BIOLOGICAL AND PHARMACEUTICAL WASTE MANAGEMENT PLAN (BPWMP)

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VISION:

A world free of vaccine preventable diseases.

MISSION:

To manufacture and commercialize safe, effective and quality vaccines and other health products and improve access to affordable healthcare.

CORE VALUES:

Integrity

Collaboration

Innovation

Excellence

Contents

1 INTRODUCTION

1.1 Project Overview and Purpose

The health landscape in Kenya has seen notable advancements over the past five years, yet significant challenges persist, particularly in the realms of geographic and economic inequities. As of the 2019 census, Kenya's population was estimated at 47.6 million, with 36 percent living below the poverty line and 65 percent residing in rural areas. While life expectancy has risen from 63 years in 2013 to 67 years in 2020, the nation continues to grapple with critical health issues, including a high neonatal mortality rate of 21 deaths per 1,000 live births in 2022.

In this context, the Kenya BioVax Institute plays a pivotal role in addressing these health challenges through its commitment to vaccines and biologics manufacturing, commercialization, research and development. The Institute's efforts are particularly crucial in combating infectious diseases, which remain a leading cause of mortality, despite improvements in overall health metrics. With outbreaks of diseases like polio, measles, HPV, HIV/AIDS, malaria, and lower respiratory infections still prevalent, despite a robust National immunization program the need for innovative vaccines and public health solutions is more pressing than ever.

Moreover, as non-communicable diseases (NCDs) rise to become the primary cause of morbidity and mortality in the country, the Kenya BioVax Institute is strategically positioned to contribute to the development of interventions that tackle both communicable and non-communicable diseases. The Institute also recognizes the importance of proper pharmaceutical waste management in safeguarding public health, particularly in light of the 220 tons of healthcare waste generated daily and the growing antimicrobial resistance burden. This focus aligns with its mission to protect health and promote activities necessitate the implementation.

By fostering a collaborative approach to health innovation and policy implementation, the Kenya BioVax Institute aims not only to enhance vaccine and biologics access but also to address the broader determinants of health that affect the Kenyan population. Through comprehensive research, community engagement, and a commitment to quality, the Institute stands at the forefront of Kenya's journey towards a healthier future.

2 BACKGROUND

Kenya has made measurable progress in improving population health outcomes over the past decade; however, significant challenges remain in relation to infectious diseases, health system resilience, and equitable access to essential medical products. Despite improvements in life expectancy and immunization coverage, communicable diseases continue to pose a substantial public health burden, while non-communicable diseases are increasingly contributing to morbidity and mortality.

In response to these challenges, the Government of Kenya established the Kenya BioVax Institute (BioVax) to strengthen national and regional capacity for vaccine and biologics manufacturing. The Institute’s mandate includes local manufacture, fill–finish, quality control, research and development, and distribution of vaccines and other biological products in compliance with national regulatory requirements and international Good Manufacturing Practices (GMP).

Pharmaceutical manufacturing, laboratory, and research activities inherently generate infectious, chemical, and pharmaceutical wastes that, if improperly managed, may pose risks to personnel, the public, and the environment. Effective infection prevention and pharmaceutical waste management are therefore essential to safeguard product quality, occupational health and safety, environmental protection, and regulatory compliance.

This Biological and Pharmaceutical Waste Management Plan (BPWMP) has been developed to define the systems, controls, and procedures required to prevent risks and ensure the safe, compliant, and environmentally sound management of all wastes generated during Kenya BioVax Institute.

2.1 Project component and context

The Kenya BioVax Institute project aligns closely with the objectives of the World Bank Group's support under the Health Emergency Preparedness, Response and Resilience (HEPRR) project. As a multiyear, multiregional initiative, HEPRR aims to strengthen regional capacity to prevent and respond to health emergencies by supporting critical health systems infrastructure, including local vaccine manufacturing.

Through the HEPRR project, WBG is contributing to long-term pandemic preparedness and regional self-reliance in Africa. BioVax's mandate to establish local vaccine production directly supports this goal by reducing dependence on imports, ensuring timely access to vaccines, and building sustainable manufacturing and regulatory systems in the region. The technical and financial support provided through HEPRR is therefore instrumental in operationalizing BioVax's manufacturing capabilities and aligning Kenya's health security priorities with regional resilience efforts.

2.2 Targeted Facility

The project aims to build the capacity of the Kenya BioVax Institute (BioVax) for the local manufacturing of human vaccines and biologics.

2.3 Project Activities

The Kenya BioVax Institute undertakes a range of integrated activities associated with the research, manufacture, quality control, and support of human vaccines and biologics. These activities are conducted within a regulated Good Manufacturing Practice (GMP) environment and inherently result in the generation of different categories of waste that require controlled management.

The key project activities relevant to Biological and Pharmaceutical Waste management Plan include:

i. **Research and Development Activities**

Laboratory-based research and development involving the handling of biological specimens, culture media, reagents, reference standards, and laboratory consumables, which may generate biological, chemical, and contaminated laboratory waste.

ii. **Manufacturing and Fill–Finish Operations**

Vaccine and biologics manufacturing processes, including formulation, filling, finishing, and packaging activities, involving the use of biological materials, raw materials, single-use consumables, personal protective equipment (PPE), and packaging components. These activities generate pharmaceutical waste, contaminated disposables, rejected or damaged vials, expired or off-specification materials, and associated packaging waste.

iii. **Quality Control and Analytical Laboratory Activities**

Quality control testing of raw materials, intermediates, and finished products using test kits, reagents, solvents, glassware, pipettes, slides, and other analytical materials, resulting in chemical, biological, sharps, and laboratory waste.

iv. Utilities, Support, and Ancillary Operations

Operation and maintenance of utilities and support systems, including water treatment systems, effluent treatment plants, HVAC systems, cleaning and sanitation activities, equipment maintenance, and waste handling operations, which generate liquid effluents, sludge, maintenance waste, and general non-hazardous waste.

These activities necessitate the implementation of a structured Biological and Pharmaceutical Waste Management Plan (BPWMP) to ensure that all wastes generated throughout the project lifecycle are segregated, handled, treated, transported, and disposed of in a safe, environmentally sound, and regulatory-compliant manner.

3 OBJECTIVES

The objectives of the BPWMP;

1. To implement safe and effective procedures for managing Biological and Pharmaceutical Waste.
2. To reduce occupational and public health risks associated with exposure to hazardous materials.
3. To comply with international, National regulatory frameworks and WBG and WHO waste management standards.
4. To support environmental sustainability through responsible waste minimization and disposal.
5. To enhance institutional capacity through staff training, proper documentation, and continuous improvement of waste handling practices.

4 SCOPE

The BPWMP applies to all departments and operational areas within Kenya BioVax Institute that generate, handle, or dispose of infectious or hazardous waste. It covers the full waste lifecycle, including generation, segregation, collection, transport, treatment, storage, and final disposal.

The plan includes internal processes and any outsourced services related to waste handling and disposal at BioVax.

5 DEFINITIONS AND ABBREVIATIONS

1. **KBI**- Kenya BioVax Institute
2. **Bio-kill System** – A treatment system used to deactivate or destroy biological contaminants in liquid or semi-liquid waste prior to discharge or further treatment.
3. **Biological Waste** – Waste containing or contaminated with biological materials such as microorganisms, cell cultures, vaccines, or other infectious agents generated from laboratory, production, or quality control activities.
4. **Biosafety Level (BSL)** – A classification system defining the containment precautions required when handling biological agents, based on their risk to human health and the environment.
5. **Chemical Waste** – Waste consisting of chemical substances such as reagents, solvents, disinfectants, and cleaning agents generated from laboratory, manufacturing, or maintenance activities.
6. **Contamination** – The unintended presence of biological, chemical, or particulate matter that may compromise product quality, safety, or environmental integrity.
7. **Cytotoxic Waste** – Waste containing substances with mutagenic, carcinogenic, or teratogenic properties, including cytotoxic drugs and contaminated materials.
8. **Effluent** – Liquid waste or wastewater generated from manufacturing, laboratory, or cleaning processes, which may contain biological or chemical contaminants.

9. **Effluent Treatment Plant (ETP)** – A facility designed to treat liquid waste to remove contaminants and ensure compliance with environmental discharge standards before disposal or reuse.
10. **General (Non-Hazardous) Waste** – Waste that does not pose biological, chemical, or physical hazards and is comparable to domestic waste, such as office waste and uncontaminated packaging materials.
11. **Good Manufacturing Practice (GMP)** – A system of regulations, codes, and guidelines ensuring that pharmaceutical and biological products are consistently produced and controlled according to quality standards.
12. **Hazardous Waste** – Waste that poses a potential risk to human health or the environment due to its biological, chemical, toxic, flammable, corrosive, or reactive properties.
13. **Infectious Waste** – Waste suspected or known to contain viable microorganisms that can cause disease, including contaminated laboratory materials, PPE, and production residues.
14. **Licensed Waste Transporter** – An entity authorized by the National Environment Management Authority (NEMA) to transport hazardous or pharmaceutical waste.
15. **Personal Protective Equipment (PPE)** – Specialized clothing or equipment worn to protect personnel from exposure to hazardous materials, including gloves, masks, gowns, and eye protection.
16. **Pharmaceutical Waste** – Any material generated during the lifecycle of pharmaceutical or biological products, including research, manufacturing, quality control, and packaging that is expired, unused, rejected, or no longer suitable for use.
17. **Waste Disposal** – The final placement or destruction of waste in a manner that ensures protection of human health and the environment, in compliance with regulatory requirements.
18. **Waste Generator** – Any department, unit, or individual within the facility whose activities produce waste.

19. **Waste Segregation** – The process of separating waste at the point of generation into distinct categories based on type, hazard level, and disposal requirements.
20. **Waste Treatment** – Processes applied to waste to reduce or eliminate its hazardous properties, including methods such as autoclaving, chemical disinfection, or incineration.
21. **HEPRR** – Health Emergency Preparedness, Response and Resilience
22. **BSL** – Biosafety Level
23. **BSC** – Biosafety Cabinet
24. **ETP**– Effluent Treatment Plant
25. **EPR**: Emergency Response Plan
26. **EHS**– Environmental Health Safety
27. **EHSG** – Environmental Health and Safety Guidelines
28. **WBG** – World Bank Group
29. **ESCP** – Environmental and Social Commitment Plan
30. **GMP** – Good Manufacturing Practices
31. **HTPs** – Health Technologies & Products
32. **HVAC** – Heating, Ventilation, and Air Conditioning
33. **HEPA** – High Efficiency Particulate Air
34. **BPWMP** – Biological and Pharmaceutical Waste Management Plan
35. **MOH** – Ministry of Health
36. **NEMA** – National Environmental Management Authority
37. **NCDs** – Non-Communicable Diseases
38. **PPE** – Personal Protective Equipment
39. **QA & QC –** Quality Assurance & Quality Control
40. **SOPs –** Standard Operating Procedures

6 ROLE AND RESPONSIBILITIES

Biological and Pharmaceutical Waste Management Plan (BPWMP) effectiveness shall be ensured through clear assignment of roles and responsibilities across various departments and personnel.

6.1 Management Responsibilities

Provide overall strategic oversight and institutional commitment to infection control and waste management through;

i. Ensuring alignment of BPWMP objectives with national regulatory frameworks and international standards (e.g., NEMA, OSHA, WHO, GMP).
ii. Approve budgetary allocations, infrastructure development, and resource mobilization to support waste management systems.
iii. Endorse relevant policies, SOPs, and monitoring frameworks for Biological and Pharmaceutical Waste Management handling.
iv. Ensure periodic review of BPWMP effectiveness, including review of monitoring results, incidents, and corrective actions.

6.2 Technical Departments (Production, Laboratory, Quality Assurance, Safety Health & Environment Engineering and Maintenance)

i. Enforce correct segregation, labeling, and containment of waste at generation points.
ii. Ensure compliance with Good Manufacturing Practices (GMP) and biosafety protocols in all operational areas.
iii. Supervise staff adherence to SOPs for disposal of biological, chemical, and pharmaceutical materials.
iv. Maintain cleanliness and hygiene in workspaces, waste collection zones, and equipment.
v. Document and report incidents, non-conformities, or contamination risks to the SHE Officer for corrective action.

vi. Coordinate and support the safe internal movement and transportation of waste to designated storage and disposal areas

vii. Maintain sanitation and hygiene in waste storage areas, wastewater systems, and common spaces.

viii. Coordinate with external service providers for equipment servicing, calibration, and decontamination, where applicable.

6.3 Waste Handlers and Sanitation Staff

i. Segregate and transport waste in accordance with color-coded NEMA guidelines.

ii. Wear appropriate PPE during all handling operations.

iii. Clean, disinfect, and maintain waste collection tools and containers.

iv. Report abnormalities or contamination risks to their supervisors or the SHE Officer.

6.4 All Staff

i. Comply with all SOPs related to infection prevention and waste handling.

ii. Use designated bins and PPE correctly.

iii. Participate in periodic training and emergency drills.

iv. Promptly report incidents, breakages, or unsafe conditions

7 COMPLIANCE

7.1 Context and application of the BPWMP

The BPWMP is designed to align with Kenya BioVax Institute's internal policies as well as the country's laws, regulations, and policies governing the safe management of medical and hazardous waste. It also incorporates international guidelines and industry best practices, ensuring that all waste management activities are conducted safely, compliantly, and in accordance with recognized quality and environmental standards, as summarized below.

Table 1. Regulatory framework

Sr. No.	Framework (policy /legislation/guidelines/ industry standards)	Clause/ section	Relevance
	Kenya Environmental Sanitation and Hygiene Policy 2016-2030	Part III: Sanitation and Hygiene Management	The policy supports safe and sustainable management of healthcare, laboratory, and industrial waste by promoting proper segregation, containment, transportation, and disposal practices.
	Sustainable Solid Waste Management Policy:	Section 2.2: Waste Management Hierarchy; Section 3: Roles & Responsibilities	Supports sustainable and safe management of solid and biomedical waste, ensuring compliance with environmental standards and best practices.
	Kenya BioVax Institute's internal policies on Occupational Safety, Health and Environment (OSHE)	Section 3.7 Waste management	BioVax commitment to environmental sustainability and occupational health and safety.
	Constitution of Kenya, 2010	Articles 42	Right to a clean, healthy environment, emphasizing its protection for current and future generations.
	Environmental Management and Coordination Act (EMCA), Cap 387	Section 87	prohibits the discharge, deposit, or disposal of any waste into the environment except in accordance with the Act and its regulations.
	Plastic Waste Regulations of 2017	Established under the powers conferred by sections 86 Management and Co-ordination Act	Regulations prohibit the use, manufacture, and importation of plastic carrier bags for commercial.

		(EMCA).	
	Public Health Act, Cap 242	Section 6	Prohibits the discharge or connection of stormwater or other non-sewage water into sewage or wastewater systems, cesspools, or septic tanks without written permission or direction from the local authority.
	Occupational Safety and Health Act (OSHA), 2007	Sections 83–84	Require employers to establish systems for the safe collection, recycling, and disposal of chemical wastes and containers to protect workers' health and the environment.
	EMCA Waste Management 2006	Part VI — Biomedical Wastes (Regulations 26–37)	These provisions regulate how biomedical waste shall be managed
	Biosafety Act, 2009	Part V	Requires safe treatment, destruction, or disposal of biological and GMO-related waste to prevent release into the environment or harm to human health.
	Water Act, 2016	Sections 72, 73, and 74	Require the protection of water resources by preventing pollution.
	Health Act No 21 of 2017	Part X – Environmental Health	Provides for the management of healthcare waste, including segregation, handling, treatment, storage, transportation, and disposal of waste generated by health facilities and laboratories.
	World Health Organisation guidelines on safe management of waste from health care	General	Provide globally accepted best practices for managing healthcare and biomedical waste.
	World Bank Environmental Health and Safety Guidelines	General	Provide internationally recognized performance standards for managing environmental, occupational health, and safety risks associated with development projects.
	National environment management authority	General	Provides procedures for segregating, storing, and disposing of lab, chemical,

	technical guidelines		and biomedical waste safely.
	Ministry of Health Kenya standards and protocols for Infection Prevention and Control	Chapter 3: Standard Precautions; Chapter 5: Waste Management	Protects staff and public by guiding safe handling and disposal of infectious and biomedical waste
	Ministry of Health HCWM guidelines	Part II: Waste Segregation; Part III: Treatment and Disposal	Operational procedures for safe collection, treatment, and disposal of healthcare waste, including sharps, infectious, and chemical waste.
	CDC guidelines on medical waste management	Section 2: Handling and Storage; Transportation and Treatment	Segregation, labeling, packaging, storage, transport, treatment of infectious and hazardous waste; PPE and worker safety.
	ISO 14001: Environmental Management Systems	Clause 6: Planning; Clause 8: Operation	Provides framework to manage and reduce environmental impacts from waste.
	ISO 45001: Occupational Health and Safety Management Systems	Clause 8: Operational Planning and Control;	Risk assessment and worker protection.
	WHO standards for pharmaceutical manufacturing waste disposal	Section 7: Waste Management in Pharmaceutical Operations	Safe handling, segregation, neutralization, and disposal of chemical and pharmaceutical waste.

Note:

Environmental Impact Assessment (EIA) and Environmental Audit (EA) approvals shall be required as per EMCA regulations for certain waste management activities. All on-site treatment and disposal processes shall meet the set emission and effluent discharge standards and BioVax shall ensure strict adherence to NEMA licensing requirements, regular reporting, and compliance monitoring.

8 IMPLEMENTATION MECHANISM

8.1 Requirement for the level Biosafety control

8.1.1 Biosafety Levels

The human vaccine and biologics manufacturing facility at BioVax will comply with established WHO biosafety levels (BSL-3) requirements. This will be achieved by use of controlled air flow to manage air flows from non-production and non-laboratory areas (such as the hallway) into production and laboratory areas. Other engineering safety features will include entry through two self-closing, interlocked doors, sealed windows, floors and walls, High Efficiency Particulate Air filters ventilation systems. BSL-3 labs will also have autoclaves for decontamination and secure waste disposal pathways. Quarterly trainings various safety practices shall be conducted to ensure staff are well-versed in risk management and safe operational procedures.

Biosafety controls at the Kenya BioVax Institute will be implemented in accordance with World Health Organization (WHO) biosafety guidance, with the facility designed and operated to meet Biosafety Level 2 (BSL-2) requirements, appropriate for the vaccine and biologics manufacturing activities undertaken.

Biosafety control will be achieved through the use of controlled airflow to manage air movement from non-production and non-laboratory areas into production and laboratory areas, thereby reducing the risk of cross-contamination. Engineering controls will include self-closing doors, sealed floors, walls, and surfaces, and Heating, Ventilation, and Air Conditioning (HVAC) systems fitted with High-Efficiency Particulate Air (HEPA) filtration where required.

Decontamination of biological materials and waste will be carried out using validated autoclaves, supported by defined and secure waste handling and disposal pathways.

Biosafety prevention training shall be conducted on a regular and documented to ensure personnel remain competent in safe work practices, risk management, and emergency response procedures consistent with BSL-2 operations.

8.1.2 Associated facilities

8.1.2.1 Access to Water

BioVax will have a dedicated water supply systems that can withstand operational demands during regular manufacturing and for emergencies. The municipal water may not be reliable enough to be considered as a sole water supply source and shall be supplemented. As part of the enabling works for the Fill and Finish facility, BioVax shall drill a borehole and the water will be treated for general use and purified further for the production processes. BioVax shall install a bio kill system and Effluent Treatment Plant (ETP) that meets the requirements of the Association ESF and World Bank Environmental Health and Safety Guidelines (EHSG) or Pharmaceuticals and Biotechnology Manufacturing and meet Environmental and Social Commitment Plan (ESCP.) The treated water can be reused for gardening and cleaning activities.

8.1.2.2 Access to Power Supply

In addition to power supply provided by Kenya Power and Lighting Company, a backup power generator will be put in place to ensure uninterrupted operations, particularly for critical systems like refrigeration for vaccine storage and waste treatment facilities. Further, BioVax shall install solar panels for energy utilization in common areas. BioVax shall develop a green energy policy to mitigate against climate change impact from its manufacturing activities. This dual provision of water and power is vital for sustaining operations during unforeseen disruptions.

8.2 Facility Design Requirements

8.2.1 Vaccine Manufacturing Design and Lay Out

8.2.1.1 Overview

The Kenya BioVax Institute fill–finish facility is designed and operated in accordance with current Good Manufacturing Practices (cGMP), World Health Organization (WHO) guidance, and applicable national regulatory requirements. From a Biological and Pharmaceutical Waste Management perspective, the facility layout and zoning are structured to minimize the risk of contamination, ensure safe handling of biological materials, and support effective segregation, containment, and disposal of waste generated during operations.

This section provides a description of facility areas as they relate to Biosafety and Pharmaceutical waste management. Detailed process design and engineering specifications are addressed in dedicated GMP design and utilities documentation.

8.2.1.2 Personnel Flow and Gowning Areas

The facility includes controlled personnel entry points and gowning areas designed to prevent the introduction and spread of contamination. Gowning areas are arranged to support unidirectional personnel flow and include designated spaces for handwashing, storage of clean garments, and donning and doffing of appropriate personal protective equipment (PPE) such as gloves, masks, hair covers, and cleanroom garments. Waste generated from gowning activities, including used PPE, is segregated and managed in accordance with this BPWMP.

8.2.1.3 Cleanroom Processing Areas

The fill–finish operations are conducted within classified cleanroom environments designed to maintain appropriate levels of environmental control. These areas support aseptic handling of inactivated or purified vaccine bulk supplied from licensed upstream manufacturers. Infection control measures include controlled access, defined material and personnel flows, routine cleaning and disinfection, and environmental monitoring. Waste generated within cleanrooms, including single-use consumables and rejected materials, is managed through defined containment and removal procedures to prevent cross-contamination.

8.2.1.4 Aseptic Fill-Finish Area

The aseptic fill–finish area is designed to ensure product sterility and operator safety. Heating, Ventilation, and Air Conditioning (HVAC) systems are designed to control temperature, humidity, and air quality in accordance with GMP and infection control requirements. Waste generated during filling, stoppering, sealing, and inspection activities including contaminated disposables, damaged vials, and cleaning materials is promptly segregated and transferred through designated waste pathways.

8.2.1.5 Quality Control Laboratories

Quality control laboratories support testing of raw materials, in-process materials, and finished products. These laboratories operate under Biosafety Level 2 (BSL-2) conditions appropriate for the materials handled. Biosafety control measures include the use of biological safety cabinets where required, validated decontamination methods, and controlled handling of laboratory waste such as sharps, biological materials, and chemical residues.

8.2.1.6 Labeling, Packaging, and Support Areas

Labeling and secondary packaging activities are conducted in controlled areas designed to prevent mix-ups and contamination. Packaging waste, including paper, cardboard, and uncontaminated plastics, is segregated from pharmaceutical and infectious waste streams. Support areas, including equipment cleaning and maintenance zones, are managed to ensure that waste and effluents generated do not compromise hygiene or environmental safety.

8.2.1.7 Interface with Waste Management Systems

The facility layout incorporates defined interfaces with on-site waste storage, treatment, and effluent management systems. Designated routes are established for the internal movement of waste to minimize exposure risks to personnel and prevent cross-contamination with production areas. These arrangements support effective implementation of the Biological and Pharmaceutical Waste Management Plan throughout facility operations.

8.3 Waste Management

The nature of BioVax's pharmaceutical manufacturing and fill–finish operations, together with the handling of biological and chemical materials, necessitates the effective management of all waste generated. Proper waste management is essential to minimize risks to personnel, the public, and the environment arising from potential exposure to hazardous, infectious, or improperly handled waste.

8.3.1 Types of Waste

Waste generated at the Kenya BioVax Institute may be broadly categorized based on its physical state, source, and potential risk to human health or the environment. The principal waste categories include the following:

i. **Solid waste**: Includes tangible materials such as used personal protective equipment (PPE), packaging materials, and broken or discarded glassware.
ii. **Liquid waste**: Refers to fluid waste streams including chemical effluents, disinfectant run-off, and other aqueous waste generated during cleaning, laboratory, and production support activities.
iii. **Hazardous waste**: Includes waste that poses significant health or environmental risks, such as infectious waste, pathological waste and sharps, chemical waste, cytotoxic materials, and flammable substances.
iv. **Organic and recyclable waste**: Comprises biodegradable materials such as food waste and recoverable materials including uncontaminated paper, plastics, and glass.

Within BioVax's fill–finish operations, activities ranging from formulation and aseptic filling to quality control and packaging result in the generation of multiple waste types across these categories, necessitating appropriate segregation and management measures.

8.3.2 Waste and their sources

8.3.2.1 Biological Waste

Biological waste arises primarily from laboratory, fill–finish production, and cleanroom operations. This waste stream includes used personal protective equipment (PPE) such as gloves, masks, gowns, and shoe covers; sharps including needles, syringes, scalpels, and broken glassware; expired or rejected vaccines; residual materials from formulation and aseptic filling activities; and contaminated vials, ampoules, and associated packaging materials. All biological waste is managed in accordance with applicable, Biological and Pharmaceutical Waste Management Plan requirements to minimize risks to personnel and the environment.

8.3.2.2 Chemical Waste

Chemical waste is generated through quality control testing, research, equipment cleaning, and maintenance. Common chemicals include reagents, solvents like ethanol and methanol, disinfectants, pH stabilizers, and detergents. Waste lubricants from equipment servicing also fall under this category. Many of these substances are hazardous and require controlled storage, neutralization, or third-party disposal in accordance with NEMA and WHO guidelines.

8.3.2.3 Packaging Waste

Packaging waste arises during the vaccine packaging and distribution preparation stages. This includes; Outer cardboard cartons, plastic shrink wraps, paper inserts, defective vials, and incorrectly labeled packaging. Although much of this waste is non-hazardous, any material that comes into contact with pharmaceuticals or cleanroom environments shall be treated cautiously to prevent contamination.

8.3.2.4 Electronic Waste

As a modern biomedical facility this is waste from the routine replacement of laboratory and ICT equipment. This includes outdated computers, laboratory analyzers, batteries, circuit boards, and data storage devices. E-waste contains hazardous substances such as lead and mercury.

8.3.2.5 General Waste

General waste includes non-contaminated refuse such as paper, food waste, and general office waste. While not hazardous, its proper segregation from clinical and chemical waste is crucial to ensure that recyclable or compostable materials are not unnecessarily incinerated or landfilled.

8.3.3 Categories of waste

In line with the World Health Organization (WHO) Good Manufacturing Practices for Biological Products (Annex 2, TRS No. 999), the Pharmacy and Poisons (Pharmaceutical Waste Management) Rules, 2022, WHO guidelines on the safe management of pharmaceutical waste, and the National Healthcare Waste Management Plan (2016–2021), pharmaceutical waste generated at the Kenya BioVax Institute shall be classified into distinct categories to ensure appropriate handling, treatment, and disposal.

i. **Infectious waste:** Waste containing or suspected to contain viable microorganisms generated from quality control microbiological testing, environmental monitoring activities, laboratory consumables, contaminated personal protective equipment (PPE), and materials exposed to biological products during formulation, aseptic filling, and related support activities.
ii. **Pathological waste:** Biological materials generated from laboratory activities where applicable, including contaminated biological residues requiring special handling and disposal in accordance with biosafety and regulatory requirements.

iii. **Chemical waste:** Waste containing chemical substances such as laboratory reagents, solvents, disinfectants, sterilants, and materials containing hazardous chemical constituents, including heavy metals from equipment components and batteries.

iv. **Pharmaceutical waste:** Any pharmaceutical material generated during formulation, filling, quality control, labeling, or packaging activities that is expired, rejected, damaged, spilled, or does not meet established quality specifications.

v. **Non-hazardous or general waste:** Waste that does not pose biological, chemical, radioactive, or physical hazards, including non-contaminated office waste and packaging materials.

vi. **Liquid waste:** Effluents generated from cleaning, sanitation, laboratory operations, and manufacturing support activities that may contain microorganisms or chemical residues and require appropriate treatment prior to discharge.

8.3.4 Waste Prevention

In line with the General World Bank EHS Guidelines, all the biomanufacturing processes will be designed and operated to prevent, or minimize, the quantities of wastes generated and hazards associated with the wastes generated in accordance with the following strategy:

i. Substituting raw materials or inputs with less hazardous or toxic materials, or with those where processing generates lower waste volumes·

ii. Applying manufacturing process that convert materials efficiently, providing higher product output yields, including modification of design of the production process, operating conditions, and process controls ·

iii. Instituting good housekeeping and operating practices, including inventory control to reduce the amount of waste resulting from materials that are out-of-date, off specification, contaminated, damaged, or excess to plant needs·

iv. Instituting procurement measures that recognize opportunities to return usable materials such as containers and which prevents the over ordering of materials.

v. Minimizing hazardous waste generation by implementing stringent waste segregation to prevent the commingling of non-hazardous and hazardous waste to be managed.

vi. In addition to the implementation of waste prevention strategies, the total amount of waste may be significantly reduced through the implementation of recycling plans.

8.3.5 Waste Management System

The Biological and Pharmaceutical Waste Management system at Kenya BioVax encompasses all aspects of waste management, from generation to disposal. This system is supported by existing policies and guidelines, while Standard Operating Procedures (SOPs) and work instructions for each stage of waste management are currently under development as part of preparations for ISO 9001:2015 certification. Once finalized and approved, these SOPs and work instructions will be annexed to the BPWMP or hyperlinked where applicable, ensuring that staff have clear, detailed instructions to maintain compliance and uphold safety, quality, and environmental standards. In addition, Training of all staff on Safety and Clear Protocols for Waste Management Strategies will be undertaken to ensure adherence.

8.3.5.1 Biological and Pharmaceutical Waste Generation

BioVax recognizes that appropriate handling, treatment and disposal of waste by type will help to reduce cost and serve as safeguard in the protection of public health and the environment. Daily logs for waste by type origin and volume will be maintained. Further ISO procedure for management of waste shall be developed with clear key performance indicators. Monitoring of the KPIs on monthly basis shall be conducted to estimate the volume of waste produced. Data obtained shall inform the Terms of reference and requirements needed to engage a NEMA licensed waste handler and identify trends and potential areas for waste minimization.

A. Waste Minimization Strategies

BioVax recognizes that the quantities of all waste generated need to be reduced and the hazardous elements minimized or eliminated. This shall be achieved through;

i. Source Reduction;

a) Minimize purchases especially through green procurement
b) Ensure selection/specification of good quality supplies, and less hazardous.
c) Use of physical rather than chemical cleaning methods (e.g., steam disinfection instead of chemical disinfection).
d) Segregate all waste at the source to avoid contamination and promote recycling of recyclable material.

ii. Recyclable and Reuse of Products

a) Use of materials that may be recycled, either on-site or off-site.
b) Encourage extended producer responsibility.

iii. Product substitution

a) Substitute products with much waste-producing characteristics with one that produces less waste.
b) Product changes - use better, safer, more efficient products.

8.3.5.2 Waste Segregation

Biological and Pharmaceutical waste management options may themselves lead to risks in human health; raw, intermediate and finished products and the environment. Proper handling of pharmaceutical waste is critical to prevent exposure and accidents. To achieve sound implementation of waste management BioVax shall adopt the following steps as a strategy for success.

a) **Waste Segregation Practices**: Segregation will be achieved through provision and use of color-coded bins and bin liners as guided by the WHO recommendations, Ministry of Health (MOH), Pharmacy and Poisons Board (PPB) and National guidelines and legislation by NEMA in regards to the following categories:

i. Red for highly Infectious Laboratory Waste
ii. Yellow for Biopharmaceutical Infectious / Microbiological Waste
iii. Black for general waste not contaminated with hazardous substances
iv. Brown for chemicals and pharmaceuticals
v. Blue for recyclable Waste

b) **Packaging of the waste**: The waste shall be packaged in resistant and sealed bags or containers to prevent spilling during handling and transportation. The bags or containers shall be of a material resistant to their content e.g. (puncture-proof for sharps, resistance to aggressive chemicals) and to environmental conditions. Once the color-coded bin liner is full, with a little room at the top remaining, staff will secure it. While wearing gloves, the staff responsible will gather the bag edges and twist the top of the bag to seal the contents by making a strong, hand tied single or gooseneck knot to prevent any leakage.

c) **Labelling**: Labelling of each waste to ensure each waste category is easily identified, and waste loads can be traced back to their point of generation. The label envisaged above shall contain the following information:

i. A description of the waste;
ii. The name, physical address and telephone contact of the waste generator;
iii. Warning or caution statements, as may be appropriate.

Table 2. Color Coded System for Waste segregation

Segregation Category	Color Coding	Container	Examples	Marking
Biopharmaceutical Infectious / Microbiological Waste	Yellow	Strong, leak-proof plastic bag or bin with biohazard symbol	Contaminated disposables from controlled laboratory or fill–finish areas (e.g. culture media residues, single-use tubing, filters, gloves, wipes used in microbiological testing or aseptic operations)	
Highly Infectious Laboratory Waste	Red (clearly marked *Highly Infectious*)	Rigid containers capable of autoclaving	High-risk laboratory waste requiring pre-treatment (e.g. microbiological cultures, inoculated media, contaminated specimen containers from QC microbiology laboratories)	 Biohazard symbol + "Highly Infectious"
Non-infectious / Non-hazardous	Black	Plastic bag or container	General office and facility waste (e.g. food	None

Segregation Category	Color Coding	Container	Examples	Marking
Waste			remains, paper towels from non-production areas)	
Recyclable Waste	Blue	Plastic bag or container	Clean, uncontaminated packaging materials (e.g. plastic bottles, cardboard, paper inserts, glass containers not exposed to product or cleanroom environments, metal cans)	 Recycling symbol (where applicable)
Chemical and Pharmaceutical Waste	Brown	Resistant plastic container or bag	Laboratory reagents, solvents, expired disinfectants, cleaning chemicals, expired or rejected vaccine products, chemical residues, batteries, broken thermometers	Marking according to chemical hazard classification

Staff shall receive comprehensive training on handling protocols, including the use of PPE such as gloves, masks, and protective clothing. Clear guidelines will be established emphasizing the importance of immediate segregation and containment to prevent spills.

Below is a table that shows appropriate PPE per category of waste, tailored for staff handling waste at Kenya BioVax Institute.

Table 3. PPE per waste category

Waste Category	PPE Required
General Waste	Gloves, lab coat, closed shoes
Recyclable Waste	Cut-resistant gloves, lab coat/apron, eye protection, closed shoes
Infectious Waste	Heavy-duty gloves, gown/coverall, mask (N95 if needed), goggles/face shield, waterproof boots
Sharps Waste	Puncture-resistant gloves, gown, eye protection, closed boots
Pharmaceutical Waste	Chemical-resistant gloves, gown/apron, goggles, respirator (if dust/aerosol)
Chemical Waste	Chemical gloves, lab coat/apron, goggles, face shield, respirator (if needed), boots
Cytotoxic Waste	Chemotherapy gloves (double), impervious gown, respirator, eye protection, impermeable boots
Biological waste	Disposable gloves (single-use and heavy-duty utility gloves for waste handling), laboratory coat or disposable gown/coverall, impermeable plastic apron, closed protective footwear surgical mask, particulate respirator goggles, face shield, head cover (cap), and arm or sleeve protectors.

8.3.5.3 Solid Waste Handling

In compliance to the Environmental, Health, and Safety Guidelines, On-site and Off-site transportation of waste shall be conducted so as to prevent or minimize spills, releases, and exposures to employees and the public.

A. Onsite transportation

Waste transportation within BioVax will adhere to applicable contamination control, segregation, and safety requirements consistent with WHO, WBG EHSG, and national regulatory guidance. Onsite waste transportation will entail conveying of waste from the various points of generation to a temporary storage location within the facility as detailed in the SOP on waste management-. WHO good manufacturing practices for pharmaceutical products: Main Principles. Annex 2, WHO Technical Report Series, No. 986, 2014(31) states that Waste Material should not be allowed to accumulate and shall be collected in suitable receptacles for removal to collection points. Transportation will be conducted using dedicated, clearly identified trolleys segregated by waste category to prevent cross-contamination as detailed in the SOP on waste management. The waste trolleys will be drawn using designated routes for waste transport to waste storage treatment sites.

B. Waste storage

BioVax will provide a temporary waste storage facility that will have restricted entry. Storage facilities will follow the World Bank EHS guidelines, WHO, NEMA and PPB guidelines.

The waste storage facility shall be labeled on the outside with appropriate hazard signage consistent with the waste classification (e.g. biohazard, chemical hazard, cytotoxic), in accordance with applicable regulations. The frequency of waste collection shall be defined based on waste type, risk level, and operational intensity, as specified in the draft Waste Management SOP. BioVax will ensure that waste storage receptacles are leak-proof and clearly labeled. BioVax will ensure that regular inspections of the storage containers and facility is done to identify and address potential risks.

C. Offsite transportation

Off-site transportation refers to the controlled movement of the Biological and pharmaceutical waste from the Kenya BioVax Institute facility to an approved external treatment and disposal facility. This process shall be undertaken in strict compliance with the requirements of the National Environment Management Authority under the Environmental Management and Coordination Act (EMCA) and the Waste Management Regulations 2006, as well as applicable World Bank Environmental and Social Framework requirements.

I. Engagement of Licensed Waste Transporter

Kenya BioVax Institute will engage a waste transportation service provider through a transparent procurement process in accordance with institutional procurement procedures and applicable World Bank procurement guidelines. The selected company must demonstrate the legal, technical, and operational capacity to safely transport hazardous pharmaceutical waste. Prior to engagement, the waste transport company will be required to provide the following documentation for verification:

i. A valid waste transportation license issued by the National Environment Management Authority authorizing the transport of hazardous and pharmaceutical waste.
ii. Documentation demonstrating that the company operates appropriately licensed vehicles designed for hazardous waste transportation.
iii. Proof of trained and certified personnel responsible for handling and transporting hazardous waste.
iv. Evidence of valid insurance coverage, including environmental liability and third-party risk coverage.
v. A formal agreement or contract with a NEMA-licensed treatment or disposal facility authorized to receive Biological and pharmaceutical waste.

BioVax will verify that the disposal facility identified by the transporter is gazetted and licensed by NEMA to receive and treat pharmaceutical or hazardous waste streams.

II. Contractual Requirements

The contract between Kenya BioVax Institute and the licensed waste transporter will clearly define roles, responsibilities, and compliance obligations. The contract will require the transporter to:

i. Transport Biological and pharmaceutical waste only to NEMA-approved treatment and disposal facilities.
ii. Maintain traceability and documentation for each consignment of waste transported.
iii. Ensure compliance with national hazardous materials transport regulations and internationally recognized safety standards.
iv. Provide periodic reports on quantities of waste transported and final disposal confirmation.

BioVax reserves the right to audit the waste transporter and the receiving disposal facility to verify compliance with regulatory requirements.

III. Transportation and Documentation

Before leaving the BioVax facility, all waste shipments will be loaded onto authorized transport vehicles in a secure and safe manner. Each shipment will be accompanied by a waste consignment note (waste manifest) carried by the driver. The consignment note will include:

i. Source of the waste (Kenya BioVax Institute).
ii. Date and time of waste collection.
iii. Name and identification details of the driver.
iv. Vehicle registration details.
v. Destination disposal facility.
vi. Total weight and category of waste.
vii. Description of the waste and associated hazards.
viii. Emergency handling instructions where applicable.

Both the waste transporter and the receiving disposal facility will sign the consignment documentation to confirm receipt and proper handover of the waste. Copies of all consignment notes will be retained by BioVax for regulatory compliance, monitoring, and audit purposes.

IV. Monitoring and Compliance

Kenya BioVax Institute will maintain oversight of off-site waste transportation activities to ensure compliance with regulatory and environmental requirements. This will include:

i. Verification of valid NEMA licenses for both the transporter and disposal facility.
ii. Maintenance of a waste tracking register documenting all waste movements.
iii. Periodic compliance audits of the waste management service provider.
iv. Immediate reporting and investigation of any incidents such as spills, accidents, or unauthorized disposal.

Through these measures, Kenya BioVax Institute will ensure that all pharmaceutical waste transported off-site is managed in a safe, traceable, and environmentally responsible manner.

8.3.5.4 Waste Treatment and Disposal

A. Treatment of Biological and pharmaceutical waste

Waste treatment renders the waste safe before final disposal and will aim at eliminating hazards and exposures. A variety of waste treatment methods will be used at BioVax tailored to the type of waste generated as described in the draft Waste Management. BioVax shall engage a waste transport company that is duly registered and licensed by relevant Kenyan regulatory authorities (including NEMA and other applicable national agencies) through the standard public procurement process for transportation to the final disposal facility.

The transporting services shall be procured in accordance with the Public Procurement and Asset Disposal Act (2015) and Public Procurement Regulations

Below is a process diagram on the internal waste management cycle applicable at BioVax.

Figure 1. Waste treatment process

8.3.5.5 Waste Monitoring

BioVax shall continuously monitor waste management process from generation to final disposal to ensure alignment with applicable regulatory requirement. These shall be as described in the SOP on waste management.

A. Liquid Waste Treatment and Disposal

In line with WHO good manufacturing practices relevant to pharmaceutical and biopharmaceutical operations, including requirements for liquid waste and effluent management, all effluent shall be handled in such a manner as not to present a risk of contamination to the product, personnel or to the environment.

Effluent generated from utility operations, Laboratories, production lines, stormwater, and sanitary sewage shall be managed through use of a bio kill system and effluent treatment plant (ETP) located within the facility. All wastewater will be collected from the facility by pipe system and passed into bio kill system and ETP for treatment. The final output from the treatment plant will be sludge and treated water. The treated water will undergo through a combination of visual, physical, bacteriological, chemical various tests to ensure that it meets the stipulated standards by NEMA for effluent discharge into the environment. The treated water shall be reused for non-potable purposes such as gardening and facility cleaning activities or discharged into the municipal sewerage system for further treatment in accordance with local authority requirements and subject to further treatment.

Sludge from ETP will be disposed as part of the solid waste and through a licensed contracted waste handler in full compliance with national regulatory requirements in a manner that ensures the protection of public health and safety, and conservation and long-term sustainability of water and land resources.

To maintain the onsite waste treatment operating system and ensure sustainability, BioVax shall perform continuous monitoring for proper performance and the achievement of public health and environmental goals. A combination of visual, physical, bacteriological, chemical, and remote monitoring approaches shall be used to assess system performance to meet both international and National standards for effluent discharges. In the event that external contractors are used for effluent disposal, BioVax shall ensure compliance to National Regulation and certification

authorizing them to handle and treat hazardous waste. BioVax shall adhere to the national Guidelines for Effluent Discharge to Public Sewers and World Bank Environmental, Health, and Safety (EHS) General Guidelines for Environmental Wastewater and Ambient Water Quality. Treated wastewater having met the effluent quality standards, shall be discharged to off-site sewer lines.

Table 4. Disposal Methods and Applicable Biopharmaceutical Waste Types (BioVax – Fill–Finish Operations)

Sr. No.	Disposal Method	Types of Biopharmaceutical Waste
1.	Return to manufacturer / supplier (where applicable)	Bulk rejected, expired, recalled, or off-specification biopharmaceutical products and raw materials where a take-back mechanism exists, with full traceability and QA disposition records.
2.	Incineration (licensed facility) - High-temperature incineration (where available) - Controlled incineration (engineered, licensed)	Contaminated solids and semi-solids; rejected/expired biopharmaceutical product residues; packaging contaminated with product; sharps (via safety boxes) where required by national guidance; highly hazardous waste where incineration is the approved route.
3.	Immobilisation prior to disposal - Encapsulation - Inertisation	Solid/semi-solid pharmaceutical or chemical residues requiring stabilization prior to final disposal; selected solids where immobilisation is required before landfill, subject to national requirements and disposal facility acceptance criteria.
4.	Landfill (engineered, licensed only) - Highly engineered sanitary landfill - Engineered landfill	Non-hazardous general waste; recyclable rejects not contaminated; immobilized / stabilised pharmaceutical residues where permitted; non-contaminated packaging waste (where recycling is not feasible).

Sr. No.	Disposal Method	Types of Biopharmaceutical Waste
5.	Sewer / municipal effluent system (controlled discharge)	Diluted aqueous waste streams and small quantities of approved cleaning/disinfectant solutions after on-site treatment (e.g., ETP/bio-kill) and only where permitted by the local sewer authority and applicable discharge standards.
6.	Advanced chemical treatment (specialist method, where available)	Selected chemical waste streams requiring specialist neutralisation or treatment (e.g., strong acids/alkalis, reactive chemicals), performed by competent personnel or licensed contractors with appropriate controls.

8.3.6 Occupational Health & Safety

BioVax as an employer is obliged to implement all reasonable precautions to protect the health and safety of workers. This section provides guidance and examples of reasonable precautions to implement in managing principal risks to occupational health and safety. The focus is placed on the operational phase of project, construction and decommissioning activities. Occupational, safety, Health, and Environment policy in line with OSHA Act 2012 that will be implemented to protect all staff and environment shall be put in place. The policy areas include Provision and use of PPE, training, risk assessments and Health surveillance and Biosafety/Biosecurity.

Preventive and protective measures such as;

i. Eliminating the hazard by removing the activity from the work process. Examples include substitution of a chemical with less hazardous chemicals
ii. Controlling the hazard at its source through use of engineering controls. Examples include HVAC systems serving areas handling biological agents equipped with High Efficiency Particulate Air (HEPA) filtration systems.
iii. Minimizing the hazard through design of safe work systems and administrative or institutional control measures. Examples include job rotation, training safe work procedures.
iv. Providing appropriate personal protective equipment (PPE) in conjunction with training, use, and maintenance of the PPE.

Incident management procedures and Emergency response procedures shall be in place and implemented to respond promptly to any incidents involving exposure or injuries. In addition, BioVax shall ensure that staff are trained and equipped to handle such situations.

8.3.6.1 OSH Training

In line with OSHA Act of Kenya 2007, BioVax shall ensure that all employees and contractors engaged at the workplace receive orientation training to familiarize them with site rules, personal protection requirements, and measures for preventing injury to themselves and others as well as to ensure they are apprised of the basic site rules. Training shall consist of basic hazard awareness, site specific hazards, safe work practices, and emergency procedures for fire, evacuation, and natural disaster, as appropriate. Any site-specific hazard or color coding in use will be thoroughly reviewed as part of orientation training.

Further, all staff at BioVax shall receive induction training on Biological and Pharmaceutical Waste Management during recruitment; transfer or change of job; the introduction of new work equipment or materials or change in equipment or materials or introduction of new technology. Regular training sessions shall be held, covering topics such as; Codes of conduct, institutional policies, proper waste segregation, handling procedures, and emergency/incident response measures.

Competency assessment shall be used to identify any other specific training required based on job function. A basic occupational training program and specialty courses will be provided, as needed, to ensure that employees are oriented to the specific hazards of individual work assignments. Employees assigned occupational first-aid duties shall receive refresher training so as not to inadvertently aggravate exposures and health hazards to themselves or their co-workers.

8.3.6.2 OSH Monitoring

Occupational health and safety monitoring programs are meant to verify the effectiveness of prevention and control strategies. The occupational health and safety monitoring program at BioVax will include:

1) **Safety inspection, testing and calibration**: The regular inspection and testing of all safety features and hazard control measures focusing on engineering and personal protective features, work procedures, places of work, installations, equipment, and tools used. The inspection will be used to verify that issued PPE continues to provide adequate protection and is being worn as required. All instruments installed or used for monitoring and recording of working environment parameters should be regularly tested and calibrated, and the respective records maintained.

2) **Surveillance of the working environment:** Monitoring to be performed during commissioning of facilities or equipment and at the end of the defect and liability period, and otherwise repeated according to the monitoring plan.
3) **Surveillance of workers' health:** In accordance with ethical and technical guidelines for workers health surveillance given by the International Labor Organisation (Occupational Safety and Health Series No. 72), employees shall be provided appropriate and relevant health surveillance prior to first exposure. Medical examinations may take place at periodic intervals during employment and should be appropriate to the occupational risks of the enterprise. These examinations may also occur:
    i. On resumption of work after a prolonged absence for health reasons, for the purpose of determining any possible occupational causes, recommending appropriate action to protect workers, and determining suitability for the job or the need for reassignment and rehabilitation;
    ii. At the request of the worker, for example, when a worker changes work and, in particular, when a worker changes work for medical reasons. BioVax BioVax shall establish and implement an occupational health surveillance program.
4) **Training:** Training activities for employees and visitors will be adequately monitored and documented (curriculum, duration, and participants). Emergency exercises, including fire drills, will be documented adequately.

5) All reported occupational accidents, occupational diseases, dangerous occurrences, and incidents together with near misses will be investigated with the assistance of the designated safety officer. The investigation should: Establish what happened; Determine the cause of what happened; Identify measures necessary to prevent a recurrence.

NOTE:

- OSH monitoring activities under this section support the effective implementation of Biological and Pharmaceutical Waste Management measures and do not replace detailed OSH procedures defined in approved SOPs.

8.4 Emergency Preparedness and Response (EPR)

It is important to develop procedures and practices for the handling of hazardous materials that allow for quick and efficient responses to accidents that may result in injury or environmental damage.

The Emergency Response Plan (ERP) for BioVax is aimed at providing emergency responses to potential threats associated with injury, infectious diseases to staff or contamination to the environment. The Emergency Preparedness and Response Plan covers:

i. Planning Coordination which covers procedures for Informing the public and emergency response agencies, documenting first aid and emergency medical treatment, taking emergency response actions and reviewing and updating the emergency response plan to reflect changes while ensuring that the employees are informed of such changes
ii. Emergency Equipment: The plan includes procedures for using, inspecting, testing, and maintaining emergency response equipment.
iii. Training: Employees in any relevant procedures.

Emergency incidents that may occur include spillage, occupational exposure to infectious materials or radiation, accidental releases of infectious or hazardous substances to the environment, equipment failure, failure of solid waste and wastewater treatment facilities, or fire. These emergency events are likely to seriously affect workers, communities, operations and the environment.

8.4.1 Planning Coordination

To reduce the likelihood of exposure to/release of a biological agent to environment, or to reduce the consequences of such incidents, BioVax will develop a site-specific contingency plan that provides specific standard operating procedures (SOPs) to be followed in possible emergency scenarios that apply to the work and local environment. The plan will be tailored to the specific operational realities and potential risks associated with BioVax activities, ensuring a structured response to emergencies. Emergency preparedness and Response will ensure a rapid and effective response to incidents.

The ERP will incorporate risk assessment that will be conducted to identify potential biological hazards linked to laboratory operations, vaccine and biologics production, and research activities. These assessments will inform the development of the emergency scenarios SOPs, that will clearly outline how to activate the emergency response and evacuation criteria. The procedures will detail containment measures, such as securing the area and isolating affected individuals, recording details of the incident, the response actions taken, and any follow-up measures. Post-incident reviews will be conducted to analyse the effectiveness of the response and to refine the ERP based on lessons learnt. Regular drills will be conducted to ensure staff familiarity with these plans and procedures, enhancing overall readiness.

8.4.2 Emergency Resources and Equipment

An emergency response plan shall be established and maintained to address incidents such as spills, exposures, injuries, fires, and other emergencies related to biological waste management, and regular emergency drills shall be conducted to ensure preparedness and effective response by all relevant personnel.

BioVax will provide emergency kits, stocked with necessary supplies such as personal protective equipment (PPE) and decontamination materials, strategically placed throughout the facility for easy access. Additionally, protocols are in place to ensure that medical care is readily available, either on-site or through nearby facilities, BioVax has provided employees with a medical cover that caters for medical care and any form of emergencies to provide immediate assistance in case of exposure. The contracted medical insurance provider has provided emergency telephone numbers which are 24 hours operational for any clarifications or medical services access

Further BioVax has a list of nine (9) trained first aiders that are equipped with knowledge and skills to handle occupational first aid and serving currently 30 employees Continuous training shall be provided.

BioVax will put up an up-to-date list of contact information for all internal and external resources and personnel. The list will include the name, description, location, and contact details (telephone, email) for each of the resources, and will be maintained annually.

8.4.3 Business Continuity and Contingency

Measures to address business continuity and contingency that will be employed will include;

i. Identification of replacement supplies or facilities to allow business continuity following an emergency e.g. alternate sources of water, electricity, and fuel are commonly sought.
ii. Use of redundant or duplicate supply systems as part of facility operations to increase the likelihood of business continuity.
iii. Maintaining back-ups of critical information in a secure location to expedite the return to normal operations following an emergency.

8.5 Training and Induction

8.5.1 Induction Program

All new staff shall undergo a mandatory induction program upon onboarding. The induction includes orientation on the following key areas:

i. The scope and objectives of the BPWMP
ii. Applicable national and international waste management regulations (e.g., NEMA, OSHA, WHO, GMP)
iii. Safety protocols, including use of personal protective equipment (PPE), hand hygiene, and incident reporting
iv. Segregation of waste using color-coded bins in accordance with NEMA guidelines
v. Safe handling and disposal procedures for biological, pharmaceutical, chemical, and sharps waste
vi. The induction will be coordinated by the relevant technical department in collaboration with Human Resources and relevant departmental heads, and must be completed before staff are assigned to operational or laboratory areas.

8.5.2 Ongoing Staff Training

Regular refresher training sessions shall be conducted to:

i. Reinforce compliance with the BPWMP policies and Standard Operating Procedures (SOPs)
ii. Update staff on any regulatory changes or revisions to internal waste management protocols

The trainings shall be mandatory and documented, with attendance records, training materials, and evaluation tools maintained for audit and compliance purposes.

All training activities will be periodically evaluated through staff assessments, audits, and feedback mechanisms to identify knowledge gaps and improve training content. The technical departments shall use these insights to update training modules and ensure they remain relevant and effective in meeting BioVax's safety, health, and environmental objectives.

8.5.3 Emergency Response training

The emergency preparedness facilities and emergency response plans require maintenance, review, and updating to account for changes in equipment, personnel, and facilities. Training programs and practice exercise provide for testing systems to ensure an adequate level of emergency preparedness.

These training programs will:

i. identify training needs based on the roles and responsibilities, capabilities and requirements of personnel in an emergency.
ii. Develop a training plan to address needs, particularly for firefighting, spill response, and evacuation.
iii. Conduct annual training.
iv. Provide training exercises to allow personnel the opportunity to test emergency preparedness.
v. Debrief upon completion of a training exercise to assess what worked well and what aspects require improvement.
vi. Update the plan, as required.
vii. Record training activities and the outcomes of the training. Table 6. Staff Training plan outlines the capacity building plan in relation to Biological and Pharmaceutical waste management practices at BioVax.

8.6 Risk Mitigation Plan

BioVax will address the potential risks associated with its activities of waste management processes. This includes risk assessments to evaluate current practices and implement a mitigation strategy focusing on minimising risks related to Biological and pharmaceutical waste collection, handling, storage, transportation, treatment, and disposal. The strategy key areas of focus to ensure the safety of employees, the community, and the environment will include:

Table 5. Risk Mitigation Plan

Sr. No.	Risks identified	Mitigation measures
i.	Improper Biological and Pharmaceutical Waste Collection, Storage, and Segregation	a) Regular training sessions for all staff involved in waste management on proper waste segregation techniques, emphasising the importance of categorising waste at the point of generation. b) Developing and implementing procedures for Biological and Pharmaceutical waste collection and storage, ensuring that all staff are familiar with the correct procedures for handling different types of waste. This includes using color-coded bins that are clearly labeled for infectious, sharps, and general waste. c) Conducting periodic audits to assess compliance with waste segregation protocols. Immediate corrective actions should be taken for any identified lapses.
ii.	Increased Disease Transmission from Poor Biological and Pharmaceutical Waste	a) Ensuring waste storage facilities meet the required standards b) Establishing partnerships with licensed waste disposal companies to ensure that all waste is treated and disposed

Sr. No.	Risks identified	Mitigation measures
	Treatment & Disposal Systems	of in compliance with local and international regulations. c) Implementing a monitoring system to track the effectiveness of waste treatment methods and identify areas for improvement.
iii.	Environmental Pollution Due to Poor Biological and Pharmaceutical Waste Practices	a) Adopting GMP best practices for Biological and Pharmaceutical Waste Management, including proper waste segregation, collection, and disposal methods. b) Conducting regular environmental impact assessments to evaluate the effects of waste management practices and implement changes based on findings.
iv.	Risk of Disease Transmission to Waste Scavengers and Neighboring Communities	Ensuring that waste storage areas are secured and inaccessible to unauthorized personnel, particularly waste scavengers.
v.	Shortage of Equipment and Supplies for BPWMP and PPE	a) Developing inventory management systems to monitor supplies of personal protective equipment (PPE) and waste management materials. Ensure timely reordering to prevent shortages. b) Allocation of adequate resources for the procurement of essential ICWM supplies and equipment.
vi.	Poor Management Systems for Biosafety Control and Emergency	a) Creating detailed procedures for Biosafety control and emergency response that address potential incidents and accidents, ensuring all staff are trained and familiar with

Sr. No.	Risks identified	Mitigation measures
	Response	these procedures. b) Conducting regular emergency response drills to prepare staff for potential incidents involving hazardous waste or other emergencies. This will enhance readiness and ensure effective response in real situations. c) Implementing a clear reporting system for incidents allowing for immediate response and long-term analysis to prevent future occurrences. d) Engaging with local authorities on implementation of emergency response and evacuation plans.

8.7 Monitoring and Evaluation

BioVax. Monitoring of the BPWMP implementation during the operational phase shall be undertaken by BioVax in conjunction with the National Environment Management Authority (NEMA), relevant County Environment Offices, County Departments of Water and Environment, and County Public Health Departments.

Monitoring will verify if predicted impacts have actually occurred and check that mitigation actions recommended in the BPWMP are implemented and their effectiveness. Monitoring will also identify any unforeseen impacts that might arise from project implementation.

External regulatory monitoring may be undertaken by the Ministry of Health (MoH) Environment and Social Experts, NEMA County Environment Officers, County Public Health Officers, and the Directorate of Occupational Safety and Health Services (DOSHS), in accordance with their respective statutory mandates. Monitoring by NEMA or Directorate of Occupational Safety and Health Services shall be considered "third party monitoring" Monitoring will be done through site inspection, review of grievances logged by stakeholders and ad-hoc discussions with potentially affected persons.

In addition, monitoring will be done internally with additional assessments conducted during periods of heightened activity, such as increased vaccine and biologics production for public health emergencies. Incident reviews will be carried out following any breaches to ensure prompt corrective actions are implemented. Regular monitoring of BPWMP will include routine audits of waste management practices, waste generation rates, and compliance with disposal regulations. Scheduled Environmental and Social Audits (ESAs) shall be conducted annually and may be undertaken either internally by qualified Environment and Social Experts or by an external auditor contracted by the Institute, in accordance with the Environmental (Impact Assessment and Audit) Regulations, 2003 and the Environmental Management and Co-ordination Act (as amended, 2024).

8.8 Reporting System

Nationally, there is no standardized national monitoring and reporting tool mandated for Biological and pharmaceutical waste management. Accordingly, BioVax will implement customized waste monitoring tools and waste tracking logs aligned with NEMA requirements, WHO guidance, and applicable international best practices.

BPWMP monitoring reports will be compiled internally by the Safety, Health and Environment (SHE) section in collaboration with the Safety Committee and Biosafety and Biosecurity Section. During the operational phase, environmental and social audits will be conducted to verify compliance with national legislation, NEMA approval conditions, and World Bank Group (WBG) Environmental, Health and Safety (EHS) Guidelines. In addition, due diligence assessments of contracted waste treatment and disposal service providers will be undertaken.

Reporting on waste management activities including waste generation, treatment, transportation, and final disposal will be conducted on a quarterly basis. This approach will enable timely identification of incidents, non-conformities, and trends, thereby supporting transparency, corrective actions, and continual improvement of the waste management system.

9 ANNEXURES

9.1 Annexure 1 - Staff Training plan

Table 6. Staff Training plan

Capacity needs	Target participants	Cost (USD)*
Safe work practices and Occupational safety and health	**6)** All staff	15,000
Training on infection prevention and control measures, hand, and respiratory hygiene & use of PPE	**7)** Safety Health and Environment Officers **8)** Biosafety and Biosecurity team **9)** Production team **10)** QA team **11)** All persons directly handling waste	15,000
Training on infection control and waste management measures & the roles and responsibilities for all actors from cradle to Grave	**12)** Safety Health and Environment Officers **13)** Biosafety and Biosecurity team **14)** Production team **15)** QA team **16)** All persons directly handling waste	15,000
Training on biosafety and biosecurity	**17)** Safety Health and Environment team **18)** Laboratory Staffs **19)** Cleaners and waste transporters within the facility **20)** Security team **21)** Biosafety Biosecurity team **22)** Production team **23)** Legal	15,000

Capacity needs	Target participants	Cost (USD)*
Training of on proper implementation of the ICWMP and ESMP during operations	**24)** Safety Health and Environment officers **25)** Laboratory staff	10,000
Training in Bio Safety and Biohazards for vaccine manufacturing facility	**26)** Safety Health and Environment Officers **27)** Biosafety and Biosecurity team **28)** Production team **29)** QA team **30)** All persons directly handling waste	20,000
Training on EHS management in laboratories including emergency response.	**31)** Laboratory personnel	10,000
Training on the WBG Environment and Social Framework specific to ESCP and all. Project ES instruments (including ESMF, SEP, LMP, etc.)	**32)** All staff	15,000
Total cost		**115,000**

Note:

- All cost estimates provided are indicative and subject to detailed training plans, procurement procedures, and budget approvals.

9.2 Annexure 2 - Biological and Pharmaceutical Waste Management Plan Baseline Mitigation Measures for BioVax

Activities	Potential E&S Issues & Risks	Proposed Mitigation Measures	Responsibilities	Timelines
General Environmental operations	General wastes	i. Use of waste receptacles that encourage segregation to hold waste on site before its collection, ii. Use of durable, long-lasting materials that will not need to be replaced often, iii. Contract NEMA Registered waste handler to dispose of hazardous waste and have waste destruction certificate and waste transfer notes. iv. Designate temporal waste / garbage holding areas at site that meet the requirements outlined in section 8.3.5.3	Safety Health & Environment section Biosafety & Biosecurity section	Quarterly
	Waste water	i. All effluents should be discharged into the public sewer system or reused for other purposes only after being pre-treated according to WHO standards / EMCA (Water Quality Regulations, 2024)	Safety Health and Environment section Biosafety and Biosecurity section	Quarterly
	Air emissions (dioxins, furans,	i. Prohibit open burning of medical waste on site. ii. Install high-efficiency particulate	QA, QC, Lab managers,	Quarterly

	arsenic, lead, cadmium, chromium, mercury, etc. Risks by direct exposure (inhalation) or in-direct exposure (deposited in soil, water, plants	air (HEPA) filters and activated carbon filters to capture harmful pollutants. iii. Maintain and upgrade HVAC systems to ensure proper ventilation and air quality control. iv. Regular monitoring of air quality and emissions. v. Proper waste segregation and treatment to prevent airborne contamination. vi. Provide personal protective equipment (PPE) such as respirators and masks. vii. Establish containment zones with negative pressure for hazardous materials. iii. Conduct regular health surveillance and employee training on exposure risks. ix. Develop and enforce strict standard operating procedures (SOPs) for handling materials.	safety Health, Biosafety & Biosecurity	
General operation OHS issues	Physical hazards, biological hazards	i. All workers will be provided with appropriate PPE against exposure to hazards, ii. Training for all staff will be given on safe work practices /OHS and guidelines and ensure that they	QA, QC, Lab managers, safety Health, Biosafety & Biosecurity	Quarterly

	Chemical use, Ergonomic hazard	adhere to it, the production facilities and equipment will be regularly maintained to correct any electrical faults, iii. Strategic display on OHS Policy and regular review of the policy. iv. Proper maintenance of PPE, including cleaning when dirty and replacement when damaged or worn out, v. Proper use of PPE to be part of the recurrent training programs for employees, vi. Emergency eye-wash and shower facilities provided equipped with audible and visible alarms to summon aid whenever the eye-wash or shower is activated by the worker and without intervention by the worker, vii. Provision of safety systems which should cover fire, electrical emergencies with First-aid areas or rooms suitably equipped and readily accessible, iii. Provision of first aid kits and first aiders trained on first aid, ix. Materials safety data sheet for all chemicals used especially at the lab		

		should be hanged on notice boards.		
	Fire	i. Prepare and implement Fire emergency response plan. ii. Training of fire marshals in the facilities, iii. Provide fire extinguishers iv. Ensure servicing and inspection of the firefighting equipment v. Fire emergency telephone numbers should be displaced in communal areas. vi. Undertake fire drills at healthcare facility, at a minimum once quarterly	QA, QC, Lab managers, safety Health, Biosafety & Biosecurity	Quarterly
Storage and handling of specimen, cultures samples, reagents, and VBMS	Access by staff, visitors Contamination to the Environment	i. Initial processing of all specimens should take place in a validated biological safety cabinet (BSC) or primary containment device. ii. All technical procedures should be performed in a way that minimizes the generation of aerosols and droplets. iii. Use of appropriate disinfectants with proven activity against enveloped viruses should be used (for example, hypochlorite [bleach], alcohol, hydrogen peroxide, quaternary ammonium compounds,	QA, QC Production	Quarterly

		and phenolic compounds.		
Waste segregation, packaging, color coding and labeling	Increased generation of infectious waste due to poor segregation practices	i. Segregation of wastes into different categories for control of quantities and disposal methods ii. Waste containers should be of the same color as the bags and fitted with lids	Safety Health and Environment, Biosafety and Biosecurity	Quarterly
Onsite collection and transport	Infection to the waste handlers Non segregation of waste Increased generation of infectious waste due to contamination	i. Ensure proper waste management practices as recommended by the WBG EHS guidelines, WHO Safe waste management guidelines for improvement waste management and Health care waste management plan 2016-2021. ii. The collection of waste would be made at least once in 24 hours, and it would be done in such a way to minimize nuisance of smell and dust during collection and all the waste collected must be carried away from the storage site to an approved disposal point. iii. Provide appropriate waste bins for the different types of waste generated in the laboratory to allow segregation and collection at the point of generation.	Safety Health and Environment, Biosafety and Biosecurity	Quarterly
Waste storage	Littering of	i. Segregation of wastes into different	Production, QA,	Quarterly

	waste Contamination of surfaces	categories for control of quantities and disposal methods. ii. Provision of color-coded waste bins with lid, iii. Provision of appropriate PPEs for waste handlers and incinerator operators iv. Decontamination of surfaces	QC, Safety Health and Environment, Biosafety and Biosecurity	
Waste transportation to and disposal in offsite treatment and disposal facilities	Littering of wastes -Disposal in non- permitted waste sites -	i. Offsite transportation of waste should comply with the national regulations EMCA (Waste Management Regulations), 2024 ii. Use of NEMA licensed Waste transporters, Keeping record of waste transfer notes as well as waste destruction certificates at the point of disposal facility. iii. Use the appropriate vehicle type for transportation of waste. iv. Offsite Staff should be aware of emergency procedures for dealing with accidents and incidents of spillage during transportation on public roads. v. Due diligence should be undertaken for all the waste treated off site to ensure waste is transported through the required	Safety Health and Environment, Biosafety and Biosecurity	Quarterly

		routes (non-busy route) and safely treated and disposed		
Trans boundary movement of raw materials samples, reagents, medical equipment, and infectious materials	Importation of substandard raw materials and equipment Illegal importation of dangerous goods without clearance Improper handling and storage	i. Procure raw material & equipment from accredited supplier. ii. Proper handling of equipment uses, and methods of storage from cradle to crave, iii. Technical instructions for the safe transport of dangerous goods by air (Doc 9284) of the International Civil Aviation Organization.	Production, QA, Procurement	Quarterly
Emergency events	Spillage, Fire & others	i. Emergency response plan(s) for specific emergencies, ii. Regular drills would constantly follow on various possible incidences. iii. This will test the response of the involved stakeholders. iv. Such drills will keep them alert	Biosafety & Biosecurity Safety Health & Environment	Quarterly

		and they will become more responsive to in the case of incidences. v. Train relevant staff on response in risk management and emergency procedures in-case of accidents and spillages		

10 REFERENCES

10.1 Environment Management and Coordination Act Regulations of (2024)

10.2 Guidance on good practices for pharmaceuticals Quality Control Laboratories. Annex 1, WHO TRS, NO. 957, 2010(34)

10.3 Health Act No. 21 of 2017

10.4 https://kenyalaw.org/kl/fileadmin/pdfdownloads/Acts/HealthActNo.21of2017.pdf

10.5 https://www.ifc.org/content/dam/ifc/doc/2000/2007-general-ehs-guidelines-references-and-additional-sources-en.pdf

10.6 National Guidelines for Safe Management of Health Care Waste, 2nd Edition (2024). Ministry of Health, Kenya

10.7 OSHA Act 2012

10.8 Pharmacy and Poisons Waste Management Rules, 2022;

10.9 Public Health Act Cap 242 (2012)

10.10 Technical and ethical guidelines for workers' health surveillance (OSH No. 72) Geneva, International Labour Office, 1998 (Occupational Safety and Health Series No. 72)

10.11 World Bank EHS general guidelines for environmental waste water and ambient water quality

10.12 WHO Good Manufacturing Practices for Active Pharmaceutical Ingredients. Annex 2, WHO TRS, No. 957, 2010 (32)

10.13 WHO Good Manufacturing Practices for pharmaceutical products: Main Principles (31)

10.14 WHO Good Manufacturing Practices for Biological Products, Annex 2, TRS No. 999;

10.15 WHO guidelines on safe management of wastes from pharmaceutical activities and the National Healthcare Waste Management Plan (2016-2021)

11 REVIEW AND IMPROVEMENT

This document shall be reviewed after every 3 years and updated appropriately or as need arises to incorporate changes in regulations, operations, or best practices.

Document Version No	Current status	Proposed changes	Effective date of the change
01	New document	None	30/06/2026