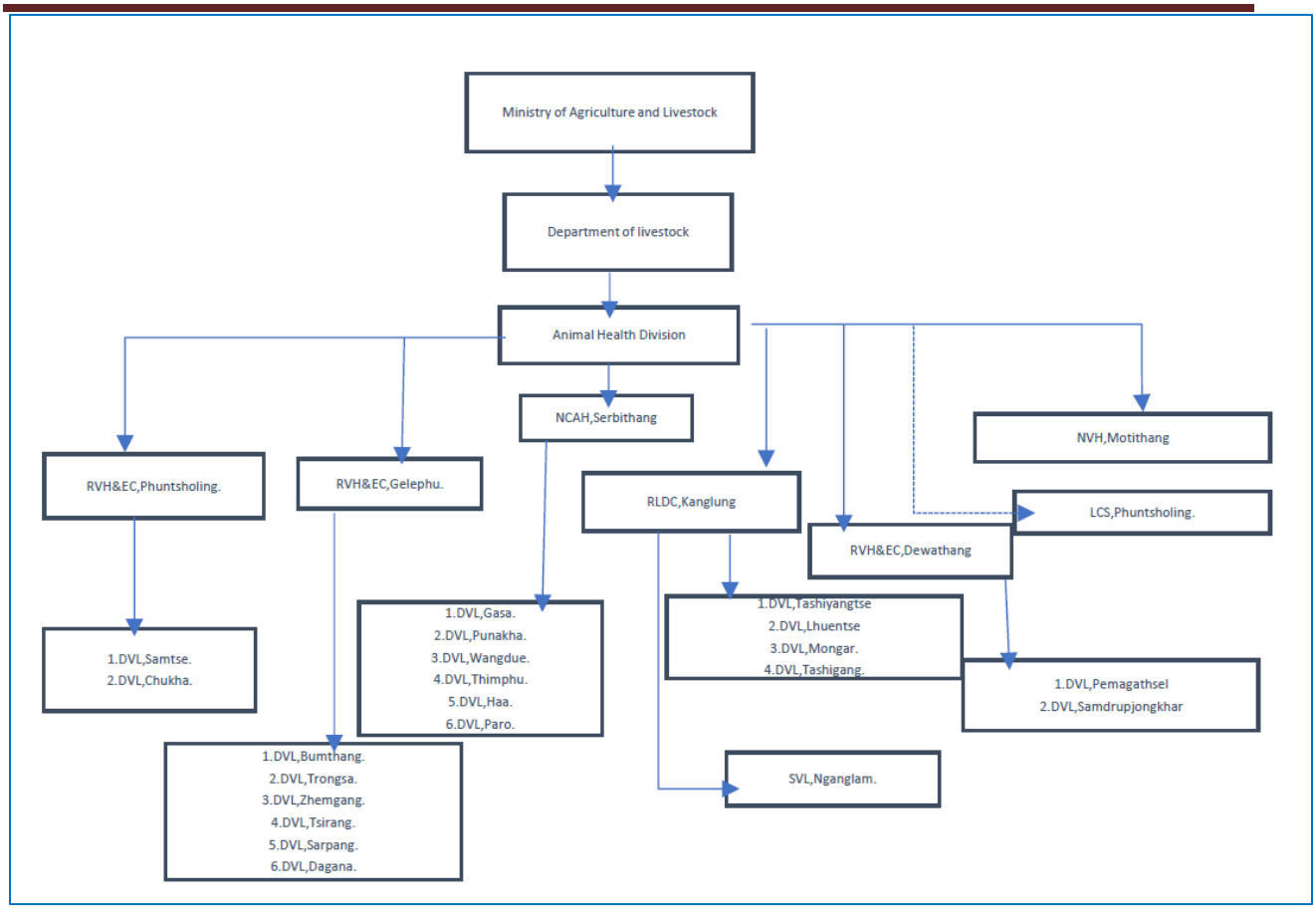


Fig. 1 Organogram

The laboratory organization organogram in the country and linkages of LSU, the relationship between the different levels of laboratory setting, technical operations and support services is provided below.

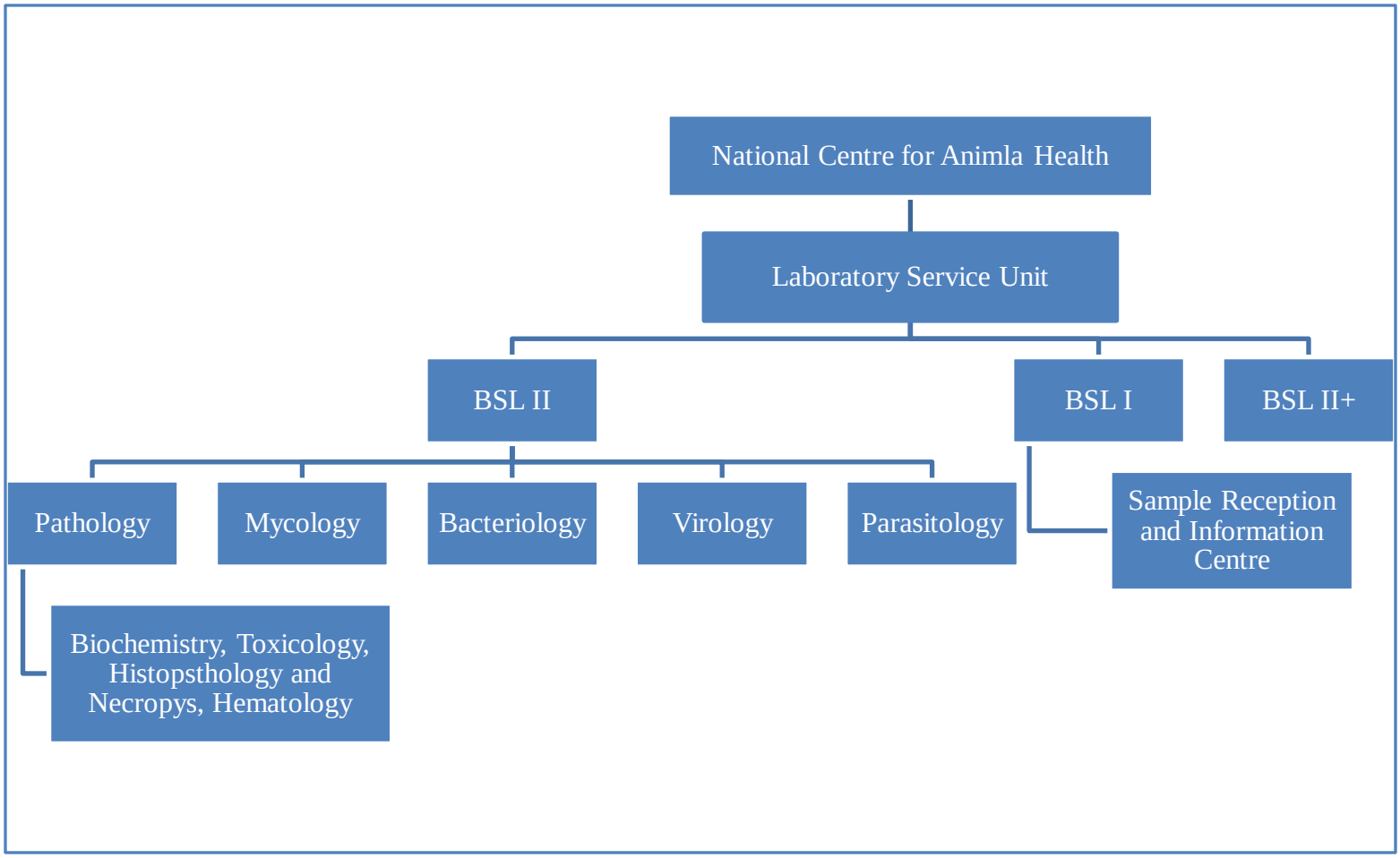


Fig. 2 Linkage of LSU

5.3 Structure

Laboratory activities are carried out in BSL I and BSL II plus laboratories. The activities are carried out as per the requirements of this document, the laboratory's clients, regulatory authorities and organizations providing recognition. The overall structure is managed administratively by the Program Director assisted by the laboratory head supervising all the activities in the laboratory unit (fig 2). Further, each laboratory section is led by laboratory incharges and supported by laboratory personnel such as laboratory technicians and attendants. The laboratory unit at NCAH has following testing capacities and facilities.

a. Pathology Section (Biochemistry/Toxicology, Hematology, Necropsy/Histopathology)

b. Bacteriology
c. Mycology
d. Virology
e. Parasitology
f. Laboratory Information Management System (LIMS)

5.4 Responsibility

The Laboratory Services Unit (LSU), one of the technical units under the NCAH caters both the routine and referral laboratory diagnostic services for animal diseases including zoonosis in the country. In addition, it also carries out laboratory-based research and surveillance. LSU carries out all the above activities through the facilities of bio-safety level 1 and 2 plus laboratories for safe handling and processing of high-risk pathogens in the laboratory. In addition, the unit is also responsible for implementing, monitoring and evaluating Bio-safety activities in the veterinary laboratories in the country. The lab also serves as the national referral lab for the Antimicrobial Resistance (AMR) in animal health.

6. Resources

6.1 General

The LSU has the required and competent personnel (veterinarian, laboratory technologist, technician and reliable infrastructure (BSLl) with designated and sufficient space, equipment and facilities to ascertain quality and safety procedures and support services to ensure quality diagnostic testing.

6.2 Personnel – education qualification and competency

I. NCAH in consultation with the DoL and the Ministry of Agriculture & Livestock has defined educational requirements. Bachelor/Masters/PhD in Veterinary Science/ Laboratory technology/Microbiology/Biotechnology for the Laboratory Head. Bachelor/Masters in Laboratory technology/Microbiology/Biotechnology for laboratory officers and diploma in laboratory technology for laboratory technicians.

II. The Human Resource Management Division of the Ministry of Agriculture & Livestock and the RCSC verifies educational qualifications prior to employment as per the Civil Service Act 2010 of the RCSC.

III. LSU maintains the individual administrative files for each staff member (temporary, permanent and trainee) that contains documents concerning qualifications. Additional documents such as training records, continuing education and job description, corrective actions are maintained by LSU. File No.4(25)NCAH/LSU- Non staff administrative file

IV. NCAH in consultation with the Department of Livestock and the Ministry of Agriculture & Livestock in collaboration with relevant agencies will provide training for all laboratory personnel which includes the quality management system, laboratory processes and procedures, the laboratory information management system, health and safety, ethics and confidentiality.

V. All laboratory personnel will be provided with the opportunity for continuous education and training identified in Competency Based Framework (CBF) for Veterinary Officers 2021 of the Department of Livestock, administered by RCSC.

VI. New, non-permanent staff such as students and attaches are being oriented on general laboratory procedures for integration in the laboratory.

VII. The staff performs duties based on specific terms of reference and as assigned by the laboratory management for individual laboratory personnel as per the Position Directory 2018 and job description of the RCSC. File No. 4(12)NCAH/LSU- TOR for laboratory staff

A. Laboratory Director/Manager/Head

1. Designs, implements and maintains the quality management system in the laboratory
2. Proposes the necessary human and material resources, as well as the necessary information and make available to enable effective operation and control of the processes of the quality management system.
3. Delegates tasks to qualified or competent personnel.

4. Evaluate and select the suppliers as per procurement rules and regulations.
5. Propose and manages contracts for suppliers.
6. Identity and propose training needs.
7. Verify the laboratory test results and communicate to laboratory officers and technicians

B. Quality manager

1. Assesses the facilities, procedures, practices, and training of personnel involved in the laboratory's activities, in regard to the quality management system.
2. Reviews the quality plan annually and recommends any revisions needed to the laboratory's director/manager.
3. Seeks advice from different units/sections and specialists and also independent experts as and when required.
4. Carry out an internal audit program in consultation with the laboratory director/manager/head and discuss audit findings.
5. Ensures that the quality management system is managed and maintained at all times.
6. Establishes and monitors all processes and procedures for the quality management system.
7. Resolves or seeks assistance for nonconformities.
8. Ensures that follow up action is taken for continuous improvement of processes/activities.
9. Ensures all staff have up-to-date QMS training.

C. Biosafety Officer

1. Ensures that all the biosafety and biosecurity measures are in place.
2. Proposes and ensure all the materials required for biosafety are available.
3. Proposes and ensure all the structures required for biosafety are available.
4. Plan and carry out internal auditing.
5. Advise on the risk assessment for all the proposed work with biological agents and the development of codes of practice.
6. Advise on waste disposal policy and arrangements.

D. Reporting & Monitoring Officer

1. Ensure all the information are received or passed efficiently
2. Manage all the information pertaining to the laboratory
3. Ensures the laboratory results are dispatched on time
4. Ensures the samples received are dispatched to respective sections for timely tests and reporting.

6.3 Facilities and environmental conditions

a. Facilities

The LSU at NCAH provides adequate space/rooms, and reliable infrastructure each designated for specific purposes and to ensure quality, safety and efficacy of the services provided and to meet the national safety regulations. The laboratories have clear demarcation with appropriate signage and areas restricted to authorized personnel.

The laboratory building has two storied (Figure 1). The ground floor consists of an entrance with a sample reception and information sharing room. It has the sample reception desk and information sharing facilities for result dissemination. The ground floor also houses laboratories of parasitology, biochemistry and toxicology, histopathology and hematology laboratory sections. This laboratory has BSL1 facilities.

The first floor has BSL 2 plus laboratory facilities with Serology, virology, molecular biology and bacteriology and mycology.

The center has a three tier security system. First, at the main entrance with restricted vehicle access, second, at the entrance of the main building with a card access system and third, at the respective designated laboratory. The building has also designated one emergency exit.

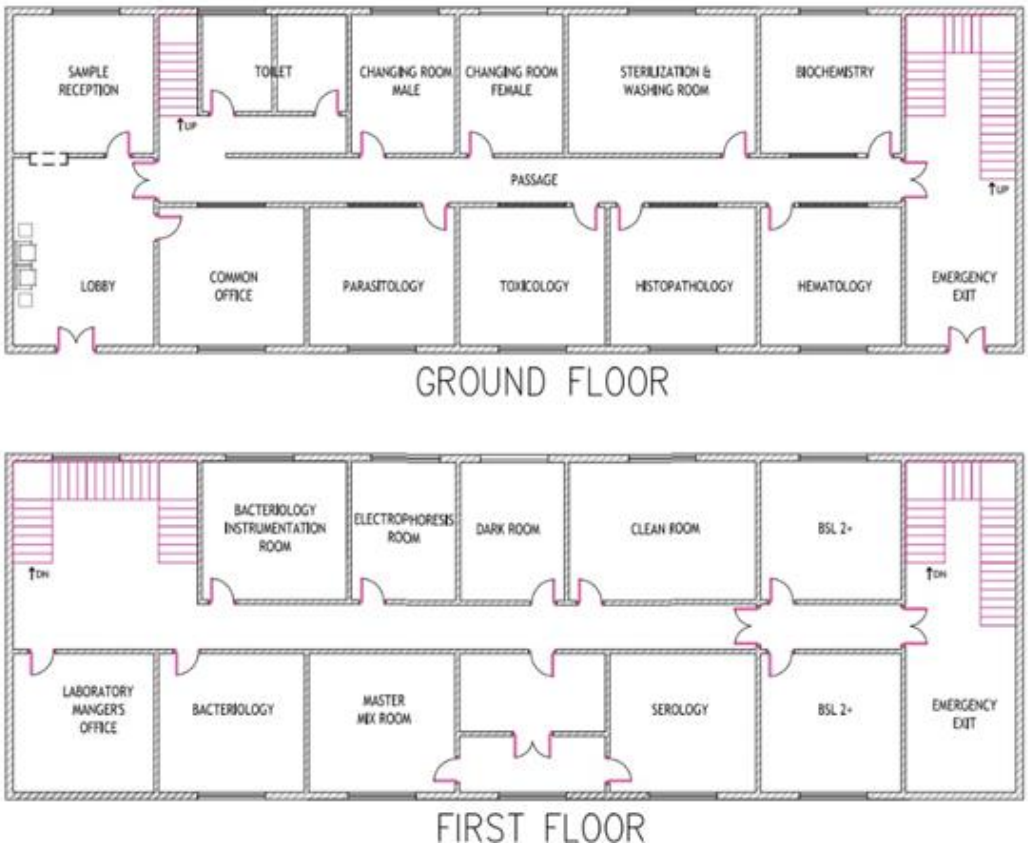


Figure 1. Layout of the laboratory structure at NCAH

a. Working environment

The specimens are received, recorded, segregated and distributed to the respective laboratory section through laboratory information management system (LIMS) database. 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. Environmental conditions (temperature, humidity) that influence the validity of results are recorded, monitored and controlled. (Temperature log chart for equipment). File no. 4 (23)NCAH/LSU-Environment/humidity monitoring report.

b. Waste disposal

Waste (chemical, biological and others) is segregated and disposed of according to the Waste Prevention and Management Act of Bhutan 2009 and Waste Prevention and Management Regulation 2012 of the National Environment Commission and National Guideline for Waste Management for Animal Health Laboratories, 2020.

All the personnel including the supporting staff are trained to handle all kinds of waste generated from the laboratory in the most appropriate manner. NCAH/LAB/BIOSAFTEY-01- SOP on Laboratory waste management.

6.4 Equipment

NCAH ensures that the laboratory equipment and instruments used for diagnostic purposes are financially planned, procured, installed, regularly calibrated, maintained and condemned according to the proper procedures as per manufacturer's recommendations.

I. Review of request, tenders and contracts

a. The requirements for laboratory equipment are developed on an annual basis, verified and procured through open tender using the online electronic Government procurement (e-GP) system for the Royal Government of Bhutan (RGOB).

Tender evaluation is done by evaluation committee which selects the lowest evaluated bidder.

Tender awarding committee awards the contract.

Supply order is issued based on the awards

After the consignment is received, a verification team will verify and accept the items if all the specifications are met.

The laboratory maintains a record in stock ledger for all laboratory items, including reagents and consumables.

b. The laboratory has access to equipment required for correct performance of laboratory activities whenever needed. Therefore, the validity of procurement tenders is kept for one year.

II. Installation and quality inspection criteria.

Newly procured or acquired instruments and equipment are installed and calibrated by the vendors and documented by the laboratory for assuring satisfactory performance. Every new equipment is checked thoroughly upon receipt to confirm if the supply meets ordered specification placed by the laboratory. (As per tender)

The LSU ensures adequate space, enough ventilation, humidity and uninterrupted power supply to meet specifications for satisfactory performance.

Logbooks, SOPs, manuals and history cards for all equipment in the laboratory are being maintained. (Equipment Log Book)

III. Inventory

The equipment is identified with unique Identification numbers in the lab and are further recorded in the centralized Government Inventory Management System (GIMS) to keep track of the equipment. The inventory and the master file of the inventory is maintained in hard as well as soft copies which includes the list of all equipment, location of the machine and person in-charge for the equipment.

IV. Calibration/validation

Calibration and validation is being carried out for new /acquired or in use equipment in the laboratory. Reproducibility, precision and accuracy tests are performed, documented, reviewed and approved before the equipment and instruments are put in place to use by the biomedical engineer. SOP- LSU/LQM/6.4/1 & LSU/LQM/6.4/2.

V. Maintenance and repair

a. Use and maintenance of each equipment is based on the manufacturer's recommendations and service manuals. Maintenance contracts and warranty service is maintained by the laboratory services unit at NCAH. The defective and malfunctioned equipment are identified with label alerting that it is not in use. Repair and maintenance are done as and when the machine breakdown occurs in the laboratory and also the equipment which are high-end are put under maintenance contracts. File no. 4(26) NCAH/LSU - Equipment maintenance request form.
b. The laboratory services unit maintains Annual Maintenance Contract (AMC) or Comprehensive Maintenance Contract (CMC) to repair and perform maintenance of especially high-end equipment and instruments for timely maintenance.

V. Condemnation

The obsolete and the non-functional equipment are removed from the laboratory as per the procedures described in Properties Management Manual (PMM),2016 and surrendered to the Department of National Property (DNP), Ministry of Finance.

6.5 Metrological traceability

The NCAH establishes and maintains metrological traceability of its measurement that is comparable nationally; Bhutan Standard Bureau (BSB) as well as internationally. The center ensures that the measurement results are traceable to the international system of units (SI) through calibration provided by competent laboratories or certified values of certified reference materials provided by competent producers.

6.6 Externally provided products and services

NCAH ensures uninterrupted supply of chemicals, reagents, kits and consumables through planned annual procurement.

The products indented are verified and procured through open tender using the online electronic Government procurement (e-GP) system for the Royal Government of Bhutan (RGOB).

Tender evaluation is done by evaluation committee which selects the lowest evaluated bidder.

Tender awarding committee awards the contract.

Supply order is issued based on the awards

After the consignment is received, a verification team will verify and accept the items if all the specifications are met.

The laboratory maintains a record in stock ledger for all laboratory items, including reagents and consumables.

Consumables used beyond the manufacturer's expiry date are validated routinely prior to each use.

The preparation of all types of standard solutions and reagents are recorded.

(Annual indent list, invoice/verification record, stock ledger)

7. Process

7.1 Review of requests, tenders, and contracts

7.1.1. LSU caters testing services to private parties as well as government entities as a routine test, where the lab does not draw any contractual agreement.

7.1.2. The laboratory follows ***SOP for review of test requests*** and maintains records in the ***review of test request form***. (SOP sample reception and review of test request form -LSU/LQM/7.1/1). While reviewing the test request the laboratory ensures the implementation of specific analytical requirements, which includes;

- well defined analytical methods are used, documented and understood.
- adequate capacity and resources are met for the testing requirements.

7.1.3. External service providers are used whenever required, as per World Organization for Animal Health (WOAH) designated laboratories and sample referral (Laboratory SOP:2018).

7.2 Selection, verification, and validation of methods.

The laboratory adheres to methods/procedures for test, in-house calibration, handling, transport, storage and preparation of samples to be tested, as stipulated in the relevant test method.

7.2.1. **Selection and verification of methods**

7.2.1.1. The laboratory uses appropriate methods and procedures as per the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2022, WOAH and as per the disease prevention and control plan document.

7.2.1.2. All The standard operating procedures are periodically reviewed and updated.

The laboratory ensures that it uses the latest valid version of a method unless it is not appropriate or possible to do so.

7.2.2. Validation of methods

7.2.2.1 LSU follows the standard methods as specified by the manufacturing company and or published protocols.

7.2.2.2. Laboratory compares results achieved with other validated methods, uses certified reference materials as controls, and participates in inter laboratory comparisons

7.2.2.3. The records of validation including the validation procedure used; specification of the requirements, determination of the performance characteristics of the method; results obtained; and a statement on the validity of the method, detailing its fitness for the intended use are maintained.

7.3 Sampling.

Generally, the laboratory receives samples from the clients for testing. In specific cases such as surveillance, disease outbreaks/investigation, etc. The laboratory service unit is involved in the

sampling as per the sample collection procedure**.** (*LSU/LQM/7.3/01- SOP for the collection of specimens*).

7.4 Handling of test or calibration items

7.4.1 LSU has established standard operating procedures for transportation, handling, storage, retention, and disposal of test items to protect the integrity of test items and the laboratory personnel.

7.4.2 A sample logbook is maintained at all times for traceability of the samples.

7.4.3 Samples which require specified storage conditions are stored as per the requirement and these conditions are regularly monitored and recorded in the equipment logbook. (SOP & forms)

7.5 Technical records

7.5.1 Record management

The sample details are recorded in sample reception log book on the receipt of the samples and simultaneously in the LIMS at the reception. Individual sections also maintain the sample details, raw data associated with testing, records of original observations and results in section registers and LIMS. Individual logbooks by laboratory staff are separately maintained to record the original observations, data and calculations identifiable with the specific task.

7.5.2 Amendment of record

The laboratory ensures that amendments to technical records are well maintained. All the mistakes in records are not erased. They are crossed out and the correct value is entered alongside with the initial of the person making such correction along with date and altered aspects in the register/section log books. In LIMS, if the results generated are unsatisfactory the verifying authority comments to retest the sample and re-enter the results.

7.6 Evaluation of measurement uncertainty

The laboratory runs control's parallel to the tests. The controls are compared with standards provided in manufacturer's instructions.

7.7 Ensuring the validity of results.

7.7.1 The laboratory validates the test results as per the individual test SOPs.

7.7.2 The laboratory monitors its proficiency by participation in the proficiency testing (PT) schemes, such as NEQAS with RCDC and EQAS with Chulalongkorn University, Thailand for bacterial identification and AST; EQAS with Australian Centre for Disease Preparedness (ACDP), Australia for Avian and Swine Molecular tests; EQAS with NIAH, Thailand for Brucella antibody testing. *File no. 4(17)NCAH/LSU- Laboratory auditing & assessment reports*

7.7.3 The laboratory analyzes the data obtained from the above monitoring activities to control and improve the laboratory proficiency. If the results of the monitoring activities are found outside the pre-defined criteria, appropriate action is taken to prevent incorrect results from being reported.

7.8 Reporting of results

7.8.1 General.

7.8.1.1 The results are verified and reviewed by the laboratory head through LIMS.

7.8.1.2 The test results generated from the laboratory are reported accurately, clearly, unambiguously and objectively and include all information necessary for the interpretation of the results obtained

7.8.2 Reports (test or sampling).

The test results will be verified by the Lab in charge and will be available online as per TAT.

The report includes the owner details, animal details, sample details, test details, performer, verifier, date of sample received. (Online reports of LIMS)

7.8.3 Specific requirements for calibration certificates

7.8.3.1 The LSU is not involved in calibration services and does not issue any calibration.

7.8.8 Amendments to reports.

7.8.8.1 LSU does not amend and re-issue the laboratory report. The lab's LIMS has a procedure to verify the test details by the veterinarian before it is released. In the case of any incident that had affected the sample report, the laboratory conducts re-test and issues the laboratory report.

7.9 Complaints

7.9.1 Laboratory receives complaints through written or verbal form. Standard forms available with LSU. *File. No 4(14)NCAH/LSU- Complaint reports*

7.9.2 LSU records the complaints for internal review/investigation and undertake the action to resolve them.

7.9.2.1 Periodically review the types of complaints.

7.9.2.2 Outcomes are communicated to the complainant after approval from LSU committee.

7.10 Nonconforming work

Nonconforming findings are recorded in hard copy in registers respective sections, identify the causes and corrective actions are taken.(SOP for non-confirming work & forms)

7.11 Control of data and information management.

LSU has made access to the laboratory data only to the authorized personnel through assigned user ID and password. All the security features are maintained at the ICT unit, MoAL. Laboratory registers data on hard copies also and they are maintained for a minimum of five years and then discarded. Data archival is generated from LIMS.

8. Quality Management System (QMS)

8.1 General

Our laboratory management system comprises software (LIMS) and hardware documentation system including the references and Standard Operating Procedures (SOPs) in order to achieve reproducibility. The systems have the control over management standards, test results, reports, laboratory staff, instruments, and workflow as per the scope and policy of this document. The management systems broadly comprise the implementations regarding management system

documentation, control of management system documents, control of records, actions to address risks and opportunities, improvement, corrective actions, audit and management reviews.

8.2 Quality Management system documentation

It is the automating and streamlining of the main processes of the laboratory system through smart solutions for the better management of the inventory, maximizing the sample analysis, test processing and turnaround time (TAT) for the final generation of the results. It is also a day-to-day activity as per the deadlines and SOP approved by the agency. It is maintained through the online system (LIMS) execution maintaining the integrity and transparency of the results. The four levels of documentation comprise of policies, processes, procedures (SOPs) and records as shown in the pyramid in **Fig 3** (WHO, 2011).

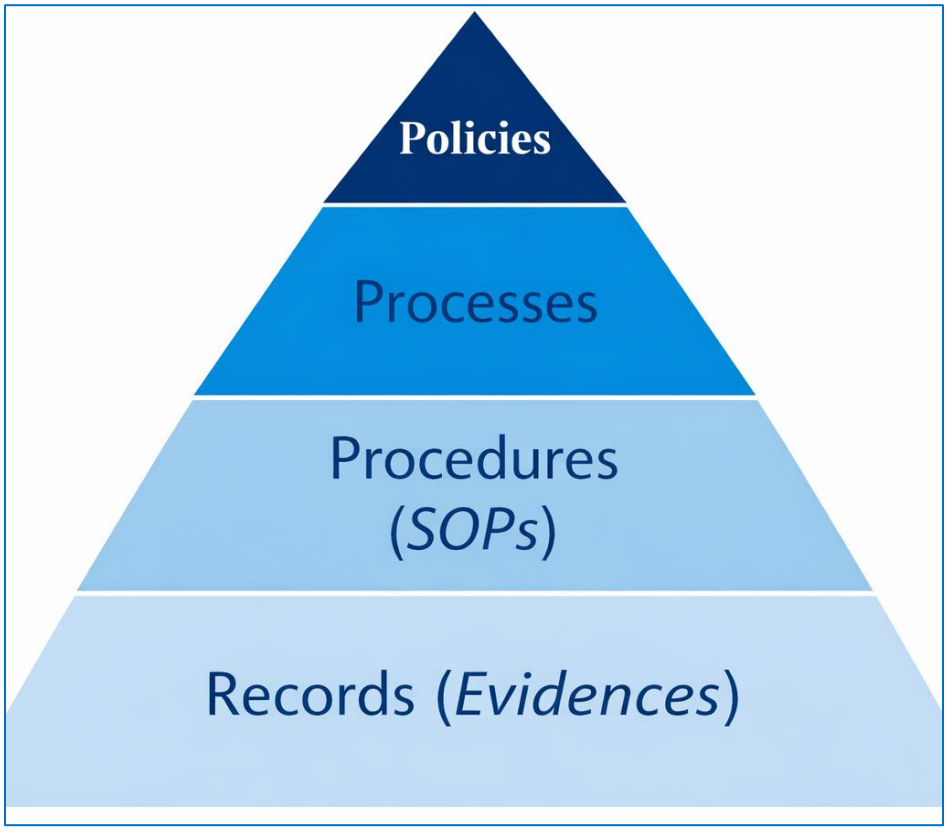


Fig 3: Types of documents under laboratory system

8.2.1 All documents are retractable with uniformity with specific reference to online or offline systems under implementation (LIMS and LQM) with reference documents accessible and transparent to the laboratory personnel.

8.2.2 The NCAH has the authority with copyright with the approval for the dynamic changes mentioned in the policy statement of the LQMS manual **(Refer LIMS and LQMS Manual with copyright authority from MOAL/DOL). (Document control log form)**

8.3 Control of management system documents

8.3.1 The documents and records are maintained for archival and destruction, according to the Evidence Act of Bhutan (2005). A copy of an obsolete document is kept to provide a means for review if the situation arises.

8.3.2 The NCAH ensures the periodic revision and approval of the laboratory documents for internal and external control. The unique and retrievable identification codes/numbers for the documents are maintained, identified, and available at the points of use with the control on its distribution The unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

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) The quality manual and SOPs are reviewed every two years or as and whenever required.

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

8.4 Control of records

All the documents are provided with unique identification like title, number, date of issue, revision, version, total number of pages and authorizing signatories with signs in a form of paper copy or authorized electronically.

8.4.1 The laboratory maintains the set of records and documents for guiding the work and also to track samples throughout the entire process of laboratory activities right from the sample collection, transportation, testing, analysis, and dispatch of the results to the clients for the last 10 years.

8.5 Actions to address risks and opportunities

In order to address the risks and opportunities associated with the laboratory management system process, the steps involved comprises of identification of hazards/risk , evaluation of the risks and risk control. (risk assessment form)

8.6 Improvement

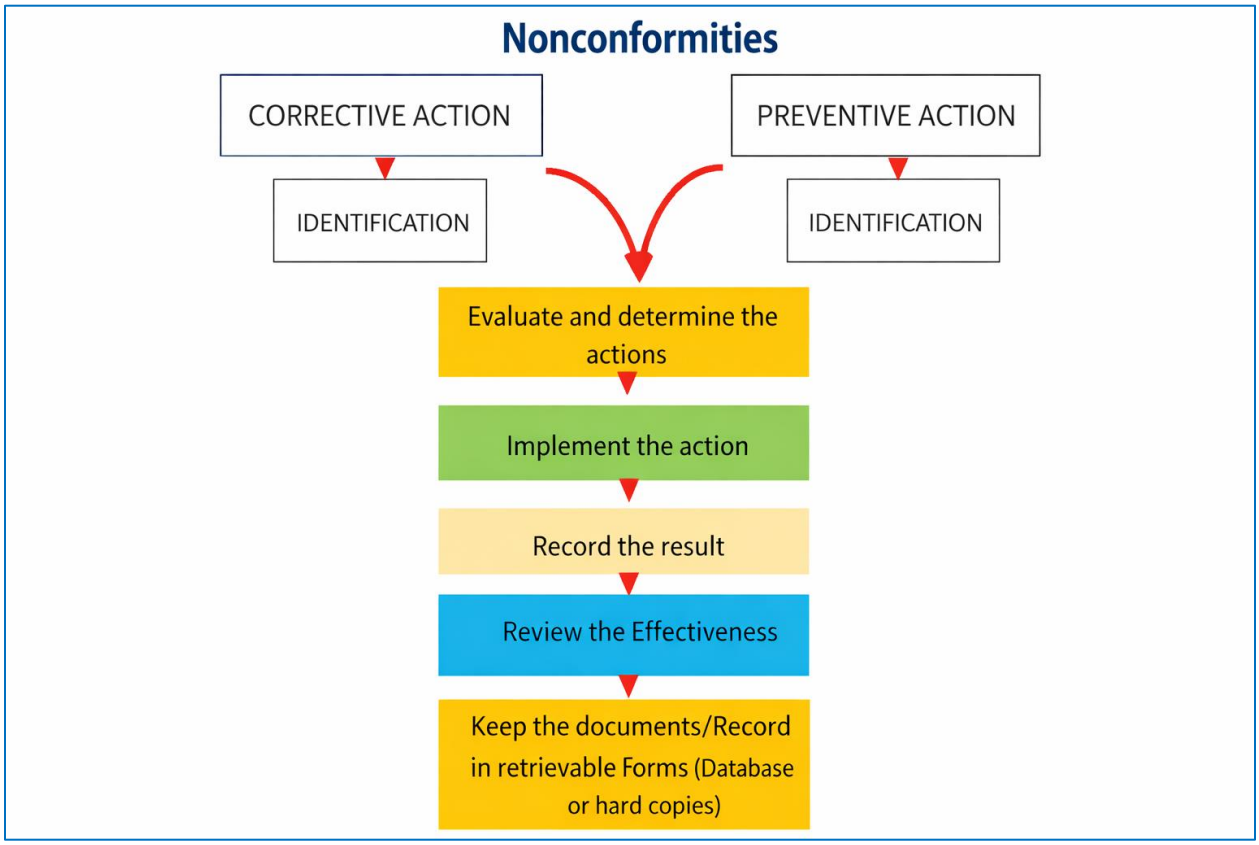
8.6.1 The laboratory develops an annual work plan for all the laboratory activities including quality management. ***(Annual work plan of LSU)***

8.6.2 The laboratory conducts biannual review meetings and also as and when required for reviews on the operational procedures, policies, scope, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results, and training of laboratory personals thereby instituting opportunities for improvement through the findings of the Auditing and management reviews. All the activities resolved are recorded and shared in the form of minutes of meeting (MoM). *(Minutes of meetings file no.)*

8.6.3 Laboratory reviews quality indicators like turnaround time (TAT) biannually to monitor and evaluate the performance of the laboratory making the evaluation a continuous process for improving the efficiency of the quality system of the laboratory ***(Yearly annual reports as per Annual performance agreement; Annual performance rating as per IWP online for individual lab personnel). (Refer Auditing and Management review SOP and or Forms)***

8.7 Corrective actions

8.7.1 The non-confirming tests are recorded in the forms and submitted to the head of the laboratory or the In-charge of the section. The root cause is identified, and rectification is done as per the fig. below: (SOP, forms)



8.8 Audit

The laboratory conducts internal auditing and external assessment at least once annually information on whether the management system is as per the auditing protocols. (SOP for auditing & forms)

8.8.1 The internal audit is being conducted by the committee comprising of the unit heads of NCAH using the auditing form.

8.8.2 The report of the auditing team is shared with the management and accordingly the corrective actions are implemented. The records of the auditing and its corrective actions and its consequences are recorded and kept for future reference.

8.8.3 The external assessment will be conducted by the teams of laboratories experts/Focal from MOH, MOAL, KGUMBS. The external assessment is also done by international agencies like WOAH, IVI, and FAO from time to time.

8.9 Management reviews

8.9.1 In order to keep the laboratory system in perfect functioning status in line with the policies and Scope of LQM, annual review is done by the committee represented by all the units. (Mid-term & annual APA review report of the institute). (SOP for management review)

8.9.2 The outputs from the management review in recorded in the form of minutes of the meeting (MoM) and or report and circulated to the relevant sections for necessary actions with follow-up actions with deadlines mentioned in the report.

8.9.3 The meeting is conducted once after annual auditing or as and when required and the reviews are recorded in the form of MoM. The same is reviewed in next meeting for the status of planned activities for follow up.

9.Annexure (Supporting Documents Lists)

Table. Showing the list of supporting documents for LQMS manual

DOCUMENT NO.	TITLE	VERSION NO.	TOTAL PAGES
LSU/LQM/6.2	SOP FOR TRAINING OF LABORATORY STAFFS	1	4
LSU/LQM/6.2(III)	TRAINING RECORD FORM	1	1
LSU/LQM/6.2(VI)	STAFFS INDUCTION CHECKLIST	1	3
LSU/LQM/6.3	SOP ON LAB. WASTE MANAGEMENT	1	22
LSU/LQM/6.3	WASTE DISPOSAL FORM	1	1
LSU/LQM/6.3	ENVIRONMENT TEMPERATURE RECORDING FORM	1	1
LSU/LQM/6.4	SOP FOR EQUIPMENT CALIBRATION	1	5
LSU/LQM/6.4	SOP FOR EQUIPMENT VALIDATION	1	5
LSU/LQM/6.6	SOP FOR CULTURE MEDIA QUALITY TEST	1	4
LSU/LQM/6.6	RECORD FOR CULTURE MEDIA QUALITY TEST	1	1
LSU/LQM/7.9.1	LABORATORY COMPLAINT FORM	1	1
LSU/LQM/7.1	SOP FOR RECEPTION OF SAMPLE AND REVIEW OF TEST REQUEST	1	5

LSU/LQM/ 7/3	SOP FOR SAMPLE COLLECTION	1	5
LSU/LQM/FORMS. 7.1/01	TEST REQUEST/ SPECIMEN SUBMISSION FORM	1	2
LSU/LQM/7.10/01	RECORD OF NON-CONFORMING WORK	1	1
LSU/LQM/7.10/0	PROCEDURE FOR CONTROL OF NON-CONFORMING TESTING	1	4
LSU/LQM/8.5/02	ASSESSMENT FOR BIO SAFETY IN THE LABORATORY	1	1
LSU/FORM/IR/7.10/ 01/	INCIDENT REPORTING FORM	1	1
LSU/FORM/RA/8.5/ 01	RISK ASSESSMENT FORM	1	1
LSU/FORM/VISITOR/6.3/01	VISITOR REQUEST FORM FOR GENERAL	1	1
LSU/SOP/IA/8.8/01	SOP FOR INTERNAL AUDIT	1	4
LSU/SOP/MRM/8.9/ 01	SOP FOR MANAGEMENT REVIEW	1	4
LSU/LQM/DC/8.3/01	LABORATORY DOCUMENT CONTROL LOG	1	4

Table. Showing the list of SoPs for LQMS manual

Sl No.	SoP	SoP No	Pages
	Virology		
1	FAT	2018.1	**11**
	Molecular Biology		
2	SoP for sample collection for molecular diagnosis	NCAH/LSU/MOLE 01	6
3	SoP on DNA extraction of DNA for molecular analysis	NCAH/LSU/MOLE 02	2
4	SoP on Detection of PCV2 by real time polymerase chain reaction	NCAH/LSU/MOLE 03	5
5	SoP on Detection of ASFV by real time polymerase chain reaction	NCAH/LSU/MOLE 04	5
6	SoP on Detection of LSDV by real time polymerase chain reaction	NCAH/LSU/MOLE 05	5
7	SoP on Extraction of RNA for molecular Analysis	NCAH/LSU/MOLE 06	4
8	SoP on detection of FMDV by real time polymerase chain reaction	NCAH/LSU/MOLE 07	5
9	SoP on detection of AIV by real time polymerase chain reaction	NCAH/LSU/MOLE 08	9
10	SoP on detection of CSFV by real time polymerase chain reaction	NCAH/LSU/MOLE 09	5
11	SoP on detection of PPMV by real time polymerase chain reaction	NCAH/LSU/MOLE 10	5
12	SoP on detection of PRRSV by real time polymerase chain reaction	NCAH/LSU/MOLE 11	4
13	SoP on detection of IBDV by real time polymerase chain reaction	NCAH/LSU/MOLE 12	4
14	SoP on detection of NDV by real time polymerase chain reaction	NCAH/LSU/MOLE 13	4
15	Trouble shooting in PCR	ANNEXURE	1
			64
	Serology		
16	SoP for serum sample collection	NCAH/LSU/SERO 01	4
17	SoP for ELISA for *Burcella aborticus*	NCAH/LSU/SERO 02	4
18	SoP for ELISA for Avian Leukosis Complex Ag	NCAH/LSU/SERO 03	3
19	SoP for ELISA for *M.paratuberculosis*	NCAH/LSU/SERO 04	3
20	SoP for NSP ELISA for FMD	NCAH/LSU/SERO 05	8
21	SoP for ELISA for *Mycoplasma.*	NCAH/LSU/SERO 06	6
22	SoP for ELISA for LPDE FMD	NCAH/LSU/SERO 07	14
23	SoP for ELISA for NCD	NCAH/LSU/SERO 08	7
24	SoP for sandwich ELISA for FMD	NCAH/LSU/SERO 09	5

25	SoP for ELISA for Rabies	NCAH/LSU/SERO 10	7
26	SoP for RBT for Brucella	NCAH/LSU/SERO 11	3
27	SoP for SAT for Salmonella	NCAH/LSU/SERO 12	5
28	SoP for SAT Mycoplasma	NCAH/LSU/SERO 13	5
29	SoP for ELISA for IBD	NCAH/LSU/SERO 14	3
30	SoP for ELISA for IBR	NCAH/LSU/SERO 15	3
31	SoP for ELISA for EIA	NCAH/LSU/SERO 16	3
32	SoP for ELISA for CSFV antibody	NCAH/LSU/SERO 17	4
33	SoP for ELISA for CSFV antigen	NCAH/LSU/SERO 18	4
34	SoP for HA/HI for NCD	NCAH/LSU/SERO 19	5
35	SoP for AGID for NCD	NCAH/LSU/SERO 20	4
36	SoP for ELISA for CBPP	NCAH/LSU/SERO 21	6
37	SoP for ELISA for BVD	NCAH/LSU/SERO 22	7
38	SoP for ELISA for *Leptospira hardjo*	NCAh/LSU/SERO 23	7
39	SoP for ELISA for Peste Petits Ruminants	NCAH/LSU/SERO 24	5
40	SoP for ELISA for *Porcine Circovirus 2*	NCAH/LSU/SERO 25	5
41	SoP for ELISA for *Japanese Enciphalitis*	NCAH/LSU/SERO 26	4
42	SoP for ELISA for PRRS	NCAH/LSU/SERO 27	5
			140

General SoP

43	NCAH/LSU/Test Categorization	NA	15
44	SoP on reception of sample and Review of test request	LSU/QMS/7.1	4
45	SoP on Collection of Samples/Specimen	LSU/QMS/7/3	5
46	SoP on Training of Laboratory Staff	LSU/QMS/6.2	3
47	SoP on annual calibration,checks and cleaning	LSU/QMS/6.4	5
48	SoP on Validation of Laboratory Equipment	LSU/QMS/6.4	4
49	SoP on Culture Media Quallity Test	LSU/QMS/6.6	6
50	SoP on Control of Non-Conforming Testing	LSU/LQMS/7.10/0	5
51	Assessment of Biosafety in the Laboratory	LSU/LQMS/8.5/02	11
52	SoP on Laboratory Waste Management	LSU/LQM/6.3	23
			81

Histopathology SoP

53	Sample Collection for Histopathology	NCAH/LSU/HISTO 01	5
54	Sample Collection by Fine Needle Aspiration (FNA)	NCAH/LSU/HISTO 02	4
55	Tissue Processing	NCAH/LSU/HISTO 03	6
56	Tissue Embedding	NCAH/LSU/HISTO 04	4
56	Hematoxylin and Eosin (H & E) staining	NCAH/LSU/HISTO 05	5
57	Gram's staining	NCAH/LSU/HISTO 06	4
58	Ziehl Neelson’s Acid Fast Staining	NCAH/LSU/HISTO 07	4

58	Giemsa staining for Cytology	NCAh/LSU/HISTO 08	4
59	Trichogram	NCAH/LSU/HISTO 09	5
			41

LFA SoP

60	Lateral Flow Assay for Antigen detection 2	NCAH/LSU/LFA 01	3
61	Lateral Flow Assay for Antibody detection 4	NCAH/LSU/LFA 02	3
			6

Parasitology SoP

62	SOP on Faecal Sample Collection	NCAH/LSU/PARA 01	4
63	SOP on Faecal Examination by Direct Method	NCAH/LSU/PARA 02	3
64	SoP on Faecal Examination by Direct Method – Mucosal Impression Smear	NCAH/LSU/PARA 03	3
65	SOP on Floatation technique for Taeniid eggs	NCAH/LSU/PARA 04	3
66	SOP on Sedimentation technique & Modified Sedimentation Technique for the detection of Fasciola eggs	NCAH/LSU/PARA 05	4
67	SOP on Floatation Method	NCAH/LSU/PARA 06	3
68	SOP on Collection of Intestinal Content for Impression Smear	NCAH/LSU/PARA 07	3
69	SOP on Quantitative Faecal Examination – Stoll's Dilution Method	NCAH/LSU/PARA 08	3
70	SOP on Adult Worms and Cyst Sample (Identification)	NCAH/LSU/PARA 09	3
71	SOP on Skin Scrapping	NCAH/LSU/PARA 10	4
72	SOP on Blood Sampling	NCAH/LSU/PARA 11	3
73	SOP on Test Procedure for the detection of haemoprotozoa	NCAH/LSU/PARA 12	4
74	SOP on Blood Sample for Heartworm Detection (Dirofilaria immitis)	NCAH/LSU/PARA 13	3
75	SOP on collection and Identification of ticks	NCAH/LSU/PARA 14	4
76	SOP on sample shipment	NCAH/LSU/PARA 15	3
77	Annexure		4
			54

Post Mortem SoP

77	Checklist for Acceptability of Carcass for PM	NA	2
78	SOP on Postmortem Examination in Mammal	NCAH/LSU/PM 01	16
79	SOP on Postmortem Examination in Avian	NCAH/LSU/PM 02	6
80	SOP on Postmortem Examination in Fish	NCAH/LSU/PM 03	5
81	SOP on Postmortem Examination in Crocodilians	NCAH/LSU/PM 04	4
82	SOP on Postmortem Examination in Elephant	NCAH/LSU/PM 05	10
			43

SoP on Biochemistry

83	SOP on Serum Collection for Biochemistry Tests	NCAH/LSU/BIOCHEM 01	5
84	SOP on Urine Collection for Biochemistry Tests	NCAH/LSU/BIOCHEM 02	4
85	SOP on Abdominal or Peritoneal Fluid Collection for Biochemistry Tests	NCAH/LSU/BIOCHEM 03	4
86	SOP on Quantitative Calcium concentration	NCAH/LSU/BIOCHEM 04	3
87	SOP on Quantitative Determination of Magnesium	NCAH/LSU/BIOCHEM 05	4
88	SOP on Quantitative Determination of Phosphorous	NCAH/LSU/BIOCHEM 06	3
89	SOP on Quantitative Colorimetric Urea Determination	NCAH/LSU/BIOCHEM 07	4
90	SOP on Quantitative Estimation of Creatinine	NCAH/LSU/BIOCHEM 08	4
91	SOP on Glucose Tolerance Test (Intravenous)	NCAH/LSU/BIOCHEM 09	3
92	SOP on Automatic Serum Analyzer for Biochemistry	NCAH/LSU/BIOCHEM 10	5
93	SOP on Biochemical test for Urine or Urinalysis	NCAH/LSU/BIOCHEM 11	10
			49
	Forms collection		**21**
	Bacteriology SoP		
94	SoP for sample collection,packaging and transporation for Bacteriology test	NCAH/LSU/BACTO 01	10
95	SoP for Culture techniques	NCAH/LSU/BACTO 02	4
96	SoP for Gram Staining	NCAH/LSU/BACTO 03	4
97	SoP for Catalase test	NCAH/LSU/BACTO 04	4
98	SoP for Oxidase test	NCAH/LSU/BACTO 05	3
99	SoP for Motility test	NCAH/LSU/BACTO 06	3
100	SoP for Oxidation/Fermentation of glucose test	NCAH/LSU/BACTO 07	3
101	SoP for Lactophenol Cotton Blue staining	NCAH/LSU/BACTO 08	3
102	SoP for Acid Fast Staining	NCAH/LSU/BACTO 09	3
103	SoP for Spore staining	NCAH/LSU/BACTO 10	3
104	SoP for Methylene blue staining	NCAH/LSU/BACTO 11	3
105	SoP for Capsule staining test	NCAH/LSU/BACTO 12	3
106	SoP for Nitrate test	NCAH/LSU/BACTO 13	3
107	SoP for Indole Production test	NCAH/LSU/BACTO 14	3
108	SoP for Methyl Red test	NCAH/LSU/BACTO 15	4

109	SoP for Urease test	NCAH/LSU/BACTO 16	4
110	SoP for Aesculin hydrolysis test	NCAH/LSU/BACTO 17	3
111	SoP for Citrate Utilization test	NCAH/LSU/BACTO 18	3
112	SoP for Triple Sugar Iron test	NCAH/LSU/BACTO 19	4
113	SoP for Voges-Praskauer test	NCAH/LSU/BACTO 20	3
114	SoP for Culture Identification of *E.coli*	NCAH/LSU/BACTO 21	4
115	SoP for Culture and Identification of *Salmonella species*	NCAH/LSU/BACTO 22	5
116	SoP for Culture and Identification of Pasturella species	NCAH/LSU/BACTO 23	3
117	SoP for Culture and Idenfication of *Bacillus anthracis*	NCAH/LSU/BACTO 24	6
118	SoP for Culture and Identification of *Staphylococcus species*	NCAH/LSU/BACTO 25	4
119	SoP for Culture and Identification of *Streptococcus species*	NCAH/LSU/BACTO 26	3
120	SoP for Culture and Identification of Enterococcus species	NCAH/LSU/BACTO 27	5
121	SoP for Culture and Identification of *Clostridium species*	NCAH/LSU/BACTO 28	4
122	SoP for Culture and Identification of *Corynebacterium species*	NCAH/LSU/BACTO 29	4
123	SoP for Culture and Identification of *Campylobacter species*	NCAH/LSU/BACTO 30	3
124	SoP for Fungal Culture and Identification	NCAH/LSU/BACTO 31	3
125	SoP for California Mastitis test	NCAH/LSU/BACTO 32	4
126	SoP for Breed's direct smear metho	NCAH/LSU/BACTO 33	4
127	SoP for Tuberculin test using Purified Protien Derivative test	NCAH/LSU/BACTO 34	4
128	SoP for Slide Agglutination test for *Salmonella species*	NCAH/LSU/BACTO 35	3
129	SoP for Slide Coagulase test for *Staphylococcus aureus*	NCAH/LSU/BACTO 36	3
130	SoP for Tube Coagulase Test for *Staphylococcus aureus*	NCAH/LSU/BACTO 37	3
131	SoP for Antimicrobial Sensitivity Test by CLSI	NCAH/LSU/BACTO 38	6
132	SoP for Plate Count Test by pour plate techniques	NCAH/LSU/BACTO 39	3
133	SoP for Bacterial glycerol stock preparation and storage	NCAH/LSU/BACTO 40	4
134	SoP for Extended Spectrum Beta Lactamase test	NCAH/LSU/BACTO 41	4
135	SoP for CAMP test	NCAH/LSU/BACTO 42	5
136	SoP for Vitek 2 test	NCAH/LSU/BACTO 43	4

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