SOP No: NCAH/LSU/Test Categorization
Title: Test Categorization
Version No: 1, Total Pages:14
Issue Month/Effective Date: 2026
Revision: Summary: Test categorization based on lab capacity and structure
Supersedes Version No: 2024.01
Prepared by: Dr (s) Tshering Choden, Karma Choezang, Rinzin Loday, Kinzang Chedup, Dezang Wangchuk
Reviewed by: Dr NK Thapa
Approved by:
Application/Distribution: Veterinary Diagnostics Labs

1. Scope

The purpose of this SOP is to establish a clear framework for categorising veterinary diagnostic tests in Bhutan, ensuring that each laboratory operates within its designated biosafety level and technical capacity. By defining responsibilities across district, regional, and national laboratories, the SOP promotes consistency, safety, and efficiency in diagnostic service delivery.

2. Objective

i. Ensures uniformity in assigning tests to appropriate laboratory tiers, from district to national centres, thereby standardising diagnostic services.
ii. The categorisation supports safe handling of pathogens by aligning test types with biosafety requirements and laboratory functions.
iii. It provides clarity on the distribution of responsibilities among laboratories, avoiding duplication and ensuring efficient resource utilisation.
iv. Ultimately, the objective is to strengthen diagnostic accuracy, biosafety compliance, and service delivery across the national veterinary laboratory network.

Biosafety Level	Lab Function	Pathogen Handled	Examples (Diagnostics)
BSL-I	Standard microbiological practices. No special barriers, decontamination or chemical disinfection	Non-pathogenic or very low-risk organisms, not known to cause disease in healthy animals/humans	Bacillus subtilis, non-pathogenic E. coli strains, harmless yeasts
BSL-II	Restricted access, biosafety cabinets, PPE, waste: Autoclaving before disposal	Moderate-risk pathogens causing disease in animals/humans, but not typically airborne	Salmonella spp., Brucella abortus, Listeria monocytogene, Rabies Hematology, Parasitology, Biochemistry
BSL-II+	Enhanced BSL-2 labs with PPE, negative airflow, waste: autoclaving/ incineration, sealed transport of waste	Pathogens requiring more containment than BSL-2, often zoonotic and aerosol-transmissible	Mycobacterium bovis (non-aerosol work), Influenza A, LSDV, ASF

Note: District veterinary Labs are either classified as BSL-I/II, Regional Laboratory, Satellite Veterinary Lab and National Veterinary Hospital is classified as class II and finally NCAH with additional class II+ biosafety level.

S.N.	Tests	NCAH	NVH	RLDC	RVH	SVL	DVL
Bacteriology							
1	Direct Staining **(Non-culture)**: Gram's stain, Giemsa, Methylene blue, Ziehl-Neelsen/Acid fast, Leishman	✓	✓	✓	✓	✓	✓
2	Bacterial culture sheep blood agar, MacConkey agar and other selective media and **genus** identification using various bio-chemical tests	✓	✓	✓	✓		
2	Staining techniques **(Culture)** - Grams, Giemsa, Methylene blue, Ziehl-Neelsen/Acid fast, Leishman, Spore staining and Capsule staining for bacteria	✓	✓	✓	✓		
3	Fungal culture using sabouraud's agar; Lactophenol cotton blue stain and identification	✓	✓	✓	✓	✓	✓

4	Species identification of important bacterial pathogens in Bhutan – Salmonella sp., E. coli, Staphylococcus spp., Bacillus anthracis, Clostridium sp., Pasteurella, Pseudomonas sp., Erysipelas rhusiopathiae, Brucella sp., Aeromonas hydrophila and Streptococcus sp.	✓		✓	✓		
5	Enumeration of bacteria - total aerobic count by pour plate technique and spread plate technique, total coli count by pour plate technique and spread plate technique, Most Probable Number (MPN) technique	✓		✓			
6	Agglutination tests: Slide agglutination test (SAT), Tray agglutination test (TAT) and Micro-titre plate agglutination test (MAT)	✓					
	Detection of mastitis in milk samples through the California mastitis test (CMT), Cell count and White side test (WST)	✓	✓	✓	✓	✓	✓
7	Antimicrobial susceptibility test (AST), disk diffusion method	✓	✓	✓	✓		

8	AST using MIC, automation (Vitek)	✓					
9	Intra-dermal test for bovine tuberculosis (TB) using purified protein derivatives (PPD)	✓	✓	✓	✓	✓	✓
Biochemistry							
1	Mineral estimation for Calcium in the serum	✓	✓	✓	✓		
2	Mineral estimation for Magnesium in the serum	✓	✓	✓	✓		
3	Mineral estimation for Phosphorous in the serum	✓	✓	✓	✓		
4	Mineral estimation for Copper in the serum	✓	✓	✓	✓		
Hematology							
1	Total White Blood Cell Count (TWBCC)	✓	✓	✓	✓	✓	✓
2	Total Red Blood Cell Count (TRBCC)	✓	✓	✓	✓	✓	✓
3	Differential Leukocyte Count (DLC)	✓	✓	✓	✓	✓	✓

4	Haemoglobin estimation (Hb)	✓	✓	✓	✓	✓	✓
5	Packed Cell Volume (PCV)	✓	✓	✓	✓	✓	✓
6	Erythrocyte Indices – MCV, MCHC and MCH	✓	✓	✓	✓	✓	✓
7	Erythrocyte Sedimentation Rate (ESR)	✓	✓	✓	✓	✓	✓
Parasitology							
1	Identification of parasitic eggs using direct technique	✓	✓	✓	✓	✓	✓
2	Identification of parasitic egg using qualitative tests: Sedimentation and Floatation methods	✓	✓	✓	✓	✓	✓
3	Egg count reduction test	✓	✓	✓	✓	✓	✓
3	Identification of Fasciola eggs using Modified sedimentation technique	✓	✓	✓	✓	✓	✓
4	Urine sedimentation test for nematodes	✓	✓	✓	✓	✓	✓
5	Skin scraping examination using 10% KOH digestion method	✓	✓	✓	✓	✓	✓

6	Blood parasite examination (blood smear)	✓	✓	✓	✓	✓	✓
7	Pepsin digestion test	✓					
8	Fecal culture (simple tube method, culture tube method, Baermann's method)	✓		✓			
9	Tick identification (stereo-zoom method)	✓	✓	✓	✓	✓	✓
10	Post-mortem recovery of helminths and worm count	✓	✓	✓	✓	✓	✓
11	Microfilaria identification from blood (modified Knott's method)	✓	✓	✓	✓	✓	✓
12	Isolation and identification of Taeniid eggs from faeces and soil samples using F/Si technique	✓	✓	✓	✓		
13	Worm staining & preservation	✓	✓	✓	✓		
Anatomic pathology							
1	Conduct post-mortem examination and diagnosis in animals (poultry, ruminants, canine, feline, equine, swine)	✓	✓	✓	✓	✓	✓
2	Conduct post-mortem examination and diagnosis wild animals	✓	✓	✓	✓	✓	✓

3	Conduct post-mortem examination and diagnosis in fish	✓	✓	✓	✓	✓	✓
Histopathology							
1	HP sample collection	✓	✓	✓	✓	✓	✓
2	Tissue processing	✓					
3	H & E staining of tissue sections	✓					
4	Giemsa staining of tissue sections	✓					
5	Cytological tests	✓	✓				
Serology							
1	Antibody ELISA for FMD	✓		✓			
2	Antibody ELISA for Brucella	✓		✓			
3	Antibody ELISA for CSF	✓		✓			
4	Antibody ELISA for NCD	✓		✓			
5	Antibody ELISA for IBR	✓		✓			

6	Antibody ELISA for PPR	✓		✓			
7	Antibody ELISA for CBPP	✓		✓			
8	Antibody ELISA for CCPP	✓		✓			
9	Antibody ELISA for PRRS	✓		✓			
10	Antibody ELISA for ALC	✓		✓			
11	Antibody ELISA for BVD	✓		✓			
12	Antibody ELISA for JD	✓		✓			
13	RBT for Brucella	✓	✓	✓	✓	✓	✓
14	ELISA for NSP antibodies against FMD	✓					
15	Typing ELISA (Sandwich) for FMD – Type O, A and Asia1	✓					
16	LPB ELISA for FMD	✓					
17	ELISA for Rabies	✓		✓			
18	ELISA for Porcine Circo virus2	✓		✓			
19	ELISA for EI	✓		✓			

20	Rapid antibody detection against NDV	✓	✓	✓	✓	✓	✓
21	HA/HI for NCD	✓		✓	✓		
22	Rapid antibody detection against PPRV	✓	✓	✓	✓	✓	✓
23	Rapid NSP Ab detection against FMD	✓	✓	✓	✓	✓	✓
24	Rapid antibody detection against Brucella	✓	✓	✓	✓	✓	✓
25	Fluoresce antibody technique (FAT) for Rabies	✓		✓	✓		
Virology							
1	Rapid antigen detection of Rabies virus	✓	✓	✓	✓	✓	✓
2	Rapid antigen detection of ASFV	✓	✓	✓	✓	✓	✓
3	Rapid antigen detection of Avian Influenza type A	✓	✓	✓	✓	✓	✓
4	Rapid antigen detection of H5	✓	✓	✓	✓	✓	✓
5	Rapid antigen detection of Canine Parvo Virus	✓	✓	✓	✓	✓	✓

6	Rapid Ag detection in ND Virus	✓	✓	✓	✓	✓	✓
7	Rapid antigen detection for MDV	✓	✓	✓	✓	✓	✓
8	Rapid antigen detection for ALC virus	✓	✓	✓	✓	✓	✓
9	Rapid antigen detection for CSF virus	✓	✓	✓	✓	✓	✓
Mycology							
1	Direct examination from skin scrapping	✓	✓	✓	✓	✓	✓
2	Culture on SDA	✓	✓	✓	✓		
3	Lactophenol cotton blue staining	✓	✓	✓	✓	✓	✓
Molecular Diagnostic test							
1	RT PCR for Brucella	✓		✓			
2	Conventional PCR for Leptospira	✓		✓			
3	Conventional PCR for Mycobacterium paratuberculi	✓		✓			

4	Conventional PCR for FMDV	✓		✓			
5	Conventional PCR for ALC	✓		✓			
6	Conventional PCR for IBDV	✓		✓			
7	Conventional PCR for Rabies	✓		✓			
8	Conventional PCR for PPR	✓		✓			
9	Conventional PCR for Brucellosis	✓		✓			
10	RT-PCR for Avian Influenza A virus	✓		✓			
11	RT-PCR for Avian Influenza (H5) virus	✓		✓			
12	RT-PCR for Avian Influenza (N1) virus	✓		✓			
13	RT-PCR for Avian Influenza (N9) virus	✓		✓			
14	RT-PCR for CSF virus	✓		✓			
15	RT-PCR for NCD virus (M & L gene)	✓		✓			
16	RT-PCR for PRRS (NA & EU)	✓		✓			
17	RT-PCR for ASF virus	✓		✓			

18	RT-PCR for LSD virus	✓		✓			
19	RT-PCR for FMDV	✓		✓			
20	RT-PCR for PCV2	✓		✓			
21	RT-PCR for IBDV	✓		✓			
22	RT-PCR for ALCV	✓		✓			
23	RT-PCR for Fowl Po✓ virus	✓		✓			
24	RT-PCR for Capri pox virus	✓		✓			
25	RT-PCR for PPMV-1	✓		✓			
Clinical Biochemistry							
1	Qualitative urine analysis-pH, sp gravity, density, colour	✓	✓				
2	Tests for Glucose, ketone, protein, crystals, pus, bilirubin, blood, urobilinogen, Nitrite, WBC	✓	✓				
3	Liver Function test (AST/ALT)	✓	✓				

4	Renal Function Test (Creatinine, BUN)	✓	✓				
	Total Billirubin, SGOT/AST, SGPT/ALT, ALKP, Total protein, Albumin, LDH , GGT , Cholesterol , Triglyceride, Amylase, Lipase, Lactate , Uric acid, Creatinine Kinase	✓	✓	✓	✓		
Toxicology							
1	Qualitative tests for Aflatoxin	✓		✓			
2	Qualitative tests for Ochratoxin	✓		✓			
3	Qualitative tests for Fumonisin	✓		✓			
4	Qualitative tests for Zearalenone	✓		✓			
5	Quantitative tests for Aflatoxin	✓		✓			
6	Quantitative tests for Ochratoxin	✓		✓			
7	Quantitative tests for Fumonisin	✓		✓			
8	Quantitative tests for Zearalenone	✓		✓			

SOP No: LSU/QMS/7.1
Title: SoP on reception of sample and Review of test request
Version No: 1, Total Pages: 04
Issue Month/Effective Date: May/2026
Revision Summary:
Supersedes Version No:2
Prepared by: LQMS, LSU,NCAH
Reviewed by: Dr Tshering Choden
Approved by:
Application/Distribution:

1. Purpose

The SOP describes the procedure for sample reception and review of test request form.

2. Scope

This procedure is applicable for the personnel involved in sample reception and review of test request form at NCAH

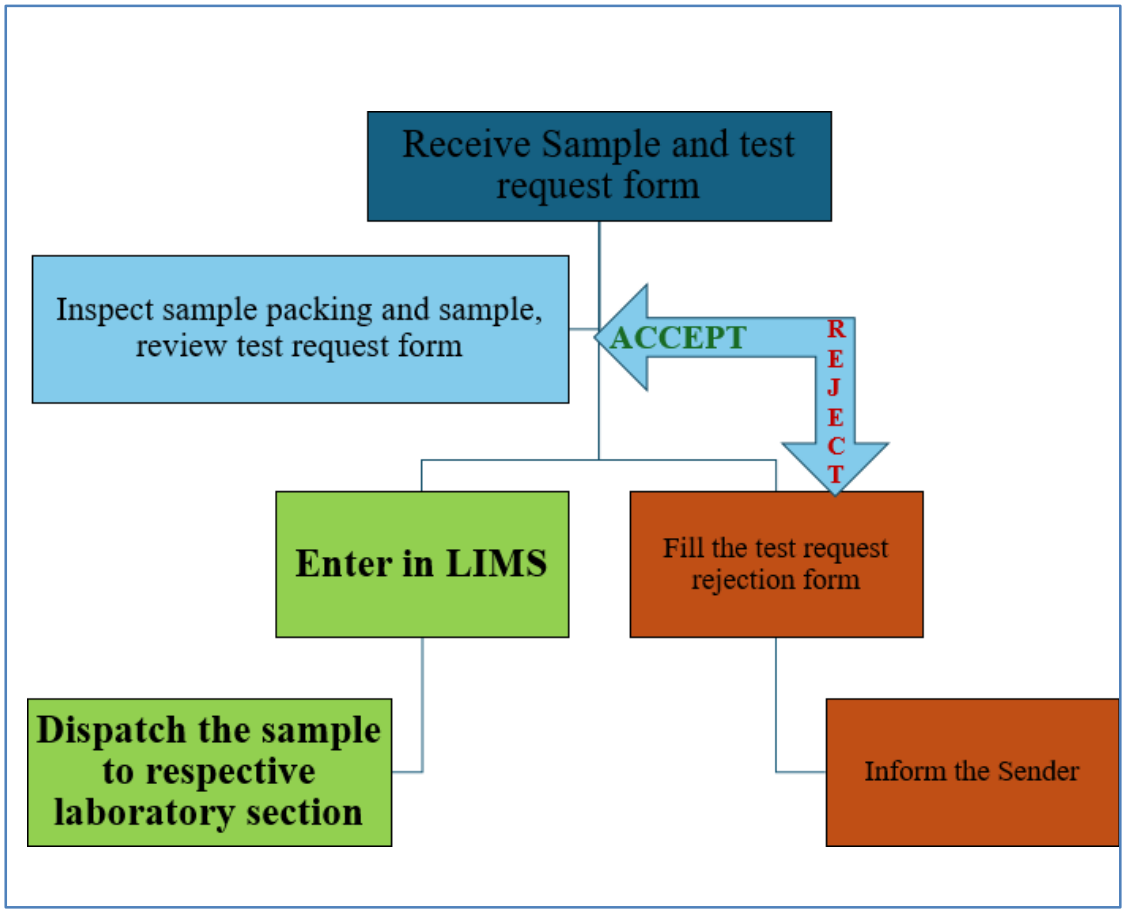
3. Responsibilities

Sl.no	**Official Designation**	**Responsibilities**
1	Sample manager	To receive, review test request form and inspect packaging and sample

4. Definitions:

LIMS: Laboratory information and management system
LQM: Laboratory Quality Management
LSU: Laboratory Service Unit
NCAH: National Center for Animal Health
SRN: Electronically generated Sample registration number in LIMS
Test Request form: It is the form that persuades the livestock health workers/ agency/ private entity to provide all information relevant for correct laboratory testing.

5. Process chart Flow:



6. Procedure

6.1. The private parties or the government entities shall submit sample along with submission form at LSU, the sample manager shall then

- Document the date and time of sample receipt in the Submission from and register.
- Assign submission number to the sample

6.2. The Sample Manager shall review the submission form on completeness of required details for proper processing of the sample and correct interpretation. The sample manager shall verify the following information on submission form/ test request form:

6.2.1. Verify if the SRN on the sample matches with SRN in the submission form

6.2.2. Patient details: Species/ Animal Identification Number/ Breed/ Age/ Colour/ Sex

6.2.3. sender details: Name of the agency or private entity, address, contact number, CID/ passport number, email address

6.2.4. Type of sample e.g.: Blood (whole/ serum), fecal, skin, urine, Fine needle biopsy, milk, body fluids/ Swabs/ feed others

6.2.5. Test requested e.g.: TLC, DLC, Blood biochemistry Test, ABST

6.2.6. Date, time and place of sample collection

6.2.7. Any other relevant Information e.g: case history, tentative diagnosis, treatment

6.3. The sample manager shall evaluate visually the physical integrity of the sample packaging (e.g. leaks, cracks) as per the SOP for sample packaging, storage and transportation.

6.4. Based on the integrity of the sample packaging and completeness of the request form, the sample manager will either accept or reject the sample.

6.4.1. If the sample is accepted, the sample manager shall enter the details of the sample in LIMS and dispatch to respective laboratory sections as per the test request.

6.4.2. If the test request form is rejected, the sample manager shall fill the test request rejection form with complete information on the rejection of the sample/ form. Refer test request rejection form.

6.4.3. Sample manager will enter the details of the sample in LIMS and dispatch to respective laboratory sections as per the test request.

6.4.4. If the test request form is rejected, the sample manager shall fill the test request rejection form with complete information on the rejection of the sample/ form (Refer test request rejection form.)

7. References

SOP for sample transportation, storage and handling
Test Submission form
Test rejection form

8. Review History

Revision	Revision Date	Reason for Revision	Revised by

SOP No: NCAH/LSU/LQMS/7/3
Title: SOP on Collection of Sample Specimens
Version No: 1, Total Pages: 05
Issue Month/Effective Date: May/2026
Revision Summary:
Supersedes Version No:2
Prepared by: LQMS, LSU, NCAH
Reviewed by: Dr N.K.Thapa, Dr Karma Choezang, Sonam Wangchuk, Punya Mata, Rinzin Dorji, Thrinang Wangdi.
Approved by:
Application/Distribution: NCAH, NVH, RLDC, RVH&EC, SVL, DVL

1. Scope

This procedure is applicable to all personnel involved in the collection of specimens for diagnostic, research, and surveillance purposes.

2. Purpose

The SOP describes the procedure for the collection of specimens intended for clinical diagnosis, research and surveillance.

3. Responsibilities

Sl. No	Official Designation	Responsibilities
1	Specimen Collector	1. Collect specimens using appropriate techniques and aseptic procedures. 2. Fill the sample collection form or record data in EpiCollect5 accurately. 3. Ensure proper labelling and identification of all specimens. 4. Package specimens appropriately according to sampling SOP. 5. Transport specimens safely under recommended conditions to the laboratory. 6. Use appropriate personal protective equipment (PPE). 7. Maintain hygiene and prevent contamination of samples. 8. Properly dispose used materials in biohazard bags and designated areas.
2	Sample Manager (Lab Reception)	1. Receive and verify specimens for proper labelling, identification, and accompanying documentation. 2. Record samples in the submission register or online LIMS. 3. Ensure proper storage of specimens under recommended conditions (temperature, time, and preservation). 4. Maintain sample traceability by assigning unique identification numbers. 5. Monitor sample quality and reject or report improperly collected or damaged specimens. 6. Coordinate sample distribution to relevant laboratory sections for analysis. 7. Ensure Biosafety compliance during handling, storage, and shifting of specimens. 8. Review test request form and specimen.

4.

5. Definitions:

4.1 LIMS**:** Laboratory information and management system.

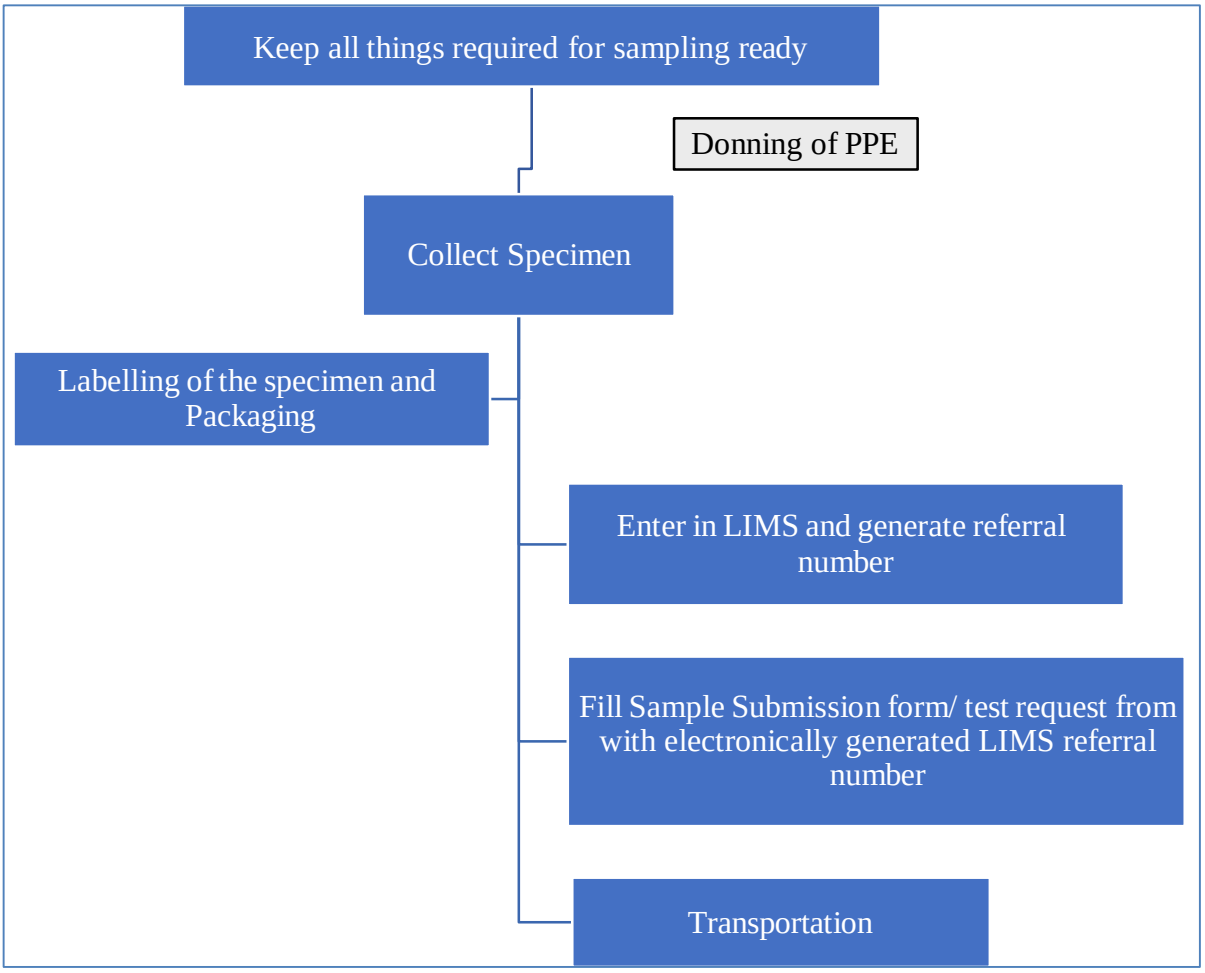
4.2 LQM**:** Laboratory Quality Management.
4.3 LSU**:** Laboratory Service Unit.
4.4 NCAH**:** National Center for Animal Health.
4.5 PPE**:** Personnel Protective Equipment.

- Sample collector**:** it refers to the Livestock personnel who are trained in collecting specimens.
- Sample manager**:** It refers to the person who receives and reviews test request form and specimen

6. **Personal protective equipment (PPE):**

It refers to protective clothing, helmets, gloves, face shields, goggles, facemasks and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness (US FDA).

7. Process chart Flow:



8. Procedure

7.1 Keep ready the required equipment/materials for specimen collection as outlined in the SOPs for sample collection of the test of interest and sample collection manual.

7.2 Select items of personal protective equipment that provide best protection for the circumstances you are dealing with based on risk assessment as per Guidelines for PPE

7.3 Method of specimen collection must be followed as outlined in SOPs of sample collection for the test of interest:

7.3.1 For Bacteriology test request refer SOP BACTO 01

7.3.2 For Hematology test request refer SOP HAEMA 01

7.3.3 For Biochemistry test request refer SOP BIOCH 01

7.3.4 For Histopathology test request refer SOP HISTO 01

7.3.5 For Molecular test request refer SOP MOLE 01

7.3.6 For Serological test request refer SOP SERO 01

7.3.7 For Parasitological test request refer SOP PARA 01

7.3.8 For Post Mortem test request refer SOP PM 01

7.3.9 Sample collection manual

7.4 Doffing of PPE, self-decontaminate and discard appropriately as per the Guideline for PPE.

7.5 Each specimen must be accurately labeled with minimum information of date of collection of specimens, specimen number and type of specimen. Indelible ink must be used to label the specimen.

7.6 Enter the details of the specimen to be referred in LIMS and generate SRN. Fill Laboratory submission form with eligible handwriting and accurate information.

7.7 The specimen must be packed and transported as per the SOP for Sample referral. The specimen must be transported by the fastest method available.

7.8 Communicate with laboratory personnel to coordinate activities, schedules, and sample reception.

9. References

8.1 LIMS**:** Laboratory information and management system
8.2 Laboratory quality management manual
8.3 Risk Assessment form
8.4 SOP for Bacterial sample collection
8.5 SOP for Biochemistry test sample collection
8.6 SOP for Hematological sample collection

8.7 SOP for Histopathology test sample collection
8.8 SOP for Molecular test sample collection
8.9 SOP for Serological test sample collection
8.10 SOP for Sample referral
8.11 OIE terrestrial manual 2008, Chapter 1.1.1 collection and shipment of diagnostic samples

10. Review History

Revision	Revision Date	Reason for Revision	Revised by
			Dr N.K.Thapa, Dr Karma Choezang, Sonam Wangchuk, Punya Mata. Rinzin Dorji, Thrinang Wangdi.

SOP No: LSU/LQMS/6.2
Title: SoP on Training of Laboratory Staff
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Revision Summary:
Supersedes Version No:2
Prepared by: LSU,LQMS,NCAH
Reviewed by: Dr. Kinzang Chedup, Lungten Dorji, Tshewang Dema, Norbula
Approved by: Head, LSU
Application/Distribution:DoL/NCAH/RLDC

1. **Scope**

This SOP shall cover all the professional development training and competency assessment programs that are provided to the laboratory staff which helps to ensure knowledgeable and competent personnel in all laboratory disciplines.

2. **Purpose**

The purpose of this Standard Operating Procedure (SOP) is to provide regular training, continuing education and competency assessment programs that meet regulatory and accreditation requirements.

3. **Responsibilities**

Sl No.	Designation	Responsibility
3.1	Head, Laboratory service unit	Secure the budget for regular training of new and existing employees to update recent knowledges
3.2	Unit heads	Propose required and relevant training which is required by subordinates.
3.3	Laboratory staff	To attend the relevant training which is provided by the administration.

4. Definitions

1) **Competency assessment**: It refers to a method to confirm that training is effective and that personnel are capable of following established procedures to accurately perform laboratory testing that produces quality results.
2) **LSU**: It refers to the Laboratory service unit**.**

5. Procedure

1) The intent of training is to provide the individual with the knowledge and skills necessary to be competent in their assigned duties and responsibilities.
2) The training program should have defined objectives, methods, and training materials. It should also specify a qualified individual as the trainer.
3) The trainer should be a qualified individual with technical laboratory experience who regularly performs the process or test procedure.
4) All new employees shall be provided with orientation and training as per the staff induction check list. LSU/LQM/6.2(IV)
5) New, non-permanent staff such as students and internees shall be oriented on general laboratory procedures for integration in the laboratory

6) All laboratory personnel shall be provided with opportunity for upskilling and reskilling based on competency assessment.
7) Competency assessments shall be carried out every six months for the first year and annually thereafter for all testing personnel, supervisors, and technical consultants.
8) All staff who have acquired training shall maintain their record in training record form LSU/LQM/6.2(III).

6. References

1. LabGuide 16 Personnel Training and Competency Assessment, www.labflorida.com
2. QMS03 Training and competence Assessment, 4th edition.

7. Review History

Revision	Revision Date	Reason for Revision	Revised by
SOP on training of laboratory staff	20/03/2026	Document corrected and updated	Dr. Kinzang Chedup Lungten Dorji Tshewang Dema Norbula

SOP No: LSU/LQMS/ 6.4
Title: SoP on preparation of annual calibration,checks and cleaning schedule
Version No: 1, Total Pages: 5
Issue Month/Effective Date: May/2026
Revision Summary: reviewed the procedure.
Supersedes Version No:2
Prepared by: LSU, LQMS, NCAH
Reviewed by: Dr. Kinzang Chedup, Lungten Dorji, Tshewang Dema, Norbula
Approved by: Head, LSU
Application/Distribution:NCAH/RLDC/RVH&ECs/SVL/DVH

1. Scope

All parameters that contribute to the overall quality of a test, calibration or check, check require measurement traceability. This includes measurements that have a significant on the accuracy or validity of the results being reported. Therefore, equipment that is used to provide a measurement of these parameters must be calibrated or checked.

2. Purpose

Routine calibration, checking and cleaning is part of the laboratory preventive action program, as equipment that is well maintained will operate satisfactorily. It is also a requirement of ISO IEC 17025 that equipment is calibrated or checked according to set of criteria and at set time points**.**

3. Responsibilities

Sl No.	Designation	Responsibility
3.1	Laboratory Officer/Quality Manager	1. Preparing the annual calibration and equipment check plan, which shall be communicated to the Biomedical Engineering Department (BMED), Ministry of Health (MoH), for necessary coordination and implementation 2. Overseeing the execution of this procedure, calibration.
3.2	Laboratory Technicians/Laboratory staff	1. Perform routine checks and calibration (internal calibration) 2. Ensuring the equipment is entered into the Calibration Program 3. Submitting or preparing equipment/instruments for calibration on schedule. 4. Record results and report deviations 5. Ensuring the equipment IS NOT USED OUTSIDE OF THE CALIBRATED RANGE
3.3	Biomedical Engineering Department (BMED)	1. Reviewing equipment calibration records 2. Perform external calibration and servicing

4. Definitions

1) **Calibration**: The process of comparing measurement and test equipment to standards of known accuracy to detect and/or rectify deviations.
2) **Range:** The smallest and the largest values associated with operation of an instrument.
3) **BMED**: It refers to Biomedical Medical Engineering Department
4) **LSU:** Laboratory service unit**.**
5) **MOH:** Ministry of Health

5. Materials and Equipment

1) Calibration standards (weights, thermometers, timers, etc.)
2) Calibration logbooks
3) Equipment inventory list
4) Labels and markers

6. Procedure

Preparation of Calibration Plan

1. Develop an annual calibration schedule for all equipment
2. Include: Equipment name and ID, Calibration frequency, Last calibration date, Next due date, and Submit the plan to BMED, MoH for coordination

Equipment list and calibration frequency

Sl. No	Name of the equipment	Frequency of Calibration
1	Balance	Biannually
2	Biological safety cabinet and Lamina flow cabinet	Annually
3	Incubator	3 Yearly
4	ELISA plate reader	2 Yearly
5	Freezer -20/40/80°C	Biannually
6	Pipettes	Biannually
7	pH meter	Yearly
8	Thermometer	6 monthly

9	Water baths	Monthly cleaning
10	PCR machine	2 yearly
11	Blood Analyzer	Weekly

Internal Calibration / Routine Checks

1) Perform routine verification using appropriate standards: (A)Standard weights for balances; (B)Timer for time-dependent equipment; (C)Thermometer for temperature-controlled equipment
2) Daily monitoring/inspection, after being labeled at schedule, as per the frequency, checks are carried out between
3) If the intermediate check results in a deviation value greater than the previous calibration, recalibration is carried out by a BMED
4) Record all observations in the logbook
5) The laboratory officer/ technician identifies equipment that has a direct effect on the test results and makes a calibration schedule for the equipment

External Calibration

1) The timing regime for calibration/check of particular equipment is noted in BMED's system and carried as per the schedule and frequency.
2) Send equipment to BMED or have BMED visit the center
3) Calibration/checks and cleaning are then performed according to the Standard Operating Procedure for each piece of equipment.
4) Calibrated tools are labeled. The label includes the date of calibration, calibration value, and measurement uncertainty.
5) Obtain and file a calibration certificate

Maintaining calibration status

1) The calibration/checks status of an item of equipment must be evident either by the records shown on the log sheet, worksheet, external certificate or by individual labeling of smaller items of equipment, such as pipettes or thermometers, where the worksheet is kept in the folder rather than with the item.
2) Pipettes must be labeled with the due date for next volume check.
3) Thermometers and -20/40/80 freezers must be labeled with the due date for next digital display check and the correction factor.
4) If an item of equipment is removed from the laboratory, it must be calibrated/checked on return.
5) Any equipment that is found to be defective must be labeled with the date taken out of service, the reason for removal and isolated from use (either by removal/tagging/labeling).

8. **References**

1) Standard Operating Procedure for preparation of annual calibration, checks and cleaning schedule- the university of Melbourne, Asia Pacific Centre for Animal Health, Faculty of Veterinary and Agricultural Sciences.
2) Standard Operating procedures for working instructions for equipment, Laboratory Service Unit, National Center for Animal Health, Bhutan.

9. **Review History**

Revision	Revision Date	Reason for Revision	Revised by
SoP on preparation of annual calibration, checks and cleaning schedule	20/03/2026	Document corrected and updated	Dr. Kinzang Chedup Lungten Dorji Tshewang Dema Norbula

SOP No: LSU/LQMS/6.5
Title: SoP on Validation of Laboratory Equipment.
Version No: 1, Total Pages: 4
Issue Month/Effective Date: May/2026
Revision Summary:
Supersedes Version No:2
Prepared by: LSU, LQMS, NCAH
Reviewed by: Dr. Kinzang Chedup, Lungten Dorji, Tshewang Dema, Norbula
Approved by: Head, LSU
Application/Distribution:

1. **Scope**
   This SOP shall be used as such for validation of laboratory instruments/equipment in the quality control section in the laboratory.

2. **Purpose**
   The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for validation of Laboratory instrument/equipment**.**

3. **Responsibilities**

Sl No.	Designation	Responsibility
3.1	Head, Laboratory service unit	1. Oversees and ensures all the laboratory equipment are validated and qualified for precise usage
3.2	Biosafety officer/ focal	2. Implements the SOP. 3. Supervise and monitors the installation and validation of the laboratory equipment
3.3	Supplier/Biomedical engineer	4. To install and validate the laboratory equipment following the manufactures instruction.

4. **Definitions**
   1) **Biomedical engineer:** It refers to a person designated to solve the problems of bio-medical equipment.
   2) **Equipment:** It refers to all instruments, measuring devices, and computer systems used in evaluating and/or performing research.
   3) **Installation qualification (IQ)**: It refers to a documented proof that the equipment meets the design intention.
   4) **LSU:** It refers to the Laboratory Service Unit**.**
   5) **Operational qualification (OQ)**: It refers to a documented proof that the equipment performs as specified.

6) **Performance qualification (PQ)**: It refers to a documented proof the equipment or systems operate as intended under challenge conditions.
7) **Validation:** It refers to a detailed process of confirming that the instrument is installed correctly, that is operating efficiently, and that it is performing without error.

5. **Procedure**

1. Compare and check off the parts and accessories received to the checklist as purchased.
2. Confirm that the equipment is complete and in good condition. Notify the supplier/manufacturer immediately of any problems found.

6. Setting up considerations

Laboratory equipment/instrumentation can be sensitive to certain environmental factors. By observing the following factors during installation, the Operator can minimize the effects of these influences where appropriate:

1. Location near the output of the air conditioner causing excessive drafts.
2. Direct sunlight and other high temperature locations, i.e. near an oven or furnace.
3. Avoid using an extension cord where possible.
4. Don't place the unit in the same circuit with large electrical motors.
5. Plug all line cords into a surge protector.
6. To allow a unit to cool properly, keep the vents on the back clean.
7. Minimize the unit's exposure to dust and provide sufficient bench space for the instrument and the computer, printer and keyboard.
8. Allow enough space nearby for sample handling.

7. Validation Process.

1. **Installation qualification (IQ)**. First, the equipment item should be checked to be sure that it meets its design and purchase specifications and is correctly installed. Installation qualification includes, checking instruction manuals, schematic diagrams, and spare parts lists are present; checking that all components of the device are installed; checking that the materials used in construction were those specified; and making sure that fittings, attachments, cables, plumbing, and wiring are properly connected.
2. **Operational Qualification (OQ)**. After installation, the equipment should be tested to verify that it performs within acceptable limits.
3. **Performance Qualification (PQ)**. Once all measuring instruments are calibrated, and all equipment is validated, process validation (or qualification) should be performed.
4. The validation of the process should be carried out under all the conditions that can be expected to occur during production. Testing includes checking the process endpoint(s) under these conditions and establishing that the process consistently meets its specifications.

8. **References**

1. Validation of laboratory instruments-GMP SOP
2. The LiberText Biology-Validation process and equipment

9. **Review History**

Revision	Revision Date	Reason for Revision	Revised by
SoP on Validation of Laboratory Equipment.	20/03/2026	Document corrected and updated	Dr. Kinzang Chedup Lungten Dorji Tshewang Dema Norbula

SOP No: LSU/QMS/6.6
Title: SoP on Culture media quality test
Version No: 1, Total Pages: 6
Issue Month/Effective Date: May/2026
Revision Summary:
Supersedes Version No:2
Prepared by: LQMS, LSU,NCAH
Reviewed by: Dr. Rinzin Loday, Tenzinla,Bindu Parajuli
Approved by:
Application/Distribution:

SOP for culture media quality test

- **Objective:**
  To lay down the procedure for checking the growth promotion test of the microbiological culture media.

- **Scope:**
  This procedure is applicable for the nutrient media used for culture of microorganism in microbiological laboratory

- **Principle:**

  The principle of culture media quality testing is to verify that the medium reliably supports the growth of target microorganisms, inhibits non-target organisms, and is free from contamination**,** ensuring accurate and reproducible laboratory results.

- **Procedure:**
  General
  This protocol requires the use of a control organism such as E.coli ATCC 25922 or Staphylococcus aureus ATCC 25923. The recovery from the new batch of culture medium will be compared to the recovery from a previously accepted batch of the same media composition.

  - **Media preparation**
    - Record the details (such as media name, batch no., brand, open date, etc.) of the new batch of media for which GPT is to be conducted and record the details of the old batch media (if available) to compared.
    - Prepare the media and sterilize as per the manufacturer's directions.
    - After sterilization, let the media cool till 56^{o}C and add supplements as per the manufacturer's instruction if required.
    - Label the plates with culture media name and date.
    - Pour the media into the plate and allow solidifying.
    - Plate the media with the control organism.
    - Plate the control organism in the old batch media.
    - Incubate the solidified plates in accordance with the conditions described in SOP for bacterial culture and identification.
    - Similarly incubate a control plate for sterility test for contamination growth.
    - After incubation, observe the plates for bacterial growth and with the recovery on a non-selective culture medium (reference medium) or a previously accepted batch of the same media composition.
    - Maintain the record in the form **growth promotion test for microbiology LSU/FORM/6.5/01)**

- **References**
  - SOP for Growth promotion test for microbiological media, National food testing laboratory.
  - Record for GPT for microbiological media form, NFTL/REC/MICRO/6.6/01

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Annexure:Table 1. Control strain and performance criteria for culture media commonly used in microbiology.

Media	**Medium Solid/liquid**	**Control strain**	**Incubation**	**Reference media**	**Method of control**	**Criteria**	**Characteristics**
Sheep blood agar	Solid	*E.coli*	(18- 24) hrs (35 - 37 ± 2) ℃	Sheep blood agar	Qualitative	Pure growth	Pure heavy growth- No hemolysis
		Staphylococci					Pure heavy growth with beta/alpha hemolysis
Mac Conkey agar	Solid	*E.coli*	(18- 24) hrs (35 - 37 ± 2) ℃	Mac Conkey agar	Qualitative	Pure growth	Lactose fermenting , Pink colonies
		Staphylococci					No growth
XLD/Hoekton/BGA	Solid	*Salmonella typhimurium*	(18- 24) hrs (35 - 37 ± 2) ℃	XLD/Hoekton/BGA	Qualitative	Pure growth	Colonies with black centre and a lightly transparent zone of reddish colour due to the colour change of the medium
		E.coli					Pure growth with orange colony

Nutrient Agar	Solid	*E.coli, Staphylococciand Salmonella*	(18- 24) hrs (35 - 37 ± 2) ℃	Nutrient Agar	Qualitative	Pure growth	Pure growth with non hemolytic
Mueller Hinton Agar	Solid	*E.coli,Staphylococci and Salmonella*	(18- 24) hrs (35 - 37 ± 2) ℃	Mueller hinton agar	Qualitative	Pure growth	Zone diameter within the quality control range
Slanetz Bartley Agar	Solid	*Entericoccus*	(18- 24) hrs(35 - 37 ± 2) ℃	Slanetz Bartley Agar	Qualitative	Pure growth	pure growth with red-pink or maroon colonies
Manitol Salt Agar	Solid	*Staphylococci*	(18- 24) hrs(35 - 37 ± 2) ℃	Manitol Salt Agar	Qualitative	Pure growth	pure growth with yellow/ pink colony
MR-VP medium	Liquid	*E.coli,Staphylococciand Salmonella*	(18- 24) hrs(35 - 37 ± 2) ℃	MR-VP medium	Qualitative	Pure growth	*E. coli* and *Salmonella* MR positive and VP negative reaction Staphylococcus - MR and VP negative reaction .
MIL	Liquid	*E.coli and Staphylococci*	(18- 24) hrs(35 - 37 ± 2) ℃	MIL	Qualitative	Pure growth	E.coli-motile, indole positive, lysine negative,Staphylococcus is non-motile, indole negative, and lysine negative
Urea	Solid	*E.coli and Salmonella*	(18- 24) hrs(35 - 37 ± 2) ℃	Urea	Qualitative	Pure growth	E. coli and Salmonella are urease negative while Staphylococcus is urease positive (pink color change).

Bile Aesculin	Solid	*Entericoccus and E.coli*	(18- 24) hrs(35 - 37 ± 2) ℃	Bile Aesculin	Qualitative	Pure growth	E.coli growth without blackening,Enteriococcus -growth with blackening of the medium
Simmon Citrate	solid	*E.coli and Staphylococci*	(18- 24) hrs(35 - 37 ± 2) ℃	Simmon Citrate	Qualitative	Pure growth	E.coli-no growth-citrate negative, Staphylococcus -blue color change (citrate positive).
OF Basal medium	Semi-Liquid	*E.coli and Staphylococci*	(18- 24) hrs(35 - 37 ± 2) ℃	OF Basal medium	Qualitative	Pure growth	E. coli- fermentative reaction, Staphylococcus-fermentative reaction
Buffer Peptone Water	Liquid	*E.coli, Salmonella and Staphylococci*	(18- 24) hrs(35 - 37 ± 2) ℃	Buffer Peptone Water	Qualitative	Pure growth	Non-selective enrichment broth used only to promote bacterial growth
RVS Broth	Liquid	*Salmonella and staphylococci*	(18- 24) hrs(35 - 37 ± 2) ℃	RVS Broth	Qualitative	Pure growth	Salmonella good growth with turbidity (selectively enriched), whereas Staphylococcus shows inhibited or no growth
Azide Dextrose Broth	Liquid	*Entericoccus*	(18- 24) hrs(35 - 37 ± 2) ℃	Azide Dextrose Broth	Qualitative	Pure growth	E.coli - no growth, Enterococcus- good growth with turbidity
EMB Agar	Solid	*E.coli and Staphylococci*	(18- 24) hrs(35 - 37 ± 3) ℃	EMB Agar	Qualitative	Pure growth	E.coli - green metallic sheen, Staphylococcus - no growth

- **Review History**

Revision	Revision Date	Reason for Revision	Revised by
Addition of the test principle	20/03/2026	It was no LQMS SOP	Dr. Rinzin Loday Tenzinla Bindu Parajuli
Addition of media in tabular form	20/3/2026	Incomplete media list	

SOP No: LSU/QMS/7.10/0
Title: SoP on Control of Non-Conforming Testing
Version No: 1, Total Pages: 05
Issue Month/Effective Date: May/2026
Revision Summary:
Supersedes Version No:2
Prepared by: LQMS, LSU, NCAH
Reviewed by: Kelzang Lhamo
Approved by:
Application/Distribution:

- **PURPOSE:**

  This procedure controls any non-conforming testing and ensures that all tests are carried out as per the laid down procedures / methods only.

- **SCOPE:**

  This procedure is applicable to all the tests carried out at LSU.

- **RESPONSIBILITY:**

  Quality Manager is overall responsible. However, other Lab in-charges/LO ensure adherence to the laid down procedures.

- **PROCEDURE:**

Sl. No.	Description	Responsibility	Reference Document
4.1	Any non-confirming test work with respect to the laid down procedure / test methods is immediately brought to the notice of Technical Manager/Lab in-charge. The non-conforming work may be detected at any stage of the testing and reported by any person of LSU during testing through the following activities: ● Quality Checks. (routine/PT) ● Surveillance check by QM and Officer in-charge ● Internal Audit. ● Supervision by LO.	All LSU Personnel	
4.2	The authority for management of non-conforming work lies with respective section in-charges. Thus, it is ensured by section in-charges that, ● All the testing is carried out as per laid down procedures / methods. ● All the non-conformance in work is evaluated for its significance.	Lab In-charges	**Records of Non-conforming testing work**

	• Suitable corrective action is taken to avoid recurrence of such non-conformance. • The clients are informed for non-conforming work, when it affects the reliability of test result & work is recalled accordingly.		
4.3	The details of the non-conforming works are maintained as per the non-conforming form.	Section in-charge	
4.4	Based on the evaluation of significance of non-confirming work by section in-charges, the corrective action is identified, initiated, and implemented immediately. The work is resumed after getting authorization from lab in-charge. The decisions on acceptance of non-conformance test work with certain correction factor or to reject the non-conformance test work and restart the testing from fresh sampling is taken by Lab in-charge	Lab in-charge	
4.5	In case the sample is disposed at the point of detection of non-conforming work, the client is informed, and fresh sample is obtained.	Section in-charge	

RECORD OF NON-CONFORMING WORK

Section and Test details		
Section	**SOP Title**	**SOP No.**
Details of non-conformance		
Step	**Description of error**	
Corrective action		
Root cause analysis		
Information on non-conformance conveyed to the client	**Yes/No** **Method of communication:**	
Date:		
Signed	**Test performer**	
	Verified by:	

- **REVIEW HISTORY**

Revision	Revision Date	Reason for Revision	Revised by

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SOP No: LSU/QMS/8.5/02
Title: Assessment of Biosafety in the Laboratory
Version No: 1, Total Pages: 11
Issue Month/Effective Date: May/2026
Revision Summary:
Supersedes Version No:2
Prepared by: LQMS, LSU,NCAH
Reviewed by:
Approved by:
Application/Distribution:

1. Purpose

To establish a systematic process for assessing biosafety practices in the laboratory, ensuring compliance with national and international biosafety standards, and safeguarding staff, animals, and the environment from potential biological hazards.

2. Scope

This SOP applies to all laboratory staff, visitors, and trainees working within the Laboratory. It covers biosafety assessments related to laboratory infrastructure, equipment, procedures, and personnel practices.

3. Responsibilities

i. *Laboratory Manager*: Ensure implementation of biosafety assessment procedures and corrective actions.
ii. *Biosafety Officer*: Conduct assessments, maintain records, and provide training.
iii. *Laboratory Staff:* Comply with biosafety requirements and participate in assessments.
iv. *Quality Management Unit (LQMS):* Monitor compliance and review assessment reports.

4. Procedure

Planning the Assessment

- Schedule assessments annually or as required.
- Define scope, objectives, and responsible personnel.

Assessment Criteria (Annexure)

- Laboratory infrastructure (containment, ventilation, waste disposal).
- Equipment safety (maintenance, calibration, PPE availability).
- Personnel practices (training, adherence to SOPs, incident reporting).

- Emergency preparedness (spill response, fire safety, evacuation).

Conducting the Assessment

- Use standardized checklists and observation forms.
- Interview staff and review documentation.
- Identify non-conformities and potential risks.

Reporting and Corrective Actions

Document findings in an assessment report.

Recommend corrective measures with timelines.

Submit report to Laboratory Manager and LQMS.

Follow-up

Verify implementation of corrective actions.

Record compliance status and update biosafety records.

Review History

Revision	Revision Date	Reason for Revision	Revised by

Veterinary Laboratory Biorisk Assessment

A. General Information (Specimen Laboratory Data Sheet) (WOAH format)

Please fill in the requisite information in details. You may not have the requisite resource at the moment but you may mention the feasibility of having them without any difficulty considering the existing resources you may have

Name of Organisation:			
Address :			
Name of Contact Person:		Designation:	
(The Contact person may preferably be a Biosafety person identified by the institute) Contact No.: Email:			
Type of Work Carried Out in Laboratory			
No. of workers :			
Scientific: Technical:	1.		

Supporting (Including Attendants) Type of Agents handled :		
(Give details including the approximate monthly load of samples of the particular agents being handled)		
	2.	
	3.	
	4.	

Please fill in the requisite information in details. You may not have the requisite resource at the moment but you may mention the feasibility of having them without any difficulty considering the existing resources you may have.

1. Do you have a designated Biosafety Officer has been formally appointed and given due authority to oversee and provide guidance in the areas of Biosafety?	**Yes/No**
2. Do you have an Institutional biosafety committee in your organisation?	**Yes/No**
3. Do you have the facility and/or the need to maintain some sort of repository of the agents being handled in your laboratory?	**Yes/No**

4. If yes, whether effective procedures have been established, implemented and maintained to address to control how the inventory is categorised and managed	
5. Do you have effective procedures and resources to manage general safety risks, for eg., a. fire safety, b. electrical safety, c. chemical safety, d. gases such as Liquid nitrogen, CO_2 e. pest control, f. Major equipment used in the lab g. Access control against unwanted individuals	
6. Do you have documented procedures that have been established, implemented and maintained to manage Good Laboratory Practices in terms of majorly the following: a. Personnel wash their hands using an appropriate technique after handling infectious materials b. No food / drink storage / consumption, smoking, applying cosmetics and / or handling contact lenses c. Restrictions prohibiting the use of personal items, including mobile telephones, clothing and accessories d. Sample receipt and handling e. Type of samples/agents to be handled in the laboratory f. Methods for waste management, including minimisation of potential for contamination of packaging materials g. Use of appropriate signage h. Safe pipetting techniques i. Cleaning and decontamination, including required validation measures j. Minimizing aerosol generation k. Control of minor spills/splashes l. Use of equipment while processing of agents/samples m. Molecular biology techniques n. Handling and disposal of consumables	

7. Do you handle laboratory animals routinely for infectious agents?	
8. If yes, whether effective procedures have been established, implemented and maintained, associated with selection, use and handling of animal including registration of Institute Animal Ethics Committee with Ministry of Environment and Forests?	
9. Do you have effective procedures and resources associated with selection, use and disposal of PPE such as gloves, masks, aprons etc.	
10. Effective procedures have been established, implemented associated with worker health and training including awareness regarding the handling of infectious agents	
11. Do you have a basic building facility to designate a biosafety laboratory in the laboratory premises? If yes, does the facility meet or can meet the following : a. The building is in overall sound condition and generally fit-for-purpose in terms of housing the work needs b. BSL2 laboratory separated from the areas that are open to unrestricted flow within the building c. The use of natural ventilation (where applicable), which does not impact on the safe and secure functioning of equipment or interfere with work practices d. Inward directional air flow is present into the laboratory preventing air from moving to the corridor or other non-laboratory areas e. Air not re-circulated to other non-laboratory parts of the building f. Areas for rest, eating / drinking and general meetings are located outside the laboratory or segregated by means of closed doors with procedures preventing potentially contaminated materials entering the area (e.g. PPE), together with appropriate hand hygiene facilities for use when entering and leaving the area.	

12. Does your laboratory have these biosafety related equipment? a. Biosafety Cabinets (If yes, Mention the numbers, class of biosafety cabinets) b. Autoclaves alongwith sterilization-validation practices) c. Centrifuges with biosafe cups (Unbreakable, Autoclavable Cups with proper lid) d. Emergency eye wash (Spray bottles filled with Sterile NSS)/ shower facility d. Automated pipettes/pipetting aids e. Liquid nitrogen and other compressed cases, (CO_2), etc f. Vacuum pumps, lines g. Hot air ovens h. Fumigation chambers. If yes for any of the above, a. How often are the biosafety equipment validated /tested for the functionality? b. Do you have written down procedures for handling these equipment?	
1. Do you have a waste segregation plan for Biomedical waste? 2. Do you decontaminate biomedical waste before discard? If yes, what method is used? a. Chemical b. Heat c. Any other Where does your laboratory discard the waste? a. Deep burial. If yes, size of the pit 2. incinerator 3. Municipal discard facility (being used for frequent collection of waste)	

B. Laboratory systems

a) Provide organisational structure and roles of the veterinary laboratory service

b) Summary of laboratory quality Management System and assurance accreditation programmes and, if any veterinary laboratories that have achieved ISO 17025 accreditation, and those actively pursuing accreditation;

d) List of diagnostic methodologies available against major diseases of farm livestock

e) Details of PT with national and external laboratories including international reference laboratories International collaborations (Laboratory Diagnosis)

f) Recent published reports of the official veterinary laboratory service

g) Details of procedures for specimen submission and results and storage and retrieval of information

h) Reports of independent reviews of the laboratory service conducted by government or private organizations (if available)

i) Strategic and operational plans for the official veterinary laboratory service (if available)

j) Procedures for coordination with public health on relevant diseases/laboratory issues (e.g., harmonization of protocols)

C. Biorisk Scoring Matrix (Likelihood × Severity)

Likelihood of Occurrence	**Score**	**Description**
Rare	1	Highly unlikely, may occur only in exceptional circumstances
Unlikely	2	Could occur occasionally, but not expected
Possible	3	Might occur at some time under certain conditions
Likely	4	Will probably occur in most circumstances
Almost Certain	5	Expected to occur frequently or regularly

Severity of Consequences	Score	Description
Negligible	1	No significant harm, minimal disruption
Minor	2	Small impact, easily managed, no long-term effects
Moderate	3	Noticeable impact on staff safety or lab operations
Major	4	Serious injury, infection, or significant operational disruption
Catastrophic	5	Severe illness, widespread outbreak, or major institutional impact

Risk Rating Formula

Risk Score=Likelihood×Severity

- **Low Risk (1–5) → Acceptable with routine controls**
- **Medium Risk (6–10) → Requires additional mitigation measures**
- **High Risk (11–15) → Immediate corrective action needed**
- **Critical Risk (16–25) → Stop activity until risks are reduced**

Biorisk Assessment Dashboard

Hazard/Activity	Risk Level	Status/Action
Rabies brain tissue handling	Critical	Halt activity until PPE & biosafety cabinet enforced
Anthrax necropsy	Critical	Stop until BSL-3 facility available
Sharps disposal	High	Improve sharps management & staff training
Sample transport	Medium	Strengthen packaging & transport SOP
Waste management	Critical	Autoclaving & incineration required

Notes: Risk Identification (Context based)

- Biological hazards: zoonotic pathogens (rabies, anthrax, avian influenza, brucellosis, etc.)
- Sample types: blood, tissue, fecal, environmental samples
- Procedures with risk: necropsy, culture, PCR, serology, animal handling

Risk Analysis and Risk Control Measures

- Likelihood of exposure: accidental spills, aerosol generation, sharps injuries
- Severity of consequences: infection, community spread, livestock impact
- Risk rating: Low / Medium / High (matrix-based scoring)
- Engineering controls: biosafety cabinets, autoclaves, ventilation systems
- Administrative controls: SOPs, access restrictions, incident reporting
- PPE: gloves, lab coats, masks, face shields, boots
- Waste management: segregation, autoclaving, incineration
- Emergency preparedness: spill kits, first aid, exposure response plan

STEPS

1. Hazard Identification → Technicians list activities they perform (e.g., necropsy, PCR, sample transport)
2. Scoring, Together with the biosafety officer, they assign likelihood and severity values.
3. Risk Calculation → Multiply likelihood × severity to get the risk score.
4. Mitigation Measures → Technicians suggest practical controls (PPE, SOPs, equipment use).
5. Validation → Manager reviews and finalizes the scoring sheet/dashboard.

Likelihood vs. Severity

- Likelihood reflects how often an event *might* occur in your lab setting.
    - If a technician says "2 = Unlikely" for handling rabies tissue without PPE, they are judging that exposure is not expected to happen often (perhaps because they are cautious or think incidents are rare).
- Severity, however, is independent of likelihood. It measures the *impact* if exposure does occur.
    - For rabies tissue: even a single exposure could cause catastrophic consequences (fatal infection, public health risk).
    - So severity should be scored 5 = Catastrophic, regardless of how "unlikely" the technician feels the event is.

SOP No: LSU/LQM/6.3
Title: SoP on Laboratory Waste Management
Version No: 2, Total Pages: 23
Issue Month/Effective Date: May/2026
Revision Summary:
Supersedes Version No:2
Prepared by: LQMS, LSU,NCAH
Reviewed by: Dr. Dezang Wangchuk, Mr. Karma Tsheten, Mr. Roshan Rai
Approved by:
Application/Distribution: NCAH/NVH/RVH/DVH/SVL

1. Introduction

Laboratories are significant generators of wastes, which can be hazardous (Infectious) or non-hazardous in nature. About 10-12% of laboratory waste is infectious and potentially zoonotic. Globally, about 60% of all human pathogens and 75% of emerging diseases are of zoonotic. Since, 39% of LAI (Laboratory Acquired Infections) occurs in Laboratory, laboratory waste management is an important aspect to safeguarding the health and wellbeing of the personnel working in the laboratories. Good laboratory waste management is also fundamental in ensuring that the laboratories and the environment are clean and healthy in order to prevent the spread of infectious pathogens. There are different categories of wastes generated from laboratories on a daily basis, which need different approaches to management, starting from the source of waste generation to the disposal of the waste. This SOP for laboratory waste management is a step towards ensuring that the environment of the laboratory premises is clean and healthy, and also ensuring the safety of the personnel working in the laboratory.

2. Scope

This SOP outlines the detailed steps required for identification, segregation, collection, storage, treatment and disposal of laboratory wastes and serves as a guiding tool for laboratory personnel in safe handling and proper disposal of laboratory wastes. This SOP applies to all the staff who work within an animal health laboratory setting across the country.

3. Responsibility

All laboratory staff are responsible for implementing this waste management SOP. Each member of staff has specific roles and responsibilities in ensuring that wastes are appropriately managed. The following table provides a brief description of the roles and responsibilities of staff working in the animal health laboratory:

SI No.	Designation	Responsibility
1	Head, Laboratory Service Unit	• Oversees and ensures laboratory personnel follow the waste management SOPs appropriately
2	Biosafety Officer/ Biosafety Focal	• Oversight and policy development at system level

		• Supervises, monitors and trains the laboratory personnel in following the Laboratory biosafety and biosecurity measures • Conduct regular risk assessment for biological waste and classify waste based on hazard level. • Design and coordinate emergency response plan during exposure incident
3	Laboratory Officer	• Implements the SOP • Supervises, monitors and trains the laboratory personnel in following the Laboratory waste management SOP • Ensures appropriate and adequate waste management kits/equipment are available • Supervises collection, storage, treatment and disposal of wastes
4	Laboratory Technician	• Collects and segregates laboratory waste in suitable waste containers according to the color coding of the bins/plastic bags • Disinfects/ supervises disinfection of wastes • Maintains the laboratory waste inventories
5	Lab Attendant	• Assists the Laboratory Technician in disinfecting wastes • Loads and operates the autoclave • Collects, stores and disposes of the wastes

4. Classification of waste

Waste categories	Description
1. Hazardous	

i. Sharps	Sharps are objects or devices that have acute, rigid corners, edges, points or protuberances capable of cutting or penetrating the skin. Sharps are considered hazardous waste and they must be managed with the utmost care. Examples: all types of needles, broken glass ware, needles, scalpel blades, lancets.
ii. Infectious	Wastes that are contaminated with blood and other bodily fluids and potentially contaminated with pathogenic materials. Examples: discarded diagnostic samples, cultures and stocks of infectious agents, wastes from autopsies.
iii. Pathological	Pathological waste could be considered to be a subcategory of infectious waste, but it is often classified separately – especially when special methods of handling, treatment and disposal are used. Examples: tissues, organs, body parts, blood, body fluids, animal fetuses and carcasses.
iv. Cytotoxic	Any substance contaminated with residues or preparations that contain materials that are toxic to cells, principally through their action on cell reproduction (i.e. mutagenic, teratogenic or carcinogenic). Examples: any expired, unused and contaminated drugs and vaccines.
v. Chemical	Chemical waste consists of discarded solid, liquid and gaseous chemicals, generated from diagnostic and experimental work from cleaning and disinfection procedures. Examples: solvents and reagents used for laboratory preparations, disinfectants, heavy metals like mercury in broken thermometers, batteries)
2. Non-Hazardous	
i. General waste	Waste that does not pose any particular biological, chemical, radioactive or physical hazard. They are free of pathogenic microorganisms or hazardous substances and therefore considered harmless and do not need special handling or treatment. Examples: papers, tissues, packing materials, plastic.

5. Equipment/ materials

For effective management of laboratory wastes, the following equipment is necessary for implementation of this SOP:

- Biohazard waste bags (color-coded)
- Autoclave bags
- Waste bins/containers - (plastic or stainless steel with lid – color-coded)
- Waste disposal trolley
- Personal protective equipment (PPE - refer to Annex 2 for the list)
- Hazardous waste symbols/labels (refer to Annex 4)
- Spill kits (refer to Annex 2 for the list)
- Absorbent mats
- Disposal pits (biological/ sharps pit/landfill)
- Autoclave
- Incinerator (depending on the volume and type of wastes generated, usually a small-scale incinerator should be sufficient)
- Disinfectants

6. General considerations

For the SOP to be implemented effectively, the relevant veterinary health institution or Local government should ensure that the following conditions are met:

- **Obtain and provide funds** to develop appropriate and adequate infrastructure and capacity to institute an effective and efficient waste management system, in particular for hazardous wastes.
- Provide all laboratory personnel with **appropriate PPE** while handling wastes
- Provide **training** to veterinary health workers and veterinary medical waste handlers about the risks and about safety measures, including correct handling of the wastes.
- Provide **waste bins** (standard waste bins as per the requirements laid out in the SOP) for collection and segregation of wastes.
- Ensure records are maintained of the generation, collection, storage, treatment and disposal of the wastes in accordance with this SOP.
- Ensure that all waste bags or containers are **labeled with basic information** about their content and on the waste producer. This information may be written directly on the bag or container or on preprinted labels that are securely attached to the bag or container.

- Materials that can be reused should be collected after appropriate treatment to minimize the wastes.

7. Procedures

7.1. Infectious waste

Infectious waste is material suspected to contain pathogens (bacteria, viruses, parasites or fungi) in sufficient concentration or quantity to cause disease in susceptible hosts. This category includes:

a. Cultures and stocks of infectious agents from laboratory work.
b. Waste contaminated with blood or other body fluids.

7.1.1. Microbial culture media plates & stocks

Waste cultures and stocks of agents that are generated by the laboratory are infectious to either animals or humans.

Collection

- Person/s who generate infectious laboratory waste are responsible for segregating the waste according to its type and degree of hazard so that potential occupational exposures and environmental contamination are minimized
- Wastes should be segregated and collected in a container/bags (marked as infectious wastes with the universal biohazard symbol) for subsequent disinfection and disposal.
- The containers should be leak-resistant stainless steel, or temperature-resistant polymers. The physical properties of the container should be compatible with the treatment process.
- The frequency of collection for such wastes should be once daily or twice a week or depending upon the work flow (as many microorganisms will proliferate at room temperature).

Storage

- The storage place must be identified as an infectious waste area by using the biohazard sign.
- Floors and walls should be sealed or tiled to allow easy disinfection.
- If present, the storage room should be connected to a special sewage system.

- Infectious waste should be kept cool or refrigerated at a temperature preferably no higher than 3°C to 8°C if stored for more than a week.
- Unless a refrigerated storage room is available, storage times for infectious waste (i.e. the time between generation of the waste and treatment should not exceed the following periods:
    - Temperate climate - 72 hours in winter and 48 hours in summer.
    - Warm climate - 48 hours during the cool season and 24 hours during the hot season.

Treatment

- Infectious wastes should be autoclaved prior to disposal to render them harmless.
- Liquid wastes (stocks) should be collected in leak-proof containers and sterilized in the autoclave at 121°C for 15 minutes.
- After autoclaving, the wastes can be destroyed in an incinerator at 1100^0C.
- If an autoclaving facility is not available, the wastes should be put into a red bag, sealed off with a cable tie once the bag is 3/4 full, double bagged and then put into a cardboard box which is closed, sealed and labeled.

Disposal

- Non-reusable infectious wastes can be disposed of as regular waste in the designated bins/disposal pits after disinfection.
- Liquid wastes (stocks) can be safely discharged into the sewer system (if available) or any designated disposal pit after disinfection.

7.1.2. Blood & body fluids

Waste contaminated with blood or other body fluids, including free flowing blood, blood components and other body fluids, dressings, bandages, swabs, gloves, masks, gowns, drapes and other material contaminated with blood or other body fluids.

Collection

- The wastes containing free flowing blood, blood components and other body fluids should be collected in containers made of a strong and leak-proof material (red colour).
- Wastes contaminated with blood, such as swabs, gloves, masks and other materials, should be collected in biohazard bags or autoclavable bags (red colour).

- The frequency of collection for such wastes should be once daily, as many microorganisms will proliferate at room temperature.

Storage

Refer to Section 7.1.1

Treatment

- The wastes containing free flowing blood, blood components and other body fluids can be disinfected as soon as possible with 10% bleach solution for 10 min or autoclaved at 121°C, 15 psi for 30 minutes.
- Wastes contaminated with blood, such as swabs, gloves, masks and other materials, should be collected in biohazard bags or autoclavable bags and autoclaved at 121^{o}C, 15 psi for 30 minutes.

Disposal

- After complete disinfection, the free flowing waste can be discharged into a laboratory sink drain but care should be taken to avoid disposing of thick/clotted bloods in this way to prevent blockage of pipes. They can also be discharged into the sewer system (if available).
- After disinfection, solid wastes contaminated with blood/ body fluids can be considered as general waste and disposed of in the designated general waste bin/pit.

7.1.3. Pathological Wastes

Pathological waste includes any detached animal organs, tissues and body parts.

Collection

a. Pathological waste should be packaged in durable, preferably opaque, plastic liners
b. These wastes should be collected and double-bagged to prevent leaks. Personnel should then store them in a secondary container, similar to liquid waste, to collect any leaks from the primary bags.
c. As a precaution, absorbent material can be added to contain any fluids that might be present.
d. Some pathological waste may be hazardous if it was in contact with chemotherapy drugs or other drugs and/or chemicals. It may also be infectious or potentially infectious. If this is the

case, it should be collected and labelled as per the specific requirements for these types of hazardous waste.

e. The frequency of collection should be at least once a day or when three quarters of the bag is full, whichever is earlier.

Storage

a. Pathological waste is considered biologically active and gas formation during storage should be expected.
b. To minimize the possibility of this happening, storage places should have the same conditions as for infectious wastes.
c. Where possible, pathological waste should be stored under refrigerated conditions.

Treatment

a. Incineration is the method of choice for destruction of pathological wastes (especially infected pathological waste).
b. Alternatively, pathological wastes can be disinfected by treating with suitable disinfectants to inactivate the pathogens.

Disposal

a. Pathological waste derived from non-infected sources can be disposed of in the designated biological pit.
b. Normal pathological wastes can be disposed directly in the biological pit.
c. Fly ash and bottom ash from incineration is generally considered to be hazardous, because of the possibility of heavy metal content and dioxins and furans (carcinogens). It should preferably be disposed of in sites designed for hazardous wastes, such as designated cells at engineered landfills.

7.1.4. Sharps Waste Management

Sharps are objects or devices that have acute, rigid corners, edges, points or protuberances capable of cutting or penetrating the skin, such as needles, broken glass, scalpel blades and lancets.

Collection

- All sharps should be collected in a rigid, puncture-proof container (white container and properly labelled with "SHARPS" to guide the waste generators and attendants to efficiently use the bins.
- Large broken glass pieces should be collected in the white buckets with lids, preferably 20 L capacity (picture). They should also be appropriately labelled as "SHARPS".
- Small items with sharp edges should be collected in the smaller sharps bins with a locking system. Alternatively, sharps can also be collected in cardboard safety boxes if standard containers are not available.
- Sharp items contaminated with cytotoxic chemicals must be discarded into a cytotoxic sharps bin (purple bin- refer to the section on Cytotoxic waste management).
- Overfilling the bins can result in sharps injuries, so do not overfill them.
- Do not force items into the container, as this could lead to breakage of the container and injuries.
- No sharp waste should be discarded into anything other than a designated sharps bin.
- The sharps bins should remain in the area where the sharps are generated until the container is full or the container is no longer required.
- Once the bins are full, the bins should be properly closed and removed from the area to the relevant waste collection point (if relevant).

Storage

- Sharps waste must be stored in an appropriate sharps bin that is kept near to where the sharps are generated.
- Containers that are filled with sharp wastes should be stored in a designated waste storage room if they are not disposed immediately.

Treatment

- Sharp wastes contaminated with infectious agents should be treated as infectious waste and treated accordingly (refer to the section on infectious waste management).
- Non-infectious/regular sharp wastes can be managed in the following ways:

  - ✓ Mechanical needle cutters or electric needle destroyers.
  - ✓ Shredding the treated plastic parts.

- ✓ Burying the metal pieces in sharps pits.
- ✓ Re-melting the plastics for recycling.

Disposal

1. Sharp wastes should ideally be destroyed in an incinerator at 850°C – 1100°C (if available). The residual ash should be disposed by deep burial. Deep burial should be at a designated site away from settlement and water sources.
2. Alternatively, sharp wastes can be disposed of in designated sharp pits if an incinerator is not available.

7.1.5. Chemical Waste Management:

Collection

- Chemical liquid waste containers should only be filled up to 75% capacity to allow for vapor expansion and to reduce potential spills, which could occur from moving overfilled containers.
- Container material must be compatible with the stored hazardous waste (refer to.http://www.calpaclab.com/chemical-compatibility-charts/ for compatibility information)
- Incompatible materials should never be mixed together in a single container.
- Label all containers with the group name from the chemical waste category and an itemized list of the contents.
- Powder waste (or similar) can be an inhalation risk (e.g. when closing a waste bag). Preferably, the original container if it is no longer needed, or a lidded plastic container, should be used.
- Biological tissues that have been chemically fixed or treated are no longer considered a biological hazard, and, therefore, need to be wrapped up and sealed into appropriate containers so that the tissues are not recognizable and there is no leakage.
- If empty glass containers are used to collect or store chemical wastes, they should be packaged to minimize damage to the container using polypacks, racks, or some other suitable non-breakable container.
- Liquid-waste containers must be kept closed (sealed) at all times, except when you are actually adding waste. It is not adequate to seal containers closed with cork, rubber or ground-glass stoppers, aluminium foil, polyethylene film or parafilm.
- All liquid waste containers must be bunded (i.e. the waste container placed within an embankment or secondary container in order to prevent any spills or leaks from travelling).

- Containers can only be filled to a maximum of 90% full. Head space is needed for expansion and/or ease of dispensing.

Storage

- Proper storage of chemical waste is extremely important because explosions could occur (e.g. nitric acid and organic solvents are extremely incompatible and the container generates pressure in a short period of time and explodes. Waste containers must remain closed or sealed at all times, except when waste is being added or removed from the container.
- Liquid waste containers must be stored in secondary containment systems to prevent migration of leakages.
- Do not allow excess accumulation of chemical waste to build up in the laboratory.
- If the waste is likely to generate gases during storage, vented caps should be used. These wastes must be stored so that vented fumes do not pose a hazard.

Disposal

- Innocuous aqueous waste (such as solutions of sodium chloride) may be poured down the sink. Some chemicals are washed down with excess water (refer to Annex for examples).
- Chlorinated solvent waste is usually incinerated at a high temperature to minimize the formation of dioxins. Non-chlorinated solvent waste can be burned for energy recovery.
- Chemical materials on the "Red List" should never be washed down a drain (refer to Annex 3 for the list).

- Broken glassware containing or contaminated with chemical waste is usually collected in plastic-lined cardboard boxes for landfill. They are usually not suitable for recycling because of the contamination. Similarly, used hypodermic needles are collected as sharps and are incinerated as medical waste.
- Containers that are empty, or contain only small residual amounts of liquid, are disposed of as chemical waste.

7.1.6. Cytotoxic waste Management

Collection

- Cytotoxic waste (soft items such as protective equipment) should be also placed in leak proof and tear-resistant containers identified with the “Cytotoxic” hazard symbol.
- Animal and fish carcasses containing cytotoxic chemicals must be bagged in a robust container and labelled with the Cytotoxic hazard symbol.

- Liquid cytotoxic waste can be sealed into 1 L bottles and labelled with a "Cytotoxic" hazard symbol.
- All the cytotoxic wastes should be collected in a bigger bin (colour-coded purple) labelled with the Cytotoxic hazard symbol.
- Bins with foot pedals and lids, which lock automatically when full, are recommended to minimize exposure.

Storage

- Cytotoxic waste in robust plastic bags must be contained in a solid-based container with a lid and the container must be labelled "Cytotoxic Waste" and must display a Cytotoxic hazard symbol.

Disposal

- Cytotoxic waste is highly hazardous and should never be disposed on in landfill or discharged into the sewerage system.
- Ideally full destruction of all cytotoxic substances is achieved through incineration at temperatures up to 1100°C.
- The other disposal option is returning the waste to the original supplier in a take-back program.
- Chemical degradation can also be used, but must be done in accordance with the manufacturer's instructions. However, chemical degradation methods require expertise.

7.1.7. General Waste

Collection

- General wastes can be collected in an appropriate collection bags (black color).
- The accumulated general waste bags should then be transferred to a larger bin (color-coded green).
- The wastes should be double bagged if the contents are heavy to prevent tearing and spillage of wastes.
- The wastes from laboratories should be collected every day and transferred to a common storage room/designated area for pick up and further disposal.

Storage

- General non-hazardous waste should be stored and kept for collection at a designated store room/area with an enclosure to prevent stray animals scavenging it.

- The storage area should be enclosed, paved and connected to a road for easy access of waste pick-up vehicles.

Disposal

- The wastes should be disposed-off from the storage area in a designated disposal pit or arrangement should be made for disposal through municipal pick-up if a designated disposal pit is not available at the facility.

8. Spill management in the laboratory

8.1. Wet spill (blood & body fluids)

- Place cloths/paper towels or suitable absorbent on the wet spill to absorb it (approximately 5 minutes).
- Carefully collect saturated cloths/paper towels or absorbent material and place them into a red bag.
- Continue to carefully wipe the area with the cloths/paper towels until all visible contamination is removed.
- Placed the used cloths/ paper towels into red biohazard bag.
- Decontaminate the spill area by carefully spraying with a sodium hypochlorite solution and wiping the area dry with a cloth/paper towel. Repeat until all contamination is visibly removed and the area is dry.
- Place the used cloths/paper towels into the red bag, close it securely, and label it correctly.
- Transfer the red bags to the designated waste storage area for disposal.

8.2. **Sharps spill**

- Collect the sharps with a brush and long handled dustpan or other suitable equipment. Never pick up sharps with your hands. Use forceps/tweezers where necessary.
- Place collected sharps into a sharps container and close it securely.
- Decontaminate the spill area by carefully spraying with a sodium hypochlorite solution and wiping the area dry with cloths/paper towels. Repeat until all contamination is visibly removed and the area is dry.
- Place used cloths/paper towels into a red bag, close it securely, and label it correctly.
- Take the sharps container(s) and the red bag to the designated waste storage area.

- Dispose of, or decontaminate, all PPE and equipment used.

8.3. General chemical spill

- Collect the chemical spill with suitable equipment (spill kit).
- Place contaminated materials into a green bag or container (where applicable), close it securely and label it correctly.
- Once the spill is cleared, decontaminate the spill area.
- Take the green bag/container to the designated waste storage area
- Decontaminate all PPE and equipment used and dispose of it.

8.4. Biological Spills

- Stop all work and evacuate all workers for 30 minutes.
- Notify laboratory personnel working in the area/section and restrict access to the spill area to prevent further contamination.
- Get the Spill Kit and put on the appropriate personal protective equipment (PPE). Wear face masks to prevent inhalation of aerosols.
- Move into the laboratory after 30 minutes; bring in the Emergency response kit.
- Place a paper towel or some other absorbent paper product over the spill.
- Spray the paper towel or other absorbent with fresh 10% bleach and water solution.
- Allow the absorbent material and sterilization compound to sit on the spill for fifteen minutes.
- During the fifteen-minute sterilization period, prepare a biohazard bag by opening the bag and folding it down from the top so that a wide opening is created and contamination of the outside bag surfaces during filling is prevented.
- When the fifteen-minute sterilization time is up, put the soaked towels or absorbent material in the biohazard bag, and then wipe up any remaining spill residue with clean paper towels.
- Pick up the absorbent towels and spill materials with forceps and dispose of them into biohazard bags.
- Remove gloves, taking care not to touch the outside surfaces of the gloves with your bare hands, and then place them in the biohazard bag.
- Wash hands thoroughly.

- Steam sterilize the loosely closed biohazard bag and contents in the autoclave.
- Disinfect the forceps and goggles with 70% ethanol.

8.5. Spills that occur within a bio-safety cabinet

- Small spills within a bio-safety cabinet (BSC) should be handled immediately.
- Cover the spill with fresh 10% bleach and water solution, allow it to sit for fifteen minutes, and then wipe it up with a paper towel or other absorbent material.
- Remove the contaminated absorbent paper towel and place it in a biohazard bag inside the bio-safety cabinet.
- Wipe the surface again with sterile water and clean paper towel(s) to remove any residual bleach, and then place the paper towel(s) in a biohazard bag.
- Wipe up any splatter on items within the cabinet, as well as the cabinet interior, with a paper towel moistened with fresh 10% bleach and water solution or an approved equivalent disinfectant.
- Remove contaminated gloves and wash hands.
- Put on clean gloves and put everything back in the cabinet.

9. Recording and reporting of laboratory wastes

All the waste generated from laboratory facilities should be recorded on daily basis to allow appropriate reporting and planning (refer to the waste inventory in annex 5).

10. Weighing

- The total waste generated by the facility should be weighed at the common storage site and recorded on the register/form (see Annex).
- The wastes should be weighed without opening the plastic bags.

11. Responsible persons

- The designated personnel should be responsible for weighing and recording of waste.
- The Biosafety officer/biosafety focal person should compile data on the total waste generated and report this to the relevant committee or agency, where relevant (Department/Ministry/NEC).

12. Reporting Frequency

- reporting should be done annually based on the final compilation in the reporting form (annex 5)

13. References

- Basic Practical Microbiology Manual, Microbiology Society, UK, 2016
- Biosafety in the Laboratory: Prudent Practices for the Handling and Disposal of Infectious Materials. National Research Council (US) Committee on Hazardous Biological Substances in the Laboratory. Washington (DC): National Academies Press (US); 1989
- Laboratory Waste Disposal Guidelines 2018 October, University of Wollongong, Australia
- National Integrated Solid Waste Management Strategy 2014, Royal Government of Bhutan
- National guideline on infection control and medical waste management: Health Care & Diagnostic Division Department of Medical Services Ministry of Health http://www.health.gov.bt/wp-content/uploads/afd-files/2014/11/ICMWM-guideline.pdf
- National Institute of Health/CDC Biosafety in Microbiological and Biomedical Laboratories (MBML) 5th Edition
- National Waste Management Strategy, 2019, Royal Government of Bhutan
- Safe management of wastes from health-care activities, 2nd edition 2017, WHO
- Swazil Laboratory Guideline for Spill Management, Laboratory Waste Management, 2013
- World Health Organization, Laboratory Biosafety Manual, 3rd Edition, Geneva 2004
- Waste prevention and management regulation (amended) 2016, Royal Government of Bhutan

ANNEX A

- **WHO recommended segregation and collection scheme**

Waste categories	Color of container and labeling	Type of container	Collection frequency
Infectious wastes	Red with biohazard symbol with additional labeling as **"INFECTIOUS"**	Strong, leak-proof plastic bag placed in a container (bags should be able to withstand autoclaving)	When 3/4 of container is filled (solid waste) or at least

			once a day (liquid waste)
Sharp waste	White, marked "**SHARPS"** with biohazard symbol	Puncture-proof container	When 3/4 of container is filled
Pathological waste	Yellow with biohazard symbol	Leak-proof strong plastic bag placed in a container	When 3/4 of container is filled (solid waste) or at least once a day (liquid waste)
Cytotoxic Waste	Purple	Leak proof and tear resistant	As and when necessary
Chemical waste	Brown, labeled with Appropriate hazard symbol	Plastic bag or rigid container	As and when necessary
General waste	Black	Plastic bag inside a container/container disinfected after each use	When 3/4 of container is filled

- **List of PPE and Spill Kit**

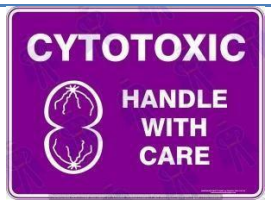
Personal protective equipment (PPE)	Spill kit
• Face mask • Cap • Goggles • Utility Gloves – elbow length • Plastic Apron – long sleeves	• Concentrated household bleach • A spray bottle for making 10% bleach solutions • Forceps, autoclavable broom and dustpan • Paper towels

• Disposable gown – long sleeves • Shoe covers • Gum boots	• Biohazard bags for the collection of contaminated spill clean-up items • Utility gloves • Face protection (goggles and mask, or full face shield)

- **Table: Chemical waste categories that should be followed for proper packaging, labeling, and disposal of chemical waste**

Innocuous aqueous waste	Organic solvent	Red list	Solid waste
• Acid • Alkali • Harmless soluble inorganic salt • Alcohol containing salt • Hypochlorite solution • Fine (TLC grade) silica and alumina)	• Chlorinated • Chloroform • Chlorobenzene • Non-chlorinated • Ethyl acetate • Hexane • Toluene • Methanol	• Cyanides • Mineral oils and hydrocarbons • Poisonous organosilicon compounds • Metal phosphides • Phosphorus element • Fluorides and nitrites	• Lightly contaminated • Gloves • Empty vials • Broken glassware
Guidance for disposal of wastes			
These chemicals should be washed down the sink with excess Water	Incineration at high temperature	Incineration at high temperature	Collected in plastic lined cardboard boxes for landfill

- **Standard biohazard symbols**

Sl. No	Type	Symbol
1.	Biohazard	
2.	Cytotoxic	 
3.	Infectious	
4.	Chemical	 
5.	Sharps	 

- **Waste inventory form to be maintained at the laboratory**

SN	Type of waste	Quantity (kg)	Date of collection	Date of disposal	Treatment method (autoclave/disinfection/ incineration, etc)	Disposal Site	Disposed by

Review History

Revision	Revision date	Reason for revision	Revised by
Responsibilities of biosafety officer and Laboratory officer	19/03/2026	Since the two position have completely different roles in general the two must also have different roles in laboratory waste management. Separating these roles enhances accountability, reduces role overlap, and improves the overall efficiency and safety of waste management practices within the laboratory.	Dr. Dezang Wangchuk Mr. Karma Tsheten Mr. Roshan Rai