

MINIMUM STANDARDS FOR VETERINARY LABORATORIES IN KENYA

1. GENERAL CONSIDERATIONS

1.1 Introduction

For purposes of this document, a veterinary laboratory refers to any facility that handles samples of animal origin or materials intended for use in animals for purposes of diagnosis, research, teaching and production.

In Kenya, there are 4 types of veterinary laboratories. These are:

- Diagnostic laboratories which support national veterinary services in diagnosis of diseases, analysis of animal production inputs and products and other analyses intended to study the properties, composition, structure, chemical and biological processes of animals and their products.
- Veterinary forensic laboratories dealing with animal specimen, and biologicals of animal origin
- Production laboratories that produce vaccines, reagents and diagnostic kits.
- Training and research laboratories whose key mandate is professional education and research.

Veterinary laboratories are either owned by the government (National or County) s, tertiary learning institutions, local and international research institutions or private entities.

This document outlines the minimum standards for the registration and licensing of veterinary laboratories in Kenya pursuant to the provisions of Section 6 (2) (e) of the Veterinary Surgeons and Veterinary Paraprofessionals (VSVP) Act Cap 366 and Sections 22 and 27 of the VSVP Regulations 2013.

1.2 Accountability and oversight

A veterinary laboratory shall be held accountable for all operations that take place in it. It is therefore important to establish processes that ensure accountability and oversight, failure to which could lead to disrepute of services provided and lack of credibility of the animal health service. A veterinary laboratory shall therefore:

- Be a legal entity
- Have a defined organization and management structure (organogram), to ensure accountability and oversight including its place in any parent organization. The structure shall document responsibilities, authority and interrelationships of all personnel to ensure quality of laboratory services.
- have documented procedures for all its operations e.g. communication, human resource (HR) management, procurement

- Have a service charter that clearly indicates the mandate, services offered and expectations of the clients.
- Demonstrate availability of resources including human and financial to ensure achievement of the mandate.
- Have guidelines, procedures and responsibilities communicated to all staff

1.3 Executive management

To be fully accountable for its outputs, and to ensure effective deployment of resources within a veterinary laboratory, the management of a veterinary laboratory at the minimum shall be organized as follows:

- The operational activities of a veterinary laboratory shall be conducted under the authority of a single individual given an appropriate title (laboratory in-charge)
- Where the overall authority does not have veterinary qualification, there must be a veterinarian responsible for interpretation of veterinary results. He/she shall be an experienced veterinarian and/or have training in laboratory work.
- The Laboratory in-charge {as referred to in (b)} shall have the authority and resources (financial and human) needed to carry out his duties including the implementation, maintenance and improvement of the laboratory management system, and to identify occurrences of departures from the management system or from the procedures for performing test(s) and to initiate actions to prevent or minimize such departures so as to ensure the laboratory outputs are relevant, accurate and timely.
- The laboratory in-charge shall be supported by a team managing various sections of the laboratory (e.g. bacteriology, virology, pathology, parasitology, etc.). The size of the team shall depend on the scope of the laboratory.
- There shall be a designated deputy laboratory in-charge to support in the management of the laboratory operations.
- Depending on the laboratory set up there will be designated personnel to perform support functions (e.g. human resource, finance, procurement, information technology (IT) and communication).
- The laboratory results shall be released by the designated authority to ensure the personnel are free from any undue influences that may adversely affect the quality of their work.

1.4 Location

Laboratories are highly specialized with very particular requirements in terms of location and operational environments. The following are the recommended minimum requirements on location of a veterinary laboratory:

- A veterinary laboratory can be located within a veterinary clinic or hospital, a purpose-built unit or part of a general-purpose building suitable for the specialized requirements, services and operational environments of a laboratory.
- The location including if part of a general-purpose building shall be isolated from activities not related to the laboratory.
- The location shall have controlled human traffic to reduce impact of accidental release of dangerous material.
- The location shall be away from any known fire hazard

1.5 General Requirements

Because of the specialized nature of laboratories, they require particular requirements in terms of maintenance and separation of non-related activities. The following are the minimum standards on these requirements:

- The laboratory shall have a cleaning procedure covering benches, floors, windows, ventilation grills, water baths, autoclaves, ventilation grills, etc.
- The laboratory management shall provide a rest area for the staff for refreshments separate from the testing area.
- Laboratories shall demonstrate existence of maintenance service support for its infrastructure, compound and plant equipment.

1.6 Laboratory design

Veterinary laboratories are highly specialized facilities with particular requirements in terms of buildings, services and operational environments. The structure and functions of the laboratory shall comply with all relevant national regulations including the National Construction Authority Act No. 41 of 2011 and the Environmental Management and Co-ordination Act (EMCA) Cap 387 and international standards such as for bio-containment, biosafety and environmental impact. Therefore, the design of a veterinary laboratory in Kenya shall have the following minimum requirements:

- Adequate ventilation
- Reliable electricity supply and back-up
- Sufficient electric outlets to minimize use of extension cables
- Sufficient sinks with adequate and uninterrupted running water
- Adequate lighting
- Continuous sealed (seamless finish) floors that are easy to clean and decontaminate
- Impervious and chemically resistant bench tops with good seals if against walls and floor and around fittings such as sinks

- Chairs and furniture made of non-cloth materials for ease of cleaning and effective decontamination
- Vermin-proof for pests including rodents and insects
- Floor designed with gradient towards the inside of the lab to avoid spillages flowing outside
- Activities shall flow from reception of samples, sample storage, analysis to disposal so as to ensure the integrity of test results
- The laboratory shall have a visitors' reception area, sample collection room, analytical working area, sample storage facilities (cold chain) and records' room.
- Functioning biosafety cabinets according to the risk group of organisms being handled
- Have effective measures to ensure restricted access.
- Separation of test procedure areas from other areas in the laboratory.
- A clearly marked and operational emergency exit.

1.7 Equipment and Maintenance

A veterinary laboratory shall be equipped with test equipment required for the correct performance of tests. Equipment shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests concerned. To be able to achieve this, the following are the minimum requirements for a veterinary laboratory in Kenya:

- The laboratory shall have a documented procedure for servicing and maintenance of laboratory equipment.
- The laboratory shall maintain an inventory of its equipment that shall also include servicing and maintenance schedules. Key testing equipment requiring calibration shall have a schedule maintained. Each equipment shall be uniquely identified.
- Calibration shall be undertaken by a Calibration Entity accredited by a Competent Authority. New equipment shall be calibrated and/or verified before use.
- Equipment shall be operated by trained and authorized personnel. Up to date instruction manuals shall be readily available to lab personnel.

1.8 Human resource

A veterinary laboratory, like any other organization employing staff in Kenya, shall comply with the requirements of relevant national laws and regulations including the Employment Act cap 226 and Labour Relations Act of 2007. At the minimum, a veterinary laboratory shall have the following requirement:

- Every laboratory shall have human resource guidelines that amongst other considerations shall demonstrate procedures for staff motivation, discipline and relevant training

- The laboratory shall have adequate personnel to meet the workload requirements
- The laboratory management shall ensure technical personnel are qualified on the basis of appropriate education, training and experience. The minimum qualification for technical staff in a veterinary laboratory in Kenya is a certificate in Animal Health or Laboratory sciences.
- All professionals need to be registered by their respective regulatory Boards where applicable
- The technical personnel shall be appropriately trained in operation and user maintenance of equipment.
- There shall be an induction process for all staff on the laboratory processes.
- The laboratory shall maintain current job descriptions for all laboratory staff. Every laboratory staff shall have a letter of appointment.

1.9 Compliance

1.9.1 Health and safety

Veterinary Laboratories are hazardous environments. There are risks from handling pathogens, hazardous chemicals, physical hazards (fire, high pressure steam, low temperature vessels amongst others) and animals' hazards (bites, kicks amongst others). The department of Occupational Health and Safety (DOSHS) under Ministry of Labor in Kenya is responsible of ensuring safety and health of all Kenyan workers under Occupational Health and Safety Act (OSHA) 2007. This ACT of parliament requires employers to assure the health and safety of their workers, and occupants of premises. Amongst other requirements for Veterinary laboratories at the minimum every lab shall have:

- Health and Safety guidelines in place.
- A Health and Safety hazard identification procedure that identifies all hazards to staff and visitors.
- Health and safety procedures in place to mitigate all risks and reduces them to acceptable levels.
- Maintain a risk register indicating the risks and mitigations in place.
- A person responsible for Health and Safety of the laboratory with a budget adequate to ensure health and safety of staff.
- Laboratory Health and safety procedure manual specific to the laboratory.
- If the Laboratory employs more than 20 staff there should be a health and safety committee with representation from staff and management.
- Clear health and safety incident and accident reporting, investigation and response procedure.
- Fire audit for the laboratory that outlines laboratory fire risk and mitigation required to minimize the risk. These may include: adequate portable fire equipment such as fire extinguishers & fire blankets, clear emergency exit routes, fire assembly points and signage indicating how to respond to a fire.

- First aid station that should have at the minimum a first aid box with supplies that respond to first aid emergencies in the laboratory and at least one person in the laboratory trained in first aid.
- Health and safety training program that includes health and safety induction for all staff at the laboratory with periodic refresher training.

1.9.2 Biosafety and Biosecurity

Veterinary Laboratories have a responsibility to contain pathogens and to prevent their accidental or intentional release that might endanger human or animal populations. To develop Biosafety and Biosecurity guideline a laboratory can make reference to various Biosafety & Biosecurity manuals including World Health Organization (WHO) Laboratory Biosafety manual, WHO Laboratory Biosecurity manual and World Animal Health Organization (OIE) Biosafety and Biosecurity guidelines for veterinary laboratories and animal facilities. In Kenya, Biosafety and Biosecurity is covered under various legislations including Animal Diseases ACT Cap 364, Public health ACT Cap 242.

At the minimum every veterinary laboratory shall:

- Carry out a Biosafety risk assessment of all their processes and procedures to identify elements where biosafety risks may arise and develop mitigation plans for the risks.
- Develop a Biosafety standard operating procedures (SOPs) on how to mitigate risks and corrective actions to non-compliance.
- Determine the biosafety level of the laboratory to establish the type of samples and analysis to be carried out in the laboratory.
- Establish a hierarchy of controls to ensure exposure of humans, animals and environment to pathogenic agents is minimized. These shall include: engineering controls e.g. Biological safety cabinets; administrative controls e.g. SOPs, signage & training; and personal protective equipment.
- Laboratory staff shall be provided with dedicated laboratory coats and any other necessary protective equipment depending on the test procedure(s) undertaken. Visitors shall have dedicated protective gear when visiting the laboratory.
- Have an Occupational Health Procedure that handles medical response in case of occupational exposure to pathogens handled in the laboratory in line with OSHA 2007.
- Carry out Biosecurity threat analysis and develop mitigation measures to manage the threats including intentional release or theft of hazardous material.
- Have access control to the laboratory with a list of authorized staff allowed access.

1.9.3 Animal welfare

Veterinary laboratories could keep animals as part of the laboratory work. In cases where animals are present at the laboratory, animal welfare requirements shall be followed to ensure standards that guarantee the five freedoms of animal welfare. Such laboratories should adhere to

Prevention of Cruelty to Animals Act Cap 360, National guidelines for care and use of animals in Research and Education in Kenya and OIE Terrestrial animal health code chapter 7.8. National Commission for Science Technology and Innovation (NACOSTI) has developed guidelines for establishment, registration and certification of Animal Care and Use Committee (ACUC). At the minimum such laboratories shall:

- Establish and register ACUC or seek services of a registered ACUC. Those services include review of procedures, inspection of animal facilities before use and recommending the number of animals to be kept in the facility
- Have a Veterinarian not part of testing team responsible for animal welfare.

1.9.4. Environment

Provision of a safe work environment is a basic right for every worker in Kenya and it is implemented under both OSHA and Environmental Management and Coordination Act (EMCA) Cap 387. Management of veterinary laboratories must ensure provision of a safe work environment and Laboratory environment do not expose worker and the environment to unsafe conditions. There are five major environmental factors that affect the operation of laboratories as follows: waste management, water quality, air quality, noise and lighting.

1.9.4.1 Waste Management

Veterinary laboratories produce waste from their activities, and some of the agents handled at the laboratories can also contaminate the environment and staff if not contained properly within the laboratory. Waste management at the laboratory is key in ensuring that the environment is not polluted. Laboratory must adhere to EMCA Cap 387 (Waste Management Regulations, 2006) on waste management.

The laboratory shall have an effective waste disposal system in accordance with EMCA Cap 387 (Waste Management Regulations, 2006).

The major goal of proper waste management is pollution prevention. At the minimum every laboratory shall:

- Develop a waste management plan that shall identify all waste streams from the laboratory and methods of waste treatment to render the waste nonhazardous.
- Have an autoclave to treat all biological waste before disposal.
- If the laboratory keeps animals then the laboratory shall have bio-pits or an incinerator or Crematorium or access to the same to treat all waste including animal carcasses and biomedical waste.
- Laboratory facilities must have waste receptacles (colour coded containers) for the expected streams of laboratory waste. General, clinical/biological, sharps and carcasses.
- These receptacles must be of durable quality such as high-grade plastic.

- Waste streams must be segregated thus the need for well labelled bins for each waste stream.
- Disposal procedures for each waste stream must be established and followed to ensure proper waste management.
- Clinical/Biological waste must be autoclaved and / or incinerated and the ash disposed appropriately.
- Chemical waste must be disposed off either as sewerable or non sewerable substances.
- Protective clothing and equipment must be made available for waste handling i.e. lab coats, gloves, masks and goggles
- Regular quality assurance checks must be done to ensure that solid and liquid waste from laboratory facilities is done properly.

1.9.4.2 Water Quality

The objective of water quality management for use in laboratory facilities is to ensure that Laboratory workers are provided with safe drinking water as per the law, water sources are not contaminated by waste from the laboratory and if laboratory test solutions are prepared using tap water the quality is ascertained.

All Laboratory owners and Management staff shall ensure:

- Laboratory workers are provided with safe drinking water.
- Waste water from the laboratory is not disposed directly to a natural water source within initial treatment.
- If tap water is used to prepare test solution the quality is ascertain as adequate for preparing the test solution.

1.9.4.3 Air Quality

Air quality management in laboratory facilities is aimed at ensuring healthy indoor ambiance to ensure fresh and clean breathing air and protection of the outside air environment.

The indoor air quality of laboratories should be free of noxious gases and volatile organic compounds as per national and international regulations. The noxious gases include Sulphur Oxides and Nitrogen Oxides. Volatile organic compounds include xylene, toluene, formaldehyde, nitric acid.

At the minimum:

- The laboratory must ensure good air quality with adequate fresh and clean breathing air absent of excessive odour. There should be adequate ventilation to ensure the recommended air change per hour (ACH) are achieved.
- Where a laboratory carries out preparations of test reagents within the laboratory using hazardous chemicals strict adherence to material data safety sheets of the chemicals must be observed. Such Laboratories should have a certified chemical fume hood that ensures

'Waste air' is kept away from the staff and also scrubbed before disposed to the environment.

1.9.4.4 Noise

Laboratories should not be located close to noisy environments. Laboratory owners must ensure the location is quiet and has low noise levels thus below 40 decibels.

Laboratory facilities have machines and equipment that produce discernable levels of noise. All laboratory equipment and activities should not produce noise beyond allowable limits. Noise as measured by decibels should not exceed 75 as produced by and laboratory equipment or activity. For equipment producing high levels of Noise, mufflers can be installed to limit exposure to noise.

1.9.4.5 Lighting

Lighting levels are measured in lumens. The lighting levels for normal activities are 100 – 300 lux.

Laboratory facilities should be designed in ways that ensure zoning so that activities that require natural light and those that do not are separated. Corridor systems ensure that light is dispersed in the correct level to all areas of the laboratory.

At the minimum laboratories should maintain adequate lighting between 100 – 300 lux at all times when laboratory work is ongoing.

1.9.5 Gene regulation

Veterinary laboratories may use modified genes or gene products in their activities. Work with genetically modified organisms including genes is regulated by National Biosafety Authority (NBA). All such work must be approved by NBA before work can begin at the laboratory.

For a laboratory intending to work with Genetically Modified Organisms (GMOs) shall at the minimum:

- Be approved by NBA
- Be able to segregate the GMO work from non-GMO work.

2. SCIENTIFIC SERVICES

Veterinary laboratory analysis is backbone of disease control and quality assurance of veterinary inputs, safety of foods of animal origin and facilitation of international trade. The integrity of the results obtained from the laboratory is therefore of paramount importance. In

order to meet the requirements of the OIE and to satisfy customer expectations a laboratory shall expected in the minimum to comply with the standards there of stipulated.

2.1 Diagnostic and/or Forensic service delivery

For efficient and effective service delivery, a veterinary laboratory shall;

- Have appropriate equipment and consumables (and in adequate amounts) for the test procedure(s) to meet the scope and workload requirements
- Have reagents sourced from reputable manufacturers and accompanied by validation data. They shall be used within expiry dates, prepared and used according to manufacturer's instructions, stored under appropriate conditions and properly labelled
- Have effective separation of incompatible activities to prevent cross contamination
- Have access to and use of areas affecting the quality of the tests controlled.
- Have a system for Identification of test items that is retained throughout the life of the item in the laboratory.
- Use methods published at international, regional or national level for regulatory functions (e.g. certification of animals for export, residue analysis for animal feeds and foods of animal origin).
- Use appropriate, validated and documented test methods and procedures for all tests within the scope i.e., sample collection, handling, transport, storage and preparation of items to be tested, testing, reporting and, result interpretation. Each of these activities shall have documented Standard Operating Procedures (SOPs).
- Maintain a list of other laboratories to which it may subcontract requests beyond its scope
- Have safety equipment available, functioning and subject to routine inspection these may include but are not limited to;
 - Emergency showers or adequate water container
 - Eyewash
 - Appropriate fire equipment e.g. fire extinguisher CO2 , fire blanket
 - Smoke/heat detectors where appropriate
- Have an inventory of changes in staff that have access to controlled biological substances.
- Have an inventory of test materials including a sample retention plan.
- Have secure storage facilities to preserve integrity of samples before and after testing.

2.2 Quality assurance

To ensure quality services, a veterinary laboratory shall:

- Have documented quality control procedures for monitoring the validity of tests undertaken e.g. use of positive and negative controls, inter-laboratory testing, duplicate testing, proficiency testing among others
- Have adequate training guidelines, procedures, and/or training plans, including cross-training within the laboratory team, one-on-one mentoring, and/or off-site external training; in line with the mandate of the lab and assesses competency on a routine basis.
- Maintain quality control data of all tests methods.
- Maintain the raw data of manual calculations and data transfers.

2.3 **Research**

To promote research and development, a veterinary laboratory will:

- Demonstrate adoption to new technology as part of continuous improvement.
- Where applicable engage in research such as development and adoption of new methods.

3. SUPPORT SERVICES

3.1 Information management

A data management system is a critical component that any veterinary laboratory shall have. The type and sophistication of such a laboratory shall vary depending on the scope and available financial resources in the laboratory. At the minimum, a veterinary laboratory shall have the following:

- A data management system (computerized or manual).
- The data management system shall be managed by a designated and competent staff.
- Sufficient measures to protect integrity of data, archiving, traceability, retrieval, privacy, confidentiality and protection of staff and sensitive items.
- Sample retention and archival guideline.
- A guideline for archiving testing data and administrative information.

3.2 Finance and Procurement

Financial resources is important in the delivery of quality veterinary laboratory services as documented in the Service Charter. There should be competent personnel to ensure prudent management of these finances. A veterinary laboratory shall therefore:

- Have adequate financial and human resources to perform its functions without compromising quality of services provided.

- Have a transparent pricing policy of the services and products it offers and this shall be documented.
- Have documented procedures for procurement of items to ensure quality of equipment, supplies and services.
- Involve relevant laboratory staff in the development of technical specifications and evaluation of equipment, supplies and services.

3.3 **Communication**

Good communication is vital in the delivery of veterinary laboratory services. A veterinary laboratory shall:

- The laboratory shall have communication guidelines that include internal communication within the laboratory and communication between the laboratory staff and the clients and other stakeholders.
- Laboratory results shall be communicated to the clients in a clear and meaningful /understandable manner as per service charter.
- The laboratory shall have procedures to ensure compliance with obligatory disease reporting and notification.
- Laboratory shall have a procedure for dissemination of scientific data and information.