MINISTRY OF HEALTH

AFE Kenya Health Emergency Preparedness, Response and Resilience

P180127

Revised Draft

ENVIRONMENTAL AND SOCIAL MANAGEMENT FRAMEWORK (ESMF)

June 6th, 2023

(Revised July 2023)

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF PHOTOS

LIST OF TABLES

ABBREVIATIONS/ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ALOS	Average Length of Stay
BAT	Best Available Technologies
BMWM	Bio Medical Waste Management
CDE	County Director of Environment
CERC	Contingency Emergency Response Component
CHERP	COVID-19 Health Emergency Response Project
CoK	Constitution of Kenya
COVID-19	Coronavirus Disease 2019
CPHO	County Public Health Officer
CPR	Comprehensive Project Report
CRPD	United Nations Convention on the Rights of Persons with Disabilities
DOSH	Director Occupation Safety and Health
DOSHS	Directorate of Occupational Safety and Health Services
E&S	Environmental and Social
ECSA-HC	East, Central and Southern Africa Health Community
EHS	Environmental, Health and Safety
EHSGs	Environmental, Health and Safety Guidelines
eIDSR	Electronic Integrated Diseases Surveillance and Response Information System
EMCA	Environmental Management and coordination Act
ERP	Emergency Response Plan
ESF	Environmental and Social Framework
ESHS	Environmental, Social, Health and Safety
ESIA	Environmental and Social Impact Assessment
ESMF	Environmental and Social Management Framework
ESMP	Environmental and Social Management Plan
ESSs	Environmental and Social Standards
FPIC	Free Prior Informed Consent
GAVI	Global Alliance for Vaccines and Immunization
GBV	Gender Based Violence
GIIP	Good International Industry Practice
GMP	Good Manufacturing Practice

GoK	Government of Kenya
GRM	Grievance Redress Mechanism
HCF	Healthcare Facility
HCW	Healthcare Waste
HCWM	Healthcare Waste Management
HIV	Human Immunodeficiency Virus
HPTs	Health Products and Technologies
HUTLCS	Historically underserved traditional local communities.
HWMS	Healthcare Waste Management System
IBRD	International Bank for Reconstruction and Development
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICT	Information and Communication Technology system
ICU	Intensive Care Unit
ICWMP	Infection Control and Waste Management Plan
IDA	International Development Association
IHR	International Health Regulations
ILO	International Labour Organization
IPC	Infection and Prevention Control
KEMRI	Kenya Medical Research Institute
LIMS	Laboratory Information Management System
LMP	Labour Management Procedures
MICDE	Ministry of ICT, and Digital Economy
ML3	Maturity Level 3
MoH	Ministry of Health
NACOSH	National Council for Occupational Safety and Health
NAPHS	National Action Plan for Health Security
NCA	National Construction Authority
NCDs	Non-Communicable Diseases
NEMA	National Environment Management Authority
NEP	National Environment Policy
NHIF	National Hospital Insurance Fund
NPHI	National Public Health Institute
NPHL	National Public Health Laboratories
NQCL	National Quality Control Laboratories

OAU	Organization of African Unity
OSH	Occupational Safety and Health
PCR	Polymerase Chain Reaction
PDO	Project Development Objective
PHEOC	Public Health Emergency Operations Centre
PMT	Project Management Team
POE	Point of Entry
POPs	Persistent Organic Pollutants
PPE	Personal Protective Equipment
PrDO	Program Development Objective
PVC	Polyvinyl Chloride
PWDs	People with Disabilities
QMS	Quality Management System
RAP	Resettlement Action Plan
RoD	Records of Decision
RPF	Resettlement Policy Framework
SDGs	Sustainable Development Goals
SEA/SHEA	Sexual Exploitation and Abuse/Harassment
SEP	Stakeholder Engagement Plan
SERC	Standards and Enforcement Review Committee
SOP	Standard Operating Procedures
SPR	Summary Project Reports
STDs	Sexually Transmitted Diseases
THS-UC	Transforming Health Systems for Universal Care
UHC	Universal Health Coverage
VCT	Voluntary Counselling and Testing
VMGs	Vulnerable and Marginalized Groups
WASH	Water and Sanitation Hygiene
WBG	World Bank group
WHO	World Health Organization
WWTP	Wastewater Treatment Plant

EXECUTIVE SUMMARY

Environmental and Social Management Framework (ESMF) Purpose and Specific Objectives

The purpose of this Environmental and Social Management Framework (ESMF) is to aid Ministry of Health (MOH) comply with World Bank Group (WBG) as well as Government of Kenya (GOK) environment and social requirements in the implementation of Eastern and Southern Africa (AFE) Health Emergency Preparedness, Response and Resilience (AFE-HEPRR) project.

This ESMF, thus, outlines a framework for environmental and social management for the project, giving details of potential environmental and social issues, and guidelines on assessing environmental and social sensitivity of subprojects through appropriate environmental and social screening, followed by an environmental and social impact analysis, if required. The ESMF will also serve as the basis in the preparation of recommended subproject specific instruments such as ESIAs, LMP, SEP, etc. Specifically, this ESMF: (i) establishes clear procedures and methodologies for environmental and social planning, assessment, review, approval, and monitoring of subprojects to be financed under the project; (ii) specifies appropriate roles and responsibilities, and outline the necessary reporting procedures, for managing and monitoring environmental and social concerns related to subprojects; (iii) determines training, capacity building and technical assistance needed to successfully implement the provisions of the ESMF; and (iv) provides practical resources for implementing the ESMF.

To meet the requirements of the WBG Environmental and Social Framework (ESF), the project has also prepared for the project: an Environmental and Social Commitment Plan (ESCP); Stakeholder Engagement Plan (SEP); Labour Management Procedure (LMP); and Gender-based Violence Action (GBVAP).

Project Description

Kenya Health Emergency Preparedness, Response and Resilience (KE_HEPRR) Project aims to strengthen national systems for public health emergency preparedness through strengthening capacity for local manufacturing and public health institutional arrangements.

The Kenya project is part a broader WBG financed multi-country and institution program covering Federal Democratic Republic of Ethiopia, Democratic Republic of Sao Tome and Principe, Intergovernmental Authority on Development (IGAD), and East, Central and Southern Africa Health Community (ECSA-HC)]. The regional program aims **to strengthen health system resilience and multisectoral preparedness and response to health emergencies in Eastern and Southern Africa**. The proposed MPA has four components:

- Component 1: Strengthening the Preparedness and Resilience of Regional & National Health Systems to manage health emergencies (HEs);
- Component 2: Improving the detection of and response to HEs;
- Component 3: Program Management; and
- Component 4: Contingent Emergency Response Component (CERC)

KE_HEPRR Project Components

The project has three main components and sub-components:

Component 1: Strengthening Capacity for Local Manufacturing (US$ 70M). This component focuses on a phased implementation of four (4) key activities**.** In the first two years, the project will support the GoK to meet the prerequisites for vaccine manufacturing (sub-components 1.1-1.3). Most of these requirements are at an advanced stage and may be achieved earlier, however, the project will aim to

fill any remaining gaps and ensure that Kenya Biovax Initiative (KBI) meets all the World Health Organization (WHO) requirements before proceeding to implement sub-component 1.4.

- Sub-Component 1.1: Human resources capacity, learning, development, and technology transfer [US$ 15M)
- Sub-Component 1.2: Strengthen the regulatory capacity of the pharmacy and poisons board (PPB) [US$ 10M]
- Sub-component 1.3: Strengthening quality control (QC)/Assurance [US$ 10M]
- Sub-component 1.4: Establishing capacity for Fill & Finish (F&F[1]) of human vaccines [US$ 35M]

Component 2: Strengthening Capacity of the National Public Health Institute (NPHI) [US$ 40M]. This component will build on support provided through the Kenya COVID-19 Health Emergency Response Project (CHERP) (P173820) that is funding: (i) development of statutory instruments including organization structure, staff establishment report, and human resources and procedures manual; (ii) strengthening human resources capacity through training, learning exchange programs with a well-functioning equivalent institution; and (iii) development and application of a dedicated Information and Communication Technology system (ICT) which is linked to existing routine health information system among others.

- Strengthening of laboratory testing and genomic surveillance capacity
- Development and deployment of the Electronic Integrated Diseases Surveillance and Response Information System (eIDSR)
- Strategic stockpiles for preparedness and response
- Strengthening cross-border surveillance at Points of Entry (POE)
- Establishment of system for health workforce surge capacity

Component 3: Project Management [US$ 10M]. This component concerns project implementation, i.e., planning, organizing, executing, controlling resources (e.g., people, budget, time, etc.) and monitoring to achieve specific goals and objectives of the project.

Component 4: Contingent Emergency Response Component (CERC). There is a high probability that during the life of this proposed MPA, the country will experience an epidemic or outbreak of public health importance, or other disaster, which causes a major adverse economic and/or social impact (e.g., Ebola), which will result in a request to the World Bank to support mitigation, response, and recovery in the country affected by such an emergency. This CERC is included under the MPA in accordance with World Bank's Investment Project Financing Policy, paragraphs 12, for situations of urgent need of assistance. This will allow for rapid reallocation of Project proceeds in the event of a natural or man-made disaster or health outbreak or crisis that has caused or is likely to imminently cause a major adverse economic and/or social impact.

Applicable World Bank Environmental and Social Standards

The environmental and social risks associated with the project is classified as "Substantial". Five (5) of the ten (10) ESSs of the WBG's ESF have been screened as relevant to the project: ESS1: Assessment and Management of Environmental and Social Risks and Impacts, ESS2: Labor and Working Conditions, ESS3: Resource Efficiency and Pollution Prevention and Management, ESS4: Community Health and Safety, and ESS10: Stakeholder Engagement and Information Disclosure. Again, WBG General

[1] F&F refers to the process of filling a container/unit (vial or syringe) with vaccine drug as quickly as possible. It entails the following: (i) receiving of bulk drug substance; intermediate bulk day storage; dilution of bulk /compounding /formulation; sterile filtration; filling and sealing; capping; inspection; labeling and manual packaging; intermediate cold storage.

Environmental, Health and Safety (EHS) Guidelines, WBG EHS Guidelines for Health Care Facilities, and WBG EHSG for Pharmaceuticals and Biotechnology Manufacturing will apply to the extent relevant.

In addition to WBG's ESSs and EHS Guidelines, the project shall comply with Kenya's environmental and social regulatory framework. Applicable laws and regulations include but are not limited to, the laws on environmental protection and natural resource management, public health, labor laws and relevant regulations, waste management, air quality, water quality, noise and excessive vibration pollution control, national infection prevention and control guidelines for healthcare services among others.

Environmental and Social Risks and Impacts

Key environmental, health and safety risks include: a) infectious waste such as waste suspected to contain pathogens (e.g., bacteria, viruses,) in sufficient concentration or quantity to cause disease in susceptible hosts; b) pharmaceutical waste such as expired, unused, spoiled, and contaminated pharmaceutical products, drugs, vaccines, and sera that are no longer needed, including containers and other potentially contaminated materials (e.g., drug bottles vials, tubing etc.); c) chemical waste which may be toxic, corrosive, flammable, reactive, and genotoxic properties and could be generated through use of chemicals during diagnostic work, cleaning, housekeeping, and disinfection; d) general healthcare waste (including food waste and paper, plastics, cardboard); e) wastewater-contaminated wastewater may result from discharges from laboratories (e.g. microbiological cultures, stocks of infectious agents), pharmaceutical and chemical stores and cleaning activities (e.g. waste storage room); f) lack provision of adequate potable water at HCF; g) potential HCF onsite existing environmental liabilities - soil/ground water contamination, asbestos, lead based paint, PCB containing equipment; h) potential EHS impact/risks from HCF rehabilitation activities; i) air emission sources of air emissions at healthcare facilities include exhaust air from heating, ventilation, and air conditioning (HVAC) systems; ventilation of medical gases and fugitive emissions released from sources such as medical waste storage areas; and exhaust from medical waste incineration; and (j) potential bio safety and bio hazard risks related to vaccine infrastructure and risks to exposure of biological agents while transportation of samples if infectious substances are not properly packaged, marked, labelled, and documented to ensure safety and containment during the transport process.

There are also potential occupational and community health safety risks and impacts that may result from project activities. Health and safety hazards that may affect workers in healthcare facilities/diagnostic laboratories include exposure to infections and diseases, hazardous materials / waste, and radiation. Hazardous waste could be generated by pharmaceutical manufacturing. The most significant community health and safety hazards associated with pharmaceutical manufacturing facilities occur during the operation phase and may include the threat from major accidents related to fires and explosions at the facility and potential accidental releases of finished products during their transport outside of the processing facility. Community hazards include potential infection hazards within facilities and at waste disposal sites. There are also potential risks of lack of appropriate refrigeration and related requirements for safe storage/transport of infectious substances, vaccine, and chemicals (including for transfer of care, custody, control) related storage.

Social risks are 'substantial' due to: a) security – potential conflict, and violence in parts of Kenya (POEs) could put project investments, services, and staff at risk and disrupt project implementation, communication, and monitoring; b) labour and working conditions risks include recruitment and employment discrimination, employer lack of compliance with terms and conditions of employment, occupational health and safety violations, and failure to provide project workers with a dedicated worker grievance mechanism; c) Gender-Based Violence (GBV); and d) community health and safety. Potential exclusion of underserved communities relates to the risk of inequity in sharing of project

benefits due to low capacity, weak infrastructure, and insecurity for communities in historically underserved (covered under ESS7) in Kenya and inaccessible/remotely located communities. Other vulnerable groups such as internally displaced persons, persons with disability, refugees and women may also be excluded from project benefits.

Mitigation measures for these and other subproject risks identified have been detailed in *Section 4.2* of this ESMF.

Procedures to Address Environmental and Social Risks and Impacts

This ESMF spells out the procedures (steps 1-7) for identifying, preparing, and implementing the project components and associated subprojects and TA activities, environmental and social screening, preparation of required E&S plans, consultation on such plans, review and approval and implementation. The purpose of the screening process is to determine whether the activities (subprojects) are eligible to be financed or part of the exclusion list. The extent of environmental and social assessments that might be required prior to the commencement of the subprojects will depend on the outcome of the screening process. The procedures entail: (1) Screening of the Sub-Projects; (2) Assigning of Environmental and Social Risk Rating; (3) Carrying out Environmental and Social Assessment; (4) Review and Approval; (5) Inclusion of All Necessary ESHS Terms and Conditions in Procurement Documents (Bids, Contracts); (6) Public Consultations and Disclosure; and (7) Monitoring, Supervision and Reporting.

Implementation Arrangements and Responsibilities

MoH will be the main implementing agency for the project and will lead the execution of project activities. Other implementing entities will include KBI, NPHI, PPB, NQCL, and selected health facilities. The following institutional arrangement will be used in the implementation of the project:

Project Management Team (PMT)

A PMT will be responsible for project implementation. The PMT will be in the MoH, and will report directly to the Principal Secretary, MoH. It will be responsible for coordinating the day-to-day implementation of activities to ensure timely implementation of the Project by the beneficiary public health institutions. It will liaise closely with the Kenya COVID-19 Health Emergency Response Project (CHERP) (P173820), project management team. The PMT, among other staff, shall recruit an environmental specialist with health and safety expertise and one social specialist with SEA/SH expertise. The other implementing agencies should also designate E&S focal points among their staff. The ESHS management staff should have qualifications and experience acceptable to the Association.

Project Steering Committee (PSC)

The MoH will establish a PSC under the leadership of the Principal Secretary. The PSC will comprise of key stakeholders in local manufacturing to provide guidance and oversight during implementation. A local manufacturing committee with the mandate of providing leadership on pharmaceutical manufacturing is already in place. The mandate and membership of this committee will be expanded to include vaccine manufacturing. Additionally, a multisectoral oversight group, will be put in place to guide the implementation process. The PMT will work closely with the oversight committee to ensure the objectives of the project are met.

Capacity Building

Given that Kenya has limited experience in managing highly infectious diseases, and the associated risks, the project will provide considerable funding, training, and capacity building to support these critical initiatives and build upon international expertise to achieve international best practice in line

with WHO guidelines. Some of the training areas include on the new WBG ESF, ESMF, subproject specific ESMPs, SEAH, GBV, ICWMP, infection prevention and control measures, community health and safety, emergency preparedness and response, among others. The other capacity building area will be in the regulation human vaccine plants with regards to bio safety.

Consultation and Stakeholder Engagement

The project has prepared a Stakeholder Engagement Plan (SEP), which defines a program for stakeholder engagement, including public information disclosure and consultation, throughout the entire project cycle. It also outlines a communication strategy with the project stakeholders, and offers mechanisms for them to raise concerns, provide feedback, or make complaints about the project. Preliminary stakeholder engagement was undertaken during the preparation of the safeguard instruments and ESIA for the pharmaceutical plant. Summary of the outcomes from the engagement is presented in *Chapter Six* of this ESMF. Detailed information can be found in the SEP.

Grievance Redress Mechanism

A grievance redress mechanism (GRM) is part of the project ESMF and SEP and will be established to resolve complaints and grievances in a timely, effective, and efficient manner. Project related grievances can be submitted for detrimental impact on the community, the environment, or on their quality of life. Stakeholders may also submit compliments and suggestions. The GRM provides complaint or resolving measures for any dispute, appropriate redress actions and avoids the need to resort to judicial proceedings. Grievances will be handled at each beneficiary public health institution and at the national level by a Grievance Redress Committee (GRC) established by MOH, including via dedicated hotline to be established.

Budget

Adequate budget should be provided for the implementation of ESMF to include training, development of E&S due diligence measures and others to be determined by E&S tools. Funds are needed to hire consultant(s) to prepare Environmental and Social Impact Assessments (ESIAs), Environmental audits, site specific ESMPs and all other associated E&S due diligence reports. Costs for undertaking travel to conduct monitoring and trainings should be allocated. It is worth noting that there is a significant overlap in project activities to achieve its objectives, and the risk management measures prescribed in the ESMF (Training areas for the implementation of ESMF is an illustrative example with estimates of 320,000 USD excluding budget on environmental and social assessments and audits. A good part of the project budget will be used for very similar activities as those outlined in the ESMF, e.g., for training, healthcare facilities health and safety requirements, and information dissemination under the SEP among others.

1 INTRODUCTION

1.1 Background

The health status of Kenyans has improved in the last five years, but significant health challenges including geographic and economic inequities remain. According to the last census in 2019, the population was estimated at 47.6 million, with 36 percent of the population living below the poverty line and 65 percent in rural areas[2]. The life expectancy of Kenyans has improved from 63 years in 2013 to 67 years in 2020[3]. Under-five and infant mortalities dropped from 52 and 39 deaths per 1,000 live births respectively in 2014 to 41 and 32 in 2022 partly due to improved primary care inputs and significant progress in the HIV/AIDS response[4]. However, challenges remain around neonatal mortality, which remains high at 21 deaths per 1,000 live births in 2022: a marginal decline from 22 per 1,000 live births in 2014. Additionally, while the country has recorded improvements in childhood nutrition, 18.0 percent of children aged below 5 years are stunted, a decline from 26 percent in 2014. Overall, there has been a decline in the disease burden with mortality dropping from 1,052 to 585 deaths per 100,000 population between 2000 and 2019 largely driven by the reduction in the burden of the communicable diseases[5]. Despite the reduction in the burden of communicable diseases, HIV/AIDS, lower respiratory tract infections, diarrheal diseases and malaria were the top 10 causes of mortality in 2019. Progress with neonatal disorders and non-communicable diseases (NCDs) has been slow. NCDs have overtaken communicable diseases and now constitute the major cause of morbidity and mortality in the country. NCDs account for 41.0 percent of all mortalities in Kenya with the share projected to increase to 55.0 percent by 2030[6]. Furthermore, over 50 percent of long Average Length of Stay (ALOS) in hospitals are attributed to NCDs and injuries (ibid). With the changing population structure (aging population), NCDs are poised to become the dominant cause of disease burden in the country.

The COVID-19 pandemic exposed Africa's unsustainable dependence on imported health products and technologies (HPTs), including human vaccines. The pandemic reinforced the case for strengthening local manufacturing of essential medicinal products, especially vaccines. During the pandemic, African countries, including Kenya, were forced to endure the exaggerated high costs, artificially imposed stock shortages due to 'vaccines nationalism' and prolonged lead times in the availability of essential supplies and life-saving medical commodities, including COVID-19 vaccines.

Kenya, like many other countries in the region, relies heavily on co-financing support from the Global Alliance for Vaccines and Immunization (GAVI) for the pooled procurement and supply of vaccines for childhood, adolescent girls, and maternal immunization programs. Currently, Kenya requires approximately 30 million doses annually of essential vaccines to adequately cater for its primary immunization programme. The co-financing arrangement with GAVI is such that the GoK exchequer contributes 12 percent of the cost (approximately US$ 43 million) whilst the GAVI through UNICEF caters for the remaining 88 percent (approximately US$ 358 million worth of the vaccines) every year. With Kenya having commenced the graduation away from this co-financing support beginning 01 January 2022, and expected to exit fully by 2029, there is an increased and significant urgency to establish a sustainable, self-reliant mechanism that will assure availability of and access to safe, effective, and quality vaccines to its citizens and, by extension, to the region.

---

[2] Kenya Demographic and Health Survey 2022

[3] World Bank Estimates: *https://data.worldbank.org/indicator/SP.DYN.LE00.IN?locations=KE*

[4] Kenya Demographic Health Survey, 2022. Key Indicators Report

[5] IHME. Global Burden of Disease 2019

[6] World Health Organization 2022. Non-Communicable Disease Progress Monitor

The project has also prepared the following to guide stakeholder engagements and environmental and social risk management:

- A Stakeholder Engagement Plan (SEP);
- Labour Management Procedures (LMP); and
- An Environmental and Social Commitment Plan (ESCP).

1.2 Project Description

1.2.1 Project Development Objective (PDO)

The overall PDO for Kenya Health Emergency Preparedness, Response and Resilience (HEPRR) Project is **to strengthen national systems for public health emergency preparedness through strengthening capacity for local manufacturing and public health institutional arrangements.**

The Kenya Project is part a broader WBG financed multi-country and institution program covering Federal Democratic Republic of Ethiopia, Democratic Republic of Sao Tome and Principe, Intergovernmental Authority on Development (IGAD), and East, Central and Southern Africa Health Community (ECSA-HC)]. The regional program aims **to strengthen health system resilience and multisectoral preparedness and response to health emergencies in Eastern and Southern Africa**.

The proposed MPA has four components and eleven subcomponents:

- **Component 1: Strengthening the Preparedness and Resilience of Regional & National Health Systems to manage health emergencies (HEs).** This component will support the strengthening of essential institutions and activities that directly contribute to the resilience of the health systems to cope with HEs and be complimentary to other HSS activities being conducted by other World Bank and partner investments. The component has five sub-components detailed as follows: **Subcomponent 1.1** will support multisectoral planning, financing and governance for HEs, emphasizing the so- called "essential public health functions" (EPHF); **Subcomponent 1.2** will support health workforce development; **Subcomponent 1.3** will support the readiness of healthcare systems and essential services continuity; **Subcomponent 1.4** will support information systems for HEs and the digitalization of the health sector; and **Subcomponent 1.5** will support climate resilient health systems;
- **Component 2: Improving the detection of and response to HEs**. This component will support operational readiness and capacities across the following critical subsystems, to effectively detect and respond to health emergencies at national, regional, and global levels. The component has four sub-components as follows: **Subcomponent 2.1** will support collaborative surveillance and laboratory diagnostics; **Subcomponent 2.2** will support emergency management and coordination; **Subcomponent 2.3** will support risk communication and community engagement, empowerment, and social protection; and **Subcomponent 2.4** will support accelerated access to and deployment of R&D, legal, and regulatory countermeasures in case of a HE, leveraging public and private sector resources;
- **Component 3: Program Management**. The component has two sub-components as follows: **Sub-component 3.1** will support monitoring and evaluation; and **Sub-component 3.2** will focus on all other aspects of program management, including equipment and materials, compliance with fiduciary, procurement, and safeguards (environmental and social) requirements. At the national level, these activities will be undertaken by the Program Implementation Units (PIUs); and
- **Component 4: Contingent Emergency Response Component (CERC)**. There is a high probability that during the life of this proposed MPA, the country will experience an epidemic

or outbreak of public health importance, or other disaster, which causes a major adverse economic and/or social impact (e.g. Ebola), which will result in a request to the World Bank to support mitigation, response, and recovery in the country affected by such an emergency. This Contingent Emergency Response Component (CERC) is included under the MPA in accordance with World Bank's Investment Project Financing (IPF) Policy, paragraphs 12, for situations of urgent need of assistance. This will allow for rapid reallocation of Project proceeds in the event of a natural or man-made disaster or health outbreak or crisis that has caused or is likely to imminently cause a major adverse economic and/or social impact.

1.2.2 PDO Level Indicators

The PDO will be monitored through the following PDO level outcome indicators:

- The national regulatory authority has achieved Maturity Level 3 (ML3).
- Country has laboratory system to test for all its endemic diseases and its priority diseases through nucleic acid amplification testing or other appropriate approach.
- Percentage of designated ports of entry that have conducted simulation exercises.
- Emergency logistics and supply chain management mechanism is developed at national and county level.

1.2.3 Project Components, Sub-components, Budgets, and Activities[7]

1.2.3.1 Component 1: Strengthening Capacity for Local Manufacturing (US$ 70M)

This component of the Project will focus on a phased implementation of four (4) key activities**.** In the first two years, the project will support the GoK to meet the prerequisites for vaccine manufacturing (sub-components 1.1-1.3). Most of these requirements are at an advanced stage and may be achieved earlier, however, the project will aim to fill any remaining gaps and ensure that Kenya Biovax Initiative (KBI) meets all the WHO requirements before proceeding to implement sub-component 1.4.

Sub-Component 1.1: Human Resources Capacity, Learning, Development, and Technology Transfer [US$ 15M)

Successful industrial production requires a range of interdependent skills. This is most evident in the case of the pharmaceutical sector where inadequate skills or poor training procedures at the manufacturing level can lead to potentially serious and very costly outcomes. Local manufacturing will require investments in learning and development with strong collaborations with experienced institutions, to effect knowledge and technology transfer[34]. The project will support:

- **Training of KBI staff:** The project will support training of KBI staff through technical courses and hands-on experimental training through exchange programmes that enable staff to spend time at experienced manufacturing facilities to gain hands on experience, in addition to having experts with experience in vaccine manufacturing come to Kenya to provide hands-on support to KBI staff. The KBI has entered partnerships with selected reputable vaccine manufacturers to provide capacity building and already some staff have undertaken short-term trainings in South Africa and South Korea to improve their capabilities in core pharmaceutical manufacturing domains. The project will support KBI to strengthen collaborations with these institutions to provide long-term training and mentorship of staff. Potential institutions include Biovac of South Africa, Serum Institute of India, and Institute Pasteur of Senegal.
- **Knowledge exchange and technology transfer:** KBI has already started discussions and memorandum of understanding and draft agreements with other experienced vaccine

[7] Project Appraisal Document April 19 2023

manufacturers are in place. KBI will contract established vaccine manufacturers to provide embedded technical assistance in key areas of manufacturing during set up and initial years of operations. The embedded TA will be expected to undertake training and skills transfer to local Kenyan specialists who will be expected to eventually take over upon the expiry of the external TA support. The Institute will also collaborate with research and development (R&D) organizations, e.g., the Kenya Medical Research Institute (KEMRI) and the University of Nairobi (UoN) to strengthen linkages between training and field experience, working closely with global experts in the field. Specific focus on training of industrial pharmacists that are required for the institutes' activities will be prioritized. This will be done in partnership with institutions that are already providing similar training with industry players providing industrial attachment opportunities. This collaboration will create opportunities for internships for undergraduate and postgraduate on-the-job training programmes to expose young professionals to a career in manufacturing. The collaboration will commence with activities linked to ongoing activities such as regulatory affairs and industrial pharmacy with a view to including upstream activities of disease surveillance, application of relevant scientific platforms, pre-clinical and clinical studies, methods of commercialization of the research outputs and post-marketing pharmacovigilance. Where necessary, the project will support recruitment of highly specialized staff at a competitive rate on contract basis to support capacity building of KBI staff. In the long term, there will be need for the country, in collaboration with other African institutions, to periodically assess the training needs and to develop relevant curricula and training packages for the local and regional Africa vaccines manufacturers.

- **Technical Assistance** to provide advisory services on matters related to equipment specification required under sub-component 1.3 and 1.4, identify/review the market for specialized equipment and guide the procurement process. The investment will also cover recruitment of a WHO accredited Good Manufacturing Practices (GMP) consultant to oversee procurement, installation, and operation of equipment to ensure high quality is maintained throughout the process.

Sub-Component 1.2: Strengthen the Regulatory Capacity of the Pharmacy and Poisons Board (PPB) [US$ 10M]

This sub-component aims at strengthening the regulatory capacity of the national regulatory authority for manufacturing of vaccines and pharmaceuticals by the public and private sector in Kenya. Strengthened regulatory capacity will also facilitate rapid procurement and deployment processes for health emergency response e.g., by facilitating lot release or accelerated approvals. This sub-component will contribute towards the PPB to achieve Maturity Level Three (ML3) though supporting the following activities:

- PPB to strengthen human resource capacity in specialized areas such as GMP inspection, evaluation of vaccine dossiers and lot release, among others.
- Recruitment of personnel on contract base in the short-term to support activities related to GMP inspections, post market surveillance for pharmaceuticals and vaccines, etc.
- Establishment of a rapid alert system (post-market surveillance dashboard) to support prompt identification and reporting of potential safety concerns and rapid sharing of adverse drug reactions.
- Strengthen collaboration between PPB and National Quality Control Laboratories (NQCL).

Sub-component 1.3: Strengthening Quality Control (QC)/Assurance [US$ 10M]

This sub-component aims at strengthening the capacity of laboratories to in-process and finished-product quality control and quality assurance activities in line with the Current GMP (cGMP) and good laboratory practices. The sub-component will support:

- ***Establishment of an internal quality control laboratory at KBI (US$ 6M):*** Establishment of QC laboratory for vaccines and biological and the complementary Quality Management System (QMS). The laboratory will provide in-house quality control and assurance processing in compliance with cGMP and link with the NQCL for lot release testing. The laboratory shall be in an existing building as the Fill & Finish (F&F) section. The quality control laboratory, with advanced laboratory machinery and equipment, would complement the efforts of the NQCL locally, but also those of other vaccines manufacturers in the region and the continent. The laboratory would also be a key centre-of-excellence 'training ground' for upcoming laboratory technologists, providing opportunities for knowledge transfer and with the resultant upskilling of the quality control professionals in the country and the region.
- **Strengthening capacity of NQCL (US$ 4M).** Expand the capacity of the NQCL for pharmaceutical product testing through laboratory refurbishment premises, clean room and class B safety room for biologics and wet chemistry laboratory; automation of laboratory processes through a specialised laboratory information management system (LIMS) that meets all data integrity systems and processes. A baseline snapshot for NQCL is included in *Annex G*.

Sub-component 1.4: Establishing capacity for F&F[8] of human vaccines [US$ 35M]

This sub-component will support the infrastructure needed for KBI to start F&F activities. Support will include Purchase, installation and maintenance of F&F equipment, and other infrastructure needed to enable KBI to produce vaccines.

Manufacturing site preparations: The building for the plant has been refurbished and is ready for installation of the modular units that will house the machinery and equipment and connect to the utilities, including electricity and water. The site has capacity to produce 30 million doses initially with plans to expand production as KBI builds expertise and the market expands. Supervision of the facility design and refurbishment is under the expertise of a WHO accredited Good Manufacturing Practices (GMP) international consultant with extensive experience in setting up vaccines manufacturing facilities. An Environmental and Social Impact Assessment (ESIA) has been conducted and license issued by National Environmental Management Authority (NEMA). More details on the KBI Facility and ESIA are included in *Annex G*.

Table 1-1 Summary of Implementation Sequencing for Component 1

	Progress to date	**Project Phase 1**	**Project Phase 2**
KBI	Feasibility assessment Staff Recruitment	Staff training Knowledge exchange Technology transfer	Purchase, installation, and maintenance of

[8] F&F refers to the process of filling a container/unit (vial or syringe) with vaccine drug as quickly as possible. It entails the following: (i) receiving of bulk drug substance; intermediate bulk day storage; dilution of bulk /compounding /formulation; sterile filtration; filling and sealing; capping; inspection; labeling and manual packaging; intermediate cold storage.

	Progress to date	Project Phase 1	Project Phase 2
	Collaborations and partnerships Manufacturing site preparations	Technical Assistance Establishment of internal quality control laboratory	Continuous collaboration and technology transfer
PPB	Staff recruitment	Strengthening HR capacity in specialized areas Establishment of rapid alert system Strengthening of post marketing surveillance	Continuous strengthening of collaboration with NQCL Continuous strengthening of post marketing surveillance
NQCL	Attainment of ISO/IEC 17025:2017 accreditation laboratory standard	Laboratory refurbishment including class B safety room for biologics & wet chemistry lab. Deployment of laboratory information management system	Continuous strengthening of collaboration with PPB Continuous strengthening of post marketing surveillance

1.2.3.2 Component 2: Strengthening Capacity of the National Public Health Institute (NPHI) [US$ 40M]

The proposed investment will build on support provided through the Kenya COVID-19 Health Emergency Response Project (CHERP) (P173820) that is funding: (i) development of statutory instruments including organization structure, staff establishment report, and human resources and procedures manual; (ii) strengthening human resources capacity through training, learning exchange programs with a well-functioning equivalent institution; and (iii) development and application of a dedicated Information and Communication Technology system (ICT). which is linked to existing routine health information system among others. Additional investments are required to accelerate the NPHI's ability to meet its mandate specifically for rapid detection and response to outbreaks. Specifically, the project will support:

Strengthening of Laboratory Testing and Genomic Surveillance Capacity

The NPHI will coordinate a network of laboratories, drawing also on those established through the COVID-19 Health Emergency Project (P173820) and the East Africa Public Health Laboratories Project, that operate at national and county level. Its coordination function will include support for adherence to quality standards, provision of commodities, information management, and sample shipment systems. The NPHI will also support genomic sequencing activities across this network by providing equipment, reagents, bioinformatics support, and training.

Development and Deployment of the Electronic Integrated Diseases Surveillance and Response Information System (eIDSR)

The proposed eIDSR information management will consolidate the existing information management systems used for disease surveillance including the Event-Based Surveillance System, Kenya Health Information System, and the electronic Community Health Information System. The consolidation of

health sector systems will also lay the foundation for future expansion with regards to a One Health Approach[9] to disease surveillance. The proposed investment will finance the development of technical specifications for the system, acquisition of required hardware, and deployment through training and monitoring and evaluation. The GoK will develop the software through the Ministry of ICT, and Digital Economy (MICDE).

The eIDSR system data is inputted and displayed through cellular (mobile) phones**,** smartphones, and computers. However, data transmission requires cellular networks or internet connection or a mobile app (Android, iOS, Windows Phone, HTML5, etc.). The eiDSR server will be located at the NPHI.

Strategic stockpiles for preparedness and response

The MoH has developed a list of health products and technologies for public health emergency preparedness and response. The strategic stockpile e.g., reagents, drugs, PPE, etc., will enhance resilience of supply chains and enhance response times in line with goals such as a 7-1-7 global strategy[10] for disease detection and response. The products will leverage on existing storage capabilities within the country include KEMSA's national and regional level warehousing (8 depots), county level storage capacities and cold chain capacities enhanced through investments by the Transforming Health Systems for Universal Care (THS-UC) project. Additional storage may be provided through standby framework contracts with national and international supply companies. The proposed project will invest in the procurement of the strategic stockpile, strengthening capacity of relevant supply chain and procurement practitioners, and support institutionalization of emergency procurement and supply chain processes through review of relevant regulations and guidance.

Strengthening cross-border surveillance at Points of Entry (POE)

The MoH has identified ports of entry as key areas for strengthening of health emergency preparedness and response capacity. The proposed investment will strengthen screening capacity through investments in essential equipment, enhance quality of isolation capacity, strengthen referral systems to designated medical management facilities and teams, and improve performance of port health and rapid response teams through ongoing training, including simulation exercises. No construction / rehabilitation work shall be done at the POEs.

Establishment of system for health workforce surge capacity

The proposed investment will enhance Kenya's capacity to recruit and deploy health workforce capacity to respond to health emergencies and ensure continuity of essential health services. The proposed investment will fund the development of a national multisectoral workforce surge strategic plan, development of health emergency workforce database for rapid call up and deployment, development of systems for management of recruitment of health workforce and volunteer lay workforce, institutionalization of health emergency preparedness & response including simulation exercises. Support will also include updating and dissemination of case management guidelines for priority health events.

1.2.3.3 Component 3: Project Management [US$ 10M]

Institutional and implementation arrangement are detailed under *Section 6*. To support implementation, the project will finance costs associated with the project coordination, activities for program implementation and monitoring and to strengthen management capacity. Key areas of support will include: (i) operational costs and logistical services for day-to-day management of the

[9] See *https://www.who.int/europe/initiatives/one-health*
[10] See *https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01250-2/fulltext*

project; (ii) project M&E activities, including process evaluation to monitor implementation progress and address implementation challenge; (iii) environmental and social safeguards related activities; (iv) stakeholder engagement; (v) fiduciary management; and (v) contracting of staff on short term basis for any required specialized skills like engineering and public works.

1.2.3.4 Component 4: Contingent Emergency Response Component (CERC)

There is a high probability that during the life of this proposed MPA, the country will experience an epidemic or outbreak of public health importance, or other disaster, which causes a major adverse economic and/or social impact (e.g., Ebola), which will result in a request to the World Bank to support mitigation, response, and recovery in the country affected by such an emergency. This CERC is included under the MPA in accordance with World Bank's Investment Project Financing Policy, paragraphs 12, for situations of urgent need of assistance. This will allow for rapid reallocation of Project proceeds in the event of a natural or man-made disaster or health outbreak or crisis that has caused or is likely to imminently cause a major adverse economic and/or social impact.

1.2.4 Beneficiary Institutions Overview

1.2.4.1 Kenya Biovax Institute (KBI)

KBI is a state corporation, under the MoH. Established in 2021, KBI's mandate is to manufacture, package and commercialize specialized human health products and technologies (HPTs), including vaccines, biotherapeutics and diagnostics. The objectives of KBI include: (i) manufacture and commercialize human vaccines for the local, regional and international market; (ii) manufacture biomedical products such as insulins, antivenoms and anti-cancer monoclonal antibody agents; (iii) manufacture pharmaceutical diagnostics/ test kits and related HPTs; (iv) support technology transfer and commercialization of outputs from medical research institutions and universities; and (v) support local pharmaceutical industries in the development and production of quality and affordable human medicinal products.

1.2.4.2 National Public Health Institute (NPHI)

NPHI was created vide a Gazette notice dated January 21, 2022**.** The NPHI is expected to improve efficiency in prevention, detection, and response activities; increase effectiveness of responses through reliance on evidence; strengthen public health workforce capacity and skills; improve relations with stakeholders; and better coordination of multi-sectoral responses. Activities of the NPHI will cut across national and county level, sectors, and stakeholders to implement a "One Health" approach to public health events. Its activities will ultimately contribute towards UHC through improved access to needed health services including prevention and health promotion.

1.2.4.3 Pharmacy and Poisons Board (PPB)

The PPB is the National Regulatory Authority (NRA) that regulates the practice of pharmacy, manufacture, and trade of drugs in Kenya**.** The PPB underwent the WHO global bench marking tool[11]

[11] The GBT is implemented by WHO to objectively evaluate, analyze, and strengthen the NRA regulatory functions. The tool is designed to evaluate the regulatory framework and functions of the NRAs by identifying various regulatory functions strengths and weaknesses and scoring them in maturity levels. Four maturity levels have been adopted, with maturity level one (ML1) indicating some level of the regulatory system exists, maturity level two (ML2) evolving NRA system that partially performs an essential regulatory function, maturity level three (ML3) stable, well–functioning and integrated regulatory system and maturity level four (ML4) exceeding the required standards. The tool enables WHO and regulatory authorities to identify areas of strength and improvement and facilitate formulating an institutional development plan (IDP) to build upon strengths and address identified gaps.

(GBT) assessment in June 2022 to assess its capacity to attain Maturity Level 3 (ML3), a prerequisite for vaccine manufacturing.

1.2.4.4 National Quality Control Laboratory (NQCL)

The NQCL is the primary institution responsible for quality assurance of drugs in Kenya. The NQCL conducts testing of drugs and any material or substance from or with which drugs may be manufactured, processed, or treated. It also ensures quality control of drugs and medicinal substances at the request of the PPB and on behalf of the Government, of locally manufactured and imported drugs or medicinal substances with a view to determining whether such drugs or medicinal substances comply with the Act or rules made thereunder. The NQCL is one of the only 57 quality laboratories globally that has complied with the ISO/IEC 17025:2017 accreditation laboratory as recommended by the WHO pre-qualification procedures. It offers support to other countries in the region, during production, importation as well as post-market surveillance and pharmacovigilance.

1.3 Environmental and Social Management Framework (ESMF)

1.3.1 ESMF Justification

Projects and programs prepared and managed by World Bank's Investment Policy Financing (IPF) support need to comply with the Environmental and Social Standards (ESSs) of the World Bank's Environmental and Social Framework (ESF). Therefore, the proposed HEPRR (P180127) is required to satisfy the World Bank's ESF in addition to conformity with environmental and social legislation of the Government of Kenya (GOK).

Given the broad nature of the project and multiple public health institutions involved in the implementation, only limited details of specific sub-projects and their locations are not known at this stage. What is known is that the project will potentially fund national systems for public health emergency preparedness through strengthening capacity for local manufacturing of human vaccines (e.g., construct human vaccine production facility, improve the regulatory environment through PPB, build capacity of NQCL for lot release, etc.) and public health institutional arrangements. Any expansion of vaccine facilities will not include any land take. As and when details of these specific subprojects are identified, information necessary to carryout site specific social and environmental assessments and prepare appropriate mitigation measures to address social and environmental impacts, would be required. Thus, while site-specific Environmental and Social Impact Assessments (ESIA) cannot be conducted at this stage, what is possible is to carry out an identification of generic risks and impacts that are typically associated with this type of intervention.

1.3.2 ESMF Purpose and Objectives

As such, the purpose of this ESMF is to outline a framework for environmental and social management for the project, giving details of potential environmental and social issues, and guidelines on assessing environmental and social sensitivity of subprojects through appropriate environmental and social screening, followed by an environmental and social impact analysis, if required. The ESMF will also serve as the basis in the preparation of recommended sub-project specific instruments such as ESIAs and/or Environmental and Social Management Plans (ESMPs), etc. As stated earlier, the ESMF is being submitted in lieu of a subproject ESIA and has formed the basis for appraising the environmental and social aspects of the project.

Therefore, the objectives of this ESMF can be summarized as:

1. To establish clear procedures and methodologies for environmental planning, assessment, review, approval, and monitoring of subprojects to be financed under the project.

2. To specify appropriate roles and responsibilities, and outline the necessary reporting procedures, for managing and monitoring environmental concerns related to subprojects.
3. To determine training, capacity building and technical assistance needed to successfully implement the provisions of the ESMF.
4. To provide practical resources for implementing the ESMF.

2 ENVIRONMENTAL AND SOCIAL MANAGEMENT REQUIREMENTS

This section outlines the existing national and international environmental and social legislation, policies, and institutions applicable to the proposed Project that will guide the development of the Project, which is subject to this ESMF. This includes a summary of the World Bank Group's (WBG) Environmental and Social Framework (ESF), Environmental and Social Standards (ESSs), and Environmental, Health and Safety Guidelines (EHSGs).

As Kenya is a signatory to various international conventions and laws, relevant international conventions are also presented. Moreover, this section assesses MOH's capacity to comply with environmental and social requirements, and gaps between national ESIA requirements and the ESSs & EHSGs.

2.1 Policy Framework

2.1.1 Constitution of Kenya

Kenya has undergone regulatory reforms over the past two decades, culminating in the enactment of a new constitution in 2010. The Constitution is the supreme law in Kenya and gives a lot of emphasis on environmental conservation and sustainable development. For instance, in the Preamble, the Constitution states that "We, the people of Kenya will be respectful of the environment, which is our heritage, determined to sustain it for the benefit of future generations".

Article 2(5) of the Constitution states that the general rules of international law shall form part of the laws of Kenya. For the purposes of protection of the environment, several principles of international environmental law are incorporated, viz:

- the polluter pays principle.
- principle of public participation.
- principle of sustainability.
- principle of inter & intra-generational equity.
- principle of prevention.
- precautionary principle.

The principle of sustainable development is entrenched in Article 102(d) of the Constitution as one of the national values and principles of governance.

The Constitution guarantees the right to a clean and healthy environment in Article 42. Article 42 further guarantees the right to have the environment protected for the benefit of present and future generations through legislative and other measures particularly those contemplated in article 69 and the right to have obligations relating to the environment fulfilled under Article 70.

Article 43 (1) provides that every person has the right to the highest attainable standard of health, which includes the right to healthcare services, including reproductive healthcare, accessible and adequate housing, and to reasonable standards of sanitation and to clean and safe water in adequate quantities.

Article (69) (2) imposes obligations on every person, to cooperate with state organs and other persons to protect and conserve the environment and ensure ecologically sustainable development and use of natural resources.

Article 70 provides an avenue for redress for any person who alleges that the right to a clean and healthy environment has been or is likely to be denied, violated, infringed, or threatened. The Court is empowered to issue preventive, cessation, or compensatory orders.

Article 70 relaxes the rule on locus standi because of which, there is no need to prove loss or injury by an applicant. Anyone may institute a claim seeking to enforce the environmental rights and obligations stipulated in the Constitution.

Enforcement contemplated by Article 70 will be done through the Environment and Land Court established under Article 162 (2) (b). The Court has the same status as the High Court. This effectively denies High Court jurisdiction over environmental matters under Article 165 (5) (b).

The Project shall be undertaken within the provisions of the constitution. MOH shall ensure project activities do not compromise the right to a clean and healthy environment. Requisite measures shall be put in place to guarantee the sustainability of the Project. Such measures shall include but not limited to pollution prevention and control and sustainable utilization of natural resources.

2.1.2 National Environment Policy (NEP), 2014

The overall goal of this Paper is to ensure better quality of life for present and future generations through sustainable management and use of the environment and natural resources.

Section 5.6 of this Policy focusses on infrastructure development and environment and makes explicit policy statements to ensure sustainable management and use of the environment and natural resources during the construction and operation of infrastructure developments including roads.

These policy statements require the commitment of the Government to:

- Ensure Strategic Environmental Assessment (SEA), Environmental Impact Assessment (EIA), Social Impact Assessment (SIA) and Public Participation in the planning and approval of infrastructural projects.
- Develop and implement an environmentally friendly national infrastructural development strategy and action plan.
- Ensure that periodic Environmental Audits are carried out for all infrastructural projects. Relevance to this Project.

In line with the above policy statements, this ESMF has been prepared to ensure that environmental and social issues are appropriately addressed throughout the project lifecycle.

2.1.3 The National Occupational Safety and Health Policy, 2012

The policy seeks to reduce the number of work-related accidents and diseases, and equitably provide compensation and rehabilitation to those injured at work or who contract occupational diseases.

The policy requires the provision of appropriate and adequate Personal Protective Equipment (PPE), avail first aid services on site as well as development of safety and health emergency contact at the site and workplace registration.

2.1.4 National Policy on Patient Safety, Health Worker Safety and Quality of Care 2022-2027

This policy provides a comprehensive framework through which the healthcare system will be transformed to deliver high quality & safer patient and family centered services. The policy also provides for health workers safety, wellness, and capacity building in compassionate care, adhering to clinical and evidence-based practices promoting social medicine and community practice.

Patient safety, health workers safety and quality of care are integral components of healthcare systems. The project should contribute to realization of this policy's objectives.

2.1.5 Kenya Health Policy, 2012 – 2030

The Policy aim is to achieve this goal through supporting provision of equitable, affordable, and quality health and related services at the highest attainable standards and minimize exposure to health risk factors to all Kenyans. The Policy calls for the provision and distribution of healthcare services to all people that is commensurate with that of a middle-income country without segregation.

The Project will contribute to realization of this Policy.

2.1.6 Infection Prevention and Control Policy for Healthcare Services, 2021

The Infection Prevention and Control Policy aims to prevent and control the spread of infections in healthcare settings. The policy aims to ensure that patients, visitors, and healthcare workers are protected from infections and that healthcare facilities adhere to best practices in infection prevention and control. The policy provides guidance on; standard precautions, environmental cleaning and disinfection, transmission-based precautions, occupational health and safety, and surveillance and outbreak management.

The policy requires healthcare facilities to monitor and track infections to identify and respond to outbreaks quickly.

The proposed policy provides resources for the realization of this Policy. For instance, the NPHI shall be supported to improve efficiency in prevention, detection, and response activities; increase effectiveness of responses through reliance on evidence; strengthen public health workforce capacity and skills; improve relations with stakeholders; and better coordination of multi-sectoral responses. Again, the local manufacturing of human vaccines can help prevent the spread of infectious diseases, reduce mortality and morbidity rates, and improve the overall health of the population.

2.1.7 Kenya Universal Health Coverage Policy, 2020 – 2030

This policy framework aims to provide access to quality and affordable healthcare services to all Kenyan citizens by the year 2030. The policy is aligned with the country's broader development goals as outlined in the Kenya Vision 2030. The policy is being implemented through a multi-sectoral approach that involves collaboration with various stakeholders, including the private sector, civil society organizations, and development partners. The policy is expected to have a significant impact on the health and wellbeing of Kenyan citizens, by providing them with access to quality and affordable healthcare services.

The local manufacturing of human vaccines can have a significant impact on the realization of this policy. Vaccines are an essential component of primary healthcare, and they can help prevent the spread of infectious diseases, reduce mortality and morbidity rates, and improve the overall health of the population.

2.1.8 National Climate Change Framework Policy

This Policy was developed to facilitate a coordinated, coherent, and effective response to the local, national, and global challenges and opportunities presented by climate change. An overarching mainstreaming approach has been adopted to ensure the integration of climate change considerations into development planning, budgeting, and implementation in all sectors and at all levels of government. This Policy therefore aims to enhance adaptive capacity and build resilience to climate variability and change, while promoting a low carbon development pathway.

MOH shall ensure low carbon technologies are utilized during the project implementation. It is advised that the proponent undertake a climate risk assessment for the project and implement mitigation measures such as climate proofing Project infrastructure from the effects of climate change.

2.1.9 National Policy on Gender and Development, 2019

The National Policy on Gender and Development seeks to create a just, fair and transformed society free from gender-based discrimination in all spheres of life practices. The National Policy highlights the fact that the patriarchal social order supported by statutory, religious, and customary laws and practices; and the administrative and procedural mechanisms for accessing rights have continued to hamper the goal of attaining gender equality and women's empowerment.

The Policy seeks to facilitate affordable, accessible, acceptable, and quality healthcare services including reproductive healthcare, emergency services, family planning, HIV and AIDS service for women and men, girls.

2.1.10 The Kenya Kwanza Manifesto

The Kenya Kwanza administration is committed and determined to realise the constitutional right to health in the shortest time possible by delivering a Universal Health Coverage (UHC) system built on three pillars as follows:

- Fully publicly financed primary healthcare (preventive, promotive, outpatient & basic diagnostic services), that gives patients choice between public, faith based and private providers, based on a regulated tariff.
- Universal seamless health insurance system comprising a mandatory national insurance (NHIF) and private insurance as complementary covers, with NHIF as the primary and private as secondary cover.
- National fund for chronic and catastrophic illness and injury costs not covered (or with very restrictive cover) by insurance (cancer, diabetes, strokes & accident rehabilitation, pandemics) to be funded by combination of insurance levy and Government.

The proposed Project will contribute towards realization of these commitments.

2.2 Relevant Legal Frameworks

Table 2-1 provides a summary of all legal frameworks relevant to the Project.

Table 2-1 Relevant Legal Frameworks

Legal Framework	Description	Relevance to the Project
Environmental Management and Coordination Act, 1999 (Revised 2015)	The Environmental Management and Coordination Act (EMCA), 1999, is the framework law on environmental management and conservation in Kenya. The National Environment Management Authority (NEMA) was established as the principal instrument of government charged with the implementation of all policies relating to the environment, and to exercise general supervision and coordination over all matters relating to the environment. The Act provides for environmental protection through: • Environmental impact assessment. • Environmental audit and monitoring. • Environmental restoration orders, conservation orders, and easements. Part VI under Section 58 of the Act directs that any proponent for any project listed on the Second Schedule of the act undertake and submit to NEMA an Environment Impact Assessment (unless exempted by NEMA), who in turn may issue a license as appropriate.	An ESIA should be carried out for any subprojects in line with the requirements of this Act. MOH is required to commit to implementing the Environmental and Social Management and Monitoring Plan (ESMMP) laid out in the ESIA Reports, as well as any other conditions as stipulated by NEMA, prior to being issued with an ESIA license.
The Environmental (Impact Assessment and Audit) Regulations, 2003	These regulations outline the procedures and guidelines for carrying out environmental impact assessments and audits. The regulation requires that the EIA/EA be conducted by a registered lead or firm of experts in accordance with the terms of reference developed during the scoping exercise. These regulations have been amended by the Environmental (Impact Assessment and Audit) (Amendment) Regulations, 2019. The amendment list projects into Low, Medium, and High Risk. For the low and medium-risk projects, an environmental	Sub-project ESIAs shall be prepared in accordance with these regulations (i.e., prepared NEMA licensed individuals/firms, level of environmental work to depend on risk classification). All sub-projects should undergo annual environmental audits.

Legal Framework	Description	Relevance to the Project
	impact assessment Summary Project Report (SPR) must be prepared. For the high-risk projects, a Comprehensive Project Report (CPR) is prepared and submitted to NEMA.	
EMCA (Air Quality) Regulations, 2014	The Kenyan Air Quality Standards as part of The Environmental Management and Co-ordination Act 1999, were transposed into Kenyan legislation through The Environmental Management and Co- ordination (Air Quality) Regulations, 2014. These standards include a consideration of the type of area within which the proposed Project is located. **Part III OTHER Sources**: 36. No person, operator or owner of any waste incinerator shall allow, or cause emission of air pollutants set out under the Second Schedule more than the appropriate mass emission rates indicated in the Third Schedule.	*The Project should implement an air pollution monitoring (stack emission measurement) for incinerators.*
EMCA (Waste Management) Regulations 2006 (Legal Notice 121)	The Regulations provide details on management (handling, storage, transportation, treatment, and disposal) of various waste streams including domestic waste, industrial waste, hazardous and toxic waste, pesticides and toxic substances, biomedical wastes, and radioactive wastes. Regulation No. 4 (1) makes it an offence for any person to dispose of any waste on a public highway, street, road, recreational area or in any public place except in a designated waste receptacle. Regulation 6 requires waste generators to segregate waste by separating hazardous waste from non- hazardous waste for appropriate disposal. Regulation 15 prohibits any industry from discharging or disposing of any untreated waste in any state into the environment. Regulation 17 (1) makes it an offence for any	*The Project should prepare a healthcare waste management plan (HCWMP) to manage generated waste.*

Legal Framework	Description	Relevance to the Project
	person to engage in any activity likely to generate any hazardous waste without a valid Environmental Impact Assessment license issued by NEMA.	
EMCA (Noise and Excessive Vibration Pollution) (Control) Regulations, 2009	These Regulations were published as legal Notice No. 61 being a subsidiary legislation to the Environmental Management and Co-ordination Act, 1999. The Regulations provide information on the following: prohibition of excessive noise and vibration. provisions relating to noise from certain sources. provisions relating to licensing procedures for certain activities with a potential of emitting excessive noise and/or vibrations; and noise and excessive vibrations mapping. According to Regulation 3 (1), no person shall make or cause to be made any loud, unreasonable, unnecessary, or unusual noise which annoys, disturbs, injures, or endangers the comfort, repose, health or safety of others and the environment. Regulation 4 prohibits any person to (a) make or cause to be made excessive vibrations which annoy, disturb, injure, or endanger the comfort, repose, health or safety of others and the environment; or (b) cause to be made excessive vibrations which exceed 0.5 centimetres per second beyond any source property boundary or 30 metres from any moving source. Regulation 5 further makes it an offence for any person to make, continue or cause to be made or continued any noise more than the noise levels set in the First Schedule to these Regulations, unless such noise is reasonably necessary to the preservation of life, health, safety, or property.	*MOH will be required to ensure compliance with these Regulations to promote a healthy and safe working environment throughout the construction and operation phases. This shall include regular inspection and maintenance of equipment to reduce noise and vibration, prohibition of unnecessary noise emitted from movement of construction equipment and Project heavy and light vehicles, adherence to the noise levels stipulated for day and night, etc.*

Legal Framework	Description	Relevance to the Project
The Environmental Management and Co-ordination (Water Quality) Regulations, 2006	The Regulations provide for sustainable management of water resources including prevention of water pollution and protection of water sources. It is an offence under Regulation No. 4 (2), for any person to throw or cause to flow into or near a water resource any liquid, solid or gaseous substance or deposit any such substance in or near it, as to cause pollution. Regulation No. 11 further makes it an offence for any person to discharge or apply any poison, toxic, noxious, or obstructing matter, radioactive waste or other pollutants or permit the dumping or discharge of such matter into the aquatic environment unless such discharge, poison, toxic, noxious, or obstructing matter, radioactive waste or pollutant complies with the standards for effluent discharge into the environment.	Any effluent discharged from Project activities to the municipal sewer / septic tank will also need to meet effluent discharge permit requirements.
Health Act, 2017	Every person has the right to the highest attainable standard of health which shall include progressive access for provision of promotive, preventive, curative, palliative and rehabilitative services. Part VIII on Promotion and Advancement of Public and Environmental Health – requires the state to develop the National health System that shall devise and implement measures to promote health and counter influences having an adverse effect on the health of the people (section 68).	To promote and advance public and environmental health, MOH should commission ESIAs for any qualified sub-projects.
Health Act, 2017 ***Guidelines on Management of Health Products and***	These guidelines provide a comprehensive framework for the regulation, management, and use of health products and technologies in the country. The guidelines cover various aspects of health products and technologies, including product registration and licensing, quality control, supply chain management, pharmacovigilance, and promotion of research	All HPTs production in the project should be done in accordance with these guidelines.

Legal Framework	Description	Relevance to the Project
Technologies (HPTs) in Kenya, 2020	and innovation. They also provide guidance on the appropriate use of health products and technologies, including the rational use of medicines and medical devices.	
Pharmacy and Poisons Act, Cap 244 ***Pharmacy and Poisons (Vaccines) Regulations, 2015***	This law provides for the regulation of the manufacture, importation, exportation, distribution, and sale of medicines, medical devices, and poisons in Kenya. The Act requires that all medicines and medical devices, including vaccines, must be registered with the Pharmacy and Poisons Board (PPB) before they can be marketed in Kenya.	All KBI products must be registered by PPB before mass production.
Pharmacy and Poisons (Vaccines) Regulations, 2015	These regulations provide for the registration and regulation of vaccines in Kenya. The regulations require that all manufacturers of vaccines must comply with the good manufacturing practices (GMP) guidelines set by the World Health Organization (WHO) and other regulatory bodies.	KBI must implement GMP guidelines set by the WHO and PPB before commencement of operations.
Pharmacy and Poisons (Manufacturing and Importation of Biological Products) Regulations, 2015	These regulations provide for the licensing and regulation of the manufacturing and importation of biological products, including vaccines. The regulations require that all manufacturers of vaccines must obtain a license from the PPB and comply with the GMP guidelines.	All KBI activities must comply with the requirements of this Act and subsidiary regulations.
Food, Drugs, and Chemical Substances Act, Cap 254	This law provides for the control of the manufacture, importation, exportation, distribution, and sale of food, drugs, and chemical substances in Kenya.	KBI must obtain a license to manufacture vaccines from the PPB before commencement of operations.
Sustainable Waste Management Act, 2022	This Act of Parliament establishes the legal and institutional framework for the sustainable management of waste; ensure the realization of the constitutional provision on the right to a clean and healthy environment.	The project healthcare WMPs should be prepared in accordance with this Act.

Legal Framework	Description	Relevance to the Project
	Part II of the Act, Section 9. (1) County governments shall be responsible for implementing the devolved function of waste management and establishing the financial and operational conditions for the effective performance of this function. Section 19 of this Act provides guidelines on the preparation of Waste Management Plans (WMPs) by counties, private entities, and individuals.	MOH should partner with respective county governments in the sustainable management of generated healthcare waste.
Water Act, 2016 ***The Water Resources Management Rules, 2007 (Amendments, 2012)***	Provides for regulation, management, conservation, use, and control of water resources, water, and sewerage services. It enables for the monitoring, regulation and protection of water resources and sewerage services from adverse. These Rules shall apply to all policies, plans, programmes, and activities that are subject to the Water Act. They also apply to all water resources and water bodies in Kenya, including all lakes, water courses, streams, and rivers, whether perennial or seasonal, aquifers, and shall include coastal channels leading to territorial waters.	Sub-projects should adhere to this Act by obtaining the required water permits, including when abstraction of water is necessary.
Climate Change Act, 2016	This Act provides a legal framework for enhanced response to climate change; to provide for mechanism and measures to achieve low carbon climate development; and other matters that relate to climate change. The Act provides incentives for the promotion of climate change incentives. This is to encourage persons to put in place measures for elimination of climate change including reduction of greenhouse emission and use of renewable energy and put in place measure to mitigate against adverse effects of climate change.	MOH should prepare and implement a climate risk strategy to minimize emissions from the Project. Again, Project design should prioritize climate-proofing of the infrastructure.

Legal Framework	Description	Relevance to the Project
Public Health Act, Cap 252	Part IX section 115 of the Act states that no person/institution shall cause nuisance or condition liable to be injurious or dangerous to human health. Section 116 requires Local Authorities to take all lawful, necessary, and reasonably practicable measures to maintain their jurisdiction clean and sanitary to prevent occurrence of nuisance or condition liable for injurious or dangerous to human health. Such nuisance or conditions are defined under section 118 and 28 include nuisances caused by accumulation of materials or refuse which in the opinion of the medical officer of health is likely to harbour rats or other vermin.	Implement mitigation and management measures detailed in Section 4 of this ESMF and any sub-project ESMPs.
The Standards Act, Cap 496	This Act promotes the standardization of the specification of commodities and provides for the standardization of commodities and codes of practice to ensure public health and safety. It establishes the Kenya Bureau of Standards (KEBS).	All KBI products should conform to both local and international standards.
The National Construction Authority (NCA) Act, 2012	This is an Act of parliament that provides for the establishment, powers, and functions of the National Construction Authority (NCA). This Authority as per this law is supposed to reign in rogue contractors and establish order within which the construction industry does its business.	MOH must ensure that all construction works are approved by NCA, and contractors registered by NCA, and works are supervised by qualified engineers.
The Occupational Health and Safety Act (OSHA), 2007	This is an Act of Parliament to provide for the safety, health and welfare of workers and all persons lawfully present at workplaces, to provide for the establishment of the National Council for Occupational Safety and Health and for connected purposes. Part VI of this Act provides for general health provisions while Part X provides for the general welfare of the workers with	All project sites should register as workplaces by DOSHS. All project sites should undergo annual OSH and fire safety audits. Project should implement the prepared Labour Management Procedure (LMP). The LMP will guide workers sustainable involvement in the project.

Legal Framework	Description	Relevance to the Project
	respect to supply of drinking water, washing facilities and first aid among other aspects. Section 53 of this Act requires that for workers employed in a process involving exposure to any injurious or offensive substances, suitable protective clothing, and appliances (gloves, footwear, goggles, and head coverage) shall be provided.	
Work Injury Compensation Benefit Act (WIBA), 2007	This Act provides for compensation for employees on work related injuries and diseases contacted in the course of employment and for connected purposes. The Act includes compulsory insurance for employees. The Act defines an employee as any worker on contract of service with employer.	MoH should comply with part II of this Act regarding obligations of the employer including compensation for temporary, total, or partial disablement, treatment as well as provision of first aid services to workers.
The Employment Act, 2007	The Act is enacted to consolidate the law relating to trade unions and trade disputes, to provide for the registration, regulation, management and democratization of trade unions and employers organizations and federations. Its purpose is to promote sound labour relations through freedom of association, the encouragement of effective collective bargaining and promotion of orderly and expeditious dispute the protection and promotion of settlement conducive to social justice and economic development for connected purposes. This Act is important since it provides for an employer – employee relationship that is important for the activities that would promote management of the environment at a workplace.	The project should implement the prepared Labour Management Procedure (LMP). The LMP will guide workers sustainable involvement in the project.
National Gender and Equality Commission (NGEC) Act, 2011	The objective of the Act is promoting gender equality and freedom from discrimination and contribute to the reduction of gender inequalities and the discrimination against all, women,	The Project should provide affordable, accessible, acceptable, and quality healthcare services including reproductive healthcare, emergency services, family planning, HIV/AIDS service for women and men, girls.

Legal Framework	Description	Relevance to the Project
	men, persons with disabilities, the youth, children, the elderly, minorities, and marginalized communities.	
The Sexual Offences Act, 2006	Relevant Sections in this Act include: 24- Sexual offences relating to position of authority and persons in position of trust. 25- Sexual relationship which pre-date position of authority or trust. 26- Deliberate transmission of HIV or any other life threatening sexually transmitted disease.	The project should Implement the prepared Sexual Exploitation, Abuse and Harassment (SEAH) Prevention and Response Plan.
County Government Act, 2012 ***Physical and Land Use Planning Act, 2019***	Part II of the Act empowers the county government to oversee function described in Article 186 of the constitution, (county roads, water and sanitation, health). Part XI of the Act vests the responsibility of planning and development facilitation to the county government with collaboration with national government, this arrangement has been adopted for interventions in order not to conflict with provisions of the Kenyan Constitution.	MoH should seek developments approval from the respective county physical planning departments for all civil works under the project. MOH should partner with respective county governments in the sustainable management of generated healthcare waste.
The Penal Code, Cap 63	Section 191 of the Penal Code makes it an offence for any person or institution that voluntarily corrupts, or foils water for public springs or reservoirs rendering it less fit for its ordinary use. Similarly, section 192 of the same act prohibits making or vitiating the atmosphere in any place to make it noxious to health of persons/institution in dwellings or business premises in the neighbourhood or those passing along a public way.	MOH should strictly adhere to prepared ESMPs throughout the project implementation cycle to mitigate against any possible negative impact on the environment and society.

Legal Framework	Description	Relevance to the Project
The National Council for Disability Act, 2003	An Act to provide for the establishment of a National Council for Disability, its composition, functions, and administration for the promotion of the rights of persons with disabilities set out in international conventions and legal instruments, the Constitution, and other laws, and for other connected matters.	Project should cater for people with disability interests e.g., access to facilities using ramps, ablution facilities, as well as access to employment and healthcare services.
HIV/AIDS Prevention and Control Act, 2012	This is an Act of Parliament to provide measures for the prevention, management and control of HIV and AIDS, to provide for the protection and promotion of public health and for the appropriate treatment, counselling, support, and care of persons infected or at risk of HIV/AIDS infection. Part II, Section 7 of this Act requires HIV/AIDs education in the workplace. In accordance with the requirements of this Act, the government is expected to ensure provision of basic information and instruction on HIV/AIDs prevention and control to: Employees of all Government ministries, Departments, authorities, and other agencies; and Employees of private and informal sectors. The information on HIV/AIDs is expected to be treated with confidentiality at the workplace and positive attitudes shown towards infected employees and workers.	MOH should implement awareness programmes to share information with regards to HIV/AIDS prevention and control to all Project employees as well as other measures to curb the spread of HIV/AIDS e.g., provision of condoms, etc.
The Environment and Land Court (ELC) Act, No. 20 of 2011	The principal objective of this Act is to enable the Court to facilitate the just, expeditious, proportionate, and accessible resolution of disputes governed by this Act. Section 13 (2) (b) of the Act outlines that in exercise of its jurisdiction under Article 162 (2) (b) of the Constitution, the Court shall have power to hear and determine disputes relating to environment and land, including disputes: Relating to environmental planning and protection, trade, climate issues, land use planning, title, tenure, boundaries, rates, rents, valuations, mining, minerals, and other	MOH should implement the project in accordance with all laid legal procedures to negate the need for any aggrieved party seeking legal redress in the ELC.

Legal Framework	Description	Relevance to the Project
	natural resources; Relating to compulsory acquisition of land; Relating to land administration and management; Relating to public, private and community land and contracts, chooses in action or other instruments granting any enforceable interests in land; Any other dispute relating to the environment and land.	

2.3 List of Environmental and Social Licenses/Permits/Approvals Required for the Project, as per the Requirements of Kenyan Law

Table 2-2 provides a summary of the environmental and social permits and licences required for civil works subprojects for both the construction and the operations phases.

Table 2-2 License/Permits/Approvals and Issuing Institutions

Institution	Licenses/Permit/Approval	Project Phase
National Environmental Management Authority (NEMA)	ESIA license for identified sub-projects	Prior to construction
	Annual environmental audits Effluent discharge license (EDL) Quarterly air quality monitoring and annual emission license Incinerator annual license	Operation
National Construction Authority	Sub-projects registration Contractor's licensing and their key staff practicing license	Prior to construction
County governments	Development planning approval Change of user Occupation certificate Hoarding permit	Prior to construction
DOSHS	Workplace registration	Construction
	Workplace registration Annual OSH and fire safety audits	Operation
PPB	License to manufacture vaccines	Operation
Proponent's Preferred Insurance company	WIBA policy	Construction

2.4 Institutional Framework

The following key administrative agencies regulate health and its environmental and social implications in Kenya and have a key role in the environmental and social assessment process:

2.4.1 NEMA

- The responsibility of NEMA[12] is to exercise general supervision and co-ordination over all matters relating to the environment and to be the principal instrument of Government in the implementation of all policies relating to the environment.
- NEMA is also responsible for granting ESIA approvals and for monitoring and assessing activities, in order, to ensure that the environment is not degraded by such project activities.

[12] *https://www.nema.go.ke*

- NEMA requires submission of an annual environmental audit report.

2.4.2 National Environmental Complaints Committee (NECC)

The NECC[13] investigates allegations and complaints of suspected cases of environmental degradation. The Committee also prepares and submits to the NEC periodic reports of its activities.

Members of the public can register or appeal to this committee regarding any aspects of the project that violates the law and its licenses.

2.4.3 National Environment Tribunal (NET)

NET[14] reviews administrative decisions made by NEMA relating to issuance, revocation or denial of license and conditions of license. It also provides legal opinion to NEMA on complex matters where the Authority seeks such advice. In addition, the Tribunal has powers to change or give an order and direction regarding environmental issues in dispute.

2.4.4 ELC

The ELC has jurisdiction over a wide range of cases, including disputes related to land ownership, land use, boundary disputes, conservation and management of natural resources, environmental impact assessments, and disputes related to pollution and degradation of the environment.

2.4.5 Water Resources Authority (WRA)

The WRA is responsible for the regulation of water resources such as water allocation, source protection and conservation, water quality management and pollution control and international waters.

2.4.6 MOH

The proposed project is under the Ministry of Health, and it shall be the primary role of the Ministry to monitor and measure the progress of implementation of the social and environmental safeguards.

2.4.7 DOSHS

- Monitor the implementation of health and safety plans for construction and operation workers and members of public encountering project activities.
- Annual health and safety and fire inspection audit reports are required to be submitted to DOSHS.
- Annual workplace registration
- Hygiene surveillance (noise survey, air quality monitoring, thermal environment survey)
- Examination and testing of plants.
- Accident investigation and WIBA processing.

2.4.8 NCA

The NCA is responsible for issuing permits to construction sites, advising the government of Kenya on construction and training professionals (continuous professional development (CPD).

MoH shall liaise with NCA to ensure licensed contractors are the ones to be awarded contract to renovate and or construct the sub-projects.

2.4.9 County Governments

County governments will:

[13] *https://www.necc.go.ke*
[14] *https://www.judiciary.go.ke/the-national-environment-tribunal/*

- Issue licenses and permits.
- Ensure compliance with health Acts.
- Authorize waste management.

2.4.10 PPB

Issue license to manufacture vaccines.

2.4.11 KEBS

Issue standardization mark (SM).

2.5 WBG Environmental and Social Standards (ESSs)

The World Bank Group (WBG) Environmental and Social Framework (ESF) sets out the Bank's commitment to sustainable development, through a Bank Policy and a set of Environmental and Social Standards (ESSs) that are designed to support Borrowers' projects, with the aim of ending extreme poverty and promoting shared prosperity. This Framework comprises:

- A Vision for Sustainable Development, which sets out the Bank's aspirations regarding environmental and social sustainability.
- The Bank Environmental and Social Policy for Investment Project Financing, which sets out the mandatory requirements that apply to the Bank.
- Ten (10) ESSs, together with their Annexes, which set out the mandatory requirements that apply to the Borrower and projects.

The ESSs set out the requirements for Borrowers relating to the identification and assessment of environmental and social risks and impacts associated with projects supported by the Bank through Investment Project Financing (IPF). The Bank believes that the application of these standards, by focusing on the identification and management of environmental and social risks, will support Borrowers in their goal to reduce poverty and increase prosperity in a sustainable manner for the benefit of the environment and their citizens. The standards will:

a) support Borrowers in achieving good international practice relating to environmental and social sustainability.
b) assist Borrowers in fulfilling their national and international environmental and social obligations.
c) enhance non-discrimination, transparency, participation, accountability, and governance; and
d) enhance the sustainable development outcomes of projects through ongoing stakeholder engagement.[15]

Five (5) of the ten (10) ESSs are relevant to the project. Table 2-3 presents a summary of some key aspects of ESSs relevant to the project. For a complete set of requirements and details, kindly refer to the *World Bank Environmental and Social Framework (ESF), 2017*.

[15] The World Bank Environmental and Social Framework (ESF), 2017

Table 2-3 ESSs Relevance to the Project

ESS No.	ESS Title	Key Requirement	Relevance to the Project
ESS1	Assessment and Management of Environmental and Social Risks and Impacts	Key requirements: • Requires the assessment, management and monitoring of E&S risks and impacts of the project throughout the project lifecycle. • Requires the application of the Bank's EHS Guidelines, or other more stringent measures where these exist. • Requires the preparation of an ESCP as part of the legal agreement with material measures and actions required for the project to achieve compliance with the ESSs.	Relevant. ESS1 applies to all projects supported by the Bank through Investment Project Financing (IPF). As such, ESS1 is relevant to this project. The required instruments and processes to comply with this standard are referred to in the environmental and social commitment plan (ESCP).
ESS2	Labour and Working Conditions	Key requirements: • Requires development and implementation of labor management procedures. • Workers to be provided with clear information and documentation on terms and conditions of employment. • Nondiscrimination of workers in employment and treatment	ESS2 is relevant to this project. The required instruments and processes to comply with this standard are reflected in the ESCP e.g., Labour Management Procedures (LMP), etc.
ESS3	Resource Efficiency and Pollution Prevention and Management	Key requirements: • Implementation of technically and financially feasible measures for improving efficient consumption of energy, water, and raw materials, as well as other resources.	ESS3 is relevant to this project mainly because of hazardous HCW and other construction related waste that will be generated from project activities.

ESS No.	ESS Title	Key Requirement	Relevance to the Project
		• Avoidance of the release of pollutants or, when avoidance is not feasible, minimization and control the concentration and mass flow of their release using the performance levels and measures specified in national law or the EHSGs, whichever is most stringent.	The required instruments and processes to comply with this standard are reflected in the ESCP e.g., HCW management plan.
ESS4	Community, Health, Safety and Security	Key requirements: • Requires the assessment, management and monitoring of E&S risks and impacts of the project on the health and safety of the affected communities (vulnerable) during the project life cycle. • Requires an assessment of how use of security by the Project to safeguard personnel and property could impact on community considering human rights.	ESS4 is relevant to this project given potential risks to the community health and safety that could result from accidental releases of finished products during their transport outside of the processing facility. Other community health and safety risks include risks related to manufacture of substandard vaccines, the transmission and spread of HIV/AIDS, and other communicable diseases, and GBV/SEA/SH risks. Moreover, the HEPRR project may also cause risks to community health stemming from inappropriate use and disposal of hazardous and other healthcare wastes.
ESS5	Land Acquisition, Restrictions on Land Use, and Involuntary Resettlement	Key requirement is to anticipate and avoid physical and economic displacement or, where avoidance is not possible, to minimize adverse social and economic impacts.	This standard is currently considered Not Relevant. The project is expected to deliver all activities through existing public health facilities. All subprojects requiring land take, will be on government land or within existing premises.
ESS6	Biodiversity Conservation and Sustainable Management of Living Resource	Key requirements: • E&S assessment as set out in ESS1 but considers direct, indirect, and cumulative project-related impacts on habitats and the biodiversity they support. This assessment should consider threats to	All project activities will take place within existing facilities. Any capacity enhancement HCWM will be done within existing systems. Hence, impacts of the project on natural resources and biodiversity are likely to be none or low, as such this standard is considered Not Relevant.

ESS No.	ESS Title	Key Requirement	Relevance to the Project
		biodiversity, for example pollution and incidental take, as well as projected climate change impacts. • E&S assessment of the systems and verification practices used by the primary suppliers.	
ESS7	Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities	Key requirements: • Full consultation and provision of opportunities for Indigenous Peoples / Sub-Saharan African Historically Underserved Traditional Local Communities in project design and in the determination of project implementation arrangements. • Obtain the Free Prior and Informed Consent (FPIC) of the affected Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities. • Culturally appropriate and accessible grievance mechanism for the project.	Not relevant as all project activities will take place within existing facilities.
ESS8	Cultural Heritage	Key requirements: • E&S assessment as set out in ESS1 but considers direct, indirect, and cumulative project-related impacts on cultural heritage. • Stakeholder consultation during cultural heritage identification process. • Listing of all legally protected cultural heritage areas affected by the project. • Chance finds procedures.	This standard is currently considered Not Relevant as the project is not expected to support any greenfield construction activities that would involve the movement of earth (thereby potentially having an impact on tangible cultural heritage), or other activities that could have an impact on intangible cultural heritage. Biovax Facility main structure is already built.

ESS No.	ESS Title	Key Requirement	Relevance to the Project
ESS9	Financial Intermediaries	Key requirements: • Development and implementation of an environmental and social management system (ESMS). • Stakeholder engagement.	This standard is Not Relevant for the project, as no financial intermediaries will be used.
ESS10	Stakeholder Engagement and Information Disclosure	Key requirements: • Stakeholder engagement during project preparation. • Stakeholder Engagement Plan (SEP). • Stakeholder engagement during project implementation and external reporting. • Grievance redress mechanism. • Organizational capacity and commitment.	ESS10 is relevant to this project due to several stakeholder groups who would benefit and be at risk from various project activities. The required instruments and processes to comply with this standard are reflected in ESCP and detailed out in the SEP.

2.6 WBG Environmental, Health and Safety Guidelines (EHSGs)

2.6.1 Overview

The World Bank Group Environmental, Health, and Safety (EHS) Guidelines are technical reference documents with general and industry specific examples of Good International Industry Practice (GIIP). These industry sector EHS guidelines are designed to be used together with the General EHS Guidelines document, which provides guidance to users on common EHS issues potentially applicable to all industry sectors. EHS Guidelines are applied as required by their respective policies and standards.

The EHS Guidelines contain the performance levels and measures that are generally considered to be achievable in new facilities by existing technology at reasonable costs. Application of the EHS Guidelines to existing facilities may involve the establishment of site-specific targets, with an appropriate timetable for achieving them. The applicability of specific technical recommendations should be based on the professional opinion of qualified and experienced persons. When host country regulations differ from the levels and measures presented in the EHS Guidelines, projects are expected to achieve whichever is more stringent. If less stringent levels or measures than those provided in these EHS Guidelines are appropriate, in view of specific project circumstances, a full and detailed justification for any proposed alternatives is needed as part of the site-specific environmental assessment. This justification should demonstrate that the choice for any alternate performance levels is protective of human health and the environment.

2.6.2 World Bank Group General EHS Guidelines

The **World Bank Group General EHS Guidelines** contain information on cross-cutting environmental, health, and safety issues potentially applicable to construction and can be downloaded via the following link:***https://www.ifc.org/wps/wcm/connect/topics_ext_content/ifc_external_corporate_site/sustainability-at-ifc/policies-standards/ehs-guidelines.***

2.6.3 World Bank Group EHS Guidelines for Construction Materials Extraction

The **World Bank Group EHS Guidelines for Construction Materials Extraction** is also applicable to the project and used as key guidance provided to contractors on the management of environmental health and safety during construction material extraction in addition to specific guidance provided in the ESMF. This document includes information relevant to construction materials extraction activities such as aggregates, limestone, slates, sand, gravel, clay, gypsum, feldspar, silica sands, and quartzite, as well as to the extraction of dimension stone. It addresses stand-alone projects and extraction activities supporting construction, civil works, and cement projects. Although the construction materials extraction guidelines Emphasize major and complex extraction schemes, the concepts are also applicable to small operations and should be used for guidance. These guidelines can also be downloaded via the link provided above.

2.6.4 World Bank Group EHS Guidelines for Waste Management Facilities

The **World Bank Group EHS Guidelines for Waste Management Facilities** is also applicable and can be used for guidance on the management of infectious and other forms of healthcare waste which are categorized as hazardous in nature. These guidelines apply to projects that use, store, or handle any quantity of hazardous materials (Hazmats), defined as materials that represent a risk to human health, property, or the environment due to their physical or chemical characteristics. Hazmats can be classified according to the hazard as explosives; compressed gases, including toxic or flammable gases; flammable liquids; flammable solids; oxidizing substances; toxic materials; radioactive material;

and corrosive substances. Guidance on the transport of hazardous materials is covered in Section 3 of the document. When a hazardous material is no longer usable for its original purpose and is intended for disposal, but still has hazardous properties, it is considered a hazardous waste (see Section 1.4 of the guide). This guidance is intended to be applied in conjunction with traditional occupational health and safety and emergency preparedness programs which are included in Section 2.0 on Occupational Health and Safety Management, and Section 3.7 on Emergency Preparedness and Response. Guidance on the Transport of Hazardous Materials is provided in Section 3.5.

2.6.5 World Bank Group EHS Guidelines for Health Care Facilities

The **World Bank Group EHS Guidelines for Health Care Facilities** is also applicable and can be used for guidance for the design and operation of HCFs. It includes information relevant to the management of EHS issues associated with healthcare facilities (HCF) which includes a diverse range of facilities and activities involving general hospitals and small inpatient primary care hospitals, as well as outpatient, assisted living, and hospice facilities. Ancillary facilities may include medical laboratories and research facilities, and POEs.

2.6.6 WBG IFC EHSG for Pharmaceuticals and Biotechnology Manufacturing

The **EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing** are also applicable to the project as the Biovax facility will be engaged in biotechnology manufacturing activities. These guidelines cover the production of active pharmaceutical ingredients and secondary processing, including intermediates, formulation, blending, and packaging, and related activities research, including biotechnology research and production.

Potential environmental issues associated with pharmaceuticals and biotechnology manufacturing projects include the following: Air emissions; Wastewater; Solid and hazardous wastes; Hazardous materials; Threats to biodiversity; and Bioethics. The most significant occupational health and safety hazards occur during the operational phase of pharmaceutical and biotechnology facilities and primarily include the following: Heat hazards; Chemical hazards including fire and explosions; Pathogenic and biological hazards; Radiological hazards; Noise; and Process safety. The most significant community health and safety hazards associated with pharmaceutical and biotechnology manufacturing facilities occur during the operation phase and may include the threat from major accidents related to the fires and explosions at the facility and potential accidental releases of finished products during their transport outside of the processing facility.

2.6.7 Parameter Specific EHS Guidelines

2.6.7.1 Air Emissions and Ambient Air Quality

The WBG recommend that the air quality guidelines as set out by the World Health Organization (WHO) be utilized in such an assessment. The WHO standards are divided into several stages, which have interim targets and a final guideline target. The WHO guidelines are recognized to be particularly conservative, as they make no consideration of the economic burden of achieving the stipulated guidelines. The WHO final guideline target is aspirational, and as such, this target should be progressively worked towards. In the case of the proposed Project, progression towards the achievement of the final guideline target may be assisted by regulatory changes to the quality of fuel used for construction and project-owned vehicles (for example, low sulphur fuels) and the regular maintenance and potential mandatory testing of those vehicle emissions. Based on the above, Table 2-5 sets out the WHO Ambient Air Quality Guidelines and Table 2-5 shows the Kenyan Air Quality Emission Standards for industrial areas. WHO guidelines are more stringent than GOK air quality

standards thus should apply to this project. Table 2-6, on the other hand, provides air quality guidelines which the constructed subprojects will comply with during operations.

Table 2-4 WHO Ambient Air Quality Guidelines

Pollutant	Averaging Period	Guideline Value in µ g/m3
Sulfur dioxide (SO2)	24-hour	125 (Interim target-1) 50 (Interim target-2)
Sulfur dioxide (SO2)	10 minute	20 (guideline) 500 (guideline)
Nitrogen dioxide (NO2)	1-year	40 (guideline)
Nitrogen dioxide (NO2)	1-hour	200 (guideline)
Particulate Matter (PM_{10})	1-year	70 (Interim target-1) 50 (Interim target-2) 30 (Interim target-3) 20 (guideline)
Particulate Matter (PM_{10})	24-hour	150 (Interim target-1) 100 (Interim target-2) 75 (Interim target-3) 50 (guideline)
Particulate Matter ($PM_{2.5}$)	1-year	35 (Interim target-1) 25 (Interim target-2) 15 (Interim target-3) 10 (guideline)
Particulate Matter ($PM_{2.5}$)	24-hour	75 (Interim target-1) 50 (Interim target-2) 37.5 (Interim target-3) 25 (guideline)
Ozone	8-hour daily maximum	160 (Interim target-1) 100 (guideline)

Table 2-5 Kenya's Ambient Air Quality Tolerance Limits for Industrial Areas

Pollutant	Time Weighted Average	Tolerance Limit
Sox	Annual average	80 µg/m^3
Sox	24 Hours	125 µg/m^3
NOx	Annual average	80 µg/m^3
NOx	24 Hours	150 µg/m^3

NO_2	Annual Average	150 µg/m^3
NO_2	24 Hours	100 µg/m^3
Suspended Particulate Matter (SPM)	Annual average	360 µg/m^3
Suspended Particulate Matter (SPM)	24 Hours	500 µg/m^3
Respirable Particulate Matter (<10µm) (RPM)	Annual average	70 µg/m^3
Respirable Particulate Matter (<10µm) (RPM)	24 Hours	150 µg/m^3
$PM_{2.5}$	Annual average	35 µg/m^3
$PM_{2.5}$	24 Hours Maximum	75 µg/m^3
Lead	Annual average	1.0 g/Nm^3
Lead	24 Hours	1.5 g/m^3
Carbon monoxide (CO)/ Carbon dioxide (CO2)	8 Hours	5.0 mg/m^3
Carbon monoxide (CO)/ Carbon dioxide (CO2)	1 Hour	10.0 mg/m^3
Hydrogen Sulphide	24 Hours	150 µg/m^3
Non-methane hydrocarbons	Instant peak	700 ppb
Total Volatile organic Compounds (VOC)	24 Hours	600 µg/m^3
Ozone	1 Hour	200 µg/m^3
Ozone	8 hour (instant Peak)	120 µg/m^3

Table 2-6 WBG Air Emissions Levels for Pharmaceuticals and Biotechnology Manufacturing

Pollutant	Units	Guideline Value
Active Ingredient (each)	mg/Nm^3	0.15
Particulate Matter	mg/Nm^3	20
Total Organic Carbon	mg/Nm^3	50
Hazardous Air Pollutants	kg/year	900-1,800[16]
Total Class A[17]	mg/Nm^3	20M)

[16] Process-based annual mass limit. 900: Actual HAP emissions from the sum of all process vents within a process; 1,800: Actual HAP emissions from the sum of all process vents within processes.

[17] Class A compounds are those that may cause significant harm to human health and the environment. They include Montreal Protocol substances, as well as others identified in the EU Directive 1999/13/EC on the Limitation of Emissions of Volatile Organic Compounds due to the Use of Organic Solvents in Certain Activities and Installations. Example of Class A compounds include acetaldehyde, acrylic acid, benzyl chloride, carbon tetrachloride, chlorofluorocarbons, ethyl acrylate, halons, maleic anhydride, 1,1,1 trichloroethane, trichloromethane, trichloroethylene, and trichlorotoluene.

Total Class B[18]	mg/Nm^3	80[19]
Benzene, Vinyl Chloride, Dichloroethane (each)	mg/Nm^3	1
VOC	mg/Nm^3	20-150[20] 50[21]
Bromides (as HBr)	mg/Sm^3	3
Chlorides (as HCl)	mg/Sm^3	30
Ammonia	mg/Sm^3	30
Arsenic	mg/Sm^3	0.05
Ethylene Oxide	mg/Sm^3	0.5
Mutagenic Substance	mg/Sm^3	0.05

2.6.7.2 Wastewater and Ambient Water Quality

WBG specifies that discharges should not result in contaminant concentrations more than local ambient water quality criteria or, in the absence of local criteria, other sources of ambient water quality. Receiving water use and assimilative capacity, taking other sources of discharges to the receiving water into consideration, should also influence the acceptable pollution loadings and effluent discharge quality.

Table 2-7 Effluents Levels for Pharmaceuticals and Biotechnology Manufacturing

Pollutant	Units	Guideline Value
pH	S.U.	6-9
BOD5	mg/L	30
COD	mg/L	150
TSS	mg/L	10
Oil and grease	mg/L	10
AOX	mg/L	1
Phenol	mg/L	0.5
Arsenic	mg/L	0.1
Cadmium	mg/L	0.1

[18] Class B compounds are organic compounds of less environmental impact than Class A compounds. Examples include toluene, acetone, and propylene.
[19] Applicable when total Class B compounds, expressed as toluene, exceed the lower of 5 t/year or 2 kg/hr.
[20] EU Directive 1999/13/EC. Facilities with solvent consumption > 50 tonnes/year. Higher value (150) to be applied for waste gases from any technique which allows the reuse of the recovered solvent. Fugitive emission values (non-including solvent sold as part of products and preparations in a sealed container): 5 percent of solvent input for new facilities and 15 percent for existing facilities. Total solvent emission limit values: 5 percent of solvent input for new facilities and 15 percent for existing facilities.
[21] Waste gases from oxidation plants. As 15-minute mean for contained sources.

Pollutant		Units	Guideline Value
Chromium (hexavalent)		mg/L	0.1
Mercury		mg/L	0.01
Active ingredient (each)		mg/L	0.05
Ammonia		mg/L	30
Total nitrogen		mg/L	10
Total phosphorus		mg/L	2
Ketones (each)[22]		mg/L	0.2
Acetonitrile		mg/L	10.2
Acetates (each)[23]		mg/L	0.5
Benzene		mg/L	0.02
Chlorobenzene		mg/L	0.06
Chloroform		mg/L	0.013
0-Dichlorobenzene		mg/L	0.06
1 ,2-Dichloroethane		mg/L	0.1
Amines (each)[24]		mg/L	102
Dimethyl sulfoxide		mg/L	37.5
Methanol ethanol (each)		mg/L	4.1
n-Heptane		mg/L	0.02
n-Hexane		mg/L	0.02
Isobutyraldehyde		mg/L	0.5
Isopropanol		mg/L	1.6
Isopropyl ether		mg/L	2.6
Methyl cellosolve		mg/L	40.6
Methylene chloride		mg/L	0.3
Tetrahydrofuran		mg/L	2.6
Toluene		mg/L	0.02
Xylenes		mg/L	0.01
Bioassays	Toxicity to fish Toxicity to daphnia		2 8

[22] Including Acetone, Methyl Isobutyl Ketone (MIBK).
[23] n-Amyl Acetate, n-Butyl Acetate, Ethyl acetate, Isopropyl Acetate, Methyl Formate.
[24] Including Diethylamine and Triethylamine.

Pollutant		Units	Guideline Value
	Toxicity to algae Toxicity to bacteria	T.U.[25]	16 8

Table 2-8 Indicative Values for Treated Sanitary Sewage Discharges[a]

Pollutants	Units	Guideline Value
pH	pH	6-9
BOD	mg/l	30
COD	mg/l	125
Total nitrogen	mg/l	10
Total phosphorus	mg/l	2
Oil and grease	mg/l	10
Total suspended solids	mg/l	50
Total coliform bacteria	MPN[b] / 100 ml	400[a]
Notes: **[a] Not applicable to centralized, municipal, wastewater treatment systems which are included in EHS Guidelines for Water and Sanitation.** **[b] MPN = Most Probable Number**		

Table 2-9 Effluent Levels for Health Care Facilities

Pollutants	Units	Guideline Value
pH	S.U	6-9
Biochemical oxygen demand BOD_5	mg/L	50
Chemical oxygen demand COD	mg/L	250
Oil and grease	mg/L	10
Total sus ended solid TSS	mg/L	50
Cadmium (Cd)	mg/L	0.05
Chromium Cr	mg/L	0.5
Lead (Pb)	mg/L	0.1
Mercury	mg/L	0.01
Chlorine, total residual	mg/L	0.2

[25] TU = 100 / no effects dilution rate (%) of wastewater. The "no effect dilution rate" should be monitored with standard toxicity tests (e.g., CEN, ISO, or OECD acute toxicity testing standards.)

Pollutants	Units	Guideline Value
Phenols	mg/L	0.5
Total coliform bateria	MPN[a] / IOOml	400
Polychlorinated dibenzodioxin and dibenzofuran (PCDD/F)	Ng/L	0.1
Temperature increase	oc	<3[b]
Notes: [a] MPN = Most Probable Number [b] At the edge of a scientifically established mixing zone which takes into account ambient water quality, receiving water use, potential receptors and assimilative capacity.		

The Biovax facility and all laboratories supported by the Project must meet these effluent guidelines. They are indicative of good international industry practice (GIIP).

2.6.7.3 Noise

The WBG EHS Guidelines – General EHS Guidelines: Environmental Noise Management 1.7 Noise (IFC 1.7 Noise) is an internationally recognized guideline document containing information for the assessment and management of noise.

Table 2-10 presents the WBG noise guidelines that should not be exceeded at the nearest Noise Sensitive receptor (NSR) locations offsite. In addition to the absolute values provided in Table 2-11, the IFC also requires that noise increase above existing (background) levels should not exceed 3dB.

Table 2-10 WBG Noise Level Guidelines

Receptor	One Hour LAeq (dB(A))	
	Daytime (07:00 – 22:00)	**Night (22:00 – 07:00)**
Residential; institutional; educational	55	45
Industrial; commercial	70	70

LAeq = A-weighted equivalent sound levels over a measurement period, dB(A) = A-weighted decibel

Table 2-11 Maximum Permissible Noise for Construction Sites in Kenya

	Facility	Maximum Permissible Noise Level in dB(A)	
		Day (0601-1800, LAeq 12 hour)	**Night (1801-0600, LAeq 12 hour)**
(i)	Health facilities, educational institutions, homes for disabled, etc.	60	35
(ii)	Residential	60	35
(iii)	Areas other than those prescribe in (i) and (ii) (and of applicability to this Project).	75	65

WBG Guidelines are designed to apply to noise emissions from facilities and stationary noise sources such as factories. The value of 70 dB(A) at the property boundary differs to the Kenyan standard (Table 2-11); hence the Kenyan noise standard of 75 dB(A) and 65 dB(A) for day and nighttime at the property boundary will apply to this Project.

2.7 Assessment of Capacity to Comply with Environmental and Social Requirements

2.7.1 MOH

GOK through MoH has the experience of preparing and implementing Kenya CHERP (P173820) using the ESF. The MoH, who will be the main implementing agency for the Project, has coordinated and effectively implemented the health emergency response project and will lead the execution of project activities. MoH have a fulltime E&S specialist on all its existing projects (P152394 and P173820) financed by the WBG who work closely with the respective county public health officers, port health managers, health promotion officers, laboratory managers and blood services managers to support the management of the E&S risks and impacts. At the project onset, PMT should recruit an environmental specialist with health and safety expertise and one social specialist with SEA/SH expertise. The two E&S specialists should have qualifications and experience acceptable to the WB.

2.7.2 KBI

Currently, KBI is staffed by pharmacists and biotechnologists. It does not have officers dedicated to E&S management. In 2022, KBI conducted an ESIA for the facility through engaging external consultants. The ESIA, however, does not meet the requirements of ESF.

KBI should hire a Good Manufacturing Practice (GMP) consultant that will design and supervise the installation of the human vaccine manufacturing plant. The consultant should possess EHS expertise. The consultant shall also have a social specialist with experience in SEAH risk management.

During operations phase, KBI should hire a full-time biosafety and biosecurity manager.

2.7.3 PPB

PPB also lacks E&S experts. They will thus rely on project-hired E&S specialists to manage E&S issues in their activities. However, PPB should designate a staff member, who will be capacity built, to act as a focal person in E&S management.

2.7.4 NQCL

NQCL too lacks specialist E&S experts. They will thus rely on project-hired E&S specialists to manage E&S issues in their activities. NQCL should also designate a staff member, who will be capacity built, to act as a focal person in E&S management.

2.7.5 NPHI

NPHI too does not have capacity to E&S issues as they do not have E&S specialists. NPHI should designate a staff member, who will be capacity built, to act as a focal person in E&S management.

2.8 Assessment Similarities and Gaps between National ESIA Requirements and WBG's ESSs & EHS guidelines on HCF

This subsection focuses on similarities and gaps between GOK environmental and social requirements and relevant Bank safeguards instruments.

2.8.1 GOK and WBG Similarities

The World Bank Group ESSs and EHS guidelines and GOK legal frameworks on environmental assessment are generally aligned in principle and objective:

- Both require screening of subprojects to determine which level of social and environmental assessment (e.g., ESMP, EIA, etc.) is needed.
- Both require detailed ESIA for projects with more significant impacts (High and substantial risk), a less detailed EIA study for projects with less significant impacts (Medium/Moderate risk) and no ESIA studies for projects likely to have minimal or no adverse environmental impacts (Low risk).
- In mitigating/managing environmental and social risks, both frameworks emphasize the adoption of the mitigation hierarchy approach (Avoid, Minimize, Restore and Offset); and
- In the ESIA process, both frameworks require key stakeholder engagement during planning, implementation, and operational phases of the project.

2.8.2 GOK and WBG ESF Gaps/Discrepancies

Table 2-12 shows some differences between GOK frameworks and WBG ESF, and designed gap filling measures.

Table 2-12 GOK and WBG ESF Discrepancies and Proposed Gap Filling Measures

No.	Aspect	GOK	WBG	Gap Filling Measures
•	Preparation of Safeguard Instruments; ESIA, ESMP	No procedure for approval of standalone ESMPs but requires them to form part of an SPR/CPR/full study ESIA report	Okay with a standalone and more detailed ESMP document for low-risk projects	All sub-project ESIAs to contain an ESMP section.
•	Scope of safeguards instruments	Requires a general determination of environmental and social impacts and mitigation measures	Requires preparation of specialist documents e.g., social assessment, Labour Management Procedures (LMP), Security Management Plan (SMP), Stakeholder Engagement Plan (SEP), Resettlement Policy Framework (RPF), Vulnerable and Marginalized Groups Assessment, and Vulnerable and Marginalized Group Action Plan (VMGAP), etc.	ESIA reports to provide detail on labour management, elaborate stakeholder engagement including with vulnerable groups.
•	Compensation for temporary loss of access to	Does not compensate people for	Demands compensation for such loss.	No land take is envisaged in the project though, when

No.	Aspect	GOK	WBG	Gap Filling Measures
	productive assets	temporary loss of access to productive assets or those without title deeds/leases.		necessary, an RPF and subsequent RAPs will be prepared.
•	Post-approval environmental performance	ESIA does not result in effective post-approval environmental performance. The mobilization of contractors is weak.	Keen on post-approval E&S performance. E&S performance part of aspect evaluated during missions.	There is need to focus E&S training on project implementation, and less on design and approval. Environmental inspection capacity by NEMA and counties needs to be significantly improved.

2.9 World Health Organization (WHO) Vaccine Standardization

The World Health Organization brings together international experts in specific fields through its biological standardization programme to develop and revise specific recommendations for the production and quality control of vaccines of major international public health importance. Authoritative, harmonized guidelines and recommendations, for use by manufacturers and regulatory authorities, are published in the reports of ECBS meetings in the WHO Technical Report Series.

These include recommendations for individual vaccines, and more general guidelines on technical or regulatory topics such as cell substrates, nonclinical evaluation, or clinical evaluation. This programme also establishes and distributes the *WHO Biological Reference Materials* required for the standardization of assays to laboratories around the world such as manufacturers and National Control Laboratories (NCLs) who are involved in the quality control of vaccines. This activity is critical to ensure the quality of essential vaccines in a global market.

2.10 Other Relevant International Conventions

As Kenya is a signatory to various international conventions and laws, it is important that national projects are in line with these laws. Some of the international and regional conventions relevant to the project that Kenya has adopted are summarized below:

2.10.1 Bamako Convention, 1991

The Bamako Convention on the Import into Africa and the Control of Trans-boundary Movement and Management of Hazardous Waste within Africa is a treaty of African nations prohibiting the import of any hazardous waste and Kenya is a signatory to it. The convention was negotiated by 12 nations of the Organization of African Unity (OAU) in Bamako in January 1991 and came into force in 1998. Parties to this convention are mindful of the growing threat to health and environment posed by the increased generation and complexity of hazardous waste, hence prohibits all imports of hazardous waste.

2.10.2 Stockholm Convention on Persistent Organic Pollutants

The Convention is a global treaty to protect human health and environment from Persistent Organic Pollutants (POPs). POPs are chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of living organisms and are toxic to human and wildlife. Under Article 5 and Annex C governments that are party to the Convention are required to reduce or eliminate release from unintentional production of POPs in particular polychlorinated dibenzo-p-dioxins and dibenzofurans which are formed and released to the environment by medical waste incinerators and other combustion processes.

2.10.3 International Health Regulations (IHR)

The IHR is a legally binding international agreement adopted by the World Health Assembly in 2005. The regulations are designed to prevent and respond to the international spread of diseases and require member states to report certain disease outbreaks to the World Health Organisation (WHO).

2.10.4 United Nations Convention on the Rights of Persons with Disabilities (CRPD)

The CRPD is an international treaty that sets out the rights of persons with disabilities, including their right to the highest attainable standard of health.

2.10.5 International Covenant on Economic, Social and Cultural Rights (ICESCR)

The ICESCR is a multilateral treaty adopted by the United Nations General Assembly in 1966. It recognizes the right to health as a fundamental human right and obliges state parties to take steps to improve the health of their populations.

2.10.6 Paris Agreement on Climate Change

While not solely focused on health, the Paris Agreement recognizes that climate change has significant impacts on human health and well-being. The agreement aims to limit global warming to well below 2 degrees Celsius above pre-industrial levels, to prevent the worst impacts of climate change on health and other aspects of human life.

3 ENVIRONMENTAL AND SOCIAL BASELINE

3.1 Overview

This Chapter provides a description of the existing physical, biological, and socio-economic conditions, which are directly or indirectly affected by Project activities. It is essential that the baseline conditions of the environment are characterized to accurately predict the potential effects the proposed project will have on the environment and society. The collection of baseline data therefore focused on providing information to support the assessment of any potential impact of the project.

3.2 Physical Environment

3.2.1 Size, Location and Geography

Kenya covers a land area of approximately 583,000 square kilometers. Kenya straddles the Equator between approximately 4.5 degrees South and 4.5 degrees North latitude. The Republic of Kenya is bordered by the Indian Ocean, Uganda, Tanzania, Ethiopia, South-Sudan, and Somalia. Nairobi, Mombasa, and Kisumu are the three main cities in Kenya. Nairobi lies in central Kenya, Mombasa on the Indian Ocean, and Kisumu on the Lake Victoria shores. Nakuru, Eldoret, Kitale and Lamu are among the major towns. The capital city of Kenya is Nairobi, which is considered the main tourist hub[26].

3.2.2 Climate and Climate Change

3.2.2.1 Climate

Kenya has a tropical climate, but there are large regional climatic variations influenced by several factors, including altitude. Temperatures drop by about 6°C for every 1,000m you climb (or 3.5°F per 1,000 ft). Kenya's daytime temperatures average between 20°C/68°F and 28°C/82°F, but it is warmer at the coast. The coast is hot and humid all year round. The dry and wet seasons are as follows: *Dry season* – June–October—These are the coldest months and temperatures vary significantly per region and with their difference in altitude.

Daytime temperatures are usually around 23°C/73°F at higher altitudes, and 28°C/82°F at lower altitudes, like the coastal areas; and *Wet season* - November to May—During the wet season daytime temperatures are between 24°C/75°F and 27°C/81°F at higher altitudes. At lower altitudes daytime temperatures are more consistent and hover at 30°C/86°F. From December to April the humidity is intense in coastal areas. There are long (March to May) and short (October to December) rainy seasons interspersed with dry spells in the months of January to March and May to October.

3.2.2.2 Climate Change

Climate change has evolved from being simply an environmental problem to a major development challenge impacting all economic sectors. There is evidence from historical records that Kenya has experienced increased temperature over the last 50 years. The frequency of intense extreme weather events like droughts and floods has also increased. Future climatic predictions indicate a possible temperature increase of 1°C by 2020 and 2.3°C by 2050. Rainfall pattern changes have also been noticed since the 1960s. Increased rainfall has been observed during the October to December rainfall

[26] ("Cities in Kenya - Major Cities and Towns - Kenya Cities," 2018)

season[27] while decreasing during the March to May season. The March to May rainfall, which is the long rain season, has become increasingly unreliable in some part of Kenya[28].

Kenya has been identified as highly vulnerable to climate change on the Notre Dame Global Adaptation Index (rank 149/182 in 2020).6 More than 80 percent of the landmass is arid and semi-arid land with poor infrastructure, and the economy is highly dependent on climate-sensitive sectors such as rain-fed agriculture. While temperatures vary across Kenya, a distinct warming trend is evident, particularly since the 1960s. Extreme rainfall events are occurring with greater frequency and intensity, as well as aridity and droughts in certain areas. These climatic trends are expected to persist and increase in climate scenarios. Repeating patterns of floods and droughts have had large socio-economic impacts and high economic costs (droughts impacting 8 percent of GDP roughly every five years). Lower-income populations reside in more hazard prone locations, with high potential for significantly increased exposure of already underserved populations. [29]

3.2.3 Geology, Topography and Soils

3.2.3.1 Geology

Kenya lies along the equator and most of the country consists of high plateau areas and Mountain ranges that rise to 3,000 meters above sea level (m.a.s.l) and more. The geology of Kenya is characterized by Archean granite/greenstone terrain in western Kenya along Lake Victoria, the neoproterozoic 'Pan-African' Mozambique Belt, which underlies the central part of the country and Mesozoic to recent sediments underlying the eastern coastal areas. The eastern Rift Valley crosses Kenya from North to South and the volcanics associated with rift formation largely obliterate the generally north-south striking neoproterozoic Mozambique Belt. Rift valley volcanogenic sediments and lacustrine and alluvial sediments cover large parts of the eastern rift[30].

3.2.3.2 Topography

Kenya is notable for its topographical variety. The low-lying, fertile coastal region, fringed with coral reefs and islands, is backed by a gradually rising coastal plain, a dry region covered with savannah and thorn bush. At an altitude of over 1,500 m.a.s.l. and about 480 km inland, the plain gives way in the southwest to a high plateau, rising in parts to more than 3,050 m, on which most of the population and many economic activities are concentrated. The northern section of Kenya, forming three-fifths of the whole territory, is arid and of semi desert character, as is the bulk of the south-eastern quarter. In the high plateau area, known as the Kenya Highlands, lie Mt. Kenya (5,199 m.a.s.l/17,057 ft), Mt. Elgon (4,310 m.a.s.l/14,140 ft), and the Aberdare Ranges (rising above 3,962 m.a.s.l/13,000 ft). The plateau is bisected from north to south by the Great Rift Valley, part of the geological fracture that can be traced from Syria through the Red Sea and East Africa to Mozambique.

In the north of Kenya, the valley is broad and shallow, embracing Lake Turkana, which is about 207 km long; farther south the valley narrows and deepens and is walled by escarpments 600–900 m.a.s.l (2,000–3,000 ft) high.

---

[27] Ongoma, V., Chen, H. and Gao, C. (2017). Projected changes in mean rainfall and temperature over East Africa based on CMIP5 models. *Int. J. Climatol*. DOI: 10.1002/joc.5252

[28] Awuor C.B., Orindi V.A. and Adwera A.O. (2008). Climate change and coastal cities: the case of Mombasa, Kenya. *Environ Urban*, 20: 231-242.

[29] World Bank, Climate Knowledge Porta, at: https://climateknowledgeportal.worldbank.org/sites/default/files/2021-05/15724-WB_Kenya%20Country%20Profile-WEB.pdf

[30] (Schluter, 1997)

3.2.3.3 Soils

Kenya has a very wide range of soils resulting from the variation in geology (parent material), in relief and climate. Soil resources vary from sandy to clay, shallow to very deep and low to high fertility. However, most of them have serious limitations such as salinity/ sodicity, acidity, fertility, and drainage problems. The major soils used in agriculture are ferralsols, vertisols, acrisols, luxisols, luvisols and nitosols[31].

3.2.4 Water Resources

Most of Kenya's water originates from its five "water towers": Mau Forest Complex, Aberdare ranges, Mount Kenya, Mount Elgon and the Cherengani Hills. They are the largest montane forests in the country and form the upper catchments of the main rivers in Kenya (except Tsavo river flowing down Mount Kilimanjaro)[32]. There are six main catchments in the country, used as unit for the water resources management by the Water Resources Authority (WRA): 1) Lake Victoria North Catchment Area (LVNCA), covering 3.0 % of the country; 2) Lake Victoria South Catchment Area (LVSCA), covering 5.0 % of the country; 3) Rift Valley Catchment Area (RVCA) which includes the inland lakes, covering 22.5 % of the country; 4) Athi Catchment Area (ACA) stretching up to the coast, covering 11.5 % of the country; 5) Tana Catchment Area (TCA), covering 21.7 % of the country; 6) Ewaso Ng'iro North Catchment Area (ENNCA), covering 36.3 % of the country[33]. The water distribution in the drainage basins is uneven with, for example, 282,600 m^3/ km^2 in Lake Victoria basin, or over 750 m^3/year per capita and 21,300 m^3/km^2 in the Athi Catchment, or 162 m^3/year per capita[34].

Inland water bodies, mainly nine large lakes, cover 11,230 km^2. Most of them are saline, except for the lakes Victoria, Naivasha and Baringo. The lakes Nakuru, Naivasha, Bogoria, Baringo and Elementeita, as well as Tana River Delta, have been declared Ramsar sites of international importance for the conservation of biodiversity, totaling over 265,000 ha[35].

Internal renewable surface water resources are estimated at 20,200 million m^3/year and renewable groundwater resources at around 3,500 million m^3/year, but 3,000 million m^3/year is overlap between surface water and groundwater, which gives a value of total internal renewable water resources (IRWR) of 20,700 million m^3/year. External water resources are estimated at 10,000 million m^3/year, which is the inflow from Lake Omo from Ethiopia into Lake Turkana. Surface water leaving the country is estimated at 8,900 million m^3/year through the Lake Victoria to Uganda (8,400 million m^3/year) and through the Ewaso Ng'iro river, also called Lagh Dera, into Somalia (500 million m^3/year). The dependency ratio is thus around 33 percent and the total renewable water resources are 30,700 million m^3/year, or 692 m^3/year per capita in 2014. This per capita value is projected to fall under the absolute water scarcity threshold of 500 m^3/year by 2030 due to population increase.

There are six hydro-geological formations, which influence the distribution and availability of the groundwater resources: eastern quaternary sediment areas, bed rock areas, western quaternary areas, volcanic rock areas in the Rift valley, volcanic areas outside the Rift valley, older sedimentary areas. The volcanic and quaternary geological formations are rich in groundwater. The country's safe yield of surface water has been assessed at 7,400 million m^3 per year while that of groundwater is

[31] (Gachene, C.K.K. and Kimaru, G., 2003)
[32] (NEMA, 2010)
[33] (WRMA, 2013)
[34] (WRMA, 2011)
[35] (RAMSAR, 2013)

about 1,000 million m³ per year[36]. However, this figure needs to be reviewed with the new aquifers identified in 2013 in Turkana County, and in particular with five deep high-capacity groundwater reserves accounting for about 250,000 million m³. Among those, the Lotikipi aquifer, west of Lake Turkana, is estimated at over 200,000 million m³ of water and the small Lodwar basin aquifer that could serve as a strategic reserve for Lodwar, regional capital of Turkana County[37].

The total capacity of large and medium dams (>15 m) is about 24,800 million m³, all for hydropower and urban water supplies. In addition, around 4,100 small dams and water pans increase the storage capacity by an additional 184 million m³ available for all uses[38].

3.3 Biological Environment

3.3.1 Biodiversity

Kenya is endowed with diverse ecosystems and habitats that are home to unique and diverse flora and fauna. Kenya's rich biodiversity can be attributed to several factors, including a long evolutionary history, the country's varied and diverse habitat types and ecosystems, diversity of landscapes and variable climatic conditions. About 70 % national biodiversity resources are found outside the protected, while the 30 % are within protected areas that include national parks, reserves, sanctuaries, gazetted forests, and heritage forests[39]. Specifically, Kenya is rich with over 35,000 species of flora and fauna found in large diversity of ecological zones and habitats, including lowland and mountain forests, wooded and open grasslands, semi-arid scrubland, dry woodlands, inland aquatic, as well as coastal and marine ecosystems. The species diversity is dominated by insects[40].

Coastal mangroves and coral reefs, critical for fisheries, storm surge protection and tourism, are damaged by rising seas and increasing ocean temperatures. Reefs are highly sensitive to heat stress and have not yet fully recovered from an extensive 1998 *El Niño*-induced coral bleaching event[41]. Inland grasslands and forests are at risk from increasing temperatures and more variable rainfall, leading to drought conditions, increased risk of grassland and forest fires, and shifting distributions of native and invasive species. These changes may have detrimental impacts on the African elephant, lion, and buffalo – important for both ecosystem functioning and tourism[42].

3.3.2 Rare or Endangered Species

International Union for Conservation of Nature (IUCN) Red List for 2018 has identified a total of 8 species in Kenya which are threatened[43]. None of the species identified are endemic and no species have been identified as extinct.

A total of 32 species were assessed and one insect, five plants and two reptile species were identified as being threatened. The IUCN regard the threatened status of animals and plants as one of the most useful signs for assessing the condition of an ecosystem and its biodiversity. Five plants of the *Magnoliopsida* class (*Euphorbia tanaensis, Bauhinia mombassae, Gigasiphon macrosiphon, Ziziphus*

[36] (WRMA, 2013)
[37] (UNESCO, 2013)
[38] (MALF, 2015)
[39] (NEMA, 2015)
[40] (NEMA, 2015)
[41] (Cinner et al., 2012)
[42] (World Travel & Tourism Council, 2017)
[43] (IUCN, 2018)

robertsoniana, Diospyros shimbaensis) are endangered. The Kenya Jewel insect is critically endangered[44].

3.4 Socio-economic Conditions

3.4.1 Population structure

According to 2019 Kenya Population and Housing Census (KPHC), Kenya has a population of 47.6 million people, and an Inter-censal growth rate was 2.2.% (from 37.7 million in 2009). The total male population was 23.6 million, total female population 24 million and total intersex population was 1,500. The population density (No. per sq. Km) was 82. The number of households was approximately 12.1 million and average household size being 3.9[45].

Kenya's population growth has averaged 2.7 percent annually since 2000, with the urban population growing at 4.4 percent, now reaching over 27% of the total, though a vast majority of Kenyans (73%) continue to reside in rural areas. The average age is only 20, reflecting the opportunity to capitalize on a demographic dividend, paired with the challenge of creating enough jobs to support the boom in the working age population.

3.4.2 Politics, Ethnicity, and languages

Kenya is the world's seventh most ethnically diverse country with an evolving political structure aimed at balancing competition and fostering national unity. In the past, political competition has been ethnically divisive, entrenching deep patron-client networks with lasting impacts on the lives of Kenyans. Access to national resources and services mirrored access to political power, widening disparities across diverse communities and accentuating concerns over political exclusion, voice, and accountability. In 2007, these tensions manifested themselves in severe political violence that ended only after parties agreed to develop a new Constitution (2010).[46]

Kenya is characterized by counties with diverse ethnicities, cultures, and languages. The commonly spoken languages include English, Swahili, and numerous other indigenous languages. The population is comprised of various ethnic groups such as Kikuyu (22%), Luhya (14%), Luo (13%), Kalenjin (12%), Kamba (11%), Kisii (%), Meru (6%), other African (15%), non-African (one %)[47].

3.4.3 Employment profile

According to Kenya National Bureau of Statistics (KNBS), Quarterly Labour Force Report released in May 2021, the overall employment to population ratio in the country, for the working age population, was 63.7% in the first quarter of 2021 compared to 64.4 % recorded in the same quarter of 2020, and 65% recorded in the last quarter of 2020. The same report notes that the unemployment rate, measured based on the strict definition of seeking work in the last four weeks, was 6.6% in the first quarter of 2021, compared to 5.2% in the same quarter of 2020 and 5.4 % recorded in the last quarter of 2020. The age groups 20-24 and 25-29 continued to record the highest proportion of the unemployed at 16.3 per cent and 9.1 per cent, respectively.[48]

3.4.4 Poverty profile

The proportion of Kenyans living on less than the international poverty line (US$1.90 per day in 2011 PPP) has declined from 46.8% in 2005/06 to 36.1% in 2015/16, according to the 17th edition of the

[44] (IUCN, 2018)
[45] ("Kenya Population and Housing Census, 2019)
[46] KDEAP PAD
[47] ("Kenya Demographics Profile 2018," 2018)
[48] *https://www.knbs.or.ke/download/quarterly-labour-force-report-2021_quarter_1/*

Kenya Economic Update. The economic update, *Policy Options to Advance the Big 4: Unleashing Kenya's Private Sector to Drive Inclusive Growth and Accelerate Poverty Reduction*, notes that current monetary and non-monetary poverty indicators in Kenya are better compared to most Sub-Saharan African (SSA) countries but continue to lag other lower middle-income countries.

Overall, given Kenya's income levels and poverty rate, human development indicators are relatively high, illustrating that Kenya performs better on non-monetary dimensions of poverty, the update says. The update also points out that the agricultural sector was a key driver of poverty reduction in the past decade. However, this also implies progress in poverty reduction remains vulnerability to agro-climatic shocks such as droughts that can force households back into poverty. To avoid recurrent seasonal spells of poverty experienced by agricultural households, the report recommends that the country build resilience, including climate-proofing its agriculture.[49]

3.4.5 Education

Most of the Kenyan population is literate (78%). Males have a slightly higher literacy rate (81.1 %) than females (74.9%)[50].

In 2003, the Kenyan government instituted a free primary education programme for all, followed by free secondary education in 2018. As a result, nearly 3 million more students were enrolled in primary school in 2012, and the number of schools grew by 7,000[51]. Between 2003 and 2012, the overall secondary school enrolment ratio increased from 43% to 67&. However, one million children were still out of school in 2010.

At a university level, between 2012 and 2014, the enrolment rates have more than doubled as the free primary and secondary learners have increasingly enrolled at universities (between 2013 and 2014, student numbers increased by 28%).

Education related issues continue to persist with over a quarter of young people obtaining less than a secondary education and one in 10 did not complete primary school[52].

3.4.6 Access to Safe Drinking Water

A total of 82% of the urban population have access to a drinking water source with only 52% of the rural population having access. Overall, 59% of the Kenyan population has access to a drinking water source. Some 18% of the urban population do not have access to a drinking water source, while 48% of the rural population do not have access to a drinking water source[53].

Kenya's scarce water resources, strained by population growth and severe forest degradation, could be further stressed by increasing temperatures, evaporation rates and rainfall variability. The country relies predominantly on surface water sources, but key rivers and lakes are highly susceptible to climate change. In 2010 Kenya's water availability was 586m^3 per person annually, well below the internationally acceptable threshold of 1,000m^3 per person; this figure is expected to fall to as low as 293m^3 by 2050. Increasingly severe droughts and flooding will impact water availability and diminish water quality, with implications for irrigation and domestic water supply and sanitation, which

[49] World Bank Website: *https://www.worldbank.org/en/country/kenya/publication/kenya-economic-update-poverty-incidence-in-kenya-declined-significantly-but-unlikely-to-be-eradicated-by-2030*. Retrieved on 19/4/2021.

[50] ("Kenya Demographics Profile 2018," 2018)

[51] (Clark, 2015)

[52] (Clark, 2015)

[53] ("Demographics of Kenya - Facts and Figures," 2018)

combined account for 87 percent of current use. Urban areas are already highly water stressed; Nairobi and Mombasa regularly implement water rationing[54].

Glacial loss on Mount Kenya is further straining water resources and turning once glacially fed perennial rivers, such as the Ewaso Ng'iro, to seasonal flows, leading to conflict over water resources between communities upstream and downstream[55].

3.4.7 Sanitation

A total of 31.2% of the urban population in Kenya have access to sanitation facilities with only 29.7% of the rural population having access to improved sanitation facilities. A total of 68.8 % of the urban population have unimproved sanitation facilities, followed by 70.3% of the rural population having unimproved access to sanitation facilities. Overall, a total of 69.9% of the Kenyan population have unimproved sanitation facilities[56].

3.4.8 Source of Energy

Much of Kenya's energy comes from non-fossil fuel sources. Eighty-nine (89)% of installed energy capacity comes from hydro (40%) and geothermal power (49%)[57]. In 2010, 19.2% of the Kenyan population had access to electricity, this percentage increased significantly to 75% in 2019[58].

Increased evaporation rates and more severe drought threaten Kenya's hydropower production, which accounts for about one-half of domestic electricity production. Hydro production is reduced by up to 40 percent in drought years, leading to persistent power outages and reliance on more expensive petroleum-based thermal generation[59]. Projections of sea level rise and increased heavy precipitation events leading to flooding and landslides put energy, transportation and building infrastructure at risk. Models estimate that in Mombasa as much as $4.8 billion worth of assets will be exposed to flooding and inundation from sea level rise by 2050, including Port Kilindini, the largest seaport in East Africa[60].

3.4.9 Waste Management

3.4.9.1 General Solid Waste Management in Kenya

Waste management is a major challenge in Kenya, especially in rapidly growing urban metropolises and coastal areas. Investigations conducted by NECC in the major cities in the Country including Nairobi, Mombasa, Kisumu, Eldoret and Nakuru listed the following findings:

- Nairobi produces around 2,400 tons of waste every day, of which only 38 per cent is collected and less than 10 per cent recycled (JICA, 2010). The remaining 62 per cent is disposed of at the uncontrolled Dandora dumpsite, illegally dumped on roadsides and waterways, or burned releases toxic air emissions and particulate matter. Illegal dumping and burning is particularly common in low-income areas of the city, which are home to over 2.5 million people who cannot afford waste collection services.
- A common observation made by NECC across most Counties is haphazard dumping of waste within towns/urban areas which is a health hazard to the public and has caused environmental pollution.

[54] (Climate Service Center Germany, 2015).
[55] (Wesangula. 2017)
[56] ("Kenya Demographics Profile 2018," 2018)
[57] (GoK. 2020)
[58] (The World Bank, 2018)
[59] (GoK. 2015. Second National Communication, UNFCCC).
[60] (Kebede et al. 2010)

- Waste transportation is largely rudimentary using open trucks, hand carts, donkey carts among others. These poor transportation modes have led to littering, making waste an eyesore, particularly plastics in the environment. However, some counties have adopted appropriate transportation trucks as stipulated by the Waste Management Regulations. In addition, County Governments have privatized waste transportation through Private Public Partnership arrangements.
- There is no current data on generation, recovery and disposed waste. These challenges designing and implementing efficient measures that match the data in ensuring efficient waste management.
- Disposal of waste in the country remains a major challenge as most of the counties lack proper and adequate disposal sites. The few towns that have designated sites practice open dumping of mixed waste as they lack appropriate technologies and disposal facilities.
- Disposal sites are undesignated this is since they are either located near residential areas, surface water sources, hospitals, schools, and other vital facilities. The proximity causes environmental pollution that increases chances for occurrence of human illnesses. Open disposal sites also face management challenges as communities around are against their location. Therefore, there is need for Counties to undertake research and identify suitable areas to cite waste management facilities.
- There is minimal prioritization for waste management in the counties has led to inadequate budgetary allocation. As a result, management of the entire waste management cycle (collection, transportation, and disposal) is hampered. Low funding has also affected investment in waste management facilities and equipment.

3.4.9.2 Healthcare Waste Management

Kenya's medical waste management baseline is provided in *annex B ICWMP*.

3.4.9.3 E- waste Management

According to the Global E-Waste Monitor report of 2020, a record 53.6 million metric tonnes of electronic waste was generated worldwide in 2019, up 21 percent in just five years. The report predicts global e-waste will reach 74 metric tonnes by 2030, making e-waste the world's fastest-growing domestic waste stream, fuelled mainly by higher consumption rates of electric and electronic equipment, short life cycles, and few options for repair.

In Kenya, an average of 3,000 tonnes of e-waste is generated each year with 99% of the total e-waste ends up in the informal sector where it's disposed in an unhealthy way.

3.4.10 Health

Kenya has an estimated population of 47,564,296 million, 75% in rural areas (see Annex II). Roughly 46% of the country's population live below the poverty line. The country's Gross Domestic Product (GDP) per capita is US$ 1377. With a Gini coefficient estimated at 0.445, nearly half of Kenyans (46%) live below the poverty line In Kenya, 75% of the population have received some formal education – 52% with primary education and 23% with secondary education and above. The main source of employment is agriculture at 32.0%, while 23.7% have wage employment. According to the Kenya Health Policy (2014–2030), the 10 leading causes of death in Kenya are HIV-related ailments (29%), perinatal conditions (9%), lower respiratory tract infections (8%), tuberculosis (6%), diarrheal diseases (6%), malaria (5%), cerebrovascular diseases (3%), ischemic heart disease (3%), road traffic accidents (2%) and violence (2%). The country has made remarkable progress in improving key health indicators over recent years. The government's health goal is attainment of universal health care coverage (UHC)

for key services, including maternal, neonatal and child health services. Public primary health facilities have been reported to be pro-poor, particularly across rural locations. Neonatal mortality rates are higher among women aged under 20 years (20 per 1000 live births) than for those aged above 20 years. The risk of losing a child during birth is lower among educated women (11 per 1000 live births, compared to 15 per 1000 for women with no education). The rate for delivery by a skilled attendant is lower in rural areas (94%, compared to 98% in urban areas). Immunization coverage stands at over 70%, with higher coverage among urban residents (78%, compared to 73% for rural locations).

There are approximately 5,000 health facilities in Kenya. Hospitals in Kenya are classified according to the agency that owns the health facility. Such agencies include the government, which manages public health institutions, faith-based organizations (FBOs), non-governmental organizations (NGOs) and private investors. The Kenya government runs 48% of hospitals, 35 % is managed by the private sector, 15% by FBOs and 2% are managed by NGOs. Kenya has two national hospitals namely, the Kenyatta National Hospital and Moi Teaching and Referral Hospital.

3.4.11 Gender-based Violence

In times of public health emergencies, households are placed under serious strain, which raises the risk of domestic violence. COVID-19 is already driving this trend and if the stay-at-home orders are prolonged, it is anticipated that GBV cases will increase significantly, especially among the young people. The potential key GBV/SEA and sexual harassment (SH) risks may emerge in schools and at the workplace among contract and supply workers. It is estimated that 6.5 percent and 2.7 percent of adolescent girls and boys (aged 10-19 years of age), respectively, have been sexually abused. The potential key GBV/SEA and sexual harassment (SH) risks may emerge in schools and at the workplace among contract and supply workers. In addition, school drop-out, particularly for girls and child labour are likely to increase because of limited economic opportunities and incomes at the household level. The proposed GBV interventions will build on the current framework being used by SEQIP to report, manage, and monitor GBV incidents on the project. Details on the GBV/SEA and mitigation measures are contained in the GBV Action Plan attached in *Annex D*.

3.4.12 Safety and security

Overlapping roles, tensions, and mistrust between various security stakeholders in counties, including county governments, National Government Administration Office, and the police have created security gaps. Youth unemployment and lack of sustainable livelihood opportunities in both rural and urban counties remain a serious challenge contributing to criminal activities among the youth in Kenya. Criminal activities such as drug abuse, gangsterism, banditry and terrorism are commonly practiced by the unemployed youth in Kenya.

Unresolved land disputes and tenure in various counties are also contributing factors to intra-County and inter-County conflicts[61]. The diversity among counties remains another challenge. Residents either have different ethnic backgrounds, or clan/regional divides, thus, 'indigenous' versus 'outsiders' divides among residents poses the potential for conflict among counties in Kenya.

3.4.13 Roads

Kenya has a road network of about 177,800 km out of which only 63,575 km is classified. The classified road network has increased from 41,800 km at independence to 63,575 km today, a development rate of less than 600 km per annum. During the same period, the paved road length grew from 1,811 km to 9,273 km. It is presently estimated that about 70% (44,100 km) of the classified road network is in

[61] (Mkutu, Marani, & Ruteere, 2014)

good condition and is maintainable while the remaining 30% (18,900 km) requires rehabilitation or reconstruction.

3.4.14 Access to telecommunication services

According to Communication Authority's 2019 Annual report, ICT sector has registered significant growth because of the Authority's continued provision of an enabling environment for service providers, which saw the sector grow from 11.0% in 2017 to 11.4% in 2018. This growth was catapulted by the continued uptake of mobile communication services whose subscriptions increased from 45.6 million to 52.2 million while those of broadband services increased from 20.4 million to 22.2 million in comparison to the preceding reporting period. Additionally, the number of mobile money subscriptions rose from 29.7 million the previous year to 32.6 million during the year in review. This increase was supported by the increase in the number of active mobile money transfer agents from 290,432 compared to 266,022 recorded the previous year. Consequently, the number of Kenyans accessing mobile information and communication services, mobile money services, e-commerce, high-speed Internet/ broadband services, and other ICT services have continued to grow[62].

[62] (Communications Authority, Annual Report 2018-2019)

4 POTENTIAL ENVIRONMENTAL AND SOCIAL IMPACTS AND RISKS AND MITIGATION

This section describes in general terms the potential environmental and social risks and impacts of the types of activities that will be supported by the project.

4.1 Environmental and Social Risk Classification as per the WBG's Risk Classification

Both the environmental and social risks are considered 'Substantial' for the Project.

Key environmental, health and safety risks include: a) infectious waste such as waste suspected to contain pathogens (e.g., bacteria, viruses,) in sufficient concentration or quantity to cause disease in susceptible hosts; b) pharmaceutical waste such as expired, unused, spoiled, and contaminated pharmaceutical products, drugs, vaccines, and sera that are no longer needed, including containers and other potentially contaminated materials (e.g., drug bottles vials, tubing etc.); c) chemical waste which may be toxic, corrosive, flammable, reactive, and genotoxic properties and could be generated through use of chemicals during diagnostic work, cleaning, housekeeping, and disinfection; d) general healthcare waste (including food waste and paper, plastics, cardboard); e) wastewater-contaminated wastewater may result from discharges from laboratories (e.g. microbiological cultures, stocks of infectious agents), pharmaceutical and chemical stores and cleaning activities (e.g. waste storage room); f) lack provision of adequate potable water at HCF; g) potential HCF onsite existing environmental liabilities - soil/ground water contamination, asbestos, lead based paint, PCB containing equipment; h) potential EHS impact/risks from HCF rehabilitation activities; i) air emission sources of air emissions at healthcare facilities include exhaust air from heating, ventilation, and air conditioning (HVAC) systems; ventilation of medical gases and fugitive emissions released from sources such as medical waste storage areas; and exhaust from medical waste incineration; and (j) potential bio safety and bio hazard risks related to vaccine infrastructure and risks to exposure of biological agents while transportation of samples if infectious substances are not properly packaged, marked, labelled, and documented to ensure safety and containment during the transport process.

There are also potential occupational and community health safety risks and impacts that may result from project activities. Health and safety hazards that may affect workers in healthcare facilities/diagnostic laboratories include exposure to infections and diseases, hazardous materials / waste, and radiation. Hazardous waste could be generated by pharmaceutical manufacturing. Other environmental issues associated with pharmaceuticals include air emissions and wastewater. The most significant community health and safety hazards associated with pharmaceutical manufacturing facilities occur during the operation phase and may include the threat from major accidents related to fires and explosions at the facility and potential accidental releases of finished products during their transport outside of the processing facility. Community hazards include potential infection hazards within facilities and at waste disposal sites. There are also potential risks of lack of appropriate refrigeration and related requirements for safe storage/transport of infectious substances, vaccine, and chemicals (including for transfer of care, custody, control) related storage.

The Project will not support the preparation of future infrastructure investment projects or Type -1 TAs according to OESRC Advisory Note classification. It will support Type 2 and Type 3 TAs which include support for the formulation of plans, strategies or legal frameworks as well as strengthening borrower capacities. Downstream, the Type-2 TAs to be supported by the project may lead to an increase in incidence the EHS risks identified above ((a) -(j)). The environmental risk of the project is therefore rated as substantial at this stage. However, this could be adaptively changed if larger pharmaceutical manufacturing facilities with potential higher EHS risks will be supported by the project.

Social risks are 'substantial' due to: a) security – potential conflict, and violence in parts of Kenya (PoE) could put project investments, services, and staff at risk and disrupt project implementation, communication, and monitoring; b) labour and working conditions risks include recruitment and employment discrimination, employer lack of compliance with terms and conditions of employment, occupational health and safety violations, and failure to provide project workers with a dedicated worker grievance mechanism; c) Gender-Based Violence (GBV); and d) community health and safety.

One (1) in three (3) Kenyan females has experienced sexual violence before attaining the age of 18, and between 39% and 47% of Kenyan women experience GBV in their lifetime. The project will have minimal civil works in public hospitals with limited number of workers. There is capacity in management of GBV/SEA-SH cases within the MoH following implementation of Kenya COVID-19 Emergency Response Project (P173820) using the ESF which mitigated these risks. Hence, the SEA/SH risk of the project on Kenya side is rated as moderate. The SEP contains consultation and information disclosure specifically to address SEA/SH related issues.

Potential exclusion of underserved communities relates to the risk of inequity in sharing of project benefits due to low capacity, weak infrastructure, and insecurity for communities in historically underserved (covered under ESS7) in Kenya and inaccessible/remotely located communities. Other vulnerable groups such as internally displaced persons, persons with disability, refugees and women may also be excluded from project benefits.

4.2 Subproject E&S Impacts and Risks and Mitigation

The following tables present specific impacts and risks per project activity and recommended mitigation measures. The tables cover the following:

- Table 4.1 – E&S Impacts and Risks Associated with Technical Assistance Activities;
- Table 4.2 – E&S Impacts and Risks from Pharmaceutical Production (Construction and Operation Phases); and
- Table 4.3 – E&S Impacts and Risks from Other Project Activities e.g., Labs, etc. (Construction and Operation Phases).

Annex F, on the other hand, shows a sample environmental and social management plan (ESMP) for some project impacts. It should be noted that the ESMP is a generic. It should be copied but customized to specific subprojects circumstances, risks, and impacts.

Table 4-1 E&S Impacts and Risks Associated with Technical Assistance Activities

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
Component 1: Strengthening Capacity for Local Manufacturing	Sub-Component 1.1: Human Resources Capacity, Learning, Development, and Technology Transfer	Risks related to labor and working conditions e.g., discrimination, SEAH, GBV, etc.	• Terms of reference (TOR), for defining the scope and outputs will be drafted so that the recruitment, training, knowledge exchange and technology transfer, and other technical assistance provided is consistent with ESSs 1-10. • Staff to sign a code of conduct. • Implement Labour Management Plan (LMP). • Implement GBV Action Plan
		OHS risks for working at buildings (including related to natural and man-made disasters) and travel.	Implement emergency response plan
		Risk of staff turnover	• Introduce competitive salary scale and competitive compensation packages to recruit and retain competent technical staff. • Provide requisite resources and support for staff well-being to mitigate the effects of working in high stress environments. • Provide opportunities for career growth and advancement.
	Sub-Component 1.2: Strengthen the Regulatory Capacity of the Pharmacy and Poisons Board (PPB)	Risks related to inadequate stakeholder engagement	• TORs should ensure that the planning process includes adequate assessment of E&S implications and that the advice provided through the TA for addressing those implications is consistent with the ESF. • Follow the guidance of the SEP. • Follow government policy on gender and other forms of social inclusion, as stated in policy and legal frameworks of this ESMF. • Conduct periodic and specific field identification of key issues of exclusion, discrimination and marginalization of women and other vulnerable groups through social inclusion analysis and impact assessment. • Assess the constraints, and opportunities in the Program for encouraging involvement of these groups.

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Assess the organizational capacities of the implementing organizations and develop Action Plan to ensure that these groups benefit equally from subproject interventions. • Utilize community structures and local administration to mobilize minority groups to participate in meetings and consultations. • Minimize the risk by ensuring inclusive, participatory, and informed consultation and information disclosure. • Provide local language interpreters to ensure understanding and ability to give feedback during engagement. • Target women and youth in project consultations and activities for their meaningful inclusion in project decisions. • Ensure involvement of women in the design of mechanisms for proactive risk communication and event-based surveillance activities.
		Procurement of substandard goods and equipment	• Adhere to the procurement plan for acquisition of all medical supplies and equipment from certified suppliers only. • Carry out due diligence for all potential suppliers to guarantee quality equipment and products. • Implement good EHS management and use of procured goods and equipment
		Biosecurity and biosafety risk due to simulation of lot releases	• Follow the guidance of subproject specific ICWMP and appropriate emergency response plans/procedures. • Conduct site-specific risk and hazard assessments to evaluate all the potential threats. • If the nature of the activity permits, use of any harmful biological agents should be avoided and replaced with an agent that, under normal conditions of use, is not dangerous or less dangerous to workers. If use of harmful agents cannot be avoided, precautions should be taken to keep the risk of exposure as low as possible and maintained below internationally established and recognized exposure limits. • Work processes, engineering, and administrative controls should be designed, maintained, and operated to avoid or minimize release of

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			biological agents into the working environment. The number of employees exposed or likely to become exposed should be kept at a minimum. • The employer should review and assess known and suspected presence of biological agents at the place of work and implement appropriate safety measures, monitoring, training, and training verification programs. • Measures to eliminate and control hazards from known and suspected biological agents at the place of work should be designed, implemented, and maintained in close co-operation with the local health authorities and according to recognized international standards. • The employer should always encourage and enforce the highest level of hygiene and personal protection. • HVAC systems should be equipped with High Efficiency Particulate Air (HEPA) filtration systems.
		Risks related to labor and working conditions	• Terms of reference (TOR), for defining the scope and outputs will be drafted so that the recruitment, training, knowledge exchange and technology transfer, and other technical assistance provided is consistent with ESSs 1-10. • Staff to sign a code of conduct. • Implement Labour Management Plan (LMP). • Implement GBV Action Plan
	Sub-component 1.3: Strengthening Quality Control (QC)/Assurance e.g., expanding the capacity of the NQCL for pharmaceutical product testing.	Risks related to labor and working conditions	• Terms of reference (TOR), for defining the scope and outputs will be drafted so that the recruitment, training, knowledge exchange and technology transfer, and other technical assistance provided is consistent with ESSs 1-10. • Staff to sign a code of conduct. • Implement Labour Management Plan (LMP). • Implement GBV Action Plan
		OHS risks for working at buildings (including related to natural and	Implement emergency response plan

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
		man-made disasters) and travel.	
		Risk of staff turnover	• Introduce competitive salary scale and competitive compensation packages to recruit and retain competent technical staff. • Provide requisite resources and support for staff well-being to mitigate the effects of working in high stress environments. • Provide opportunities for career growth and advancement.
Component 2: Strengthening Capacity of the National Public Health Institute	Subcomponent 2.1: Development of statutory instruments including organization structure, staff establishment report, and human resources and procedures manual.	Risk of non-compliance with Bank ESF	Terms of reference (TOR), for defining the scope and outputs, should be drafted so that technical assistance provided is consistent with ESSs 1-10.
	Subcomponent 2.2: Strengthening human resources capacity through training, learning exchange programs with a well-functioning equivalent institution.	Risks related to labor and working conditions	• Terms of reference (TOR), for defining the scope and outputs will be drafted so that the recruitment, training, knowledge exchange and technology transfer, and other technical assistance provided is consistent with ESSs 1-10. • Staff to sign a code of conduct. • Implement Labour Management Plan (LMP). • Implement GBV Action Plan
		OHS risks for working at buildings (including related to natural and man-made disasters) and travel.	• Implement emergency response plan

Table 4-2 E&S Impacts and Risks from Pharmaceutical Production (Construction and Operation Phases)

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
Construction Phase			
Component 1: Strengthening Capacity for Local Manufacturing	Sub-component 1.3: Strengthening Quality Control (QC)/Assurance Sub-component 1.4: Establishing Capacity for F&F for human vaccines	Environmental impacts and risks due to construction works needed at the KBI.	Preparation and implementation of ESMP and C-ESMP for construction phase. **Noise and vibration** • Planning activities in consultation with local communities/neighbours • Using noise control devices, such as temporary noise barriers and deflectors for impact and blasting activities, and exhaust muffling devices for combustion engines. • Avoiding or minimizing project transportation through community areas. • Provide PPE to project workers e.g., earmuffs, etc. and enforce usage. **Air emissions and ambient air quality** • Minimizing dust from material handling sources, such as bins, by using covers and/or control equipment (water suppression, bag house, or cyclone) • Minimizing dust from open area sources, including storage piles, by using control measures such as installing enclosures and covers, and increasing the moisture content • Dust suppression techniques should be implemented, such as applying water or non-toxic chemicals to minimize dust from vehicle movements • Avoiding open burning of solid waste. **Solid waste** • Establishing waste management priorities at the outset of activities based on an understanding of potential EHS risks and impacts and considering waste generation and its consequences • Establishing a waste management hierarchy that considers prevention, reduction, reuse, recovery, recycling, removal and finally disposal of wastes. • Avoiding or minimizing the generation waste materials, as far as practicable

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Where waste generation cannot be avoided but has been minimized, recovering and reusing waste • Where waste can not be recovered or reused, treating, destroying, and disposing of it in an environmentally sound manner. **Hazardous materials** • Providing adequate secondary containment for fuel storage tanks and for the temporary storage of other fluids such as lubricating oils and hydraulic fluids • Using impervious surfaces for refuelling areas and other fluid transfer areas • Training workers on the correct transfer and handling of fuels and chemicals and the response to spills • Providing portable spill containment and clean-up equipment on site and training in the equipment deployment • Assessing the contents of hazardous materials and petroleum-based products in building systems • Assessing the presence of hazardous substances in or on building materials (e.g., polychlorinated biphenyls, asbestos- containing flooring or insulation) and decontaminating or properly managing contaminated building materials.
		OHS impacts and risks due to due to construction works needed at the KBI.	**Over-exertion** • Training of workers in lifting and materials handling techniques in construction and decommissioning projects, including the placement of weight limits above which mechanical assists or two-person lifts are necessary • Planning work site layout to minimize the need for manual transfer of heavy loads

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Selecting tools and designing work stations that reduce force requirements and holding times, and which promote improved postures, including, where applicable, user adjustable work stations • Implementing administrative controls into work processes, such as job rotations and rest or stretch breaks **Slips and falls** • Implementing good house-keeping practices, such as the sorting and placing loose construction materials or demolition debris in established areas away from foot paths • Cleaning up excessive waste debris and liquid spills regularly • Locating electrical cords and ropes in common areas and marked corridors • Use of slip retardant footwear **Work at heights** • Training and use of temporary fall prevention devices, such as rails or other barriers able to support a weight of 90 kilograms, when working at heights equal or greater than two meters or at any height if the risk includes falling into operating machinery, into water or other liquid, into hazardous substances, or through an opening in a work surface • Training and use of personal fall arrest systems, such as full body harnesses and energy absorbing lanyards able to support 2,300 kilograms (also described in this section in Working at Heights above), as well as fall rescue procedures to deal with workers whose fall has been successfully arrested. The tie in point of the fall arresting system should also be able to support 2,300 kilograms • Use of control zones and safety monitoring systems to warn workers of their proximity to fall hazard zones, as well as securing, marking, and labeling covers for openings in floors, roofs, or walking surfaces. **Struck by objects**

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Using a designated and restricted waste drop or discharge zones, and/or a chute for safe movement of wastes from upper to lower levels • Conducting sawing, cutting, grinding, sanding, chipping or chiseling with proper guards and anchoring as applicable • Maintaining clear traffic ways to avoid driving of heavy equipment over loose scrap • Use of temporary fall protection measures in scaffolds and out edges of elevated work surfaces, such as hand rails and toe boards to prevent materials from being dislodged • Wearing appropriate PPE, such as safety glasses with side shields, face shields, hard hats, and safety shoes **Moving Machinery** • Planning and segregating the location of vehicle traffic, machine operation, and walking areas, and controlling vehicle traffic through the use of one-way traffic routes, establishment of speed limits, and on-site trained flag-people wearing high-visibility vests or outer clothing covering to direct traffic • Ensuring the visibility of personnel through their use of high visibility vests when working in or walking through heavy equipment operating areas, and training of workers to verify eye contact with equipment operators before approaching the operating vehicle • Ensuring moving equipment is outfitted with audible back-up alarms • Using inspected and well-maintained lifting devices that are appropriate for the load, such as cranes, and securing loads when lifting them to higher job-site elevations. **Dust** • Dust suppression techniques should be implemented, such as applying water or non-toxic chemicals to minimize dust from vehicle movements • PPE, such as dusk masks, should be used where dust levels are excessive.

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
		Community Health and Safety (CHS) impacts and risks due to construction works at KBI.	**General Site Hazards** • Restricting access to the site, through a combination of institutional and administrative controls, with a focus on high risk structures or areas depending on site-specific situations, including fencing, signage, and communication of risks to the local community • Removing hazardous conditions on construction sites that cannot be controlled affectively with site access restrictions, such as covering openings to small confined spaces, , or locked storage of hazardous materials **Community exposure to health issues** • Prevention of larval and adult propagation through sanitary improvements and elimination of breeding habitats close to human settlements. • Elimination of unusable impounded water • Implementation of integrated vector control programs • Promoting use of repellents, clothing, netting, and other barriers to prevent insect bites. • Collaboration and exchange of in-kind services with other control programs in the project area to maximize beneficial effects. • Educating project personnel and area residents on risks, prevention, and available treatment • Monitoring communities during high-risk seasons to detect and treat cases. **Traffic and road safety** Road safety initiatives proportional to the scope and nature of project activities should include: • Identify, evaluate, and monitor the potential traffic and road safety risks to workers, affected communities and road users through-out the project life cycle and, where appropriate, develop measures and plans to address them. • Driving for work policy • Signage – collaboration with local community

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Erection of bumps • Registered vehicles and drivers • Regular maintenance of vehicles • Minimizing pedestrian interaction with construction vehicles • Use of locally available materials • Coordination with emergency responders to ensure that appropriate first aid is provided in the event of accidents. ***Infrastructure and equipment design and safety*** • Design, construct, operate, and decommission the structural elements of the project in accordance with GOK requirements, the WBG EHSGs and other GIIP, taking into consideration safety risks to third parties and affected communities. • Structural elements of a project will be designed and constructed by competent professionals and certified or approved by competent authorities or professionals. Structural design will take into account climate change considerations, as appropriate. • Where technically and financially feasible, apply the concept of universal access to the design and construction of buildings and structures. ***Management and safety of hazardous materials*** • Avoid or minimize the potential for community exposure to hazardous materials and substances that may be released by the project. • Where hazardous materials are part of existing project infrastructure or components, the project will exercise due care during construction and implementation of the project, including decommissioning, to avoid exposure to the community • Implement measures and actions to control the safety of deliveries of hazardous materials, and of storage, transportation and disposal of hazardous materials and wastes, and implement measures to avoid or control community exposure to such hazardous material.

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			Emergency preparedness and response • Identify and implement mea- sures to address emergency events. • Conduct a risk hazard assessment (RHA), as part of the environmental and social assessment undertaken pursuant to ESS1. Prepare an Emergency Response Plan (ERP) based on the results of the RHA. implementation; and (h) measures for restoration and cleanup of the environment following any major accident. • Document emergency preparedness and response activities, resources, and responsibilities, and disclose appropriate information, as well as any subsequent material changes thereto, to affected communities, relevant government agencies, or other relevant parties.
Operations Phase			
Component 1: Strengthening Capacity for Local Manufacturing	Sub-component 1.3: Strengthening Quality Control (QC)/Assurance Sub-component 1.4: Establishing Capacity for F&F for human vaccines	Environmental impacts and risks due to KBI operations.	Preparation and implementation of KBI EHS Management Plan for operation and maintenance phase **Air emissions** <u>*Volatile Organic Compounds (VOC)*</u> • Venting of emissions from sterilization chambers into control devices such as carbon adsorption or catalytic converters. • Condensation and distillation of solvents emitted from reactors or distillation units. Possible installation of cryogenic condensers, reducing the gas stream temperature below dew point to achieve higher VOC recovery efficiencies. • Installation of wet scrubbers (or gas absorbers), which may remove VOCs as well as other gaseous pollutants from a gas stream, and addition of hypochlorite to the scrubber in order to reduce emissions of nuisance odors. • Installation of activated carbon adsorption or destructive control devises such as thermal oxidation / incineration, catalytic incinerators, enclosed oxidizing flares, or other methods <u>*Particulate Matter (Dust)*</u>

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Collection with air filtration units and recycling of particulate matter into the formulation process (e.g., tablet dust), depending on batch record requirements and on process characteristics. • Installation of dedicated filtration systems (sometimes double stages of filtration) in granulation equipment. An abatement room should be also provided where the particulate is removed from the air, decreasing flow speed. • Installation of high efficiency particulate air (HEPA) filters in the heating, ventilating and air conditioning (HVAC) systems to control particulate matter emissions internally and externally as well as to prevent indoor cross-contamination. Air ducts should be segregated to prevent air cross-contamination from different processes and to ease the air stream treatment. • Collection of particulates through air filtration units, typically baghouse / fabric filters. • Depending on the volume of emissions and prevailing size of particulate matter, additional particulate emissions control methods should be considered, such as wet scrubbing and wet electrostatic precipitators, especially after combustion / thermal oxidation treatments. *Odors* • Considering the location of new facilities, considering proper distances to neighbors and the propagation of odors. • Post-combustion of venting gases. • Use of exhaust stack heights that are consistent with practices as described in the General EHS Guidelines. • Use of wet scrubbers to remove odors with a high affinity to water. • Condensation of vapors combined with scrubbers. **Wastewater** • Material substitution, especially adoption of biodegradable water-based materials for organic solvent-based materials (e.g., in tablet coating). • Condensation and separation processes to recover used solvents and aqueous ammonia, including:

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Low-boiling compounds from wastewater stream by fractioned distillation • VOC from wastewater stream by inert gas stripping and condensation • Solvent extraction of organic compounds (e.g., high or refractory halogenated compounds and high COD loads) • Combination of solvent waste streams to optimize treatment. **Solid and Hazardous waste** • Prepare and implement a site-specific ICWMP for KBI. • Waste reduction by material substitution (e.g., use of water-based solvents, etc.). • Waste disposal of equipment • Process modifications (e.g., continuous rather than batch operations to reduce spillage and other material losses). • Spent solvent recycling and reuse, through distillation, evaporation, decantation, centrifugation, and filtration. • Other potential recovery options should be investigated, including inorganic salts recovery from chemical liquors produced during organic synthesis operations, high organic matter materials from biological extraction, and filter cakes from fermentation. • Potentially pathogenic waste from biotechnology manufacturing should be inactivated through sterilization or chemical treatment before final disposal. • Hazardous and non-hazardous industrial wastes should be stored, transported, and managed as described in the relevant sections of the General EHS Guidelines.
		OHS impacts and risks due to KBI operations.	**Exposure to hazardous materials and waste** • Replacement of the hazardous substance with a less hazardous substitute • Implementation of engineering and administrative control measures to avoid or minimize the release of hazardous substances into the work environment keeping the level of exposure below internationally established or recognized limits

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Keeping the number of employees exposed, or likely to become exposed, to a minimum • Communicating chemical hazards to workers through labeling and marking according to national and internationally recognized requirements and standards, including the International Chemical Safety Cards (ICSC), Materials Safety Data Sheets (MSDS), or equivalent. Any means of written communication should be in an easily understood language and be readily available to exposed workers and first-aid personnel • Training workers in the use of the available information (such as MSDSs), safe work practices, and appropriate use of PPE **Air quality** • Maintaining levels of contaminant dusts, vapors, and gases in the work environment at concentrations below those recommended by the ACGIH68 as TWA-TLV's (threshold limit value)—concentrations to which most workers can be exposed repeatedly (8 hours/day, 40 hrs/week, week-after-week), without sustaining adverse health effects. • Developing and implementing work practices to minimize release of contaminants into the work environment including: o Direct piping of liquid and gaseous materials o Minimized handling of dry powdered materials; o Enclosed operations o Local exhaust ventilation at emission / release points o Vacuum transfer of dry material rather than mechanical or pneumatic conveyance o Indoor secure storage, and sealed containers rather than loose storage • Where ambient air contains several materials that have similar effects on the same body organs (additive effects), taking into account combined exposures using calculations recommended by the ACGIH69

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures

			• Where work shifts extend beyond eight (8) hours, calculating adjusted workplace exposure criteria recommended by the ACGIH70
			
			Fire and explosions
			• Storing flammables away from ignition sources and oxidizing materials. Further, flammables storage area should be:
			  ○ Remote from entry and exit points into buildings
			  ○ Away from facility ventilation intakes or vents
			  ○ Have natural or passive floor and ceiling level ventilation and explosion venting
			  ○ Use spark-proof fixtures
			  ○ Be equipped with fire extinguishing devices and self- closing doors, and constructed of materials made to withstand flame impingement for a moderate period of time
			• Providing bonding and grounding of, and between, containers and additional mechanical floor level ventilation if materials are being, or could be, dispensed in the storage area
			• Where the flammable material is mainly comprised of dust, providing electrical grounding, spark detection, and, if needed, quenching systems
			• Defining and labeling fire hazards areas to warn of special rules (e.g. prohibition in use of smoking materials, cellular phones, or other potential spark generating equipment)
			• Providing specific worker training in handling of flammable materials, and in fire prevention or suppression
			• Installation of smoke alarms and sprinkler systems;
			• Maintenance of all fire safety systems in proper working order, including self-closing doors in escape routes and ventilation ducts with fire safety flaps;

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Training of staff for operation of fire extinguishers and evacuation procedures; • Development of facility fire prevention or emergency response and evacuation plans with adequate guest information. **Biological Hazards** • If the nature of the activity permits, use of any harmful biological agents should be avoided and replaced with an agent that, under normal conditions of use, is not dangerous or less dangerous to workers. If use of harmful agents cannot be avoided, precautions should be taken to keep the risk of exposure as low as possible and maintained below internationally established and recognized exposure limits. • Work processes, engineering, and administrative controls should be designed, maintained, and operated to avoid or minimize release of biological agents into the working environment. The number of employees exposed or likely to become exposed should be kept at a minimum. • The employer should review and assess known and suspected presence of biological agents at the place of work and implement appropriate safety measures, monitoring, training, and training verification programs. • Measures to eliminate and control hazards from known and suspected biological agents at the place of work should be designed, implemented and maintained in close co-operation with the local health authorities and according to recognized international standards. • The employer should at all times encourage and enforce the highest level of hygiene and personal protection. • HVAC systems should be equipped with High Efficiency Particulate Air (HEPA) filtration systems. **Heat**

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Steam and thermal fluid pipelines should be insulated, marked, and regularly inspected; • Steam vents and pressure release valves should be directed away from areas where workers have access; • High temperature areas of presses should be screened to prevent ingress of body parts. **Chemical Safety** • Worker training • Work permit systems • Use of personal protective equipment (PPE) • Toxic gas detection systems with alarms • Use of partitioned workplace areas with good dilution ventilation and / or differential air pressures • When toxic materials are handled, laminar ventilation hoods or isolation devices should be installed • Manufacturing areas should be equipped with suitable heating ventilation and air conditioning (HVAC) systems designed according to current Good Manufacturing Practice (cGMP) protocols, including use of high efficiency particulate air (HEPA) filters in ventilation systems, particularly in sterile product manufacturing areas • Use of gravity charging from enclosed containers and vacuum, pressure, and pumping systems during charging and discharging operations to minimize fugitive emissions • Use of local exhaust ventilation (LEV) with flanged inlets to capture fugitive dusts and vapors released at open transfer points • Conducting liquid transfer, liquid separation, solid and liquid filtration, granulation, drying, milling, blending, and compression in work areas with good dilution and LEV

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Enclosing of granulators, dryers, mills, and blenders, and venting to air-control devices • Use of dust and solvent containment systems in tablet presses, tablet-coating equipment, and capsule-filling machines. Tablet-coating equipment should be vented to VOC emission control devices • Whenever possible, less hazardous agents should be selected in all processes (e.g., alcohols and ammonium compounds in sterilization processes) • Sterilization vessels should be in separate areas with remote instrument and control systems, non- recirculated air, and LEV to extract toxic gas emissions. Gas sterilization chambers should be evacuated under vacuum and purged with air to minimize fugitive workplace emissions before sterilized goods are removed • Use vacuuming equipment with HEPA filters and wet mopping instead of dry sweeping and blowing of solids with compressed air. **Noise and excessive vibration** • No employee should be exposed to a noise level greater than 85 dB(A) for a duration of more than 8 hours per day without hearing protection. In addition, no unprotected ear should be exposed to a peak sound pressure level (instantaneous) of more than 140 dB(C). • The use of hearing protection should be enforced actively when the equivalent sound level over 8 hours reaches 85 dB(A), the peak sound levels reach 140 dB(C), or the average maximum sound level reaches 110dB(A). Hearing protective devices provided should be capable of reducing sound levels at the ear to at least 85 dB(A). • Although hearing protection is preferred for any period of noise exposure more than 85 dB(A), an equivalent level of protection can be obtained, but less easily managed, by limiting the duration of noise exposure. For every 3

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			dB(A) increase in sound levels, the 'allowed' exposure period or duration should be reduced by 50 percent. • Prior to the issuance of hearing protective devices as the final control mechanism, use of acoustic insulating materials, isolation of the noise source, and other engineering controls should be investigated and implemented, where feasible • Periodic medical hearing checks should be performed on workers exposed to high noise levels **Ergonomics, Repetitive Motion, Manual Handling** • Facility and workstation design with 5th to 95th percentile operational and maintenance workers in mind • Use of mechanical assists to eliminate or reduce exertions required to lift materials, hold tools and work objects, and requiring multi-person lifts if weights exceed thresholds • Selecting and designing tools that reduce force requirements and holding times, and improve postures • Providing user adjustable work stations • Incorporating rest and stretch breaks into work processes, and conducting job rotation • Implementing quality control and maintenance programs that reduce unnecessary forces and exertions • Taking into consideration additional special conditions such as left-handed persons **Road Safety Risks** Measures for measures for workers that are travelling (via road) • Road safety training • Induction of all project staff on their roles and responsibilities relating to road safety

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures

			Measures for truck drivers
			• Adoption of best transport safety practices across all aspects of project operations with the goal of preventing traffic accidents and minimizing injuries suffered by project personnel and the public. Measures should include:
			  ○ Emphasizing safety aspects among drivers
			  ○ Improving driving skills and requiring licensing of drivers
			  ○ Adopting limits for trip duration and arranging driver rosters to avoid overtiredness
			  ○ Avoiding dangerous routes and times of day to reduce the risk of accidents
			  ○ Use of speed control devices (governors) on trucks, and remote monitoring of driver actions
			• Regular maintenance of vehicles and use of manufacturer approved parts to minimize potentially serious accidents caused by equipment malfunction or premature failure.
			• Employing safe traffic control measures, including road signs and flag persons to warn of dangerous conditions
			• ERP training
			• Driving for work policy
			
			Process Safety
			• Physical hazard testing of materials and reactions;
			• Hazard analysis studies to review the process chemistry and engineering practices, including thermodynamics and kinetics;
			• Examination of preventive maintenance and mechanical integrity of the process equipment and utilities;
			• Worker training; and

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Development of operating instructions and emergency response procedures. **Personal Protective Equipment (PPE)** • Active use of PPE if alternative technologies, work plans or procedures cannot eliminate, or sufficiently reduce, a hazard or exposure • Identification and provision of appropriate PPE that offers adequate protection to the worker, co-workers, and occasional visitors, without incurring unnecessary inconvenience to the individual • Proper maintenance of PPE, including cleaning when dirty and replacement when damaged or worn out. Proper use of PPE should be part of the recurrent training programs for employees • Selection of PPE should be based on the hazard and risk ranking described earlier in this section, and selected according to criteria on performance and testing established.
		CHS (ESS4) impacts and risks due to KBI operations.	**Major Hazards** • Facility-wide risk analysis, including a detailed consequence analysis for events with a likelihood above 10-6/year (e.g. HAZOP, HAZID, or QRA); • Employee training on operational hazards; • Procedures for management of change in operations, process hazard analysis, maintenance of mechanical integrity, pre-start review, hot work permits, and other essential aspects of process safety included in the General EHS Guidelines; • Safety Transportation Management System as noted in the General EHS Guidelines, if the project includes a transportation component for raw or processed materials; • Procedures for handling and storage of hazardous materials; • Emergency planning, which should include, at a minimum, the preparation and implementation of an Emergency Management Plan prepared with the participation of local authorities and potentially affected communities.

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			Safety of services Establish and implement appropriate quality management systems to anticipate and minimize risks and impacts that such services may have on community health and safety. Consider applying the concept of universal access, where technically and financially feasible.

Table 4-3 E&S Impacts and Risks from Other Project Activities e.g., Labs, POEs Rehabilitation, etc. (Construction and Operation Phases)

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
Construction Phase			
Component 1: Strengthening Capacity for Local Manufacturing	Sub-component 1.3: Strengthening Quality Control (QC)/Assurance	Environmental impacts and risks due to any necessary construction/rehabilitation works needed at NQCL and other laboratories.	• Preparation and implementation of ESMP and C-ESMP for construction phase. **Noise and vibration** • Planning activities in consultation with local communities/neighbours • Using noise control devices, such as temporary noise barriers and deflectors for impact and blasting activities, and exhaust muffling devices for combustion engines. • Avoiding or minimizing project transportation through community areas. • Provide PPE e.g., earmuffs and enforce usage.

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			Air emissions and ambient air quality • Minimizing dust from material handling sources, such as bins, by using covers and/or control equipment (water suppression, bag house, or cyclone) • Minimizing dust from open area sources, including storage piles, by using control measures such as installing enclosures and covers, and increasing the moisture content • Dust suppression techniques should be implemented, such as applying water or non-toxic chemicals to minimize dust from vehicle movements • Selectively removing potential hazardous air pollutants, such as asbestos, from existing infrastructure prior to demolition • Avoiding open burning of solid waste. **Solid waste** • Establishing waste management priorities at the outset of activities based on an understanding of potential Environmental, Health, and Safety (EHS) risks and impacts and considering waste generation and its consequences • Establishing a waste management hierarchy that considers prevention, reduction, reuse, recovery, recycling, removal and finally disposal of wastes. • Avoiding or minimizing the generation waste materials, as far as practicable • Where waste generation cannot be avoided but has been minimized, recovering and reusing waste • Where waste cannot be recovered or reused, treating, destroying, and disposing of it in an environmentally sound manner.

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			Hazardous materials • Providing adequate secondary containment for fuel storage tanks and for the temporary storage of other fluids such as lubricating oils and hydraulic fluids, • Using impervious surfaces for refuelling areas and other fluid transfer areas • Training workers on the correct transfer and handling of fuels and chemicals and the response to spills • Providing portable spill containment and clean-up equipment on site and training in the equipment deployment • Assessing the contents of hazardous materials and petroleum-based products in building systems • Assessing the presence of hazardous substances in or on building materials (e.g., polychlorinated biphenyls, asbestos- containing flooring or insulation) and decontaminating or properly managing contaminated building materials
		OHS impacts and risks due to any necessary construction/rehabilitation works needed at NQCL, other laboratories, POEs, etc.	**Over-exertion** • Training of workers in lifting and materials handling techniques in construction and decommissioning projects, including the placement of weight limits above which mechanical assists or two-person lifts are necessary • Planning work site layout to minimize the need for manual transfer of heavy loads • Selecting tools and designing work stations that reduce force requirements and holding times, and which promote improved postures, including, where applicable, user adjustable work stations

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Implementing administrative controls into work processes, such as job rotations and rest or stretch breaks **Slips and falls** • Implementing good house-keeping practices, such as the sorting and placing loose construction materials or demolition debris in established areas away from foot paths • Cleaning up excessive waste debris and liquid spills regularly • Locating electrical cords and ropes in common areas and marked corridors • Use of slip retardant footwear **Work at heights** • Training and use of temporary fall prevention devices, such as rails or other barriers able to support a weight of 90 kilograms, when working at heights equal or greater than two meters or at any height if the risk includes falling into operating machinery, into water or other liquid, into hazardous substances, or through an opening in a work surface • Training and use of personal fall arrest systems, such as full body harnesses and energy absorbing lanyards able to support 2,300 kilograms (also described in this section in Working at Heights above), as well as fall rescue procedures to deal with workers whose fall has been successfully arrested. The tie in point of the fall arresting system should also be able to support 2,300 kilograms • Use of control zones and safety monitoring systems to warn workers of their proximity to fall hazard zones, as well as securing, marking, and labeling covers for openings in floors, roofs, or walking surfaces.

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			Struck by objects • Using a designated and restricted waste drop or discharge zones, and/or a chute for safe movement of wastes from upper to lower levels • Conducting sawing, cutting, grinding, sanding, chipping or chiseling with proper guards and anchoring as applicable • Maintaining clear traffic ways to avoid driving of heavy equipment over loose scrap • Use of temporary fall protection measures in scaffolds and out edges of elevated work surfaces, such as hand rails and toe boards to prevent materials from being dislodged • Wearing appropriate PPE, such as safety glasses with side shields, face shields, hard hats, and safety shoes **Moving Machinery** • Planning and segregating the location of vehicle traffic, machine operation, and walking areas, and controlling vehicle traffic using one-way traffic routes, establishment of speed limits, and on-site trained flag-people wearing high-visibility vests or outer clothing covering to direct traffic • Ensuring the visibility of personnel through their use of high visibility vests when working in or walking through heavy equipment operating areas, and training of workers to verify eye contact with equipment operators before approaching the operating vehicle • Ensuring moving equipment is outfitted with audible back-up alarms • Using inspected and well-maintained lifting devices that are appropriate for the load, such as cranes, and securing loads when lifting them to higher job-site elevations.

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			Dust • Dust suppression techniques should be implemented, such as applying water or non-toxic chemicals to minimize dust from vehicle movements • PPE, such as dusk masks, should be used where dust levels are excessive.
		Community Health and Safety (CHS) impacts and risks due to any necessary construction/rehabilitation works needed at NQCL, other laboratories, POEs, etc.	**General Site Hazards** • Restricting access to the site, through a combination of institutional and administrative controls, with a focus on high-risk structures or areas depending on site-specific situations, including fencing, signage, and communication of risks to the local community • Removing hazardous conditions on construction sites that cannot be controlled affectively with site access restrictions, such as covering openings to small confined spaces, , or locked storage of hazardous materials **Community exposure to health issues** • Prevention of larval and adult propagation through sanitary improvements and elimination of breeding habitats close to human settlements. • Elimination of unusable impounded water • Implementation of integrated vector control programs • Promoting use of repellents, clothing, netting, and other barriers to prevent insect bites. • Collaboration and exchange of in-kind services with other control programs in the project area to maximize beneficial effects. • Educating project personnel and area residents on risks, prevention, and available treatment

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Monitoring communities during high-risk seasons to detect and treat cases. **Traffic and road safety** Road safety initiatives proportional to the scope and nature of project activities should include: • Identify, evaluate and monitor the potential traffic and road safety risks to workers, affected communities and road users through-out the project life cycle and, where appropriate, develop measures and plans to address them. • Driving for work policy • Signage – collaboration with local community • Erection of bumps • Registered vehicles and drivers • Regular maintenance of vehicles • Minimizing pedestrian interaction with construction vehicles • Use of locally available materials • Coordination with emergency responders to ensure that appropriate first aid is provided in the event of accidents. ***Infrastructure and equipment design and safety*** • Design, construct, operate, and decommission the structural elements of the project in accordance with GOK requirements, the WBG EHSGs and other GIIP, taking into consideration safety risks to third parties and affected communities. • Structural elements of a project will be designed and constructed by competent professionals and certified or approved by competent authorities or professionals. Structural design will take into account climate change considerations, as appropriate.

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Where technically and financially feasible, apply the concept of universal access to the design and construction of buildings and structures. ***Safety of services*** Establish and implement appropriate quality management systems to anticipate and minimize risks and impacts that such services may have on community health and safety. Consider applying the concept of universal access, where technically and financially feasible. ***Management and safety of hazardous materials*** • Avoid or minimize the potential for community exposure to hazardous materials and substances that may be released by the project. • Where hazardous materials are part of existing project infrastructure or com-ponents, the project will exercise due care during construction and implementation of the project, including decommissioning, to avoid exposure to the community • Implement measures and actions to control the safety of deliveries of hazardous materials, and of storage, transportation and disposal of hazardous materials and wastes, and implement measures to avoid or control community exposure to such hazardous material. ***Emergency preparedness and response*** • Identify and implement measures to address emergency events. • Conduct a risk hazard assessment (RHA), as part of the environmental and social assessment undertaken pursuant to ESS1. Prepare an Emergency Response Plan (ERP) based on the results of the RHA. implementation; and (h) measures for

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			restoration and cleanup of the environment following any major accident. • Document emergency preparedness and response activities, resources, and responsibilities, and disclose appropriate information, as well as any subsequent material changes thereto, to affected communities, relevant government agencies, or other relevant parties.
Operations Phase			
Component 1: Strengthening Capacity for Local Manufacturing	Sub-component 1.3: Strengthening Quality Control (QC)/Assurance	Environmental impacts and risks due to operations of NQCL, other laboratories and project facilities.	Preparation and implementation of respective institution EHS Management Plan for operation and maintenance phase. **Waste Management** Each laboratory to develop a site-specific Healthcare Waste Management System (HWMS) following guidance of the ICWMP contained in Annex B of this report. **Emissions to Air** • Application of waste segregation and selection including removal of the following items from waste destined for incineration: halogenated plastics (e.g., PVC), pressurized gas containers, large amounts of active chemical waste, silver salts and photographic / radiographic waste, waste with high heavy metal content (e.g., broken thermometers, batteries), and sealed ampoules or ampoules containing heavy metals; • Incinerators should have permits issued by authorized regulatory agencies and be operated and maintained by trained employees to ensure proper combustion temperature, time, and turbulence specifications necessary for adequate combustion of waste. • Wet scrubbers to control acid gas emissions (e.g., hydrochloric acid [HCl)], sulfur dioxide [SO2, and fluoride compounds]). A

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			caustic scrubbing solution will increase the efficiency for SO2 control; • Control of particulate matter may be achieved through use of cyclones, fabric filters, and / or electrostatic precipitators (ESP). Efficiencies depend on the particle size distribution of the particulate matter from the combustion chamber. Particulate matter from hospital incinerators is commonly between 1.0 to 10 micrometers (µm). ESPs are generally less efficient than baghouses in controlling fine particulates and metals from HWI; • Control of volatile heavy metals depends on the temperature at which the control device operates. Fabric filters and ESP typically operate at relatively high temperatures and may be less effective than those that operate at lower temperatures. Venturi quenches and venturi scrubbers are also used to control heavy metal emissions. The volatile heavy metals usually condense to form a fume (less than 2 µm) that is only partially collected by pollution control equipment; • Management of incineration residues such as fly ash, bottom ash, and liquid effluents from flue gas cleaning as a hazardous waste (see General EHS Guidelines) as they may contain high concentrations of POPs. **Wastewater** Waste segregation measures should be employed to minimize entry of solid waste into the wastewater stream,
		OHS impacts and risks due to operations of NQCL, other laboratories and project facilities.	**Exposure to infections and diseases** • Formulate an exposure control plan for blood-borne pathogens; • Provide staff members and visitors with information on infection control policies and procedures;

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures

			• Establish Universal / Standard Precautions to treat all blood and other potentially infectious materials with appropriate precautions, including:
			  • Immunization for staff members as necessary (e.g. vaccination for hepatitis B virus)
			  • Use of gloves, masks, and gowns
			  • Adequate facilities for hand washing.
			  • Procedures and facilities for handling dirty linen and contaminated clothing, and preparing and handling food
			  • Appropriate cleaning and waste disposal practices for the health care workplace
			
			<u>*Using and handling of needles / sharps*</u>
			• Use safer needle devices and needleless devices to decrease needlestick or other sharps exposures
			• Do not bend, recap, or remove contaminated needles and other sharps unless such an act is required by a specific procedure or has no feasible alternative
			• Do not shear or break contaminated sharps
			• Have needle containers available near areas where needles may be found
			• Discard contaminated sharps immediately or as soon as feasible into appropriate containers
			• Used disposable razors should be considered contaminated waste and disposed of in appropriate sharps containers
			• Establish policies to exclude animals from facility property.

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			Personnel involved in Waste Management • Implement immunization for staff members, as necessary (e.g., vaccination for hepatitis B virus, tetanus immunization); • Provide adequate supplies of PPE for personnel involved in waste management including: overalls / industrial aprons, leg protectors, boots, heavy duty gloves, helmets, visors / face masks and eye protection (especially for cleaning of hazardous spills), and respirators (for spills or waste involving toxic dust or incinerator residue) as necessary; • Provide washing facilities for personal hygiene, particularly at waste storage locations. **Exposure to hazardous materials / waste** • Replacement of the hazardous substance with a less hazardous substitute • Implementation of engineering and administrative control measures to avoid or minimize the release of hazardous substances into the work environment keeping the level of exposure below internationally established or recognized limits • Keeping the number of employees exposed, or likely to become exposed, to a minimum • Communicating chemical hazards to workers through labeling and marking according to national and internationally recognized requirements and standards, including the International Chemical Safety Cards (ICSC), Materials Safety Data Sheets (MSDS), or equivalent. Any means of written communication should be in an easily understood language and be readily available to exposed workers and first-aid personnel

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures

			• Training workers in the use of the available information (such as MSDSs), safe work practices, and appropriate use of PPE
			
			Fire and explosions
			• Storing flammables away from ignition sources and oxidizing materials. Further, flammables storage area should be:
			  ○ Remote from entry and exit points into buildings
			  ○ Away from facility ventilation intakes or vents
			  ○ Have natural or passive floor and ceiling level ventilation and explosion venting
			  ○ Use spark-proof fixtures
			  ○ Be equipped with fire extinguishing devices and self-closing doors, and constructed of materials made to withstand flame impingement for a moderate period of time
			• Providing bonding and grounding of, and between, containers and additional mechanical floor level ventilation if materials are being, or could be, dispensed in the storage area
			• Where the flammable material is mainly comprised of dust, providing electrical grounding, spark detection, and, if needed, quenching systems
			• Defining and labeling fire hazards areas to warn of special rules (e.g. prohibition in use of smoking materials, cellular phones, or other potential spark generating equipment)
			• Providing specific worker training in handling of flammable materials, and in fire prevention or suppression
			• Installation of smoke alarms and sprinkler systems;

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Maintenance of all fire safety systems in proper working order, including self-closing doors in escape routes and ventilation ducts with fire safety flaps; • Training of staff for operation of fire extinguishers and evacuation procedures. Development of facility fire prevention or emergency response and evacuation plans with adequate guest information.
		Community Health and Safety (CHS) impacts and risks due to operations at NQCL, other laboratories, POEs, etc.	***Infrastructure and equipment design and safety*** • Design, construct, operate, and decommission the structural elements of the project in accordance with GOK requirements, the WBG EHSGs and other GIIP, taking into consideration safety risks to third parties and affected communities. • Structural elements of a project will be designed and constructed by competent professionals, and certified or approved by competent authorities or professionals. Structural design will take into account climate change considerations, as appropriate. • Where technically and financially feasible, apply the concept of universal access to the design and construction of buildings and structures. ***Safety of services*** Establish and implement appropriate quality management systems to anticipate and minimize risks and impacts that such services may have on community health and safety. Consider applying the concept of universal access, where technically and financially feasible. ***Management and safety of hazardous materials*** • Avoid or minimize the potential for community exposure to hazardous materials and substances that may be released by the project.

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			• Where hazardous materials are part of existing project infrastructure or com-ponents, the project will exercise due care during construction and implementation of the project, including decommissioning, to avoid exposure to the community • Implement measures and actions to control the safety of deliveries of hazardous materials, and of storage, transportation and disposal of hazardous materials and wastes, and implement measures to avoid or control community exposure to such hazardous material. ***Emergency preparedness and response*** • Identify and implement measures to address emergency events. • Conduct a risk hazard assessment (RHA), as part of the environmental and social assessment undertaken pursuant to ESS1. Prepare an Emergency Response Plan (ERP) based on the results of the RHA. implementation; and (h) measures for restoration and cleanup of the environment following any major accident. • Document emergency preparedness and response activities, resources, and responsibilities, and disclose appropriate information, as well as any subsequent material changes thereto, to affected communities, relevant government agencies, or other relevant parties. **Traffic Safety** • Adoption of best transport safety practices across all aspects of project operations with the goal of preventing traffic accidents and minimizing injuries suffered by project personnel and the public. Measures should include: o Emphasizing safety aspects among driver o Improving driving skills and requiring licensing of drivers

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
			○ Adopting limits for trip duration and arranging driver rosters to avoid overtiredness ○ Avoiding dangerous routes and times of day to reduce the risk of accidents ○ Use of speed control devices (governors) on trucks, and remote monitoring of driver actions • Regular maintenance of vehicles and use of manufacturer approved parts to minimize potentially serious accidents caused by equipment malfunction or premature failure
Component 2: Strengthening Capacity of the National Public Health Institute (NPHI)	Strengthening of laboratory testing and genomic surveillance capacity	Ethical concerns, privacy, and data security risks	• obtain informed consent for genetic testing. • ensure the privacy and confidentiality of individuals' genetic information.
		EHS risks related to exposure to hazardous materials	• Conduct a Hazard Assessment considering accident history in the last five years, worst case scenario, and alternative release analysis. • Identify and implement management procedures including process safety, training, management of change, incident investigation, employee participation, contractor training and oversight. • Implement prevention measures including process hazard analysis, operating procedures, mechanical integrity, pre-start review, work permit, and compliance audits. • Develop and implement an Emergency Response Program including emergency response procedures, emergency equipment, training, review, and updates. • use of PPE to minimize the risk of exposure.

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
		Environmental pollution from use of chemicals and other hazardous materials.	Follow the guidance of the ICWMP, *Annex B*.
	Development and deployment of the electronic integrated diseases surveillance and response information system (eIDSR)	Privacy and data security risks	• follow strict data security and privacy protocols, including secure storage and handling of data. • regular cybersecurity risk assessments, • ensuring the use of up-to-date software and security protocols. • ethical considerations should be considered, such as obtaining informed consent for data collection and ensuring the privacy and confidentiality of individuals' data.
		e-waste generation	• Prepare and implement an e-waste management plan for the project to ensure proper disposal of electronic devices and equipment. • Provide training and awareness on use of the e-waste management plan to project beneficiaries.
		Infrastructure requirements e.g., electricity, internet, etc.	Lobby power transmission and internet connection providers to provide reliable infrastructure in areas where eIDSR is being implemented.
	Strategic stockpiles for preparedness and response	Environmental pollution related to expired medications or outdated equipment.	• Follow the guidance of the ICWMP, *Annex B*.. • Maintain a resilient and reliable supply chain to ensure that strategic stockpiles can be effectively replenished and maintained over time. • Adhere to the procurement plan for acquisition of all medical supplies and equipment from certified suppliers only. • Carry out due diligence for all potential suppliers to guarantee quality equipment and products.
		Socio-economic risks related access to strategic stockpiles.	• Ensure that strategic stockpiles are managed and maintained in a way that is environmentally sustainable and socially equitable. • NPHI should co-opt different stakeholders in the management of strategic stockpiles to assure equitable access.
		Security risks related to vulnerability to theft, vandalism, or misuse	Collaborate with Interior Ministry to ensure security of stockpiles.

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
	Strengthening cross-border surveillance at Points of Entry	Privacy and data security risks	• cross-border surveillance efforts should be guided by ethical principles, such as the principle of informed consent. • establish strong data protection laws and data security measures to ensure that surveillance data is handled in a way that protects individuals' privacy and security.
		Cultural and linguistic risks related to misunderstandings and communication gaps	Efforts should also be made to bridge cultural and linguistic barriers to improve communication and understanding between countries.
		Political risks related to unwillingness to share data due conflicts between countries.	cross-border surveillance efforts should be depoliticized as much as possible to ensure that they are not impacted by political tensions or conflicts.
		Increased risk of disease transmission	Enforce environmental and health regulations and strict border control measures.
	Establishment of system for health workforce surge capacity	• Worker burnout and stress • Inadequate training and supervision (Suboptimal care) • Reduced quality of care • Disruption of healthcare systems • Increased transmission of infectious diseases • Risk of child and forced labour.	• Follow the guidance of the LMP, annex H. • plan and prepare for health workforce surge capacity in advance of emergencies. This includes developing training and supervision programs that can quickly prepare health workers to provide care during emergencies, as well as establishing systems for monitoring and addressing worker burnout and stress. • ensure that adequate infection control measures are in place to prevent the transmission of infectious diseases during emergency response activities. • efforts should be made to minimize disruption to healthcare systems and ensure that non-emergency patients continue to have access to care during emergencies. • Rapid training and certification • Cross-training and upskilling.
		Increased risks of GBV/SEAH	• Implement Labour Management Plan (LMP). • Implement GBV Action Plan • Staff to sign a code of conduct

Component	Subcomponent / Activity	Impacts and Risks	Recommended Mitigation Measures
Project management		Lack of Institutional Capacity	• Put in place, as a risk reduction measure, a separate environmental and social specialists at each beneficiary institution. • Deliver capacity enhancement trainings for the safeguard professionals and PMT in selected areas of safeguard management. • Deploy relevant professional staff to monitor the process of environmental and social safeguard management. • Reduce the risk by carrying out tailored and customized capacity building trainings for ESMF implementing institutions. • Making periodic assessment and understanding of the root causes of the observed problems and introduce appropriate measures to address them.
		Ineffective GRM	• Ensure the Project implements the developed grievance redress mechanism, in which potential project beneficiaries/project affected communities have reasonable representation. • Ensure multiple entries to grievance mechanism and publicise GRM including through media, training, and meetings and through communication using local languages. • Enhance the capacity of individuals who will be involved in grievance handling processes particularly at beneficiary institutions through appropriate trainings.
		The Risk of Staff Turnover	• Offer competitive salary scale and competitive compensation packages to recruit and retain competent technical staff. • Providing resources and support for staff well-being to mitigate the effects of working in high stress environments. • Provide opportunities for career growth and advancement.

5 PROCEDURES TO ADDRESS ENVIRONMENTAL AND SOCIAL ISSUES

5.1 Overview

Section Four shows that AFE HEPRR Kenya project has both positive and negative environmental and social impacts/risks. This section sets out the procedures (steps 1-7) for identifying, preparing, and implementing the project components and associated subprojects and TA activities, environmental and social screening, preparation of required E&S plans, consultation on such plans, review and approval and implementation.

The purpose of this screening process is to determine whether the activities (subprojects) are eligible to be financed or part of the exclusion list. The extent of environmental assessments that might be required prior to the commencement of the sub-projects will depend on the outcome of the screening process described below:

5.2 Environment and Social Screening Steps

The environmental and social process of screening consists of the following steps:

5.2.1 Step 1: Screening of the Sub-Projects

The objectives of environmental and social screening are: i) determine whether activities are eligible to be financed; ii) to evaluate the environmental, social, occupational safety and health risks associated with the proposed operation; iii) to determine the depth and breadth of Environmental Assessment (EA); and iv) to recommend an appropriate choice of EA instrument(s) suitable for a given project. Criteria for classification include type, location, sensitivity, and scale of the project, as well as the nature and magnitude of its potential environmental and social impacts. The initial screening for the selection of the sub-projects will be conducted based on the exclusion criteria in the Environmental and Social Commitment Plan (ESCP). The following is an exclusion list of activities that will not be financed under the project and that will be screen out:

- High risk Environment subprojects (per WB ESF and ESSs definition).
- Any technical assistance (TA) activities that are classified as Type 1 as per WB Operations Environmental and Social Review Committee (OESRC) Advisory Note.
- Activities that may cause long term, permanent and/or irreversible impacts (e.g., loss of major natural habitats including habitats of wildlife and fisheries).
- Activities that may cause any significant loss of biodiversity.
- Activities that have a high probability of causing serious adverse effects to human health and/or the environment.
- Activities that may have significant adverse social impacts and/ or may give rise to significant social conflict.
- Activities that may potentially affect the quality or quantity of water or a waterway shared with other nations.
- Activities that may involve significant land acquisition, forced eviction and involuntary physical displacement.
- Activities that would disproportionately affect the historically underserved and vulnerable groups.
- Activities that may cause damage to cultural heritage.
- Activities that may impact on known cultural heritage sites including sites that are important to local communities.

- In sum activities that may cause large-scale physical disturbance on wildlife habitat; block access to or use of water points etc. used by others; located in or adjacent to protected area, significant impact on cultural heritage; create encroachment and/or cause significant adverse impacts to critical natural habitats (e.g., wildlife reserves; parks or sanctuaries; protected areas; forests and forest reserves, wetlands, national parks or game reserve; any other ecologically/environmentally sensitive areas) and contravene international and regional conventions on environmental and social issues are not eligible for the project financing

The PMT Environment and Social specialists will then complete the Environmental and Social Screening Form (ESSF) (see *Annex A*), to facilitate identification of potential environmental and social impacts, the Environmental and Social standards relevant and assignment of appropriate environmental and social risk rating, and where required recommend the relevant due diligence actions such as preparation of ESIA, ESMP and Stakeholder Engagement Plan (SEP) as required. Finalized ESSFs will be submitted to the Bank for review and approval. In addition, each beneficiary health facility or laboratory will be required to prepare its own ESMP which includes ICWMP prepared using the guidance provided in *Annex B*.

5.2.2 Step 2: Assigning of Environmental and Social Risk Rating

Assignment of appropriate environmental and social risk rating to a particular activity will be based on information provided in the ESSF *Annex A* that the MoH Environment and social specialist will have administered.

5.2.2.1 WBG Environmental and Social Risk Classification

According to World Bank Environment and Social Framework (ESF), projects are classified as high, substantial, moderate, and low risk depending on the environmental and social sensitivity of the subproject. The Bank requires the Borrower to carry out appropriate environmental and social assessment of Projects, and prepare and implement such Projects, as follows:

a. *High Risk* subprojects, in accordance with the ESSs; and
b. *Substantial Risk, Moderate Risk* and *Low Risk* subprojects, in accordance with national law and any requirement of the ESSs that the Bank deems relevant to such subprojects.[63]

As discussed in Section 4.1, the overall environmental and social risks classification for this Project is ***Substantial***, *therefore,* appropriate environmental and social assessment for subprojects will be carried in accordance with GOK legal frameworks.

5.2.2.2 GoK Environmental and Social Risk Classification

The Second Schedule of Environmental Management and Coordination Act (EMCA) No. 8 of 1999 amended in 2019 by a regulation (Legal Notice No. 31) too adopts a risk-based reclassification of projects and facilities. *Low, medium,* and *high-risk* categories are adopted. For instance, an *activity out of character with its surrounding; and Any structure of a scale not in keeping with its surrounding* are categorized **High Risk.** Limited scale projects such as *Business premises including shops, stores, urban market sheds* are categorized **Low Risk**.

The Act and its subsidiary regulations require project proponents to carry out the following tiered environmental and social assessment:

1. *High Risk* projects – prepare and submit to NEMA headquarters, an ESIA full study report;

[63] Where subprojects are likely to have minimal or no adverse environmental or social risks and impacts, such subprojects do not require further environmental and social assessment following the initial screening.

2. *Medium Risk* projects – prepare and submit to NEMA county offices, a comprehensive ESIA project report (CPR); and
3. *Low Risk* projects – prepare and submit to NEMA county offices, a summary ESIA project report (SPR).

Subprojects involving civil works will be classified as either low or medium risk thus will require some form of Environmental and Social Impact Assessment (ESIA). The subproject ESIA will include ESMPs that should be adopted by contractors to form C-ESMP. For instance, an ESIA in accordance with Kenyan legal frameworks was prepared for the Biovax manufacturing facility, approved by the Authority (NEMA) and license issued. The subproject was classified medium risk thus a CPR was prepared.

TA activities will be assessed per WB OESRC procedure through applying strategic environmental and social analysis (SESA) tools and/or cumulative impact assessments. As with any projects to which Bank ESF applies, TA activities shall be evaluated for purposes of project risk classification in accordance with the Environmental and Social Policy paragraph 20, and Part C of the Bank Directive, Environmental and Social Directive for Investment Project Financing. The Project will not support the preparation of future infrastructure investment projects or Type -1 TAs according to OESRC Advisory Note classification. It will support Type 2 and Type 3 TAs which include support for the formulation of plans, strategies or legal frameworks as well as strengthening borrower capacities.

5.2.3 Step 3: Carrying out Environmental and Social Assessment

After analyzing data contained in the sub-project environmental and social screening form and having identified the right environmental and social risk classification and hence scope of the environmental assessment required, then MoH Environment and Social specialists will make a recommendation to the MoH as to whether: (a) no Environmental Assessment will be required; (b) implementation of mitigation measures will be required and thus development of subproject specific SPR; or (c) a detailed ESIA CPR will be carried out.

The preparation of the supplementary environmental assessment instruments ESIA and/or ESMP (Summary Project Report (SPR) based on the screening outcome will be done by a NEMA licensed Lead Expert hired by MoH. The ESMP prepared will constitute an integral part of the bidding documents for contractors carrying out civil works under the project, in addition some ESHS clauses will be included in the project bid/contract documents. The beneficiary healthcare facilities will prepare site specific EHSMP which includes ICWMP as part of ESIA/SPR. Subproject ESMPs will identify the specific monitoring measures to be performed/required.

5.2.4 Step 4: Review and Approval

The prepared environment and social instruments e.g., ESSFs, Subproject ESIA which include ESMPs, etc., will be submitted to the World Bank for prior review and no objection. The pharmaceutical production plant ESIA[64] (I.e., existing ESIA) shall also be reviewed and subjected to approval. Thereafter the World Bank and the implementing agency (MOH or beneficiary institutions) will reassess whether prior review is needed for further ESMPs or a certain category of ESMPs (for example, for activities exceeding a certain budget, for certain types of activities). For an ESIA, once World Bank has cleared, it will be submitted to NEMA for approval and licensing.

[64] The pharmaceutical plant ESIA was prepared in October 2022 and submitted to NEMA. Consequently, an ESIA license was issued. However, for this ESIA report and license to form part of the Project safeguard instruments, it should be submitted to the WB for review and no objection. Thereafter disclosed on WB, KBI, and MOH websites.

5.2.5 Step 5: Inclusion of All Necessary ESHS Terms and Conditions in Procurement Documents (Bids, Contracts)

Inclusion of all necessary ESHS terms and conditions in procurement documents (bids, contracts) based upon standard terms and conditions and any subproject specific additional requirements shall be done in this step.

The implementing agency will also complete the documentation, permits and clearances required under the government's environmental regulation before any project activities begin.

At this stage, staff who will be working on the various subproject activities should be trained in the environmental and social management plans relevant to the activities they work on. The responsible party in the implementing agency should provide such training to field staff.

The responsible party in the implementing agency should also ensure that all selected contractors, subcontractors, and vendors understand and incorporate environmental and social mitigation measures relevant to them as standard operating procedures for civil works. The responsible party in the implementing agency should provide training to selected contractors to ensure that they understand and incorporate environmental and social mitigation measures; and plan for cascading training to be delivered by contractors to subcontractors and vendors. The responsible party in the implementing agency should further ensure that the entities or communities responsible for ongoing operation and maintenance of the investment have received training on operations stage environmental and social management measures as applicable.

5.2.6 Step 6: Public Consultations and Disclosure

In carrying out ESIA evidence of comprehensive public consultation including duly signed minutes of consultation meetings with project affected persons and key stakeholders, attendance lists and filled questionnaires are required[65]. These public consultations will take place during the environmental and social screening process and during validation of the draft ESIA report, with the input from the public consultations will be reflected in the design of the mitigation and monitoring measures.

World Bank requires disclosure of the environmental assessment report both in-country by the client (MoH), in a manner accessible to all project stakeholders, and at World Bank website.

All ESIA reports in Kenya are public documents and can be accessed from NEMA's EIA licensing portal and respective county offices. Project Reports (PR) are not uploaded directly on the NEMA website (*www.nema.go.ke*) unless under request. On the website, only study reports (High Risk Projects) that are published in Kenya Gazette and in two local newspapers of national circulation to enable the public to review the report and send their views or comments to the Director General NEMA to inform decision making within 30-days of the publication in accordance with the law.

5.2.7 Step 7: Monitoring, Supervision and Reporting

During implementation, the PMT will conduct regular monitoring visits. Subproject contractors will be responsible for implementing the mitigation and monitoring measures in the E&S risk management documents, with PMT oversight.

---

[65] World Bank requires public consultations to be conducted for all EA type documents prepared under WB-financed projects (World Bank, ESS1, 2017), while NEMA requires public consultations to be conducted for Medium and High-Risk projects (NEMA, 2020).

The PMT working to implement the project will ensure that monitoring practices include the environmental and social risks identified in the ESMF and will monitor the implementation of E&S risk management mitigation plans as part of regular project monitoring.

At a minimum, the reporting will include (i) EHS performance reporting (including incident reporting) by Contractors to PMT; (ii) EHS performance reporting (including incident reporting) by entities responsible for operations/maintenance phase to PMT; (iii) EHS performance reporting (including incident reporting) by PMT to WB; (iv) community health and safety; (v) stakeholder engagement updates, in line with the SEP; (vi) public notification and communications; (vii) progress on the implementation and completion of project works; (viii) summary of grievances/beneficiary feedback received, actions taken, and complaints closed out; (ix) SEA/SH related measures and (x) implementation of security related measures, where appropriate.

Throughout the Project implementation stage, the PMT will continue to provide training and awareness raising to relevant stakeholders, such as staff, selected contractors, and communities, to support the implementation of the environmental and social risk management mitigation measures. An initial list of training needs is proposed below, in *Section 6.4*.

The PMT will also track grievances/beneficiary feedback (in line with the SEP) during project implementation to use as a monitoring tool for implementation of project activities and environmental and social mitigation measures.

Last, if the PMT becomes aware of a serious incident in connection with the project, which may have significant adverse effects on the environment, the affected communities, the public, or workers, it should notify the World Bank within 48 hours of becoming aware of such incident. A fatality is automatically classified as a serious incident, as are incidents of forced or child labor, abuses of community members by project workers (including gender-based violence incidents), violent community protests, or kidnappings.

5.2.7.1 Monitoring Indicators

The monitoring requirements and indicators will be included in the sub-project specific construction ESMP (C-ESMP) and operational phase EHS plan which includes ICWMP. The plans shall include: i) Construction management requirements ii) healthcare waste management iii) compliance with legislations, iv) Environment, Social Health, and Safety (ESHS) performance of the project, including but not limited to, stakeholder engagement activities and grievances log. Use of the indicators for environmental and social monitoring will be included in the training and capacity building program.

5.3 Social Screening Steps

Social screening will be undertaken for each sub-project at the time of project identification and before the sub-project design is finalized to identify the key social risks and outline appropriate mitigation measures. Table 5-1 illustrates the key steps to be followed in ensuring social risks are appropriately managed.

Table 5-1 Social Screening Checklist

No.	Activity	Rationale
1.	Identify the key social risks	The objectives of social screening are to assess the social risks associated with a proposed operation; to determine the depth and breadth of social assessment; and to recommend an appropriate mitigation measure. Project screening will be based on.

No.	Activity	Rationale
2.	Assign a social risk classification	Assignment of appropriate social risk classification to a particular activity will be based on information provided in the environmental and social screening form that the MoH Environment and social officers will have administered.
3.	Conduct a social assessment	If the project/sub-project is perceived to have social impacts on a community, a social management plan will be developed including consultations with different stakeholder groups. The MoH will define the ToRs which will be shared with the Bank for approval.
4.	Public consultations and disclosure	Documents, including the ESIA, ESMP, etc. conducted as part of this project will be disclosed by the World Bank on its website and by the MoH as part of public consultation process and prior to commencement of project activities.
5.	Monitoring of the social mitigation plans.	Social monitoring will be implemented to monitor the implementation of the mitigation plans. The indicators to be monitored will include: • Access to information and services for the VMGs/HULTCs • The progress in the implementation of the SEP • Grievance reporting and resolution

5.4 Review and Evaluation – E&S Completion

Upon completion of Project activities, the PMT will review and evaluate progress and completion of project activities, and all required environmental and social mitigation measures. Especially for civil works, the PMT will monitor activities regarding site restoration and landscaping in the affected areas to ensure that the activities are done to an appropriate and acceptable standard before closing the contracts, in accordance with measures identified in the ESMPs and other plans. The sites must be restored to at least the same condition and standard that existed prior to commencement of works. Any pending issues must be resolved before a subproject is considered fully completed. The PMT will prepare the completion report describing the final status of compliance with the E&S risk management measures and submit it to the World Bank.

5.5 Technical Assistance Activities

The PMT will ensure that the consultancies, studies (including feasibility studies, if applicable), capacity building, training, and any other technical assistance activities under the Project are carried out in accordance with Terms of Reference acceptable to the Bank, that are consistent with the ESSs. They will also ensure that the outputs of such activities comply with the Terms of Reference.

5.6 Contingency Emergency Response Component

The Contingency Emergency Response Components (CERC) Manual to be prepared for the Project will include a description of the environmental and social risk assessment and management arrangements if the CERC component becomes activated. This may include a CERC ESMF or an Addendum to this ESMF based on the subproject activities that will be funded under the CERC component. If such additional documentation or revision to documentation is needed, the PMT will prepare, consult,

adopt, and disclose these in accordance with the CERC Manual, and implement the measures and actions necessary.

6 STAKEHOLDER CONSULTATION, GRIEVANCE REDRESS AND INFORMATION DISCLOSURE

Stakeholder engagement for the proposed Project was undertaken using a staged approach in line with the various phases of its development as follows:

- ESMF / ESIA process engagement; and
- Post ESMF engagement.

A separate Stakeholder Engagement Plan (SEP) has been prepared for the Project, based on the World Bank's Environmental and Social Standard 10 on Stakeholder Engagement.

This ESMF, as well as the SEP and the Environmental and Social Commitment Plan (ESCP) that have been prepared for this project, have been disclosed in draft for stakeholder consultations on May 11, 2023, at Mercure Hotel, Nairobi.

Error! Reference source not found. presents a summary of the stakeholder engagements conducted during the ESMF / ESIA process, while a summary of the key issues raised/ comments made is presented in Table 6-2 and minutes presented in annex C. The results of the stakeholder consultations have been incorporated into the baseline information as well as into the impact assessment section (Section 3 of this ESMF Report).

Table 6-1 Summary of the Stakeholder Engagements Conducted during the ESMF / ESIA Process

Safeguard Instrument	Stakeholder	Mode of Engagement	Engagement Date	Venue
ESIA for Biovax Manufacturing Facility	Area chief, area OCS, the representatives of CITAM Church Embakasi, KEMSA, Kenya Airways and community members (the elderly, women, youth, people with special needs)	Public Baraza	September 14 2022	KEMSA, Embakasi Warehouse
ESMF, LMP, GBVAP, SEP, ESCP	Kenya Biovax Initiative (KBI)	Courtesy call and site inspection	May 5 2023	KEMSA, Embakasi Warehouse
ESMF, LMP, GBVAP, SEP, ESCP	Pharmacy and Poisons Board (PPB)	Courtesy call and site inspection	May 5 2023	PPB headquarters along Lenana Road, Nairobi.
ESMF, LMP, GBVAP, SEP, ESCP	National Quality Control Laboratory (NQCL)	Courtesy call and site inspection	May 5 2023	NQCL laboratory within UoN Pharmacy Department, KNH
ESMF, LMP, GBVAP, SEP, ESCP	Project beneficiaries, health sector practitioners, local healthcare products and products (HPTs) manufacturers	Meeting	May 11 2023	Mercure Hotel, Upperhill, Nairobi.

Outcomes of Engagement Conducted to Date

As indicated in Table 6-1 stakeholder engagement meetings were held during the ESMF / ESIA process of the Project.

The key questions and concerns raised by stakeholders during the ESMF / ESIA process are outlined in Table 6-2 and further details included in the *SEP*. Detailed minutes of the stakeholder engagement meetings conducted during the ESMF / ESIA process, meeting photos, attendance registers, and the developed stakeholder engagement database, are all annexed to this report.

Table 6-2 Safeguards Instruments Public Consultation Outcome

Participant	Key Issue / Concern / Comment	Response
Human Vaccine Manufacturing Facility ESIA		
Participants	Liquid and solid waste treatment	Biovax team explained that they were going to deploy a wastewater treatment plant, to ensure that all the wastewater from the facility shall be treated to the required standards before discharging into the public sewer line. They explained that autoclaving (killing of vaccines that are below the standards to render them harmless shall be done with diligence to keep the environment safe). For solid waste and any waste that requires incineration, Biovax will work with partners who are licensed to collect and dispose of the same safely. The ESIA experts further explained that Biovax shall be renewing their effluent discharge license annually and that will act as a check of the standards of wastewater from their system before discharge into the public sewer line.
	Integration of the proposed human vaccine manufacturing facility with other activities in the area	The Biovax responded that the area in which the facility would be set up is an industrial zone and therefore the proposed project was in conformance with the zonation laws of the area, he further explained that Biovax would build synergy with respective partners such as KQ which would be used during importation of vaccines and other raw materials. Bollore could be contracted to offer transport and logistics to move the vaccines from the airport to the manufacturing facility and to transport the manufactured vaccines from the facility to KEMSA go-down for storage in the cold rooms. KEMSA would be the partner offering storage space before distribution to local health facilities. KEMSA would also give the distribution network for the manufactured vaccines since

Participant	Key Issue / Concern / Comment	Response
		they have been in the distribution of medical products for long.
Billy, CITAM rep	What sensitization channels will Biovax put in place to educate members of public about the vaccines and possible impacts to human health?	Biovax team explained that Biovax Institute Ltd has a communications department that will disseminate information to members of public through various channels such as social media (Facebook and twitter) as well the print media and TV stations. Biovax will also have a website where they will post updates and information and live chats will be encouraged for members of public to seek clarification on any matters to do with the vaccines.
Gatobu, KQ	With growing population and demand of the vaccines locally and internationally, what plans does Biovax have as far as future expansion is concerned?	It was explained that highly efficient machines make production faster. For start, the current space is sufficient since the machines will produce up to ten million vials per month. For future expansion, Biovax Kenya Limited will consider leasing the adjacent go-downs and negotiate with KQ for a possible purchase of part of their land. Biovax plans to venture into manufacturing of anti-venoms and vaccines against cancer in future.
Safeguards Instruments Disclosure (ESMF, ESCP, SEP, LMP, GBVAP)		
Dr. James Kimotho, KEMRI	What is the project?	Dr. Lusiola, KBI, response – the project is about strengthening Kenya's health emergency preparedness, response, and resilience. It is implemented by KBI, PPB, NPHI and NQCL.
Kari Mwanga, PPB	The policy on patient safety Patient Safety, Health Worker Safety and Quality of Care is not included among those relevant for the project.	Bosco Lolem, Environmental Safeguards at MOH, in response – this is noted and will be included in the ESMF.
Pauline, KNH	Appreciated the microwave donated to KNH for management of clinical waste. What is the role of KNH in the project	Bosco Lolem in response – KNH is one of the buyers of health products. KNH can also help build capacity of the beneficiary institutions in healthcare waste management.
Dr. Peter Mburu, WHO	Does the project budget include co-financing?	Dr. Rabera, KBI – yes, the project includes co-financing. Constructing the KBI will cost approximately US$ 100 million.

Participant	Key Issue / Concern / Comment	Response
	What is being done to avoid duplication of the project by other ongoing initiatives	Dr. Rabera – The project's overarching objective is assuring commodity considering covid-19 vaccine nationalism experience and GAVI graduation. MOH is the umbrella organization for the project. Dr. Lusiola – Development Partners in Healthcare in Kenya (DPHK) are aware of the project.
Dr. Mwai	Is KEPI aware of the initiative to manufacture vaccines locally? During Covid-19 emergency, Kenya wanted to buy vaccines from Biovac but that was changed to Serum institute.	Dr. Kariuki, PPB – yes, KEPI is aware, and this explains why PPB wants to achieve Maturity Level 3 with human vaccine production.

7 IMPLEMENTATION ARRANGEMENTS, RESPONSIBILITY & CAPACITY BUILDING

This section describes the institutional arrangements to implement the ESMF including the screening of sub-projects for environmental and social risks and impacts, preparation, and consultation in relation to the assessment and identification of mitigation measures for sub-projects, review, clearance and disclosure of documentation and instruments, and monitoring the implementation of the ESMP. A clear delineation of responsibilities has been spelled out as well.

The MOH and the KBI will be the main implementing agencies for the Project. While the MoH has over two decades of implementing World Bank supported activities, the KBI was recently established, and it is still putting in place institutional structures to guide its operations. Activities under the NPHI, PPB will also be implemented through the MoH. The KEMSA will be responsible for procurement and distribution of medical supplies and equipment where applicable. The institution and implementation arrangements are summarized in Figure 7-1.

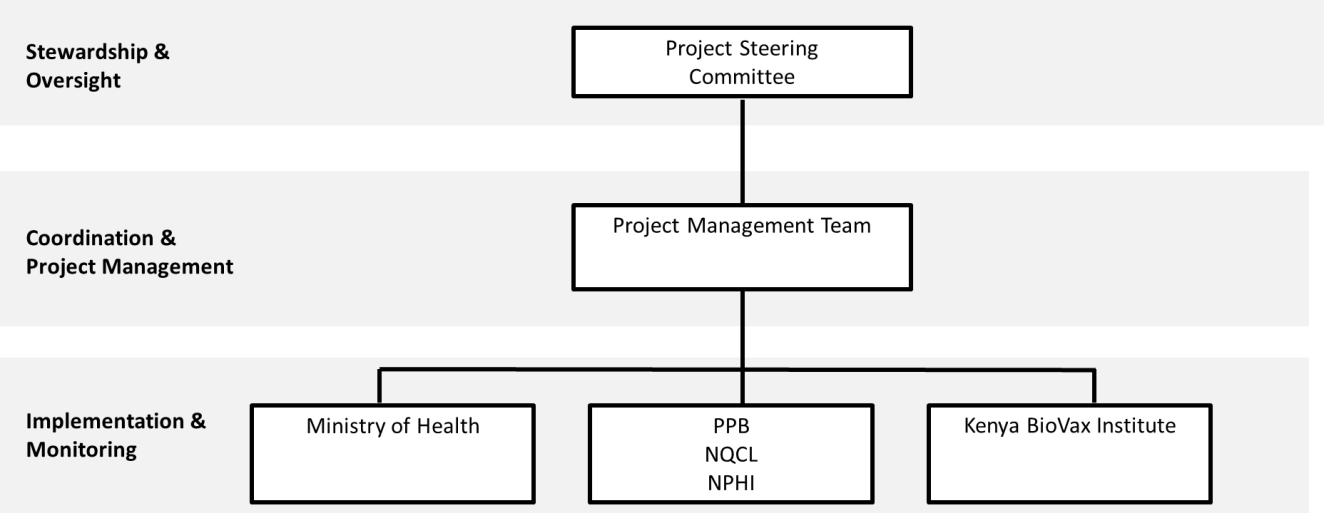


Figure 7-1 Project implementation arrangements

7.1 Project Management Team (PMT)

Project management will be the responsibility of a PMT established specifically for this Project. The PMT will draw on existing structures that have been put in place to oversee the implementation of ongoing projects, include the Transforming Health Systems for Universal Care Project (P152394) and the Kenya COVID-19 Emergency Response Project (P173820). The MoH will be required to:

1. set up a dedicated PMT.
2. designate staff with appropriate skill sets and recruit on exceptional basis to fill skills gaps.
3. build staff capacity.
4. make resources available to conduct day-to-day functions.

The PMT will be led by a dedicated project manager and will be responsible for coordinating and managing the timely and effective implementation of the Project. The PMT shall be staffed with an environmental specialist with health and safety expertise and one social specialist with SEA/SH expertise. The ESHS management staff should have qualifications and experience acceptable to the Association.

The MoH will release those staff assigned to this PMT of any other duties and responsibilities. The PMT will prepare quarterly financial and technical reports and submit these to the World Bank within the stipulated timelines.

7.2 Project Steering Committee (PSC)

The MoH will establish a PSC under the leadership of the Principal Secretary. The PSC will comprise of key stakeholders in local manufacturing to provide guidance and oversight during implementation. A local manufacturing committee with the mandate of providing leadership on pharmaceutical manufacturing is already in place. The mandate and membership of this committee will be expanded to include vaccine manufacturing. Additionally, a multisectoral oversight group, will be put in place to guide the implementation process. The PMT will work closely with the oversight committee to ensure the objectives of the project are met.

7.3 Monitoring Roles & Responsibilities during Planning, Design, Construction and Operational Phase

7.3.1 Ministry of Health

MOH recruited environmental specialist with health and safety expertise and one social specialist with SEA/SH expertise shall take lead in guiding and implementing environmental requirements of the project, working in close collaboration with the respective beneficiary public health institutions key personnel responsible for monitoring the respective environmental and social impacts of the sub-projects.

There will be a public health works engineer to monitor the construction phase (Biovax Facility) and will work closely with the project environment and social (E&S) specialists as well as the designated beneficiary public health institutions key personnel. Hired MoH E&S specialists' technical capacity will be enhanced by induction training at the beginning of project implementation to appreciate the new ESF. This will facilitate a better understanding and appreciation of safeguard requirements through discussion of modalities for implementation of the project ESMF provisions. Financial facilitation would however be necessary for their effective participation. The specific roles and responsibilities of the MoH E&S specialists are as follows:

- Oversee the production/updating of the ESMF, update the SEP and LMP and project specific ESMPs, ICWMP, C-ESMPs) and other instruments.
- Ensure the implementation of the instruments and the ESCP.
- Undertake overall coordination and oversight for all the E&S safeguards activities.
- Oversee the implementation of provisions of the Contractor's ESMP through the Public health works Engineer.
- Review the ESMP/ICWMP and submit to WB for review and clearance.
- Take overall responsibility of ensuring that the mitigation measures proposed in the prepared ESIAs and ESMPs, ESCP are implemented by the contractor and other applicable entities (e.g., Biovax Facility, HCF, laboratories, medical waste disposal facilities, etc.).
- Ensure that E&S risks and impacts related to the project are monitored and mitigated including: (i) management of highly infectious medical waste; (ii) risks that project impacts fall disproportionately on individuals and groups who, because of their particular circumstances, may be disadvantaged or vulnerable; (iii) any prejudice or discrimination toward individuals or groups in providing access to development resources and project benefits, particularly in the case of those who may be disadvantaged or vulnerable; (iv) impacts on the health, safety and well-being of workers and project-affected communities and other risks as outlined in the World Bank's ESF.
- Ensure inclusive and genuine stakeholder engagement and feedback mechanism, including a functional grievance redress mechanism for the project.

- Ensure the functioning of the GRM and follow-up on all social issues as reported on the GRM and/or as gleaned from other sources including the media.
- Monitoring of management of hazardous materials, management, and disposal of both solid and liquid wastes: treatment of the waste at respective sites, in addition to the disposal of both hazardous and non-hazardous wastes.
- Provide monthly reports for the Government and quarterly reports on environment and social safeguards implementation to the World Bank.

7.3.2 Public Works Engineers

PMT will work with the public works engineers who will be responsible for the designs and general compliance of engineering and construction works in relation to the Biovax Manufacturing Facility. The engineers will work closely with the project environment and social specialists and the county public health officers to oversee the civil work activities as well as on construction and installation of the waste treatment facilities. S/he will be responsible in preparation of project progress reports on civil works for sharing with MoH and the Bank on a quarterly basis.

7.3.3 County Governments

County governments will play the following roles:

- County Governments shall supervise project roll out within respective counties to ensure no activity being implemented shall not become a source of danger, discomfort, or annoyance to the neighborhood.
- Issue licenses and permits.
- Ensure compliance with health Acts.
- Authorize waste management.

7.3.4 Contractors for Civil Works

Local contractors will be required to comply with the Project's E&S risk management plans and procedures, including the ESMP, ESCP, LMP, and local legislation. This provision will be specified in the contractor's agreements. Contractors will be expected to disseminate and create awareness within their workforce of environmental and social E&S risk management compliance for their effective implementation. Contractors for civil works have the following responsibilities:

- The contractors for construction activities will be responsible for planning, implementation, and reporting on implementation of mitigation measures during the execution of civil works. The contractor will also be required to apply standard quality assurance procedures in full compliance with the approved sub-project specific ESMP.
- Have a full time E&S safeguards specialist for the day-to-day guidance of the project on matters of E&S compliance.
- Construction supervision will include monitoring of, and reporting on, E&S aspects, daily. In this regard, the contractor is required to have in place an Environmental and and Social Management System (ESMS).
- Develop a Contractor's ESMP (C-ESMP) guided by the sub-project's ESMP. C-ESMP should include the following:
    - Occupational Safety and Health Plan;
    - HIV/AIDS management Plan;
    - Waste Management Plan;
    - GBV Action Plan;
    - Labour management Plan; and

    - Emergency Response Plan and others (Security Plan if prepared later in the project).
- The contractor will be responsible for the relevant training of staff and ensuring that they are fully qualified, sufficiently experienced and certified in accordance with contractual requirements for the work contracted to undertake.
- The project's Monthly Progress Reports shall contain a section referring to E&S matters, which summarizes the results of site monitoring, remedial actions, which had been initiated from the previous months, and whether resultant action is having the desired outcome. The report will also identify any unforeseen E&S related challenges and will recommend a suitable additional action.
- Promptly notify the MoH (and other relevant parties, such as Public Health works Engineer) and World Bank of any incident or accident related to the Project which has, or is likely to have, a significant adverse effect on the environment, the affected communities, the public or workers. Major issues (fatal accidents, injuries) will be reported to the Bank within 24 hours of occurrence. Provide sufficient detail regarding the incident or accident, indicating immediate measures taken or that are planned to be taken to address it, and any information provided by any contractor and supervising entity, as appropriate. Subsequently, as per the MoH request, prepare a report on the incident or accident and propose any measures to prevent its recurrence.
- Progress site meetings with the contractor will also include a review of E&S safeguards and a section will be presented on the progress of implementation of safeguards in the monthly site meetings.
- The Contractor's E&S specialists or Community Liaison Officer shall also be in constant engagement with local leaders and community and ensure that any arising environment and social grievances are addressed.
- Ensure contractor's E&S monitoring report will be prepared monthly over the construction period. Detailed monthly monitoring reports with clear illustrations of implementation of mitigation measures shall be compiled by the contractor under the supervision of the R.E. These detailed reports with evidence of compliance will be prepared and appended to summary monthly site meeting reports.

Other entities responsible for operating project related aspects:

7.3.5 Head of Beneficiary Public Health Institutions (KBI, PPB, NQCL, NPHI)

Head of beneficiary PHIs have the following EHS responsibilities:

- Assess the Subproject and its environmental and social risks and impacts;
- Prepare the Subproject's environmental and social documentation, in accordance with GOK laws and ESSs;
- Engage with people affected by the Project and other stakeholders, through information disclosure, and meaningful consultation in accordance with the GOK laws and ESSs; and
- Furnish all required information, including executive summaries and reports on the environmental and social assessment, all the Subproject's required environmental and social documentation, and monitoring reports, to the Bank for review;
- Comply with the Subprojects environmental and social obligations under the Project in accordance with the legal agreements with the Bank governing the Project; and
- Ensure that contractors appropriately implement the agreed measures, the Heads of the PHIs includes the relevant environmental and social requirements in the tendering documents and contracts for goods and services required for the Project.

7.3.6 External Supervision and Support Implementation

7.3.6.1 National Environment Management Authority

The responsibility of the NEMA is to exercise general supervision and co-ordination over all matters relating to the environment and to be the principal instrument of government in the implementation of policies relating to the environment. NEMA will provide approvals of sub-projects and ESIA licenses to all the sub-projects based on the environmental assessment reports submitted. NEMA will also undertake periodic monitoring of the sub-projects by making regular site inspection visits to determine compliance of sub-projects with the ESIA/ESMPs approved and will further rely on the submitted annual audit reports submitted for each sub-project annually as required by EMCA as a way of monitoring. All monitoring reports as well as annual environmental audit report will be submitted to NEMA as specified by the environmental assessment and audit regulations, 2003.

7.3.6.2 World Bank Group

World Bank implementation support mission shall be periodically done to ascertain the level of implementation in line with the ESCP and other environment and social instruments prepared for the project namely: ESMF, LMP and SEP. The Bank monitors the Project on an ongoing basis until Project completion. In supervising and monitoring implementation of the environmental and social aspects of the Project, the Bank:

- Conducts periodic site visits if the Project has adverse environmental or social risks and impacts;
- Conducts comprehensive field-based reviews if the Project has significant adverse environmental and social risks and impacts;
- Reviews the periodic monitoring reports furnished by the Client to ascertain whether adverse risks and impacts are mitigated as planned and as agreed with the Bank;
- Consults with the Client on corrective measures to rectify any failures to comply with its environmental and social obligations, as documented in the legal agreement governing the Project; and
- Prepares a completion report that assesses whether the objective and desired outcomes of the Project's environmental and social measures have been achieved, considering the baseline conditions documented in the safeguard instruments or other approved documentation (as applicable), and the results of monitoring.

7.4 ESMF Implementation Costs

7.4.1 Capacity Building and Training

The project requires a strong Infection control and waste management system including Environment, Social, Health and Safety (EHS) monitoring and inspection capacity that will ensure implementation of ESMP, ICWMP, SEP and LMP. The project will provide considerable funding, training and capacity building and build upon international expertise to achieve international best practices on these matters in line with WHO guidelines and WB ESF, ESSs, EHSGs, and good practice notes.

The training in the areas of: Infection prevention and control measures, hand and respiratory hygiene and the use of appropriate PPE, laboratory safety (laboratory technicians), workers and community safety and health, MSDS, Healthcare waste handling and management, as well as in environmental and social monitoring. Implementation support monitoring will be provided to relevant staff to enhance their skills in handling emerging challenges. The budget for technical support and capacity

building training will be **110,000.00 USD** (this is a baseline budget, with availability of supplemental budget support for additional training based on needs assessment to be done during implementation).

The Training Plan for staff and support staff is detailed on Table 7-1.

Table 7-1 Initial Trainings Plan and Budget for Staff and Support Staff

Capacity Needs / Training areas	Target Participants	Cost (US$)
Infection prevention and control measures, hand, and respiratory hygiene & use of PPE	• Professionals working in in Biovax facility, Laboratory, HCF, PoE, Consultant & Contractor staff. • Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators.	10,000.00
Training on infection control and waste management measures & the roles and responsibilities for all actors from cradle to Grave	• Professionals working in in Biovax facility, Laboratory, HCF, PoE, Consultant & Contractor staff. • Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators.	10,000.00
Training on the Environment and Social Framework	MoH E&S Experts, procurement officer and other technical support team in the PMT and selected NEMA personnel	10,000.00
Training on SEA/SH Risk and management	Project beneficiaries and contractors	10,000.00
Training in community health and safety practices	• Professionals working in in Biovax facility, Laboratory, HCF, PoE, Consultant & Contractor staff. • Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators	5,000.00
Training on biosafety and biosecurity	• Professionals working in Biovax Facility, and Laboratories. • Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators	10,000.00
Training on emergency preparedness and response	• Professionals working in in Biovax facility, Laboratory, HCF, PoE, Consultant & Contractor staff. • Cleaners, waste transporters and handlers, incinerator operators,	10,000.00

Capacity Needs / Training areas	Target Participants	Cost (US$)
	liquid waste treatment facility operators.	
Training LMP and SEP	• Consultants and contractor staff carrying out construction. Training of officers involved in the project on E&S safeguards. • Professionals working in Biovax Facility, and Laboratories.	10,000.00
Training on handling pathogenic and potentially lethal agents	• Professionals working in Biovax Facility, and Laboratories. • Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators	10,000.00
Training on use of MSDSs, health and safe work practices, and appropriate PPE	• Professionals working in Biovax Facility, and Laboratories. • Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators	10,000.00
Training of HCF on proper implementation of their specific ICWM/ESMP during operations	Professionals working in Biovax Facility, and Laboratories.	10,000.00
Training of the HCF with medical waste disposal facilities installed on proper implementation of their specific ICWMP/ESMP during operations	Professionals working in Biovax Facility, and Laboratories.	10,000.00
Training of contractors and workers on the sub-project specific ESMP	Construction company workers	5,000.00
Environmental Assessments and Audits	Contracted NEMA registered Lead Experts Consultants	200,000.00
Indicative Total		**320,000.00**

7.4.2 Other ESMF Costs

There are costs that will be incurred during this ESMF implementation beyond capacity building. These are E&S staff costs, M&E, and Preparation of safeguard instruments e.g., ESIAs, EAs, etc. These costs cannot be estimated as project activities are not fully known. However, they will form part of the budget earmarked for project management (US$10 million).

7.5 Management of Change Process

Management of Change (MOC) is a systematic approach to dealing with organizational change. Although typically applied in industrial facilities and operations, it can be implemented in any workplace, especially for those that change their practices and processes from time to time. The goal of MOC is to safeguard workers from potential harm during crucial periods of transition.

In collaboration with NEMA and DOSHS, the project should create and implement an MOC strategy focused on potential consequences of the change it will introduce, assess the risks involved, and make sure that actions are in place to alleviate the risk and make the implementation possible for all employees.

In creating an MOC system for the project, the following steps should be followed:

- **Step 1 – Look at the bigger picture:** Assess the change the project wishes to implement and consider all possible outcomes and consequences. Recognizing all the changes and potential outcomes are crucial in figuring out the appropriate safety measures to take;
- **Step 2 – Understand that hazards aren't permanent:** certain measures and actions can do wonders at reducing risks and hazards that arise during a change in the workplace. Not all risks can be avoided, and that's a fact, but the project can still take measures to ensure that the risk is as low as possible;
- **Step 3 – Check if the change is feasible:** it's important to understand whether the project can accomplish the change without running into major issues. And if any issues arise from the change, they need to be accounted for;
- **Step 4 – Conduct a Pre-safety Startup Review (PSSR):** a PSSR is crucial before implementing any change. This is to ensure that also safety measures are in place before implementing a change;
- **Step 5 – Implement the change only if safe:** if there are high risks involved with the change, it's not worth doing. So, the project should only proceed with changes after determining all the risks and deciding that they are manageable; and
- **Step 6 – Make the necessary changes:** there's a high chance that project teams will meet some bumps in the road when implementing a change. So, it's important to take notes from people on the ground and make adjustments accordingly.

ANNEXES

Annex A: Sub-Project Environmental & Social Screening Form (ESSF)

This form will be completed during identification of project activities by the Environment and Social Specialists in Project Management Team (PMT) to screen for the potential environmental and social risks and impacts of a proposed sub-project. It will help the PMT in: (i) identifying the relevant Environmental and Social Standards (ESS); (ii) establishing an appropriate E&S risk rating for these sub-projects; and (iii) specifying the type of environmental and social assessment require; including specific instruments/plans. The completed forms will be signed, and the record stored.

This form will allow the PMT to form an initial view of the potential risks and impacts of a sub-project**. It is not a substitute for project-specific E&S assessments or specific mitigation plans.**

A note on Considerations and Tools for E&S Screening and Risk Rating is included in this Annex I to assist the process.

Sub-project Name	
Sub-project Location	
Sub-project Proponent	
Estimated Investment	
Start/Completion Date	

Questions	**Answer**		**ESS relevance**	**Safeguard Instrument(s)**
	Yes	**No**		
Does the sub-project involve civil works including new construction, expansion, upgrading or rehabilitation of healthcare facilities and/or waste management facilities?			ESS1	ESIA/ESMP, SEP
Does the sub-project involve long-term, permanent and/or irreversible adverse impacts (e.g., loss of major natural habitat);	*		ESS1	ESIA/ESMP, SEP
Does the sub-project involve significant adverse social impacts and may give rise to significant social conflict.	*		ESS1	ESIA/ESMP, SEP
Does the sub-project involve land acquisition and/or restrictions on land use?	*		ESS5	RAP, SEP
Will the activities affect lands or rights of VMGs or other vulnerable minorities.	*		ESS5	RAP, SEP

Questions	Answer		ESS relevance	Safeguard Instrument(s)
	Yes	No		
Does the sub-project involve permanent resettlement or land acquisition?	*		ESS5	RAP, SEP
Does the sub-project involve acquisition of assets for quarantine, isolation, or medical treatment purposes?			ESS5	
Is the sub-project associated with any external waste management facilities such as a sanitary landfill, incinerator, or wastewater treatment plant for healthcare waste disposal?			ESS3	ESIA/ESMP, SEP
Is there a sound regulatory framework and institutional capacity in place for healthcare facility infection control and healthcare waste management?			ESS1	ESIA/ESMP, SEP
Does the sub-project have an adequate system in place (capacity, processes, and management) to address waste?				HASP (Health and Safety Plan)
Does the sub-project involve recruitment of workers including direct, contracted, primary supply, and/or community workers?			ESS2	LMP/SEP
Does the sub-project have appropriate OSH procedures in place, and an adequate supply of PPE (where necessary)?				HASP
Does the sub-project have a GRM in place, to which all workers have access, designed to respond quickly and effectively?				SEP/LMP
Does the sub-project involve trans boundary transportation (including Potentially infected specimens may be transported from healthcare facilities to testing laboratories, and trans boundary) of specimen, samples, infectious and hazardous materials?			ESS3	ESIA/ESMP, SEP
Does the sub-project involve use of security or military personnel during construction and/or operation of healthcare facilities and related activities?			ESS4	ESIA/ESMP, SEP
Will the activities have high probability of causing serious adverse effects to human health and/or the environment?			ESS4	ESIA/ESMP, SEP

Questions	Answer		ESS relevance	Safeguard Instrument(s)
	Yes	No		
Is the sub-project located within or in the vicinity of any ecologically sensitive areas?	*		ESS6	ESIA/ESMP, SEP
Does the sub-project have an adequate system in place (capacity, processes, and management) to address waste?				HASP
Does the sub-project involve recruitment of workers including direct, contracted, primary supply, and/or community workers?			ESS2	LMP,/SEP
Does the sub-project have appropriate OSH procedures in place, and an adequate supply of PPE (where necessary)?				HASP
Does the sub-project have a GRM in place, to which all workers have access, designed to respond quickly and effectively?				SEP/LMP
Does the sub-project involve trans boundary transportation (including Potentially infected specimens may be transported from healthcare facilities to testing laboratories, and trans boundary) of specimen, samples, infectious and hazardous materials?			ESS3	ESIA/ESMP, SEP
Does the sub-project involve use of security or military personnel during construction and/or operation of healthcare facilities and related activities?			ESS4	ESIA/ESMP, SEP
Will the activities have high probability of causing serious adverse effects to human health and/or the environment?	*		ESS4	ESIA/ESMP, SEP
Is the sub-project located within or in the vicinity of any ecologically sensitive areas?			ESS6	ESIA/ESMP, SEP
Are there any indigenous groups (meeting specified ESS7 criteria) present in the sub project area and are they likely to be affected by the proposed sub-project negatively or positively?			ESS7	Indigenous Peoples Plan (IPP) / other plan reflecting agreed terminology
Does the sub-project require Free Prior Informed Consent (FPIC);	*		ESS7	IPP / other plan reflecting agreed terminology

Questions	Answer		ESS relevance	Safeguard Instrument(s)
	Yes	No		
Is the sub-project located within or in the vicinity of any known cultural heritage sites?	*		ESS8	ESIA/ESMP, SEP
Does the project area present considerable Gender-Based Violence (GBV) and Sexual Exploitation and Abuse (SEA) risk?			ESS1	ESIA/ESMP, SEP

∗ The exclusion list of the sub-projects. If any of these parameters are "Yes", the sub-project is excluded from financing under the program.

The Environmental and Social Commitment Plan (ESCP) prepared for the project has clearly outlined the activities considered as ineligible for financing under the project/exclusion list of activities that will not be financed under the project and that will be screen out. These include:

- High risk environment subprojects (per WB ESF and ESSs definition);
- Any technical assistance (TA) activities that are classified as Type 1 as per WB OESRC Advisory Note;
- Activities that may cause long term, permanent and/or irreversible impacts (e.g., loss of major natural habitats including habitats of wildlife and fisheries);
- Activities that may cause any significant loss of biodiversity;
- Activities that have a high probability of causing serious adverse effects to human health and/or the environment;
- Activities that may have significant adverse social impacts and/ or may give rise to significant social conflict;
- Activities that may potentially affect the quality or quantity of water or a waterway shared with other nations;
- Activities that may involve significant land acquisition, forced eviction and involuntary physical displacement;
- Activities that would disproportionately affect the historically underserved and vulnerable groups;
- Activities that may cause damage to cultural heritage; and
- Activities that may impact on known cultural heritage sites including sites that are important to local communities.

In sum activities that may cause large-scale physical disturbance on wildlife habitat; block access to or use of water points etc. used by others; located in or adjacent to protected area, significant impact on cultural heritage; create encroachment and/or cause significant adverse impacts to critical natural habitats (e.g., wildlife reserves; parks or sanctuaries; protected areas; forests and forest reserves, wetlands, national parks or game reserve; any other ecologically/environmentally sensitive areas) and contravene international and regional conventions on environmental and social issues are not eligible for the project financing

Conclusions:

Proposed sub-project is eligible for financing under the project criteria: ……

Proposed Environmental and Social Risk Ratings (High, Substantial, Moderate or Low). Provide Justification: ……

Proposed E&S Management Plans/ Instrument: ……

Certification:

Reviewed and approved by:			
MoH Environment Specialist **Name:**		**MoH Social Specialist** **Name:**	
Date	**Signature**	**Date**	**Signature**

Annex B: Infection Control & Waste Management Plan (ICWMP) Template

1. Introduction

1.1 Describe the project context and components.

1.2 Describe the targeted Institution or health facility:

- Type: e.g., Biovax facility, NQCL or NPHI Laboratory, PPB Warehouse, general hospital, clinics, inpatient/outpatient facility, medical laboratory, quarantine or isolation centers;
- *Special type of HCF in response to COVID-19: E.g., existing assets may be acquired to hold yet-to-confirm cases for medical observation or isolation;*
- Functions and requirement for the level infection control, e.g., biosafety levels;
- Location and associated facilities, including access, water supply, power supply; and
- Capacity: storage or biosafety levels, storage space, beds

1.3 Describe the design requirements of the facility, which may include specifications for general design and safety, separation of workstations/wards, heating, ventilation, and air conditioning (HVAC), autoclave, and waste management facilities.

2. Infection Control and Waste Management

2.1 Overview of infection control and waste management in the Institutions and/or linked facilities

- Type, source, and volume of healthcare waste (HCW) generated in the HCF, including solid, liquid and air emissions (if significant);
- Classify and quantify the HCW (infectious waste, pathological waste, sharps, liquid and non-hazardous) following WBG *EHS Guidelines* for Healthcare Facilities and pertaining GIIP;
- *Special attention should be given to the identification, classification, and quantification of the healthcare wastes;*
- Describe the healthcare waste management system in the HCF, including material delivery, waste generation, handling, disinfection and sterilization, collection, storage, transport, and disposal and treatment works;
- Provide a flow chart of waste streams in the HCF if available;
- Describe applicable performance levels and/or standards; and
- Describe institutional arrangement, roles, and responsibilities in the HCF for infection control and waste management.

2.2 Management Measures

- Waste minimization, reuse, and recycling: Institution or facility should consider practices and procedures to minimize waste generation, without sacrificing patient hygiene and safety considerations.
- Delivery and storage of specimen, samples, reagents, pharmaceuticals, and medical supplies: Institution or its facility should adopt practice and procedures to minimize risks associated with delivering, receiving and storage of hazardous medical goods. Hampered
- Waste segregation, packaging, color coding and labeling: Institution or related facility should strictly conduct waste segregation at the point of generation. Internationally adopted method for packaging, color coding and labeling the wastes should be followed.
- Onsite collection and transport: Institution or related facility should adopt practices and procedures to timely remove properly packaged and labelled wastes using designated trolleys/carts and routes. Disinfection of pertaining tools and spaces should be routinely conducted. Hygiene and safety of involved supporting medical workers such as cleaners should be ensured.

- Waste storage: The institution or related facility should have multiple waste storage areas designed for different types of wastes. Their functions and sizes are determined at design stage. Proper maintenance and disinfection of the storage areas should be carried out. Note that infectious wastes should be removed from the institution or related facility's storage area for treatment and disposal within 24 hours.
- Onsite waste treatment and disposal (e.g., an incinerator): Many health facilities in Kenya have their own waste incineration facilities installed onsite. Due diligence of an existing incinerator or the waste treatment equipment of choice should be conducted to examine its technical adequacy, process capacity, performance record, and operator's capacity. In case any gaps are discovered, corrective measures should be recommended. For new facilities financed by the project, waste disposal facilities should be integrated into the overall design and ESIA developed. Good design, operational practices and internationally adopted emission standards for healthcare waste incinerators or other waste treatment technologies can be found in EHS Guidelines and GIIP.
- Transportation and disposal at offsite waste management facilities: Not all HCF or related health facilities have adequate or well-performed waste treatment equipment onsite. Not all healthcare wastes are suitable for incineration. An onsite incinerator produces residuals after incineration. Hence offsite waste disposal facilities provided by local government, or the private sector are probably needed. These offsite waste management facilities may include incinerators, hazardous wastes landfill. In the same vein, due diligence of such external waste management facilities should be conducted to examine its technical adequacy, process capacity, performance record, and operator's capacity. In case any gaps are discovered, corrective measures should be recommended and agreed with the government or the private sector operators.
- Wastewater treatment: Beneficiary Institutions or linked facilities wastewater is related to hazardous waste management practices. Proper waste segregation and handling as discussed above should be conducted to minimize entry of solid waste into the wastewater stream. In case wastewater is discharged into municipal sewer sewerage system, the facility or institution should ensure that wastewater effluent comply with all applicable permits and standards, and the city or municipal wastewater treatment plant (WWTP) can handle the type of effluent discharged. In cases where municipal sewage system is not in place, the institution or facility should build and properly operate on site primary and secondary wastewater treatment works, including disinfection. Residuals of the on-site wastewater treatment works, such as sludge, should be properly disposed of as well. There're also cases where such institutional wastewater is transported by trucks to a municipal wastewater treatment plant for treatment. Requirements on safe transportation, due diligence of WWTP in terms of its capacity and performance should be conducted.

3. Emergency Preparedness and Response

Emergency incidents occurring in an institution or linked facility may include spillage, occupational exposure to infectious materials or radiation, accidental releases of infectious or hazardous substances to the environment, medical equipment failure, failure of solid waste and wastewater treatment facilities, and fire. These emergency events are likely to seriously affect medical workers, communities, the inistution's or linked facility's operation and the environment.

Thus, an Emergency Response Plan (ERP) that is commensurate with the risk levels is recommended to be developed. The key elements of an ERP are defined in ESS 4 Community Health and Safety (para. 21).

4. Institutional Arrangement and Capacity Building

A clearly defined institutional arrangement, roles and responsibilities should be included. A training plan with recurring training programs should be developed. The following aspects are recommended:

- Define roles and responsibilities along each link of the chain along the cradle-to-crave infection control and waste management process;
- Ensure adequate and qualified staff are in place, including those in charge of infection control and biosafety and waste management facility operation.
- Stress the chief of an Institution takes overall responsibility for infection control and waste management;
- Involve all relevant departments in the institution, and build an intra-departmental team to manage, coordinate and regularly review issues and performance;
- Establish an information management system to track and record the waste streams in HCF; and
- Capacity building and training should involve medical workers, waste management workers and cleaners. Third-party waste management service providers should be provided with relevant training as well.

5. Monitoring and Reporting

Many health Institutions in developing countries face the challenge of inadequate monitoring and records of healthcare waste streams. Institutions should establish an information management system to track and record the waste streams from the point of generation, segregation, packaging, temporary storage, transport carts/vehicles, to treatment facilities. The Institution is encouraged to develop an IT based information management system, should their technical and financial capacity allow.

As discussed above, the Institution's chief takes overall responsibility, leads an intra-departmental team, and regularly reviews issues and performance of the infection control and waste management practices in the institution. Internal reporting and filing systems should be in place.

Externally, reporting should be conducted as per government and World Bank requirements.

Annex C: Minutes from Stakeholder Engagement

TITLE	**MINUTES OF STAKEHOLDER CONSULTATIVE MEETING FOR THE REGIONAL PROJECT ON STRENGTHENING HEALTH EMERGENCY PREVENTION, PREPAREDNESS, RESPONSE AND RESILIENCE (SHEPPRR):** **KENYA PROJECT.**
OBJECTIVE	**PUBLIC CONSULTATION ON DRAFT SAFEGUARDS FOR ENVIRONMENTAL AND SOCIAL MANAGEMENT FRAMEWORK (ESMF), INFECTION CONTROL AND WASTE MANAGEMENT PLAN (ICWMP),** **STAKEHOLDERS ENGAGEMENT PLAN AND LABOUR MANAGEMENT PLAN**
DATE	**11th May 2023**
TIME	**0835 – 1100 hours**
VENUE	**Crowne Hotel Plaza, Nairobi**

Members present

S/No	Members	Organization	Designation
1.	Dr. Michael Lusiola	Kenya BioVax Institute (KBI)	**Chief Executive Officer**
2.	Poline Njue	Kenyatta National Hospital (KNH)	**Disaster Coordinator**
3.	Peter Mutua	Kenya BioVax Institute	**Consultant**
4.	Ireen Mueni	Kenya BioVax Institute	**Consultant**
5.	Lolem Bosco	MoH	**Safeguards Specialist**
6.	Ethnzy Kibet	Dawa Limited	**Business Development**
7.	Sonali Saula	BIODEAL	**Regulatory**
8.	Mwai Ngibuini	United States Pharmacopeia (USP)	**Technical Advisor**
9.	Col. Robert Gatata	Kenya BioVax Institute	**Facility Readiness / Safety / ICT**
10.	Lucas Nyangweso	Kenya BioVax Institute	**Supply Chain Management**
11.	Loise Wanja	Federation of Kenya Pharmaceutical Manufacturers	**Executive Officer**
12.	Okach Kephas	Ministry of Health	**Social Safeguards Consultant**
13.	Jacquline Ressa-Mbala	Ministry of Health	**Environmental Safeguards Specialist**
14.	John Ambuya	Ministry of Health /World Bank	**Safeguards Consultant**
15.	Cecilia Wanjala	Kenya BioVax Institute	**Regulatory**

S/No	Members	Organization	Designation
16.	James Kimotho	KEMRI	**Head of Innovation, KEMRI**
17.	Michelle Omondi	Federation of Kenya Pharmaceutical Manufacturers	**Pharmacist**
18.	Dominic Kariuki	Pharmacy & Poisons Board	**Head of GMP**
19.	Karim Wanga	Pharmacy & Poisons Board	**Director, Regulatory**
20.	Rebecca Manani	National Quality Control Laboratories	**Deputy Director Pharmaceutical services**
21.	Dr. Serah Muteru	National Quality Control Laboratories	**Ag. Director-General**
22.	Dr. Sultani Matendechero	Ministry of Health	**Deputy Director-General**
23.	**Dr. Joseph Kamau**	**Institute of Primate Research**	**Director**

S/No	Members	Organization	Designation
24.	Javan Wachenje	Kenya BioVax Institute	**Projects Officer, Facility Readiness**
25.	Dr. Felistas Chepwogen	Pharmacy & Poisons Board	**Head of Bioequivalence**
26.	Dr. Winnie Ng'ang'a	Kenya Assn. of Pharma. Industries / GlaxoSmithKline	**Chairperson**
27.	Safari Kithi	Association of Medical Laboratory Scientific Officers	**Chairman**
28.	Ibrahim Baswol	Ministry of Health	**DPHO**
29.	Peter Borus	WHO	**Scientist**
30.	Edward Abwao	United States Pharmacopeia	**STA-RSS**
31.	Dr. Rabera Kenyanya	Kenya BioVax Institute	**Head, Technical Operations**
32.	Suge Titus	Kabarak University	**Dean**
33.	**Ian Oduor**	**Kenya BioVax Institute**	**ICT Officer**

Agenda:

1. Preliminaries, welcoming and opening remarks
2. Presentation by the Implementing Agencies:
    a. Kenya BioVax Institute
    b. National Public Health Institute
    c. National Quality Control Laboratory
    d. Pharmacy and Poisons Board
    e. Presentation from NCQL
3. Overview of safeguards instruments:
    a. Environmental safeguards.
        i. ESMF,
        ii. ICWMP,
    b. Social safegurds;
        i. SEP,
        ii. LMP.
4. Plenary session with Q&A
5. A.O.B and Close.

Minute 1/11/05/2023: Preliminaries & remarks by the CEO, Kenya BioVax Institute

The meeting was opened by the Chief Executive Officer (CEO), Kenya BioVax Institute (KBI) at 8.35am followed by a welcoming address to stakeholders. In his remarks, the CEO appreciated stakeholders for their attendance and spelt out the purpose of the meeting as being for consultations and engagement on strengthening health systems emergency prevention, preparedness, response, and resilience as would be presented by representatives from the BioVax, National Quality Control Laboratories (NCQL), Pharmacy and Poisons Board (PPB), National Public Health Institute (NPHI) and safeguards experts from the Ministry of Health and World Bank.

He noted that the BioVax project under the oversight of the Ministry of health, is a project with cross-border collaborations and will contribute to this cause by strengthening of local national institutional capacity which includes pharma-manufacturing to avert shortage of essential medical supplies as witnessed during the Covid-19 pandemic. The ultimate expectations, he noted, will be better capacity to respond to public health emergencies, improved health security, strengthened health systems and enhanced universal health coverage.

Dr. Lusiola finished by mentioning that the regional project has four (4) components with the beneficiary institutions being the Pharmacy & Poisons Board (PPB), the National Quality Control Laboratory (NQCL), the National Public Health Institute (NPHI) and the Kenya BioVax Institute (KBI). The components will also have subcomponents which touch on human resources development and technology transfer, regulatory strengthening for PPB, Strengthening of Quality Control/assurance and establishing capacity for local vaccines manufacturing of 'fill-and-finish'.

Minute 2/11/05/2023: Presentation from National Public Health Institute (NPHI)

Dr. Sultan Matendechero – Deputy Director General, NPHI presented a high-level summary on the establishment and operationalization of NPHI. He highlighted that the role of NPHI is to promote public health issues by consolidating the management and coordination of response strategies and activities in prevention and early detection of public health issues of concern.

He explained NPHIs operational strategy and administrative strategy. The operational strategy involves; establishment of NPHI complex, organizational establishment, equipping & networking labs, Human resource, and training, establishing strategic national stockpile for public health response

commodities, establishment of data systems and coordinated emergency response. The administrative strategy involves, Leveraging existing brick and mortar facilities, Laboratory network, Coordination of public health emergencies response and strategic national stockpiles of essential commodities, Human resource management and development, Public health data management, Public health education and management of public health surveillance and disease surveillance.

Dr. Matendechero then gave the regional project scope whose objective is to support the establishment and operationalization of NPHI by, strengthening genomic surveillance, strengthening cross border surveillance at Port of entries, strengthening lab networks, enhancing disease surveillance, and having strategic national stockpiles for medical commodities.

Minute 3/11/05/2023: Presentation from National Quality Control Laboratory (NQCL)
Dr. Serah Muteru - Acting director, NCQL gave a presentation on NQCL regarding to its establishment, history and legal mandate, its administration and organization, Pre-qualification (PQ) status by World Health Organization (WHO) and Global Benchmarking Tool (GBT), support by development partners, range of clientele, gaps, and outlook. She stated NQCLs legal mandate as; Testing Health Products and Technologies (HPTs) on behalf of the Government and Administering the data bank for quality of HPTs in Kenya.

She further informed participants that NQCL is one of the only nine (9) WHO pre-qualified quality control Laboratories in Africa and among the forty-five (45) in the world, which is a significant achievement in the field of quality control. She highlighted major challenges and gaps as; Inadequate Staff which affect Turn-around-Times, lack of experts and infrastructure for analysis of vaccines and other biologics, old equipment, and inadequate Information Communication Technology Infrastructure.

Minute 4/11/05/2023: Presentation from Pharmacy and Poisons Board (PPB)
Dr. Dominic Kariuki gave an overview of the regulatory role of PPB in as regards to Health Products and Health Technologies (HPTs); to ensure that all HPTs comply with the requisite safety, quality, and efficacy standards.

He reported that Kenya is making remarkable progress towards attainment of WHO maturity level three (ML3) as it underwent WHO GBT Assessment in 2022. He explained that the attainment of WHO ML3 means a functional level of maturity: a stable, well-functioning and integrated regulatory system to ensure the quality, safety, and effectiveness of HTPs that are manufactured, imported or distributed in the country. Its attainment, he added, is a pre-condition for the penetration of Kenya into the international market for locally manufactured HPTs and will join five (5) other African countries that have already attained the status. He also informed members that already two assessments have been made by the WHO GBT team in November 2022 and April 2023 where recommendations reduced from 119 to 84, and from 84 to 53 respectively.

The presentation also highlighted priority areas and requests to World Bank; development of key Regulatory information management system (RIMS) including batch tracing systems and GCP inspections, development of a robust Post Marketing Control system, implementation of Bioequivalence Framework, establishment of Lot release function, establishment of a Monitoring and Evaluation framework and support of local manufacturers.

Minute 5/11/05/2023: Presentation on Safeguards instruments (ESMF, ICWMP, SEP, LMP): Jacky Mbala gave an overview of the social safeguards project and stated that its aim is to ensure that the project does not hurt people and the environment and, promotes right working conditions, and ensures that the community is not affected negatively. She noted that it's a constitutional requirement for stakeholder engagement to be done before any project is implemented. She then invited

Consultants John Ambuya, Okach Kephas and Bosco Lolem to make presentations as she wrapped up with the last presentation.

Presentation on Environmental Safeguards Management Framework (ESMF) by John Ambuya
Consultant John Ambuya gave an overview that the project is Kenya Health Emergency Preparedness, Response & Resilience (HEPRR) with a Project development objective of strengthening national systems for public health emergency preparedness through strengthening capacity for local manufacturing and public health institutional arrangements.

He listed the policy, regulatory, legal, and institutional frameworks relevant to the project and the four concerned institutions citing various pieces of policies and legislations such as Environmental Management and Coordination Act, 1999 (Revised 2015), Health Act 2017, National Environment Policy, 2014, Kenya Health Policy, 2012 – 2030, among others.

The presentation also listed some of the anticipated environmental and social impacts and risks at the design & planning phase, construction phase and the operations phase. It further enlisted procedures to address environmental and social impacts and risks and detailed the steps involved in the environmental and social screening process. Areas for capacity building and training were also highlighted such as; training on biosafety and biosecurity, training on environmental and social framework, infection control and waste management, among other areas.

Presentation on Infection Control and Healthcare Waste Management (ICHWM) by Lolem Bosco

Expert Lolem Bosco elaborated on healthcare waste management (HCWM), Emergency preparedness & response, Institutional arrangement, Infection control & waste management plan, and Capacity building and training.

He highlighted on two components where component 1 targeted: KBI, PPB and NQCL while component 2 targeted laboratories at county and national level, KEMSA national or regional warehouses and the Points of Entry (POE). He stressed on the design requirements of laboratory facilities, quarantine / Isolation Rooms at Healthcare Facilities, KBI vaccine manufacturing facility, waste treatment equipment installation & shed as well as provision for Biosafety Levels 3 Laboratories (BSL III). The presentation also factored in various areas of health care waste management such as Waste Management Hierarchy, Waste Segregation, Waste Treatment & Disposal Methods and Emergency Preparedness and Response (EPR).

Members were informed that beneficiary institutions will be required to prepare, receive approve and implement a specific ICWMP for their facility/operation based on MOH environmental health guidance. The specific plan should be based on their specific characteristics and conditions and meet the prescribed requirements; identify indicators to be tracked, specific tasks to be executed, and responsibility assigned for waste collection.

Presentation on Stakeholder Engagement Plan (SEP) by Kephas Okach
Consultant Kephas Okach gave an overview of the Stakeholder Engagement Plan, categories of stakeholders and the requirements of Environmental and Social Standard 10 (ESS10) of the ESF on Stakeholder Engagement and Information Disclosure.

He went on and explained the methods and communication models used in stakeholder engagement, the communication Escalation Process and the Grievance redress mechanism which is a mandatory requirement in World Bank projects.

Presentation on the Labour Management Plan (LMP) by Jacky Mbala

In her overview of LMP, Expert Jackie Mbala explained its purpose; it identifies the key labor requirements, related risks, processes, and resources required to manage the labor-related challenges for the project. The LMP defines different types of project workers; - direct workers, contracted workers and supply chain workers, and key requirements to manage labor issues.

She listed the following as the potential Occupational Safety and Health (OSH) risks that could be associated with the project: Sexual harassment, exploitation and abuse, Child labor, Labor disputes over terms and conditions of employment, Non-compliance of employers to terms and conditions of employment, Discrimination and exclusion of vulnerable groups, Labor influx related risks (including spread of diseases among workers and the nearby communities, including HIV/AIDS and COVID-19 through project activities.

The presentation also shed light on the need to formulate and implement Grievance redress mechanism, Capacity building matters and Gender-Based Violence Action Plan (GBVAP), all being requirements for the project.

Minute 6/11/05/2023: Plenary session

The following questions were asked, and responses given during the plenary session:

i. Dr. Kimotho (Head of Innovation, KEMRI) asked about the aim of the project to which Dr. Lusiola replied that it is for strengthening health systems, resilience, and health commodity security where the implementing agencies would participate in building resilience and enhancing preparedness for the next pandemic.
ii. Dr Wanga (PPB) pointed out that safety of workers was not captured in the presentation, a point noted by Mr. Lolem).
iii. Ms. Poline (Rep. of CEO, KNH) placed a question about the role of KNH in the project and at what point is it expected to execute its role. Dr. Rabera replied that KNH is an important stakeholder whose role will be vital during clinical trials of KBI products and consumption/use.
iv. Dr. Peter Borus (Scientist, WHO Country Office) enquired about the budget scope and if there was co-financing, the connection of the project to the bigger health strengthening component while avoiding duplication or efforts and if there is the overarching of the project regarding health strengthening. Dr. Rabera responded that KBI is exploring co-financing options and that there is no duplication of roles between PPB, NCQL, NPHI and KBI. Dr. Rabera added that KBI contributes to health systems strengthening by ensuring commodity security for vaccines and specialized health products and technologies.
v. Dr. Mwai Ngibuini (Technical Advisor, the USP) sought to know about the sustainability plan, measures to ensure vaccine uptake during transition from GAVI and plans for procurement processes even as Kenya is yet to attain ML3. Dr. Karuiki (PPB) replied that based on current progress, Kenya would have attained ML3 by December 2024, which is way ahead of GAVIs exit in 2027. Dr. Rabera and Dr. Lusiola also replied that engagement with vaccine users' community is ongoing, and the process will be quickened.
vi. Dr. Edward Abwao (Director of Regulatory PPB) enquired about the place of other prospective human vaccine manufacturers in the region and whether the KBI is a member of the association of pharmaceutical manufacturers. Dr. Lusiola responded that other prospective human vaccine manufacturers, including Moderna Inc., serve complementary roles. He also mentioned that the KBI is indeed part of the association of pharmaceutical manufacturers.

There being no other business the meeting was adjourned at 1100 hours.

Minutes prepared by: Mr. Javan, Wachenje, Projects Officer, Kenya BioVax Institute.

Minutes approved by: Dr. Michael Lusiola – Project Lead / CEO Kenya BioVax Institute. Signed:

Date: 11th May 2023.

Annex D: Gender-Based Violence Action Plan (GBVAP)

AFE Health Emergency Preparedness, Response and Resilience MPA (P180127)

GENDER-BASED VIOLENCE (GBV) ACTION PLAN

Introduction:

The MPA Program Development Objective (PrDO) is to strengthen health system resilience and multisectoral preparedness and response to health emergencies in Eastern and Southern Africa. The MPA has four components, namely: (i) Strengthening the preparedness and resilience of regional and national health systems to manage HEs; (ii) Improving the detection and response to HEs at the regional and national levels; (iii) Program management; and (iv) Contingent Emergency Response Components (CERC). Countries have the flexibility to choose or introduce relevant activities under the components, based on the specific country context and priorities, provided they are aligned with the MPA PrDO and theory of change.

Kenya experiences social issues include poverty, inequality, and Gender Based Violence (GBV) and approximately 47% of Kenyan women experience GBV in their lifetime. The country has high unemployment rate with limited access to education, healthcare, and other basic services. According to the2019 census, 2.2% (0.9 million people) of Kenyans live with some form of disability. The census results indicate that 1.9% of men have a disability compared with 2.5% of women. There are parts of the country experiencing ethnic conflicts and terrorism which may impact project implementation due to exposure of project workers to security and GBV risk.

The project has been screened for SEAH risks and rated them Moderate.

GBV Action plan

The GBV action plan is focused on ensuring all actions are *people centered* and enable the safety, dignity, and agency of those affected by supported operations. Mainly by ensuring safety and security of women, children and other vulnerable groups, and meaningful engagement with stakeholders including community, and partners. The action plan is derived from a review of grey literature and documentation of lessons learnt, consultations with stakeholders including professionals, staff, and members of the public. The plan consolidates and groups the recommendations across the following key areas:

- **Develop a methodology for assessing SEA/SH/GBV risk:** Clear guide and methodology for identifying SEA/SH and GBV risks, existing factors, capacity gaps, and project-related risks to guide staff and partners. The guide may include a list of experts to provide technical assistance (TA) and support in risk assessment.
- **Prepare SEA/GBV management manuals and training materials for capacity:** should provide for differentiated approaches for identifying, assessing, and classifying risks, and supporting boys, girls, women and other vulnerable groups, community partners, and map potential SEA/GBV service providers and referral pathways.
- **Enhance SEA/GBV incidence reporting and response protocol:** to include incidence prevention measures, guidelines for promoting, reporting and escalation, and on survivor-centered and ethical responses.
- **Strengthen and mainstreaming SEA/GBV operational processes:** includes mandating Codes of Conduct for standard procurement documents with prohibitions against SEA/GBV and sexual relationships with minors, appropriate GRM, monitoring and reporting on incidences, with provisions for third Party Monitors/investigators where required.
- **Sensitization and outreach campaigns: towards** building an enabling environment (internal and external) to promote appropriate culture and attitude to address SEA/GBV grievances in the project.

- **Adequate SEA/GBV resourcing and budget:** Adequate resources to meet costs of capacity building (internal and external) including identifying and offering needed training, information, education, and communications (IEC) materials.
- **Knowledge management and learning to improve capacity to address SEA/GBV concerns:** MOH should ensure systematic review, documentation, and adoption of lessons to expand understanding of effective approaches to prevent or respond to SEA/GBV.

Gender-Based Violence (GBV) Action Plan

Recommendation	Key Actions	Timeline	Resp. Unit	Comments
1. Develop mechanism for SEA/GBV Risk Assessment and identification	Develop guidelines for Staff on SEA/SH and GBV in project operations.	First 3 months after disbursement	PMT working together with stakeholders including Gender and human rights program (in NASCOP), Division of Neonatal and Child health, Division of adolescents health, Division of reproductive and maternal health, Division of Health promotion, Division of Community Health, Division of Pathology and forensic, Public health labs, Judiciary, National police service, Division of mental health	To leverage on developed guidelines by Gender and human rights program in NASCOP
	SEA/SH and GBV risk assessment methodology integrated with ES Risk Management guidelines and relevant trainings.	First six (6) months after disbursement	PMT, Gender and human rights program in NASCOP	To be spearheaded by safeguards team
	Build roster of qualified firms/ consultants with experience working on SEA/GBV, and children	Prior to implementation the project activities and	PMT, Gender and human rights program in NASCOP, Division of Neonatal and Child health,	To be spearheaded by safeguards team and Gender and human rights

Recommendation	Key Actions	Timeline	Resp. Unit	Comments
			Division of adolescents health Division of reproductive and maternal health, Division of Health promotion Division of Community Health, Division of Pathology and forensic, Public health labs Judiciary, National police service, Division of mental health	program in NASCOP
2. Enhance capacity to handle SEA/SH and overall GBV in the organization	2.1 Prepare SEA/GBV guidance for use by staff.	First six (6) months of project approval	Gender and human rights program in NASCOP PMT	To be spearheaded by safeguards team
	2.2 Identify, build capacity and train internal GBV focal person to respond to GBV at workplace	First six (6) months of project approval Through out the implementation of project	PMT	To be spearheaded by safeguards team
	2.3 Build technical expertise to address SEA/GBV in operations by developing a Master Class Training to build SEA/GBV expertise among staff.	First six (6) months of project approval	PMT, Gender and human rights program in NASCOP, Division of Neonatal and Child health, Division of adolescents health Division of reproductive and maternal health, Division of Health promotion	Multi-disciplinary approach spearheaded by safeguards team

Recommendation	Key Actions	Timeline	Resp. Unit	Comments
			Division of Community Health Division of Pathology and forensic Public health labs, Judiciary National police service, Division of mental health	
	2.4 Develop a dedicated SEA/GBV training that is mainstreamed in the existing modules	First six (6) months of project approval	PMT, Gender and human rights, program in NASCOP, Division of Neonatal and Child health, Division of adolescents health, Division of reproductive and maternal health, Division of Health promotion, Division of Community Health Division of Pathology and forensic, Public health labs, Judiciary National police service, Division of mental health	Multi-disciplinay / agency approach
3. Enable continuous knowledge exchange and learning.	3.1 Organize biannual SEA/GBV learning and review events for staff and communities	Bi-annual	PMT, Gender and human rights program in NASCOP, Division of Neonatal and Child health, Division of adolescents health, Division of reproductive and maternal health, Division of Health	To be spearheaded by safeguards team

Recommendation	Key Actions	Timeline	Resp. Unit	Comments
			promotion, Division of Community Health, Division of Pathology and forensic, Public health labs, Judiciary, National police service, Division of mental health	
4. Develop and promote internal Reporting and Response protocol for incidences on SEA/GBV.	4.1 Establish clear guidance for staff on incidence reporting and escalation of SEA/GBV	Immediately after effectiveness of the project	PMT	Spearheaded by safeguards and on site GBV focal person
	4.2induction of contracted staff /contractors on GBV/SEA	Prior to implementation of project activities	PMT	
5. Strengthen operational processes to address other aspects	5.1 Establish requirement that contractors must declare any suspensions linked to SEA/GBV	Before contract award for all subprojects	PMT Procurement Accounts department	Safeguards team to spearhead
	5.2 Require contractors to develop mechanisms for mitigating SEA/GBV risks in allcontracts		PMT	Safeguards team to spearhead
	5.3 include in contractor Codes of Conduct for workers, prohibition of all forms of SEA/GBV		PMT, Human resource department, Procurement Accounts department	Safeguards team to spearhead
	5.4 SEA/GBV requiring preparation and monitoring of such Codes of Conduct.		PMT, M&E departments	Safeguards team to spearhead

Recommendation	Key Actions	Timeline	Resp. Unit	Comments
	5.5 Develop list of mandatory SEA/GBV procurement requirements for contractors in Projects	Before contract award for all subprojects	Gender and human rights, program MoH, ICT division MoH, PMT, Procurement department, Accounts department, Division of Health promotion, Division of community Health	To be spearheaded by the social safeguards
	5.6 Develop one pagers posters/flyers on GBV/SEA at the project site	Prior to implementation of project activities		
	5.7 Embed accountability for monitoring risks linked to SEA/GBV in Supervisory Engineer contracts.		Safeguards team	Social safeguards to spearhead
	5.8 Deploy pilot community messaging campaigns in "High Risk" projects as a tool to strengthen community engagement and feedback.		Division of Health, promotion, Division of community Health, Gender and human rights program MoH ICT division MoH, PMT	Multi-disciplinary team to be spearheaded by safeguards team
6. Develop Internal and External Outreach Campaigns	6.1 Appoint institutional champions in relevant sectors to spearhead implementation of action plan	Within 6 months of project effectiveness	PS MoH through various Directorates and Divisions	To be spearheaded by the Project Team Lead
	6.2 Develop an internal campaign/sensitization towards enhanced understanding and awareness of the risks of SEA/GBV and how to address them in projects		PMT, Division of Health promotion, Division of Community Health	To be spearheaded by the social safeguards team

Recommendation	Key Actions	Timeline	Resp. Unit	Comments
	6.3 Raise awareness among industry partners of new requirements and attention to SEA/GBV.		PMT, Division of Health promotion, Division of Community Health	To be spearheaded by the social safeguards team
	6.4 Build client capacity and awareness of need to address SEA/GBV.		Gender and human rights program in NASCOP, Division of Neonatal and Child health , Division of adolescents health, Division of reproductive and maternal health, Division of Health promotion, Division of Community Health, Division of Pathology and forensic, Public health labs, Judiciary, National police service, Division of mental health	Safeguards team to spear head
	5.6 Develop externally oriented training materials targeting client partners to build awareness and capacity to address SEA/GBV. Community sensitization on GBV /SEA using CORPs with IEC materials in English and Swahili to include printing		Gender and human rights program in NASCOP, ICT division MoH, PMT, Division of Health promotion, Division of Community Health	Team work between the MoH divisions
7. Ensure Budget Is Available to Implement Task Force Recommendations	7.1 Provide required budget to cover incremental costs associated with SEA prevention and response measures (to cover 2-year period).	Within one (1) month of project effectiveness	WB, WHO, Treasury, MoH	Timely submission of budgets/AWPs to WB and treasury for approvals

Recommendation	Key Actions	Timeline	Resp. Unit	Comments
	7.2 Conduct periodic reviews of risk levels in projects to capture lessons on implementation.	Throughout project implementation	PMT led by Safeguards team. M&E Teams MoH	Teamwork between PMT, safeguards and M&E Teams MoH

Annex E: Generic ESIA TOR for a Subproject

Introduction and context

This section will be completed at the appropriate time and will provide the necessary information with respect to the context and methodological approaches to be undertaken.

Objectives of the study

This section will (i) outline the objectives and particular activities of the planned activity; and (ii) indicate which activities are likely to have environmental and social impacts that will require appropriate mitigation (Adapted to specific activities).

Terms of Reference

1. To undertake an Environmental and Social Impact Assessment (ESIA) for proposed project to meet the requirements of the WBG Environmental and Social standards (ESSs) and Environmental Health and Safety Guidelines (EHSGs) and the Kenya legal requirements.
2. To provide relevant environment and social baseline conditions on the proposed project area,
3. Review the relevant WBG's ESSs triggered for the project, the national legal requirements, and guidelines that the project will be implemented.
4. Assess and predict the potential site specific environmental and social impacts of the project during site preparation, construction, and operation phase.
5. Develop proposed feasible and cost-effective mitigation measures for the potential adverse environmental and social impacts as well as safety risk associated with the proposed project site activities.
6. Assess safeguards capacity of ICT Authority and recommend appropriate measures to address gaps through capacity building during implementation of the project; and
7. Develop Environmental and Social management and monitoring plans and prepare appropriate budget for Environmental, Social, Health and Safety mitigation measures for the project.

ESIA Report Outline

The ESIA report will be expected to include (but not limited to) the following, which are also indicative of the depth of the scope:

1. **Executive Summary**. Concisely discuss significant findings and recommended actions.
2. **Introduction.** This shall include a concise description of the proposed project background, project objectives, scope, and objectives of ESIA.
3. **Description of the Project Activities.** The consultant shall give the proposed project an introduction covering a short description of the project area, project activities (where possible during construction, operations, and maintenance) – including the project execution methodology and technology to be used for the project.
4. **Policy, Legal and Administrative/Institutional Framework**. This shall include a detailed description of World Bank Group's Environmental and Social standards (ESSs) triggered by the project and the National laws and regulations environment the project will operate. The level of compliance to the applicable laws and regulations shall be clearly stated.
5. **Environmental and Social Baseline Conditions.** The Consultant is required to collect, and present baseline information on the existing physical, biological, and social cultural environment of, within and around the project sites/area of influence.

6. **Environmental and Social Impacts identification and assessment**. The consultant shall identify and summarize all anticipated significant positive and adverse environmental and social impacts, because of interaction between the proposed project and environment that are likely to bring changes in the baseline environmental conditions.
7. **Impact Mitigation Measures**. The consultant shall come up with proposals of feasible and cost-effective mitigation measures, taking into consideration designs and equipment descriptions used for the negative impacts that could result from construction activities.
8. **Environmental and Social Management Plan**
    a. The Consultant shall develop a comprehensive environmental and social management plan comprising of a programme of assessing and managing the impacts during site preparation, construction, and operation phases.
    b. This will provide time frames and implementation mechanisms, reporting responsibilities, description and technical details of monitoring measures, assessment of the institutional needs, staffing requirements and cost outlay for implementation. The plan should show how management and mitigation methods are phased with project implementation.
    c. The plan shall also include measures to manage occupational health and safety risks and to ensure safety in the working environment for the employees and the communities adjacent to the project sites and project affected people.
9. **Institutional Arrangements, Capacity Development and Training.** The consultant is expected to review the institutional arrangements, responsibilities, and procedures within ICT Authority to effectively carry out implementation of environmental project components and mitigation measures and recommend appropriate measures to address capacity gaps identified.
10. **Conclusions and Recommendations**.
11. **References**. Documents, whether published or not, that were used to prepare the studies and outputs; list of related reports; and
12. **Appendices**. E.g., Design Concepts, record of the public consultations, ToR for the ESIA, etc.

Qualification of the Consultant

The Consultant will ensure that there will be a sociologist working with him/her in undertaking the ESIA. (Bachelor's Degree in Sociology or related field from recognized university and 5-10 years post-graduation experience and at least three (3) experience in large scale infrastructure project. The sociologist should be conversant with the WBG's ESSs).

The Consultant will have the following minimum qualifications:

- MSc. Degree in Environmental Sciences or a BSc. Environmental Engineering from a recognized University
- NEMA Registered Lead EIA Expert or equivalent
- Minimum overall experience of 10 years, with at least 5 years' experience on similar projects in Sub-Saharan Africa
- Participation in an ESIA for large infrastructure project that met the requirements of an International Financial Institution, such as the World Bank, IFC, AfDB, or EIB.

ESIA Deliverables and Reporting

The ESMP will be prepared in English. The assignment shall be carried out and completed within sixty (60 days) from the contract signing to NEMA licensing.

Table 0-1 ESIA Deliverables

Report	Description	Submittal date	Copies	
			Hard	Soft
Report 1:	Acceptable inception report including clear description of understanding the assignment, methodology to be used and work plan	5 days after contract effective date.	2	2
Report 2:	Submission of Draft ESIA Report	20 days after contract effective date.	2	2
Report 3:	Submission of acceptable final ESIA Report to NEMA	30 days after contract effective date	8	1

Annex F: Generic ESMP for a Subproject

Note: This is a generic ESMP that provides guidance for subprojects involving civil works (construction phase). It should be copied but customized to specific subprojects circumstances, risks, and impacts.

Table 0-2 Generic ESMP for a Subproject

Subcomponent/ Activity	Potential Negative Impact	Environmental and Social Mitigation Measures	Responsibility for Implementation	Monitoring Indicator	Frequency
Sub-Component 1.1: Human Resources Capacity, Learning, Development, and Technology Transfer	Risks related to labor and working conditions e.g., discrimination, SEAH, GBV, etc.	• Terms of reference (TOR), for defining the scope and outputs will be drafted so that the recruitment, training, knowledge exchange and technology transfer, and other technical assistance provided is consistent with ESSs 1-10. • Staff to sign a code of conduct (COC). • Implement Labour Management Plan (LMP). • Implement GBV Action Plan	KBI NPHI NQCL PPB	• ESF standards compliant TORs • Number of staff signing the COC • LMP and GBV provisions implemented by beneficiary institutions	Throughout project lifecycle
Sub-component 1.4: Establishing Capacity for F&F for human vaccines.	Environmental impacts and risks due to construction work needed at the KBI.	Preparation and implementation of ESMP and C-ESMP for construction phase. **Noise and vibration** • Planning activities in consultation with local communities/neighbours • Using noise control devices, such as temporary noise barriers and deflectors for impact and blasting activities, and exhaust muffling devices for combustion engines. • Avoiding or minimizing project transportation through community areas.	KBI	• Minutes from stakeholder engagement • PPEs provided to workers. • Number of workers wearing PPE.	Throughout construction phase

Subcomponent/ Activity	Potential Negative Impact	Environmental and Social Mitigation Measures	Responsibility for Implementation	Monitoring Indicator	Frequency
		• Provide PPE to project workers e.g., earmuffs, etc. and enforce usage.			
Sub-component 1.4: Establishing Capacity for F&F for human vaccines	Environmental impacts and risks due to KBI operations.	Preparation and implementation of KBI EHS Management Plan for operation and maintenance phase **Solid and Hazardous waste** • Prepare and implement a site-specific ICWMP for KBI. • Waste reduction by material substitution (e.g., use of water-based solvents, etc.). • Waste disposal of equipment • Process modifications (e.g., continuous rather than batch operations to reduce spillage and other material losses). • Spent solvent recycling and reuse, through distillation, evaporation, decantation, centrifugation, and filtration. • Other potential recovery options should be investigated, including inorganic salts recovery from chemical liquors produced during organic synthesis operations, high organic matter materials from biological extraction, and filter cakes from fermentation. • Potentially pathogenic waste from biotechnology manufacturing should be inactivated through sterilization or chemical treatment before final disposal. • Hazardous and non-hazardous industrial wastes should be stored, transported, and	KBI	• Site-specific ICWMP • Waste disposal equipment • Contracts with licensed waste handler	Before operations Throughout operations Throughout operations

Subcomponent/ Activity	Potential Negative Impact	Environmental and Social Mitigation Measures	Responsibility for Implementation	Monitoring Indicator	Frequency
		managed as described in the relevant sections of the General EHS Guidelines.			
	CHS (ESS4) impacts and risks due to KBI operations.	**Major Hazards** • Facility-wide risk analysis, including a detailed consequence analysis for events with a likelihood above 10-6/year (e.g., HAZOP, HAZID, or QRA); • Employee training on operational hazards; • Procedures for management of change in operations, process hazard analysis, maintenance of mechanical integrity, pre-start review, hot work permits, and other essential aspects of process safety included in the General EHS Guidelines; • Safety Transportation Management System as noted in the General EHS Guidelines, if the project includes a transportation component for raw or processed materials; • Procedures for handling and storage of hazardous materials; • Emergency planning, which should include, at a minimum, the preparation and implementation of an Emergency Management Plan prepared with the participation of local authorities and potentially affected communities.	KBI	• Annual risk analysis report. • Number of employees trained in emergency preparedness. • SOPs of change in operations, process hazard analysis, maintenance of mechanical integrity	Throughout operations

Annex G: KBI Facility & NQCL Baseline Snapshot

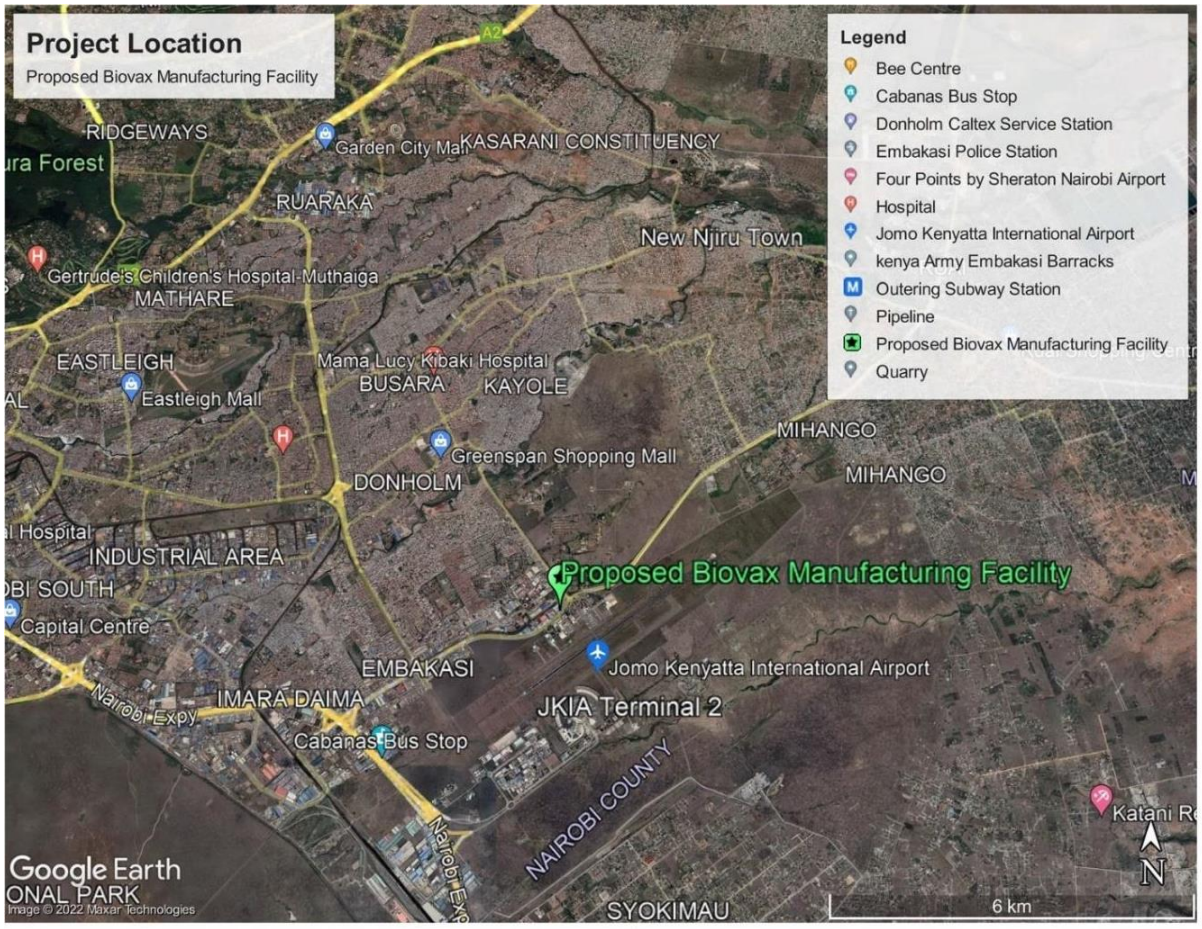
Kenya Biovax Initiative (KBI)

Introduction

The government has carried out some enabling works on the proposed building to house the KBI Biovax Facility, an ESIA study was conducted and approved by the National Environment Management Authority (NEMA). However, the ESIA does not meet the WBG ESF requirements, specifically the EHSG for pharmaceuticals and biotechnology manufacturing, ESS 3 requirement for waste management, and overall WBG ESF requirements. Therefore, before disbursement for Subcomponent 1.4, the ESIA will be upgraded to align with these requirements. Additionally, the report will get input from a WHO accredited good manufacturing practice (GMP) international consultant with extensive experience in setting up vaccines manufacturing facilities worldwide who will be recruited by KBI under the project. This commitments has been clearly spelt in ESCP as disbursement condition.

Location

The proposed project site is approximately 21km from Nairobi CBD near Kenya Airways Pride Centre and within an existing KEMSA Embakasi Warehouse in Embakasi East Constituency, Embakasi Estate. The proposed project is located on GPS coordinates 1°18'46.31"S, 36°55'8.99"E. The altitude at the project site is 1,621 meters above sea level.



Buildings

The project involves renovation (i.e., demolition and construction) of an existing warehouse. The office block located on the left-hand side of the entrance will be renovated to accommodate;

- On the First floor; server room, production control room, technical and production managers office, boardroom and an open office – this is already done. Offices are occupied by KBI staff; and
- On the Ground floor: dry storage room, cold storage room, and the equipment room – to be done under the proposed project. Photo 0-1 shows the cavernous warehouse that will be partitioned into dry storage room, cold storage room, and the equipment room.

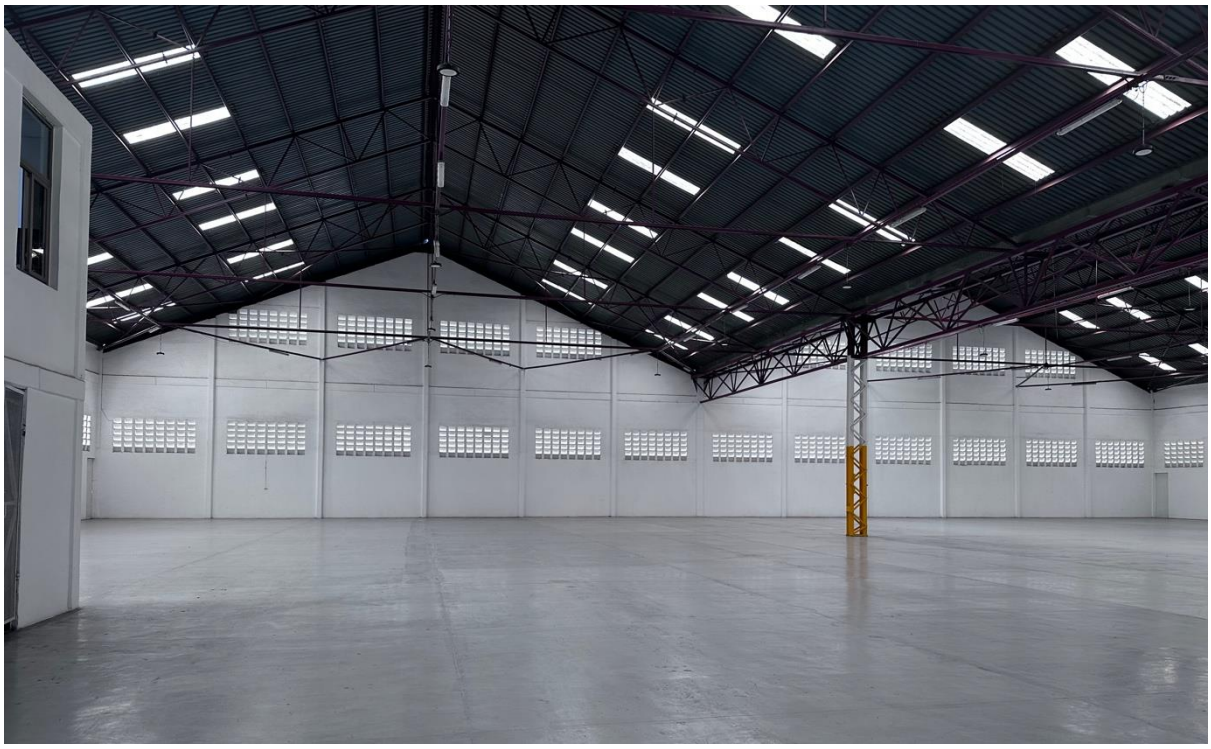


Photo 0-1 Renovated Warehouse Space at KBI

The proposed production area layout is shown in Figure 0-1.

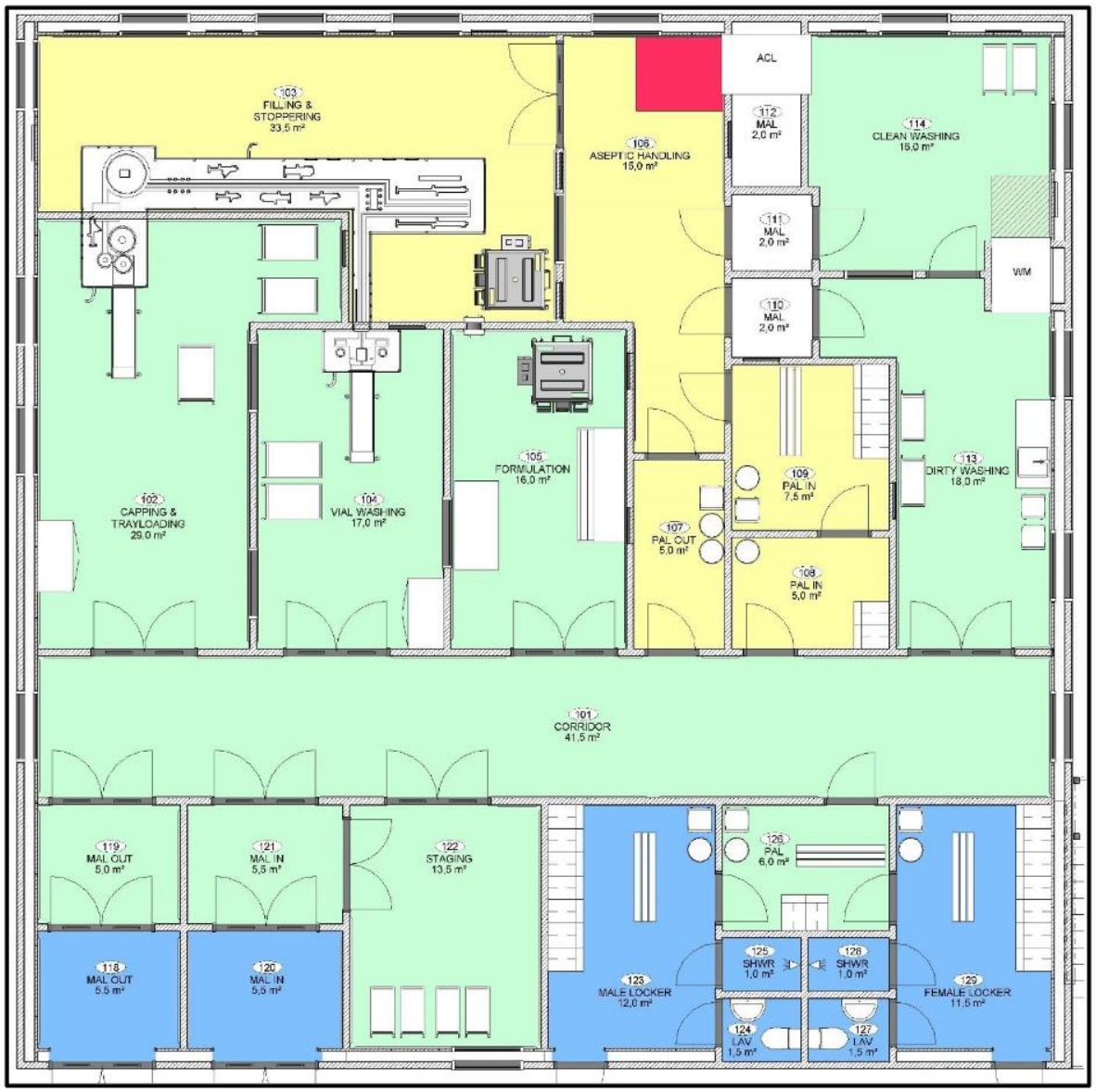


Figure 0-1 Proposed Partitioning Layout

Public and Worker Access

To secure the bioproducts/vaccine from contaminating the environment as well as individual getting into the production area and contaminating the vaccines, a highly secured entrance and exit will be installed. The public will have limited access to the facility for their safety and safety of the production process.

Biological Environment

The Facility is located in a built area (KEMSA Warehouse) with planted grass and trees along the southern perimeter. See Photo 0-2. This vegetated area has been earmarked for the development of the Facility's WWTP.

No animal was spotted during the site visit.

Photo 0-2 Vegetation at Biovax Facility

Topography

The project section traverses predominantly flat terrain in Embakasi location

Geology and Soils

The geology of the project area comprise mainly sandy sediments, gravel, or pebble beds, tuffs and pyroclastic sediments. The soils in the area are shallow, yellow-brown to yellow-red friable clays overlying a laterite horizon and black cotton soils with calcareous and non-calcareous variants being dominant within the project area.

Utilities – Water and Sewerage

The Facility is connected to the Nairobi City Water and Sewerage Company (NCWSC) mains supply and the main sewerage reticulation system for the city.

Solid Waste Management

Garbage collection is considerably adequate and the area surrounding the proposed site is clean both within the neighbouring facilities and along the drainage corridors and road junctions. There exist several logistic companies i.e., the Mitchell Cotts Logistics Company, KEMSA distribution warehouses among others with generally well managed waste management structures around the proposed project site.

Wastewater Treatment Plant (WWTP)

The operations of the Facility shall generate wastewater during operations. The wastewater may consist of various potentially hazardous components that may cause many risks on human and

environment by polluting surface and ground water. The WWTP for the BIOVAX facility will be installed as part of enabling works undertaken by governments, hence it will be an associated facility. It will be financed by the GOK. The WWTP will be installed before activities under subcomponent 1.4 begins.

Red arrow in Photo 0-2 shows where the WWTP will be sited.

A membrane bioreactor (MBR), shown in Figure 0-2 is proposed.

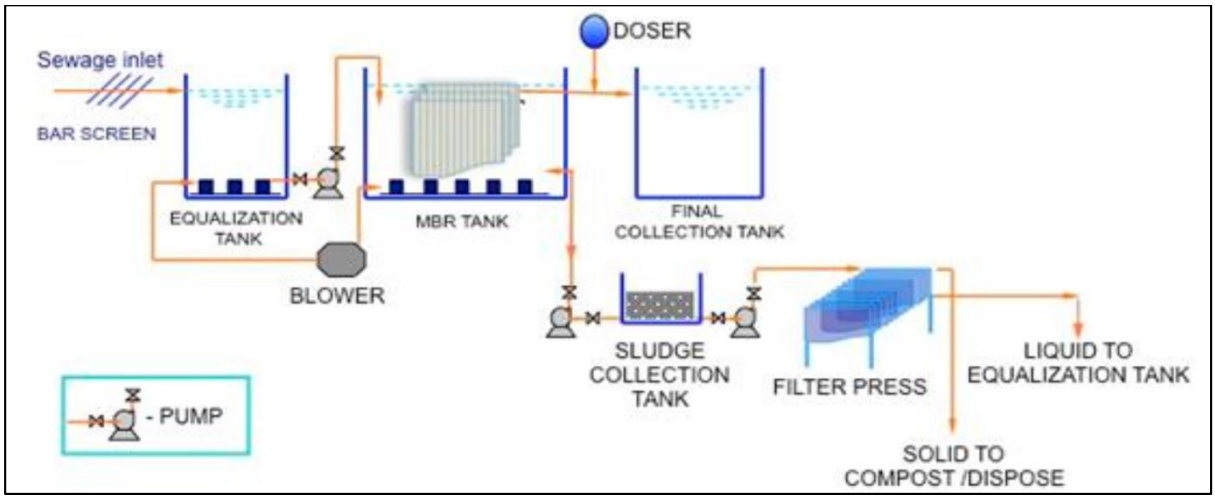


Figure 0-2 Membrane Bioreactor

Key characteristics of the MBR system are:

- Ultra filtration / Micron Filtration membranes giving very high treated effluent quality;
- Flat sheet Back washable membrane which minimizes/removes chemical cleaning requirements;
- Floating Aerators;
- Different sizes of membrane modules to suit site conditions;
- Robust system design ensures plant performance and long life;
- Lower power consumption by removal of tertiary pumping; and
- Simple design & lesser equipment thereby reduction in dependency on operator.

Economic Activities

The economic activities near the project site are mainly industrial activities (industrial zone) entailing majorly on logistics, clearing and forwarding procedures. The location is a major economic hub of the county and is generally considered one of the main economic, commercial, financial and logistics hub of county with the strongest industrial base in East Africa served by the main Kenya Airways airline. The main settlement areas are located more than 5 kms from the proposed area though Simba Villas Estate is only 250 meters to the North-east.

National Quality Control Laboratories

Location

NQCL is approximately 3km from Nairobi CBD and within Kenyatta National Hospital (KNH) Complex, Woodley Ward, Kibra Constituency, Nairobi City County. The proposed project is located on GPS coordinates 1°18'9.92"S, 36°48'25.35"E. The altitude is 1,726 meters above sea level. The Laboratory occupies the top level of a building shared with University of Nairobi (UoN)

Departments for Pharmacology and Pharmacognosy, and Pharmaceutics and Pharmacy Practice. As such, one passes lecture rooms enroute to the Laboratory.

Public and Worker Access

Only workers are allowed access to the laboratory. Other persons have limited access must seek clearance.

Biological Environment

Since the Laboratory is on the top level a building, no plants or animals were observed during the site visit.

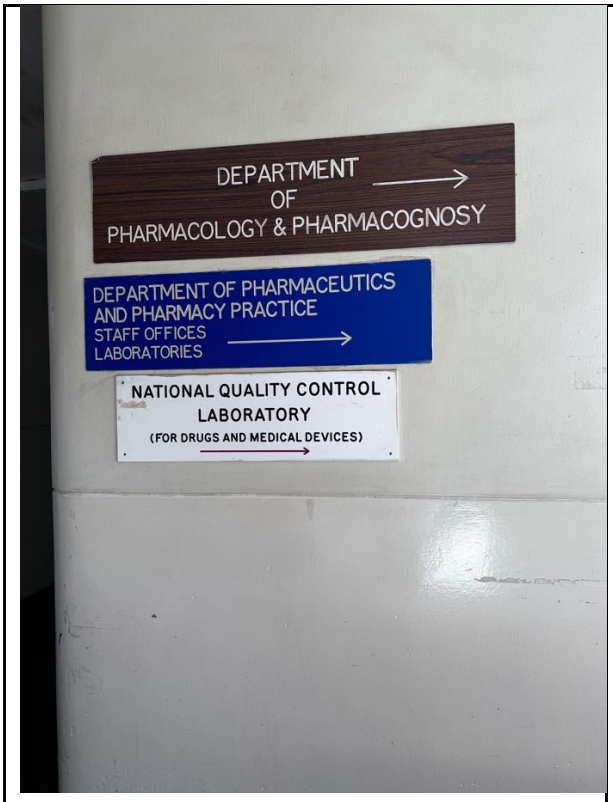


Photo 0-3 NQCL Neighbors

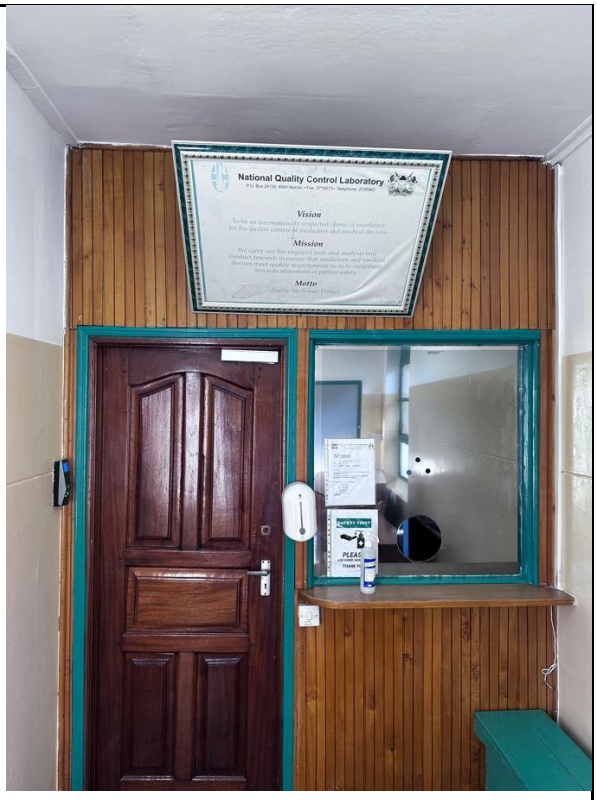


Photo 0-4 NQCL Reception

Utilities – Water and Sewerage

The Facility is connected to the Nairobi City Water and Sewerage Company (NCWSC) mains supply and the main sewerage reticulation system for the city.

Waste Management

The project will support NQCL by expanding the capacity of the NQCL for pharmaceutical and vaccine product testing through laboratory refurbishment premises, clean room and class B safety room for biologics and wet chemistry laboratory; automation of laboratory processes through a specialized laboratory information management system (LIMS) that meets all data integrity systems and processes. Proposed renovation works will include installation of a waste chute. The waste chute will be installed before activities under subcomponent 1.3 begins. The government will ensure waste management for NQCL complies with Bank ESF, ESHG for Pharmaceuticals and Biotechnology Manufacturing and all applicable regulations

Economic Activities

The economic activities near the Laboratory are education and health services.

Annex H: Chance Finds Procedure

Purpose

Chance finds procedure cover the reporting and management of any heritage finds during project implementation.

Scope

The "chance finds" procedure covers the actions to be taken from the discovery of a heritage site or item to its investigation and assessment by a trained archaeologist or other appropriately qualified person.

Compliance

The "chance finds" procedure is intended to ensure compliance with the requirements of ESS8 (Cultural Heritage) and relevant provisions of the National Museums and Heritage Act of 2006, especially Section 30 that requires all discoveries of buried artifacts to be reported to the National Museums of Kenya (NMK). The procedure of reporting set out below must be observed so that heritage remains reported to the NMK are correctly identified in the field.

Responsibility

- Operator: To exercise due caution if archaeological remains are found
- Foreman: To secure site and advise management timeously
- PMT: To determine safe working boundary and request inspection.
- Archaeologist: To inspect, identify, advise management, and recover remains.

Procedure

Table 0-3 Chance finds procedure

Mitigation/Monitoring Action	Responsibility	Schedule
Should a heritage site or archaeological site be uncovered or discovered during the construction phase of the project, the "chance finds" procedure should be applied. The details of this procedure are highlighted below:	MOH/PMT	Where necessary
• If operating machinery or equipment: stop work. • Identify the site with flag tape. • Determine GPS position if possible. • Report findings to foreman.	Person identifying archaeological or heritage material.	
• Report findings, site location and actions taken to PMT. • Cease any works in immediate vicinity	Foreman	
• Visit site and determine whether work can proceed without damage to findings. • Determine and mark exclusion boundary. • Site location and details to be added to project GIS for field confirmation by archaeologist.	PMT	
• Inspect site and confirm addition to project GIS. • Advise the NMK and request written permission to remove findings from work area.	Archaeologist	

Mitigation/Monitoring Action	Responsibility	Schedule
• Recover, packaging and labelling of findings for transfer to NMK.		
Should human remains be found, the following actions will be required: • Apply the chance find procedure as described above. • Schedule a field inspection with an archaeologist to confirm that remains are human. • Advise and liaise with the NMK and Police. • Remains will be recovered and removed either to the National Museum or the National Forensic Laboratory.	Archaeologist NMK Police Community elders	