Environmental and Social Impact Assessment (ESIA) for the Establishment of cGMP Compliant Vaccine Manufacturing Facility (Fill-Finish) in Kilinto Industrial Park, Addis Ababa, Ethiopia

Client

Federal Democratic Republic of Ethiopia

Ministry of Health, Addis Ababa, Ethiopia

Consultant:

Techinvention Lifecare Private Limited
#1004, The Summit Business Bay, Andheri-Kurla Road
Mumbai 400093, India; +91-22-40052123; www.techinvention.biz

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EXECUTIVE SUMMARY

Ethiopia's current reliance on imported vaccines presents vulnerabilities in light of a growing population, fluctuating global supply chains, and the nation's long-term public health goals. To address these challenges, the Ethiopian government has prioritized the development of local vaccine production capacity, recognizing immunization as a critical and cost-effective strategy for safeguarding the health and future of its children. The government's commitment extends to ensuring vaccine availability for both domestic consumption and potential export. Significant progress has been made in facilitating the establishment of cGMP-compliant facilities for the production of vaccines, through financial support from the World Bank and the Ethiopian Government. The project is envisaged to be completed in three stages namely; Stage 1 - Fill-finish (2028-30); Stage 2 - Formulation & Fill-finish (2030-2033); Stage 3 - Drug substance manufacturing for recombinant and conjugate vaccines & live attenuated measles vaccines (2034 - 2036).

According to World Bank Environmental and Social Standards and national regulations, the sub-project needs to obtain environmental clearance and funding approval before the commencement of the project. Hence, the Ministry of Health has carried out an Environmental and Social Impact Assessment for the proposed Vaccine Manufacturing Facility (VMF) construction for the fill-finish stage. The assessment sought to gather baseline information for the project site and identify related impacts through the use of checklists, key informant interviews (KII), literature review, and field observations.

The project presents considerable positive outcomes, especially in the areas of job creation, income enhancement, and the expansion of business opportunities. It is expected to foster better community health and contribute to the development of a more skilled workforce throughout various stages of implementation. These benefits indicate the project's potential to enhance economic growth and improve the overall quality of life for local suppliers and residents. The project's efforts to cultivate a skilled workforce will equip individuals with valuable competencies, thereby increasing their employability and contributing to the economy of the country.

While the project offers numerous advantages at local, national, and regional levels, it is important to acknowledge the possibility of potential negative impacts associated with its various phases, including pre-construction, construction, operation, and decommissioning. The construction phase, in particular, is linked to a range of adverse effects that can vary in

significance from moderate to severe. These impacts include air and soil contamination, erosion, disturbances from noise and vibrations, alterations to the landscape and visual appeal, traffic safety issues, generation of wastewater, production of solid waste, and heightened demand on public services. However, there will be no biohazardous or infectious waste generated out of this facility during stage 1, fill-finish operation, which is the scope of the assessment. Fill-finish operations deal with fully inactivated/recombinant/polysaccharide conjuga.es which are absolutely non-infectious. Such fill-finish operation/s generate liquid waste, solid waste and in small quantities, chemical waste.

Occupational health and safety concerns are particularly pronounced during both the construction and operation phases. During the operation phase, additional negative impacts may arise, such as air and water pollution, the generation of hazardous and biological solid and liquid waste, risks to occupational health and safety, risks related with vaccine storage and distribution, challenges related to waste handling and transportation, and fire hazards. These issues are generally regarded as having moderate to severe significance.

Consultations with key stakeholders, including Kilinto Industrial Park (KIP), security personnel, and the Ethiopian Food and Drug Authority, were conducted to inform the proposed project, associated impacts and mitigation measures. Also, consultation with the surrounding residents was conducted on the proposed VMF concerns and KIP impacts. Participants emphasized the potential benefits of local vaccine production, while raising concerns about material flow, waste management, risk of infection and phased implementation of mitigation measures and CGMP compliance of the facility.

To address project related risks, the Environmental and Social Management Plan (ESMP) was designed to identify actions needed to prevent, mitigate, and control potential adverse environmental impacts throughout the project's various phases. Mitigation measures include training, good biosafety biosecurity practice, provision of waste treatment systems like the kill tank/s and onsite effluent treatment plant (ETP) construction, onsite biomaterial waste incinerator construction, construction of onsite secured ash pit, and separate safety tank construction for hazardous and non-hazardous wastes. The enabling conditions in the Kilinto Industry Park like Zero Liquid Discharge (ZLD) central wastewater treatment plant, separate waste sorting place, fire brigade, and access control system availability will ease the ESMP implementation. It was estimated that the ESMP implementation and monitoring will incur about 11,625,900 ETB.

In conclusion, the project holds significant benefits for improving public health and creating economic opportunities. To advance the project from Stage 1 to Stages 2 and 3, a comprehensive assessment focusing on the operational risks of associated activities must be undertaken. By prioritizing local engagement and ensuring effective implementation of strategies, it would be possible to ensure compliance with World Bank and national environmental and social safeguards regulations.

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ACRONYMS & ABBREVIATIONS

BSL	Biosafety Level
CDC	Centres for Disease Control and Prevention
EPA	Environmental Protection Authority
EPHI	Ethiopian Public Health Institute
ESIA	Environmental and Social Impact Assessment
ESMF	Environmental and Social Management Framework
ESMP	Environmental and social Management Plan
GTP	Growth and Transformation Plan
HSTP	Health Sector Transformation Plan
HVAC	Heating, Ventilation and Air Conditioning
IPDC	Industrial Parks Development Corporation
KIP	Kilinto Industrial Park
MoLSA	Ministry of Labor and Social Affairs
MoWCA	Ministry of Women and Children Affairs
NIH	National Institutes of Health
NPEW	National Policy on Ethiopian Women
OSH	Occupational Health and Safety
SEUs	Sectoral Environmental Units
VMF	Vaccine Manufacturing Facility
WHO	World Health Organization
HSTPs	Health Sector Transformation Plan
cGMP	Current General Manufacturing
SCADA	Supervisory Control and Data Acquisition
AMR	Antimicrobial Resistance
cGMP	Good Manufacturing Practice compliant
ETP	Effluent Treatment Plant
ZLD	Zero Liquid Discharge
KII	Key Informant Interview
EFDA	Ethiopian Food Drug Authority
WHO TRS	World Health Organization Technical Report Series
AHU	Air Handling Unit
BOD	Biological Oxygen Demand
CNC	Controlled Not Classified

DTwP	Diphtheria, Tetanus, Whole-cell Pertussis
DS	Drug Substance
EMP	Environmental Monitoring Program / Laboratory
GPT	Growth Promotion Test
Hep B	Hepatitis B
HPV	Human Papillomavirus
HVAC	Heating, Ventilation, and Air Conditioning
IPV	Inactivated Polio Vaccine
Lf	Limit of Flocculation
MDV	Multi-Dose Vial
MMRV	Measles, Mumps, Rubella, Varicella
OCV	Oral Cholera Vaccine
PCV	Pneumococcal Conjugate Vaccine
PCR	Polymerase Chain Reaction
PFS	Pre-Filled Syringe
PM	Packaging Material
PS	Pure Steam
PW	Purified Water
RM	Raw Material
RO	Reverse Osmosis
RV	Rotavirus Vaccine
SDS	Sodium Dodecyl Sulfate
TOC	Total Organic Carbon
WFI	Water for Injection

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1. INTRODUCTION

1.1. Project Background

Ethiopia is Africa's second-most populous country with a population of more than 115 million in 2021. The COVID-19 pandemic, civil conflict and climate shocks including drought have severely impacted the wellbeing of Ethiopia's people. The event exposed the continuous weaknesses of the health system to adjust itself in responding to the shock while continuing the delivery of essential health services. The Government of Ethiopia has given the development of the health sector utmost priority. Accordingly, during the successive Health Sector Development Plans (HSDP) from 1997 to 2015 and Health Sector Transformation Plan (HSTP) plans from 2015 to 2025, substantial investments have been made in the health sector and as a result the country's health infrastructure and health service coverage has expanded significantly. Moreover, as part of its overall health policy, the Government has recognized and prioritized immunization as one of the most cost-effective ways to protect children's lives and their future. Consequently, the government has been implementing a comprehensive Expanded Program on Immunization that strictly follows WHO recommendations. As a result, measurable achievements in terms of reducing morbidity and mortality associated with Vaccine Preventable Diseases (VPDs) have been documented since the national immunization program was commenced in 1980.

In addition, the Government of Ethiopia is giving priority to the manufacturing sector, such as the development of an Kilinto Industrial Park, dedicated to the pharmaceutical industry. Moreover, the recently inaugurated bioequivalence center in the country, together with Ethiopia Food and Drug Authority (EFDA's) Drug Quality Testing Laboratory which is accredited to international standards (ISO 17025) and has attained WHO Maturity Level 3 provides a strong foundation for advancing the local pharmaceutical manufacturing sector by enabling product interchangeability studies, clinical research for new formulations, and marketing authorization processes that meet international standards. Availability of infrastructure is a major requirement for the development of manufacturing sector, including pharmaceuticals such as vaccines. In this regard, during the past two decades, the Government has invested heavily on expanding and improving the quality and coverage of the country's infrastructure, which has resulted in what will amount to a quantum improvement in the country's infrastructure including road, power, water, transportation and telecommunication.

Accordingly, the government of Ethiopia has received financing from the World Bank and intends to apply part of the proceeds for the establishment of cGMP compliant vaccine, diagnostics and pharmaceuticals manufacturing capacity in Ethiopia. In order to obtain the environmental permits and funding approvals for the establishment of cGMP compliant Fill-Finish Vaccine Manufacturing Facility in Kilinto industrial Park, the Ministry of Health (MOH) has planned to carry out an Environmental and Social Impact Assessment (ESIA), which must have to comply with the national environmental legislation and the World Bank (WB) Environmental and Social Standards.

1.2. Objectives of the ESIA

1.2.1 General Objective of ESIA

To conduct an environmental and social assessment, establish baseline conditions, anticipate potential project impacts and risks, propose suitable mitigation measures, and supply the World Bank and/or decision-makers with adequate information.

1.2.2 Specific Objectives of ESIA

Specifically, this ESIA was conducted:

- To assess the existing policies, legal backgrounds, and binding regulatory issues associated with the project.
- To present basic biological and physical environment and socioeconomic baseline information of the project and identify sensitive environmental components.
- To investigate potential risks and impacts associated with the construction, operation and decommissioning of the proposed project.
- To prepare mitigation measures for risks and impacts identified.
- To engage stakeholders in the project design and implementation.

1.3. Rationale for the Need of Environmental and Social Impact Assessment Study

An Environmental and Social Impact Assessment (ESIA) is essential for aligning socio-economic development projects with environmental safety, thereby promoting sustainable economic growth. Given that development is a continuous process, its effects on the environment are also escalating, resulting in a swift decline in environmental conditions. Consequently, conducting an ESIA and the formulation of an Environmental and Social Management Plan (ESMP), is required for the proposed VMF as outlined in the FRDE

Proclamation No 299/2002 and the World Bank's Environmental and Social Standards as a requirement for fund approval for the proposed project.

1.4. Scope of the Environmental and Social Impact Assessment Study

This assessment is focused on only inactivated/recombinant/conjugate injectable and inactivated oral liquid vaccines manufacturing (fill-finish vaccine production) and is limited to the VMF project site and associated facilities of Kilinto Industrial Park (KIP) used for VMF. It will include vaccine manufacturing and distribution process to health facilities only.The scope of the study is to carry out ESIA in compliance with the national and World Bank Standards and regulations. Accordingly, the scope of the study is:

- Review of relevant laws, regulations, and policies to be considered in the assessment.
- Assessment and description of baseline biophysical and socio-economic conditions at the project site.
- A comprehensive assessment of the waste management system of KIP and municipality as a whole.
- Identification and description of significant impacts associated with the project and proposing feasible and appropriate mitigation measures.
- Development of an Environmental and Social Management Plan (ESMP) and ESMP Monitoring Plan.
- Stakeholder consultations to gather input and feedback.

2. METHODOLOGY

2.1. Approaches of the ESIA

The ESIA approach was developed to meet the requirements of Proclamation № 299 of 2002. To achieve this, both published and unpublished literature were reviewed to understand the area's environmental and social conditions. A mixed-methods approach was utilized for data collection and analysis, incorporating qualitative and quantitative data from project staff, beneficiaries, stakeholder consultations, field visits, and secondary sources. Data was obtained through key informant interviews and document reviews, including KIP ESIA reports. Physical observations were conducted at project sites and waste management facilities in Addis Ababa. Questionnaires were designed to collect information on the project's impacts and risks, aiding in the development of an environmental and social management plan at the city administration level.

2.2. Data Record Review

A checklist was employed to identify key information sources and the relevant data required from each source. The checklist facilitated a comprehensive description of the project, encompassing design elements such as site plans and architectural drawings, as well as aspects related to construction and operation. Furthermore, pertinent documents were collected to provide essential baseline information on demographic trends, land use practices, climate conditions, soil quality, hydrology, coverage, health service availability, and both local and national development strategies and policies. Additionally, record of public consultations from KIP ESIA conducted in 2017 was reviewed and summarized in this report.

2.3. Field Visits and Observation

The field visits primarily concentrated on a physical assessment of the project area, examining landform trends, land use patterns, biodiversity, natural resources, hydrology, and the presence of residential structures, waste management facilities, and other properties such as buildings and facilities impacted by the project. Additionally, the evaluation included an assessment of the waste management facilities available in Addis Ababa to gauge their capacity and current conditions. The visits also aimed to observe socio-cultural and socio-economic activities. Furthermore, these field assessments were designed to precisely identify the enabling conditions and environmental features near the project site that may be affected and to recognize both potential positive and negative impacts.

Figure 1: Field Visit to Project Site with ShieldVax/MoH Representatives

2.4. Stakeholder and Public Consultations

Community participation and comprehensive stakeholder consultation are fundamental components of the Environmental and Social Impact Assessment (ESIA) process, particularly for evaluating the socio-economic effects of projects. The proposed Vaccine Manufacturing Facility (VMF) is strategically located within the Kilinto Industrial Park (KIP), a project financed by the World Bank. Given the KIP's established status and prior World Bank safeguards review, understanding the context of its development is crucial.

The establishment of KIP involved a thorough Environmental and Social Impact Assessment conducted by the Industrial Parks Development Corporation (IPDC). This assessment, which received clearance from both the national Environmental Protection Authority (EPA) and the World Bank in March 2017, included extensive public consultations with diverse groups within the local community, specifically Akaki Sub-City Administration, Woredas 9 and 10, government officials, and project experts. These consultations revealed a generally positive reception to the KIP project, with stakeholders acknowledging the anticipated environmental and social impacts and agreeing on the proposed mitigation measures.

The KIP ESIA process further incorporated participatory approaches, including interviews and discussions with federal and local authorities and stakeholders in Addis Ababa and the project area. Consultations were conducted with Akaki-Kaliti Sub-city (February 7, 2014),

Woreda 10 leadership (February 5, 2014), and project-affected populations (March 24, 2014). Given that the VMF project is situated within the established KIP, on government-owned land managed by IPDC, and that there are no direct impacts on nearby livelihoods, the necessity for extensive public consultation at the VMF-specific level was deemed limited.

Nevertheless, for the proposed VMF facility within KIP, recent and targeted stakeholder consultations were conducted to address specific operational and regulatory considerations. These consultations involved key stakeholders, neighboring communities, including KIP management, surrounding security stakeholders, KIP investors, Shield Vax representatives, the Ethiopian Food and Drug Authority (EFDA), and the Ministry of Health (MOH). These consultations focused on:

- **Operational Impacts:** Assessing potential environmental and social impacts related to the VMF's specific operations, including waste management, biosafety protocols, and potential emissions.
- **Regulatory Compliance:** Ensuring alignment with national and international standards, particularly regarding biosafety and waste disposal.
- **Security and Logistics:** Addressing security concerns related to biosecurity.
- **Community Health and Safety:** Discussing measures to protect the health and safety of the surrounding community, including emergency response plans and risk mitigation strategies.
- **Economic Impacts:** Evaluating the VMF's potential contributions to the local economy and employment opportunities.
- **Long-Term Sustainability:** Ensuring the facility's operations are sustainable and minimize environmental footprint.

Moreover, following the approval of the VMF ESIA report by both the World Bank and the national EPA, public disclosure of the VMF ESIA will occur to ensure transparency and maintain community awareness regarding the project’s potential impacts and mitigation measures. This disclosure will be accompanied by mechanisms for ongoing feedback and grievance redress, ensuring continuous stakeholder engagement throughout the project's lifecycle.

Figure 2: Consultation with KIP management

Figure 3: Consultation with KIP surrounding security stakeholders

Figure 4: Consultation with ShieldVax's representatives and MoH's 'Engineering & Design' team.

Figure 5: Stakeholder consultation on draft project design: MoH experts, ShieldVax's experts, and other participants (February 19, 2025)

Figure 6: Review of draft project design with MoH experts and ShieldVax's experts (March 11, 2025)


Figure 7: Evaluation of draft project design by EFDA experts and ShieldVax (February 20, 2025)

Figure 8: Public Consultation with residents surrounding KIP/Project Site (June 04, 2025)

2.5. ESIA Methodological Flow

The fundamental principles and methodological steps, detailing the techniques used for project screening, impact identification, quantification, analysis, and mitigation are crucial in the Environmental and Social Impact Assessment (ESIA). The process undertaken for the ESIA of the Vaccine Manufacturing Facility (VMF) construction project is summarized as follows:

Step 1: Screening

The Ministry of Health (MOH) initiated the Environmental and Social Impact Assessment (ESIA) process by conducting an initial screening of the proposed Vaccine Manufacturing Facility project. This screening aimed to determine the appropriate level of assessment

required under Ethiopian law and the World Bank Environmental and Social Framework (ESF). The Environmental Impact Assessment Proclamation (No. 299/2002) of Ethiopia mandates that ESIA for specific categories of projects, with detailed classifications and requirements outlined in directives issued by the Environmental Protection Authority (EPA). The ESIA procedural guidelines published by the Federal EPA in 2003 provide further clarity on the type of development projects and activities necessitating full, partial, or no environmental and social impact assessments. As a project within the pharmaceutical sector, the proposed VMF construction project is classified as a schedule I category according to the Ethiopian EPA guidelines, requiring a Full ESIA. This classification is based on the inherent potential for significant adverse environmental and social impacts associated with pharmaceutical manufacturing, including waste generation, potential for pollution, and occupational health and safety risks.

Furthermore, aligning with the World Bank's Environmental and Social Framework (ESF), a preliminary risk classification of **High Risk** has been assigned to this project. This classification is based on a number of key factors, including:

1. **Substantial Occupational and Public Health Risks:** The manufacturing of vaccines, particularly those involving live or attenuated organisms, inherently carries significant risks to both the workforce and the public if biosafety and biosecurity measures are inadequate. Potential exposure to pathogens and hazardous chemicals necessitates a rigorous assessment and robust mitigation strategies.
2. **Significant Biosafety and Biosecurity Risks:** The handling, storage, and potential release (accidental or intentional) of biological agents requires stringent biosafety and biosecurity protocols to prevent harm to human health and the environment. The complexity of vaccine production processes and the nature of the biological materials involved elevate these risks.
3. **Complex Waste Management Risks:** Vaccine manufacturing generates diverse waste streams, including biological waste, hazardous chemical waste, and general industrial waste. Improper management of these wastes can lead to significant environmental contamination (water, soil, air) and pose risks to public health.

Consequently, based on both the Ethiopian EPA's categorization of pharmaceutical projects requiring a Full ESIA and the World Bank ESF's High-Risk classification, the project proponent (SHIELDVAX/MoH) is mandated to conduct and submit a comprehensive Environmental and Social Impact Assessment (ESIA) study for the proposed Vaccine

Manufacturing Facility development project. This comprehensive assessment will thoroughly evaluate the potential environmental and social risks and impacts associated with all phases of the project lifecycle (construction, operation, and decommissioning) and propose appropriate mitigation measures in line with both national regulations and the World Bank's Environmental and Social Standards (ESSs).

Step 2: Scoping

Following the initial screening and determination of the need for a Comprehensive ESIA, a thorough **Scoping process** was undertaken. This crucial step involves a multi-faceted approach to define the project boundaries, understand the existing environmental and social context, and identify the key issues and potential impacts that require detailed investigation in the subsequent assessment stages. The primary objective of this scoping phase was to focus the comprehensive ESIA on the priority issues – those activities with the highest likelihood of causing significant adverse impacts on both natural and socio-economic environments throughout the subsequent stages of the assessment. By strategically narrowing the scope of the detailed assessment, we aim to ensure that the ESIA resources are effectively directed towards the most critical potential impacts, allowing for a more in-depth and meaningful evaluation and the development of targeted and effective mitigation measures. This early identification of key issues ensures that the subsequent impact assessment stages are efficient, focused, and ultimately provide valuable information for informed decision-making regarding the sustainable development of the VMF.

Step 3: Detailed Data Gathering on Baseline Conditions

Following the completion of the scoping phase, we proceeded to gather detailed data on baseline conditions across various environmental and socio-economic factors. Our data gathering efforts included:

- Assessed the quality and characteristics of water, air, soil, groundwater, and biodiversity (flora and fauna) in the project area.
- Conducted evaluations of demographic data, economic activities, and the provision of services within the community.
- Examined existing waste management facilities operated by KIP and local municipalities to understand current capacities and practices.
- Identified other factors, including legacy issues, that would be necessary for the successful implementation of the project.

Step 4: Project Alternatives Analysis

Project alternatives were analyzed to identify viable options that could lead to a feasible base-case design. This initial step was crucial in minimizing potential environmental and social impacts. The alternatives evaluated included:

- No Project Alternative: This scenario considered the implications of not proceeding with the project, allowing us to understand the potential benefits and drawbacks of maintaining the status quo.
- Alternative Site: Different locations were explored for the project to assess whether relocating could mitigate environmental or social impacts while still achieving project goals.
- Alternative Schedule: Examined different timelines for project implementation to determine if phasing or adjusting the schedule could lessen impacts on the surrounding environment and communities.
- Alternative Designs: Evaluated various design options for the project infrastructure to identify configurations that would be more sustainable or less intrusive.
- Waste Management Technology Alternative: This included assessing different waste management technologies to determine which would be most effective in minimizing environmental impacts while ensuring compliance with regulatory standards.

Step 5: Consultations

Stakeholder consultation is essential in the ESIA process, focusing on effectively communicating information about the proposed VMF establishment. This involves gathering feedback on key issues, identifying potential impacts, and allowing affected parties and stakeholders to raise concerns or suggest alternatives. All relevant stakeholders were identified, and consultations were conducted at various levels to ensure that those impacted by the project had the opportunity to voice their opinions.

Step 6: Identification and Analysis of Environmental and Social Impacts

We identified key beneficial and adverse impacts on the physical, biological, and socio-economic environments associated with the construction, operation and decommissioning phases of the VMF project. This was achieved through checklists, site surveys, stakeholder consultations, and literature reviews.

Step 7: Developing ESMP

Developing ESMP to outline necessary actions for preventing, mitigating, and controlling potential negative environmental impacts throughout the project's various phases. It assigns responsibilities to different stakeholders and establishes a timeframe for implementing mitigation measures and monitoring activities. The primary goal of this management plan is to ensure compliance with relevant legislation and guidelines while minimizing risks. By integrating the proposed actions, this ESMP will help the project set and achieve its environmental performance objectives, goals, and targets.

Step 8: Capacity Development Plan

Developing a capacity development plan to increase staff awareness and ensure robust occupational health and safety monitoring and inspection capabilities for the vaccine manufacturing facility (VMF). This includes providing technical support and training in occupational health and safety, worker and community safety, and environmental monitoring to support ESMP implementation throughout construction and operation.

Step 9: Environmental and Social Monitoring Plan

Environmental and social monitoring plan were prepared based on indicators of air, water, and noise pollution; solid and liquid waste generation; socio-economic impacts; occupational health and safety; and resource use. Responsible bodies were identified for each monitoring action. Key components identified to monitor include solid waste generation, air emissions, noise levels, and occupational health and safety practices.

2.6. Impact Identification, Analysis, and Prediction Methods

A multi-criteria method, using likelihood and consequence matrix values, assessed the potential impacts (positive and negative) of the VMF project across three phases: construction, operation, and decommissioning. Potential impacts on human health (occupational and public), socio-economic factors, and the biophysical environment were anticipated. Impact prediction involved examining processes, machinery, raw materials, and products, integrated with planned impact management mechanisms.

Impact analysis

Impact analysis involved a team of experts systematically evaluating the size and characteristics of identified impacts based on physical, biological, socio-economic, and cultural data. A weighted matrix was utilized to assist in total impact estimation, with results displayed in Table 1.

Table 1: Impact classification

Character (C)	Negative (-)	Neutral (0)	Positive (+)
Disturbance (D)	Important (3)	Regular (2)	Limited (1)
Significance (S)	High (3)	Moderate (2)	Low (1)
Occurrence (O)	Very probable (3)	Probable (2)	Unlikely (1)
Extension (E)	Regional (3)	Local (2)	Specific (1)
Duration (D*)	Permanent (3)	medium- term (2)	Short-term (1)
Reversibility (R)	Irreversible (3)	Partial (2)	Reversible (1)
Total	18	12	6

If **environmental disturbances (D)** occur too frequently or occur multiple times during an ecosystem's recovery period classified as important. If disturbances occur periodically and predictably it is called regular and the disturbance occurs in a limited time and area it is called limited.

Significance of impacts is high/severe, if the natural, cultural or social processes will be altered to the extent temporary. Medium/moderate impact significance occurs if the affected environment is altered but the natural, cultural or social functions and processes are continuing in a modified way. The impact significance is low when natural, cultural or social functions and processes are not affected.

The **occurrence** of the impact can be very probable if the impact is very likely to occur under normal operational conditions. If the impact is likely to occur at some time under normal operating conditions its occurrence will be probable. Unlikely impact is unlikely but may occur at some time under normal operating conditions.

If the **extension** of impacts is regional, the distribution of impact will occur at a regional level. If the distribution of impacts occurs at a national level, it is called local and if the distribution of impact occurs onsite, it is called specific.

If the **duration** of impacts is permanent, the length of expected impact occurrence has been measured based on permanent effects. If the duration will cease after the operation of the site

(5-15 years), it is called medium term, and if the duration stays from 0-5 years of life or period, it is called short term.

If the impacts are **irreversible,** the impact will remain after the implementation of mitigation measures. If the reversibility of the impact is partial, some of the impacts are reversible after the application of mitigation measures and removal of the impacts. If the impact is **reversible**, the impact will be reversed after the application of mitigation measures and removal of the impacts.

The total impact for the identified anticipated impacts was assessed as indicated below formula.

Total Impact (TI) = C x (D + S + O+ E + D* + R)

The result is interpreted as follow:

Negative (-) impact	**Positive (+) impact**
High (≥17)	High (≥17)
Substantial (-18>15)	Substantial (≥15)
Moderate (-15>-9)	Moderate (15>9)
Low (≤-9)	Low (≤9)

2.7. Impact Mitigation and Enhancement Measures

Identified significant impacts need appropriate mitigation measures. Hence, feasible and cost-effective mitigation measures for significant impacts and benefit enhancement measures were recommended mainly based on WHO TRS Standards, WB EHS Guidelines, and National EFDA and EPA guidelines.

2.8. Limitation and Assumptions

1. This Environmental and Social Impact Assessment (ESIA) report has been prepared based on the following assumptions:
2. The assessment assumes the KIP wastewater treatment plant and solid waste management systems will be fully operational and maintained per design; any delay or malfunction could alter predicted impact levels.
3. The study covers only the first phase (fill-finish) of vaccine manufacturing and does not include the full vaccine production cycle or off-site distribution logistics. It assumes that future expansion (Stage 2 and 3; full-cycle development) will be subject to a separate ESIA update.

3. LEGAL, INSTITUTIONAL AND POLICY FRAMEWORK OF THE ESIA FOR THE PROJECT

3.1. Rationale for Setting Legal, Institutional and Policy framework

The rationale for establishing a robust legal, institutional, and policy framework for an Environmental and Social Impact Assessment (ESIA) stems from the imperative to ensure project sustainability and responsible development. Fundamentally, these frameworks serve as the bedrock for integrating environmental and social considerations into the project lifecycle, moving beyond mere compliance to fostering a culture of proactive stewardship.

Legal mandates for ESIA processes are critical for establishing clear accountability and enforcing minimum standards. They provide the legal basis for:

- Preventing adverse environmental and social impacts: By requiring thorough impact assessments, legal frameworks compel developers to identify and mitigate potential risks, thereby minimizing harm to ecosystems and communities.
- Ensuring project legitimacy and reducing legal vulnerabilities: Adherence to legal requirements builds stakeholder trust and minimizes the risk of legal challenges that could jeopardize project timelines and viability.
- Enabling effective enforcement and deterring non-compliance: The threat of legal sanctions, such as fines or project suspension, incentivizes developers to prioritize environmental and social responsibility.

Complementing the legal framework, institutional structures define clear roles and responsibilities, ensuring efficient implementation and oversight of the ESIA process. This includes:

- Establishing competent authorities to review and approve ESIA reports.
- Facilitating meaningful stakeholder engagement and public participation.
- Providing the necessary resources and technical expertise for effective monitoring and enforcement.

Policy frameworks, in turn, provide the strategic direction for integrating ESIA into broader development goals. They:

- Align project-level assessments with national and regional sustainability objectives.
- Guide decision-making by setting clear environmental and social priorities.
- Promote a holistic approach to development, balancing economic growth with environmental protection and social equity.

In essence, the integrated legal, institutional, and policy framework for ESIA is essential for creating a predictable, transparent, and sustainable development pathway. It fosters a system where environmental and social considerations are not afterthoughts but integral components of project planning and execution, ensuring that development contributes to long-term well-being rather than short-term gains.

3.2. The Constitution of Ethiopia

The FDRE's Constitution provides a foundational framework for sustainable development, human rights, and environmental management, directly relevant to the establishment of a vaccine manufacturing facility. The Preamble underscores the nation's aspiration for development, setting the stage for integrating environmental and social considerations into all development initiatives.

Article 92 of the Constitution is particularly pertinent. It mandates that 'any design and implementation of programs and projects of development shall not damage or destroy the environment' (Art. 92, sub-art. 2). This provision necessitates a rigorous Environmental and Social Impact Assessment (ESIA) for a vaccine manufacturing facility, ensuring that the project's construction and operation minimize potential adverse impacts on air quality, water resources, waste management, and biodiversity.

Furthermore, Article 92, sub-article 3, guarantees 'the People have the right to full consultation and to the expression of views in the planning and implementation of environmental policies and projects that affect them directly.' This underscores the importance of robust stakeholder and community engagement throughout the ESIA process. For a vaccine manufacturing facility, this includes transparently addressing concerns related to potential risks, benefits, and the facility's overall impact on the local community's health and well-being. This is especially vital due to the sensitive nature of vaccine production and the potential for public anxiety.

Article 89, which guarantees citizens the right to benefit from the country's natural resources, also has implications for the facility. The ESIA must evaluate how the project will utilize resources sustainably, considering its water and energy consumption, and how it will contribute to local economic development.

3.3. Policy Framework

Ethiopia's policy framework emphasizes sustainable development, environmental protection, and social equity, directly impacting the establishment of a vaccine manufacturing facility.

- **Environmental Policy of Ethiopia (1997):**
    - Mandates sustainable resource utilization and environmental conservation.
    - Requires comprehensive Environmental Impact Assessments (EIAs) that consider human and natural impacts, public consultation, mitigation, and monitoring.
    - This is crucial for managing potential impacts of vaccine production, including waste, emissions, and resource consumption.
- **Biodiversity Conservation and Research Policy (1998):**
    - Promotes biodiversity conservation and sustainable use, ensuring community benefits from resource utilization.
    - Relevant for potential impacts on local ecosystems and the responsible sourcing of materials.
- **Ethiopian Water Resources Management Policy (1999):**
    - Focuses on equitable and sustainable water resource management.
    - Critical for assessing the facility's water consumption and discharge, ensuring no adverse effects on local water supplies.
- **National Policy on Ethiopian Women (NPEW) (1993):**
    - Promotes gender equality and women's participation in development.
    - Ensures the facility's employment and community engagement practices are inclusive and equitable.
- **Policy on HIV/AIDS (1998):**
    - Aims to prevent and mitigate HIV/AIDS, promoting multi-sectoral responses and protecting human rights.
    - Relevant in providing a safe and non-discriminatory workplace and in the impact the facility may have on the local community, and the nation’s health.

3.4. Relevant Proclamations, Guidelines and Directives for Vaccine Manufacturing Facility

Ethiopia's legal framework, through various proclamations, guidelines, and directives sets stringent environmental, health, and safety standards for development projects, particularly relevant to a vaccine manufacturing facility.

- **Environmental Protection Organs Establishment Proclamation (No. 295/2002):**
    - Establishes the Environmental Protection Authority[1] (EPA) and mandates Sectoral Environmental Units (SEUs).
    - Requires coordination to ensure projects align with environmental policies and necessitates robust Environmental Impact Assessments (EIAs).
    - This is the foundation for oversight of the facility's environmental performance.
- **Environmental Impact Assessment Proclamation (No. 299/2002):**
    - Mandates EIAs for specified projects, outlining procedures and developer responsibilities.
    - Requires detailed impact studies, including pollution control and mitigation measures, directly applicable to the facility's construction and operation.
- **Environmental Pollution Control Proclamation (No. 300/2002):**
    - Ensures citizens' right to a healthy environment, addressing solid waste management and pollution control.
    - Sets the stage for developing environmental standards and empowers inspectors to enforce regulations, critical for managing the facility's environmental footprint.
- **Solid Waste Management Proclamation (No. 513/2007):**
    - Regulates waste handling and disposal, emphasizing public health and environmental protection.
    - Essential for the proper management of waste generated during construction and operation, including potentially biohazardous waste.
- **Public Health Proclamation (No. 200/2000):**
    - Promotes public health and a healthy environment, mandating occupational health services and noise control.
    - Ensures a safe working environment for employees and protects the surrounding community.
- **Food and Medicine Administration Proclamation No.1112/2019**

The proclamation provides a national legal framework that enables to establish a coordinated food, medicine, medical device, cosmetics, and tobacco products regulatory system and seeks to prevent and control the public's health from unsafe, inefficacious, and poor-quality medicine, and unsafe and ineffective medical devices. The proclamation sets the following regulatory requirements with regard to manufacturing, import, trade and distribution of medicine and medical equipment

- Any medicine and medical device shall not be manufactured, imported, exported, stored, distributed, transported, sold, hold, used, or transfer to any other person without registration and marketing authorization.
- Any medicine or medical device shall be registered if the manufacturer complies with good manufacturing practices, dossiers are evaluated and found to fulfill safety, quality, efficacy, and efficacy or effectiveness, and as appropriate fulfills laboratory quality test requirements.
- Any medicine, its raw or packaging material shall meet quality, safety and efficacy requirements prescribed in a nationally accepted pharmacopeia.
- Any medical device shall meet quality, safety and effectiveness requirements issued or adopted by the appropriate organ.
- Where national standard is not issued or adopted, the executive organ may regulate medicine and medical device in accordance with requirements prescribed by international organizations, other countries, and requirements or guidelines issued by manufacturing companies acceptable to the executive organ.
- The manufacturer of medicine or medical device shall have the duty to ensure the quality and safety of raw materials and the legality of its supplier.
- It shall be the duty of the manufacturer or importer, as appropriate, to ensure that every medicine or medical device is produced in accordance with the appropriate good manufacturing practice.
- If the quality, safety, and efficacy or effectiveness of a medicine or medical device are not in compliance with the law, the executive organ may order the manufacturer or importer, as appropriate, to properly dispose or return it to its country of origin.
- No one may manufacture, import, export, wholesale or store any radiopharmaceutical or radiation emitting medical device unless he gets a certificate of competence from the executive organ and appropriate body.

- The handling of any regulated product under this proclamation and that is expired, unusable, or unfit for use for any reason shall not be in a manner that could contaminate other products.
- Any product that is segregated in accordance with sub-article (1) of this article shall be disposed with due care to the health of human, animal and the environment, and the cost shall be covered by its owner or another appropriate person.

- **Food, Medicine and Health Care Administration and Control Proclamation No. 661/2009**

Although this proclamation has been *partly* repealed by the Food and Medicine Administration Proclamation No. 1112/2019, relevant provisions include:

- No medicine shall be produced locally or imported and put in use unless it is duly registered by the executive organ after being tested for its safety, efficacy and quality.
- Any medicine or raw material or packaging material of a medicine shall meet quality standards and requirements prescribed in the pharmacopoeia issued or adopted by the appropriate organ or, where it is not included in such pharmacopoeia, those standards and requirements prescribed by manufacturing companies and accorded with international or the appropriate organ's acceptance.
- Where any medicine lacks the expected use of safety, efficacy and quality for which its permit is granted, or its risk outweighs its benefit, its use shall be banned and its registration shall be revoked.
- A clinical trial shall be conducted on human beings only when it is authorized by the executive organ. The clinical trial on a human being shall be conducted where the person gives consent in writing.
- Any producer, importer, distributor, retailer or health institution of medicine shall not supply it to the market or distribute it otherwise unless it is duly packed and labeled.
- Any passenger coming to or leaving Ethiopia shall be obliged to take vaccination required for international passengers in accordance with international public health requirements adopted by Ethiopia and to show, at ports of entry and exit, his certificate whenever requested by the relevant health authority and, where suspected of any communicable disease, to cooperate for medical examination.

- Any wastes generated from health or research institutions shall be handled with special care and their disposal procedures shall meet the standards set by the executive organ.

- **EFMHACA Guidelines for Registration of Vaccines (2018)**

The former Ethiopian Food, Medicine and Healthcare Administration and Control Authority of Ethiopia (EFMHACA), now reestablished as the Ethiopian Food and Drug Authority (EFDA), developed a guideline for registration of vaccines in 2018. With the aim of evaluating the safety and efficacy of vaccines for human use, the Authority set requirements for applicants to comply with. These requirements include (i) information needed for the application, (ii) evidence that the vaccine has passed the stages of research, development, production, and quality control, (iii) evidence from clinical testing, and (iv) evidence that quality, safety, and efficacy of the vaccine has been established. Also, in the vaccine evaluation process the Authority considers that the manufacturing facilities must comply with Good Manufacturing Practices (GMP).

The guideline provides modular formats to be prepared for vaccine registration including:

- Module 1: Administrative and Product Information
- Module 2: Common Technical Document Summaries
- Module 3: Quality
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports

The guideline includes (i) application form for registration, (ii) format for certificate of pharmaceutical products, (iii) template for summary of product characteristics, and (iv) requirements for registration of products accepted by a stringent regulatory authority.

- **Ethiopian Food and Drug Authority (EFDA) Guideline for Registration of Medicine (2020)**

The EFDA guideline aims to serve as the conventional medicines registration and provide recommendations on the quality, safety, and efficacy information for both active pharmaceutical ingredients (API) and finished pharmaceutical products (FPP) that should be submitted to the Authority. The guideline applies to Product Dossiers (PDs) for products containing an API of synthetic or semi-synthetic; an API that has been previously authorized through a finished pharmaceutical product (FPP) by a stringent regulatory authority; and/or an API or its finished formulation officially included in a pharmacopoeia.

The guideline provides modular formats in the Common Technical Document (CTD) to be prepared for medicine registration submission to the Authority. The modular formats include:

- Module 1 – Administrative and product information
- Module 2 – Dossier Overall Summary of Product Dossier (DOS-PD)
- Module 3 – Quality
- Module 4 – Nonclinical Study Reports
- Module 5 – Clinical Study Reports

- **Good Manufacturing Practices Guideline for Pharmaceutical Products: Main Principles (Third edition)**

The guideline rigorously present measures to ensure the safety, efficacy, and quality of human vaccines while minimizing risks of contamination and cross-contamination. The document outlines several key points associated with human vaccine production under Good Manufacturing Practices (GMP):

1. **Personnel**:
    - Staff involved in vaccine production should have relevant scientific qualifications (e.g., bacteriology, biology, immunology, virology).
    - Regular health checks and vaccinations are required for personnel handling live organisms.
    - Staff should avoid moving between areas handling different organisms without proper decontamination measures.
2. **Premises and Equipment**:
    - Dedicated facilities are required for handling live organisms like Bacillus anthracis, Clostridium botulinum, and Clostridium tetani until inactivation.
    - Air handling systems should prevent cross-contamination, with no recirculation of air from areas handling live pathogens.
    - Equipment should be designed for effective cleaning, sterilization, and containment of live organisms.
3. **Seed Lot and Cell Bank System**:
    - Vaccine production should be based on master and working seed lots or cell banks to prevent unwanted drift of properties.

- Seed lots and cell banks should be characterized, tested for contaminants, and stored securely.

4. **Production**:
    - Growth-promoting properties of culture media should be validated.
    - Virus inactivation or removal processes should be validated to avoid recontamination.
    - Chromatography equipment should be dedicated to one product and sanitized between batches.
5. **Quality Control**:
    - In-process controls are critical for ensuring vaccine consistency.
    - Continuous monitoring of production processes, such as fermentation, is necessary.
    - Retention samples of intermediate products may be required for batch control.

- **Ethiopian Food and Drug Authority (EFDA) Medicine Good Manufacturing Practice (GMP) Inspection Procedure Directive Number 830/2021**

EFDA's Medicine Good Manufacturing Practice (GMP) Inspection Procedure Directive Number 830/2021 is applicable on all local and foreign finished pharmaceutical manufacturing plants. The guideline includes provisions on inspections, roles and responsibilities of inspectors, administrative measures, and compliant handling procedures. Relevant provisions include:

- Pharmaceutical manufacturing site shall only be inspected if it has been licensed to manufacture medicines by the licensing Authority of the country of origin and it has continued production of its products in the country of origin for a period of not less than one year.
- Both local and foreign manufacturers of pharmaceuticals shall only be licensed if the Authority is convinced of compliance with the current good manufacturing practice in the production of medicines, unless otherwise justified.
- All finished pharmaceutical manufacturing facilities shall be subjected to site GMP inspection once every five years (as a requirement for complement of re-registration), unless otherwise notified.
- A manufacturer approved by Stringent Regulatory Authorities (SRAs) and World Health Organization (WHO) prequalified product shall be subjected to GMP inspection based on related documents review.

- Whenever necessary, GMP inspection shall be carried out with mutual recognition with identified and selected regulatory Authorities and IGAD. The Authority shall accept GMP Inspection report from these regulatory Authorities with pre-agreed conditions.
- GMP inspection shall be carried out using Ethiopian National GMP Guideline and/or the World Health Organization (WHO) GMP Guideline.
- Routine inspection shall be conducted under an announcement for a newly established manufacturing facility, when GMP certification has expired within 5 years or a manufacturer who has expressed interest of expanding manufacturing activities including, premises change or modification.
- Concise inspection shall be conducted when a limited number of requirements selected to serve as indicators of the overall compliance to the manufacturer and reserve for establishments that have been previously inspected for good manufacturing practice.
- Follow up inspection shall be conducted specifically to monitor the result of corrective actions of the manufacturer following a previous inspection.
- Special inspection shall undertake to conduct "spot checks" which could focus on one product, a group of related products, or a specific operation such as manufacturing, sterilization, labeling, and storage practice.
- Applicant or manufacturer shall submit a written application for medicine inspection directorate of the Authority or can submit the application through its Regulatory Information System (https://ilicense.efda.gov.et).
- Corrective notification shall be given when violations are significant enough for the issuance of a corrective notification letter and reasonable expectation exists that the inspector will correct the violation.
- Any manufacturer who tries to corrupt or deceive the inspectors in which the authority has evidence of such act, it shall be subjected to rejection of inspection for at least five years.

- **Ethiopian Food and Drug Authority (EFDA) Pharmacovigilance Directive No. 932/2022**

EFDA's Pharmacovigilance Directive No. 932/2022 provides requirements for detection, assessment, understanding, and prevention of adverse effects and other problems related to

medicines. The directive is applicable to any medicine, healthcare facility, and healthcare professional while it is not applicable to traditional medicines. Relevant provisions include:

- The pharmacovigilance center staff shall assess the causal association of the suspected drugs and the individual case safety report based on the collected information and prepare a preliminary report for the pharmacovigilance advisory committee of the Authority.
- The authority shall take regulatory measures in accordance with the seriousness of the adverse drug events and shall include (i) letters to healthcare providers describing the safety concern and how it may affect current patients on the medicine, (ii) provide warning on the safety of the medicine and give advice on being vigilant for its future prescribing and dispensing, (iii) revision of the package, designs of product labeling, packaging, product formulation, medical device, or product/technical information by the manufacturer of the medicine, (iv) medicine recall or withdrawing the medicine from the market, or (v) suspension and cancelation of the market authorization.
- All healthcare facilities have (i) the responsibility to establish and run a pharmacovigilance system as part of their routine practice and report adverse drug events to the authority or regional regulatory or the market authorization holder of the medicine, (ii) the right to get information on any regulatory measure taken by the authority, (iii) the right to obtain any capacity building activity on pharmacovigilance and training on adverse drug event reporting, (iv) the responsibility to be vigilant and prevent any adverse event from occurring as a result of medication error and system flaws, (v) the responsibility to implement the regulatory measures taken by the authority after serious adverse events investigation and analysis, (vi) the responsibility to maintain and document all records related to reported adverse drug events, share information when requested and collaborate on any pharmacovigilance activities with the authority, and (vii) refrain from dispensing the medicines with suspected products quality defects under investigation.

- Regulatory bodies have the responsibility to (i) investigate on a serious adverse event that occur at regulated healthcare facilities and provide an organized investigation report to the authority, (ii) obtain regulatory measure information shared by the authority to monitor medicine safety and ensure its implementation on healthcare facilities under its regulation, and (iii) collaborate with the Authority in strengthening

the national pharmacovigilance system and ensuring that it maintains its appropriate position with the international standard.

- **Ethiopian Water Resources Management Proclamation, No. 197/2000:**
    - Protects and manages water resources, regulating water use and preventing pollution.
    - Critical for assessing the facility's water consumption and discharge, ensuring sustainable water management.
- **Labour proclamation No. 1156/2019:**
    - Governs worker-employer relations, emphasizing occupational health and safety.
    - Ensures a safe and healthy workplace for all employees.

- **Proclamation on Hazardous Waste Management and Disposal Control No. 1090/2018:**
    - This proclamation establishes a comprehensive legal framework for the management and disposal of hazardous waste in Ethiopia, encompassing definitions, general obligations for waste handlers, permitting requirements, waste management planning, transportation regulations, treatment and disposal standards, and enforcement mechanisms.
    - Compliance with Proclamation No. 1090/2018 is of paramount importance for the proposed vaccine manufacturing facility. The facility is anticipated to generate various hazardous waste streams, including chemical, biological (potentially infectious), and pharmaceutical waste. The proclamation mandates the facility to obtain necessary permits, implement safe and environmentally sound waste management practices, ensure worker safety, and protect community health and the environment from potential adverse impacts of hazardous waste. Adherence to this legal framework is crucial for securing operational licenses, mitigating legal and reputational risks, and aligning with international best practices in hazardous waste management, thereby ensuring the sustainable and responsible implementation of the vaccine manufacturing facility in Ethiopia.
- **Ethiopian Building Proclamation No. 624/2009:**
    - Regulates building construction, ensuring quality and safety.
    - Ensures the facility's construction meets safety standards and accessibility requirements.
- **Addis Ababa City Government Environmental Impact Assessment Regulation No. 21/2006**
    - It is a regulatory framework established to ensure that environmental considerations are integrated into the planning and decision-making processes for development projects within Addis Ababa, Ethiopia.
    - It mandates that an Environmental Impact Assessment (EIA) be conducted for certain projects before approval. This process evaluates potential environmental effects and proposes measures to minimize adverse impacts.

- The regulation emphasizes the importance of involving stakeholders and the public in the EIA process, ensuring transparency and community input in decision-making.

- **ESIA Procedural Guideline (draft, 2003) & Directive No. 1/2008:**
  - Categorizes projects based on potential environmental impacts (Schedule 1, 2, 3), mandating full EIAs for high-impact projects (Schedule 1).
  - Requires projects in sensitive areas to undergo full EIAs.
  - Crucial for determining the required level of ESIA for the vaccine facility.
- **Environmental and Social Impact Assessment Guideline (2020):**
  - Provides a framework for EIAs, including sectoral environmental standards.
  - Guides the assessment of potential impacts in relevant sectors like industry, waste management, and water resources.
- **Guideline for Environmental and Social Management Plan (2022):**
  - Outlines the content and structure of Environmental and Social Management Plans (ESMPs).
  - Ensures the facility develops and implements effective mitigation and monitoring measures.
- **Guideline for Social, Environmental and Ecological Impact Assessment and Environmental Hygiene in Settlement Areas (2004):**
  - Focuses on minimizing negative impacts and maximizing positive impacts on communities.
  - Emphasizes public consultation and sustainable development, vital for community acceptance.
- **Occupational Health and Safety (OSH) Guideline (2008):**
  - Provides guidance on occupational health and safety requirements.
  - Ensures a safe working environment for facility employees.
- **Medicines Waste Management and Disposal Directive:**

  In addition to the overarching hazardous waste management framework, the **Ethiopian Food and Drug Authority (EFDA) Medicines Waste Management and Disposal Directive (2023)** provide specific guidance relevant to the vaccine manufacturing facility ESIA study. This directive, issued by the regulatory authority directly overseeing pharmaceutical activities, outlines detailed procedures and

requirements for the management and disposal of medicines waste, which will be a significant waste stream from the proposed facility.

The directive likely covers critical aspects such as:

Categorization of Medicines Waste: Defining different categories of medicines waste, including expired, damaged, unused, and contaminated pharmaceutical products, as well as potentially cytotoxic or hazardous drug substances. This categorization will influence the required handling and disposal methods.

Segregation and Storage: Specifying procedures for the proper segregation of different types of medicines waste at the point of generation to prevent contamination and ensure appropriate management. It will likely detail requirements for secure and designated storage areas within the facility.

Handling and Transportation: Outlining safe handling procedures for medicines waste to protect workers and prevent environmental release during on-site movement and transportation to designated disposal sites.

Treatment and Disposal Methods: Prescribing acceptable treatment and disposal methods for various categories of medicines waste. This could include incineration, chemical inactivation, landfilling (for specific non-hazardous types), or return programs where applicable. The directive will likely emphasize environmentally sound disposal practices.

Record Keeping and Documentation: Mandating detailed record-keeping of the generation, storage, transportation, treatment, and disposal of medicines waste to ensure accountability and traceability.

Responsibilities of the Pharmaceutical Facility: Clearly outlining the obligations of the vaccine manufacturing facility in implementing the directive, including the development of specific waste management plans and the training of personnel.

Inspection and Enforcement: Providing a framework for the EFDA to inspect pharmaceutical facilities to ensure compliance with the directive and outlining potential enforcement actions for non-compliance.

For the vaccine manufacturing facility ESIA, this EFDA directive is particularly important as it provides sector-specific requirements for managing a key waste stream. As this ESIA study thoroughly assessed how the facility will comply with each aspect of this directive, detailing the proposed infrastructure, procedures, and technologies for the safe and environmentally responsible management and disposal of all medicines waste generated throughout its

lifecycle. This will be a critical factor in obtaining regulatory approvals and ensuring the long-term sustainability of the vaccine manufacturing operation.

Regulation Pertaining to Noise with Limit Values and Ambient Air Quality Standards:

Sets standards for noise and air emissions. Ensures the facility complies with air and noise pollution limits.

Solid Waste Management Standards in Ethiopia:

Provides standards for solid waste management, including segregation, collection, transportation, treatment, and disposal.

Ensures proper handling of all solid waste generated by the facility.

Health and Safety Guidelines for Public Health Laboratories in Ethiopia, 2010:

Directs laboratory waste handling and disposal. Important for any quality control laboratories present in the facility.

National Hygiene and Sanitation Strategic Action Plan 2015/16-2019/20:

Focus on community and school sanitation and hygiene. Important for facilities impact on the surrounding community.

Guideline for Waste Handling and Disposal in Health Facilities (2006):

Categorizes healthcare waste and provides guidelines for safe handling, storage, transportation, treatment, and monitoring. Ensures proper management of healthcare waste generated by the facility.

Criminal Code of FDRE (NO 414/2004) and Environmental Compliance

The Criminal Code of the FDRE (No. 414/2004) establishes legal penalties for environmental offenses, ensuring compliance with environmental regulations. Specifically, for a vaccine manufacturing facility, the following articles are crucial:

- **Article 519 (Environmental Pollution):**
    - Punishes the unlawful discharge of pollutants into the environment with fines up to 10,000 Birr or up to five years of rigorous imprisonment.
    - This applies to potential emissions or effluents from the facility, emphasizing the need for robust pollution control measures.
- **Article 520 (Hazardous Waste Management):**
    - Penalizes the improper management of hazardous waste or materials with fines up to 5,000 Birr, up to three years of rigorous imprisonment, or both.
    - This is particularly relevant for the handling and disposal of biohazardous waste and chemical byproducts generated during vaccine production.

These provisions underscore the legal imperative for the vaccine manufacturing facility to adhere to all environmental regulations, including pollution control, hazardous waste management, and ESIA requirements, to avoid criminal penalties.

3.5. Institutional Framework for National Environmental Management

3.5.1. Environmental Protection Authority

The Environmental Protection Authority (EPA) of Ethiopia, mandated by Proclamation No. 803/2013, plays a critical role in overseeing the environmental management of development projects, including vaccine manufacturing facilities, by ensuring the realization of constitutional environmental objectives through policy development, standard setting, and national information systems; crucially, the EPA establishes and enforces Environmental and Social Impact Assessment (ESIA) systems, reviewing and approving the facility's ESIA to address potential impacts, and conducts monitoring and auditing to ensure adherence to environmental laws and the ESMP across all project phases, particularly concerning waste disposal, emissions, and overall compliance, thereby serving as the primary regulatory body guaranteeing environmentally responsible operation.

3.5.2. Ministry of Women and Social Affairs

The Ministry of Women and Social Affairs (MoWSA) plays a vital role in ensuring the social responsibility of development projects, including vaccine manufacturing facilities, by coordinating and implementing the Social Protection Policy across all levels of government and stakeholder engagement; MoWSA oversees occupational safety and health policies, ensuring a safe and equitable workplace, and champions the rights and welfare of women and children, monitoring the facility's adherence to international conventions and national laws, promoting women's empowerment, and ensuring community well-being through its coordination of development activities and focal points within other ministries, thereby safeguarding the social fabric impacted by the facility's operations.

3.6. International Conventions Ratified by Ethiopia

Ethiopia's ratification of key international environmental conventions, including the Aarhus Convention, Cartagena Protocol, Convention on Biological Diversity, World Heritage Convention, ILO Conventions, and conventions addressing pesticide and hazardous waste management like the Stockholm, Bamako, Basel, and Rotterdam Conventions, underscores its commitment to global environmental standards, directly impacting the vaccine

manufacturing facility by necessitating adherence to principles of public participation, biodiversity protection, labor standards, and stringent hazardous waste management practices, particularly regarding medical waste and emissions, to fulfill its international obligations

3.7. World Health Organization Guidance

The WHO guidance provides essential technical and regulatory frameworks to ensure the quality, safety, and environmental compliance of pharmaceutical manufacturing operations. They encompass good practices for microbiology laboratories, HVAC systems, and the manufacturing of both sterile and non-sterile products. Additionally, they address good regulatory practices, management of hazardous substances, and prevention of antimicrobial resistance. For detailed information see annex VII.

For detailed information, please refer to Annex VII of this document, which lists the specific WHO Technical Report Series (TRS) guidelines considered in the VMF design. It is important to clarify that when a WHO guideline referenced within Annex VII (WHO good practices for pharmaceutical microbiology laboratories) refers to its own "Annex 2" (as detailed in section A of this report's Annex VII), this refers to a constituent annex within that specific WHO guideline document itself.

3.7.1. WHO good practices for pharmaceutical microbiology laboratories

The document outlines WHO good practices for pharmaceutical microbiology laboratories, focusing on guidelines for personnel, environment, equipment, and testing procedures to ensure quality control and safety in microbiological testing. It emphasizes the importance of personnel training, environmental monitoring, and equipment maintenance to ensure accurate and reliable test results.

3.7.2. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products

The document provides guidelines on good manufacturing practices for heating, ventilation, and air-conditioning (HVAC) systems used in the production of non-sterile pharmaceutical products. The WHO guidelines provide recommendations for good manufacturing practices (GMP) regarding heating, ventilation, and air-conditioning (HVAC) systems specifically for

non-sterile pharmaceutical products. These guidelines emphasize the importance of HVAC systems in maintaining product quality and preventing contamination.

3.7.3. WHO good manufacturing practices for sterile pharmaceutical products

The document provides guidelines on good manufacturing practices for sterile pharmaceutical products. It recommends General considerations:

- The production of sterile preparations should be carried out in clean areas, entry to which should be through airlocks for personnel and/or for equipment and materials. Clean areas should be maintained to an appropriate standard of cleanliness and supplied with air that has passed through filters of the required efficiency.
- The various operations of component preparation (such as those involving containers and closures), product preparation, filling and sterilization should be carried out in separate areas within the clean area.

3.7.4. TRS 1044: WHO Good Manufacturing Practices for Sterile Pharmaceutical Products

- Annex 2 of TRS 1044 serves as a comprehensive guide for manufacturers of sterile pharmaceutical products, emphasizing stringent controls to ensure product quality and safety. It provides guidelines and principles for the manufacturing of sterile pharmaceutical products. These guidelines are designed to ensure the quality, safety, and efficacy of sterile medicines through adherence to good manufacturing practices (GMP).

3.7.5. TRS 1033: Good Regulatory Practices in the Regulation of Medical Products

This section outlines the principles of Good Regulatory Practices (GRP) as defined by WHO Annex 11 and their direct relevance to the establishment and operation of the proposed VMF. Adherence to these principles is crucial for ensuring the quality, safety, and efficacy of the produced vaccines and for building trust with regulatory authorities, healthcare professionals, and the public.

- **Legality:** The VMF's operations, from construction and production to quality control and distribution, must be conducted in full compliance with the existing legal framework in Ethiopia, primarily the Food and Medicine Administration Proclamation

(Proc. No. 1112/2019) and the EFDA Proclamation No. 1263/2021 and Regulation No. 531/2023. All regulatory interactions and submissions to the EFDA must have a clear legal basis.

- **Consistency:** The regulatory oversight of the VMF by the EFDA should be consistent with national health policies, pharmaceutical legislation, and established guidelines. The application of regulations and inspection procedures should be predictable and uniform across different vaccine manufacturers, ensuring a level playing field.
- **Independence:** The EFDA, as the regulatory authority, must operate independently, free from undue influence from commercial, political, or other vested interests. This independence is vital for ensuring objective decision-making regarding the VMF's licensing, inspections, and product approvals.
- **Impartiality:** The EFDA should treat the proposed VMF and all other regulated entities equitably, fairly, and without any bias. All regulatory decisions related to the VMF should be based on objective scientific evidence and regulatory requirements.
- **Proportionality:** Regulatory requirements and decisions applied to the VMF should be proportionate to the risks associated with vaccine manufacturing and the EFDA's capacity to effectively implement and enforce these requirements. Risk-based approaches should be adopted for inspections and regulatory oversight, focusing on critical control points and potential high-risk areas within the facility.
- **Flexibility:** The regulatory oversight should be adaptable to the evolving scientific landscape, technological advancements in vaccine manufacturing, and unforeseen circumstances, including public health emergencies. The EFDA should demonstrate timely responsiveness to specific needs and be prepared to expedite regulatory processes during health crises, while maintaining safety and quality standards.
- **Clarity:** All regulatory requirements, guidelines, and expectations pertaining to vaccine manufacturing should be easily accessible and clearly understood by the VMF's management and personnel. The EFDA should provide clear guidance documents and engage in open communication with the industry to ensure effective compliance.
- **Efficiency:** The regulatory processes for licensing, inspections, and product approvals related to the VMF should be conducted within reasonable timelines and with efficient use of resources by both the VMF and the EFDA. Collaboration with international regulatory bodies and adoption of best practices can enhance efficiency.

- **Transparency:** The regulatory framework, requirements, and decisions made by the EFDA regarding the VMF should be transparent and publicly available where appropriate. The EFDA should seek input from the VMF and other stakeholders on proposed regulatory changes and provide clear justifications for its decisions.

3.7.6. TRS 957: Good Manufacturing Practices for Pharmaceutical Products Containing Hazardous Substances

While the primary focus of this guideline is on facilities handling highly hazardous chemical substances, its principles regarding containment and environmental protection are directly relevant to the proposed VMF, especially considering the biological hazards associated with vaccine production.

- The VMF must be designed and operated to prevent the release of biological agents (live or attenuated pathogens) and any hazardous chemical substances used in the manufacturing process into the atmosphere or normal drainage systems.
- The external environment and the public in the vicinity of the VMF must be protected from potential harm arising from the handling and processing of these hazardous substances.
- Any liquid effluent from the VMF that poses a safety or contamination risk (biological or chemical) must be effectively treated on-site before discharge to a municipal drain, in accordance with the principles outlined in Annex 6.

3.7.7. TRS 1025: Points to Consider for Manufacturers and Inspectors: Environmental Aspects of Manufacturing for Prevention of Antimicrobial Resistance

This guideline is particularly critical for the VMF, even if the vaccines produced are not directly antimicrobial. The principles emphasize responsible waste management to prevent the environmental spread of antimicrobial resistance (AMR), which can arise from the release of even small amounts of antimicrobial agents used in the manufacturing process (e.g., for sterilization or in cell culture).

- Neither the vaccine product nor its residues, including any antimicrobial agents used in the process, should be allowed to escape into the atmosphere or be discharged directly to normal drainage systems.
- The external environment and the public near the VMF must be protected from potential harm from any hazardous substances, including those with antimicrobial properties.

- Liquid effluent posing a safety or contamination risk, including the potential to contribute to AMR, must be treated before discharge.
- Liquid and solid waste effluent must be handled in a manner that does not present a risk of contamination to the product, personnel, or the environment. This includes preventing the release of any substances that could contribute to AMR.
- All effluent disposal must be conducted safely and documented. If external contractors are used, they must have the necessary certifications to handle and treat hazardous products, including those with antimicrobial potential.

3.8. ISO 14644-1: 2015: Cleanrooms and associated controlled environments

ISO 14644-1 is an international standard that specifies the classification of air cleanliness in cleanrooms and controlled environments. The standard defines the maximum allowable levels of airborne particulate contamination, categorized by the size of particles (measured in micrometers). It serves as a foundational guideline for assessing and maintaining air cleanliness in a controlled environment.

- The standard provides a classification system ranging from ISO Class 1 (the cleanest) to ISO Class 9 (the least clean), based on the number of particles per cubic meter of air at specified particle sizes.
- It outlines methods for measuring airborne particulate contamination, including the use of specific equipment and procedures to ensure accurate results.
- ISO 14644-1 is applicable across various industries, including pharmaceuticals, biotechnology, semiconductor manufacturing, and aerospace, where maintaining air quality is critical for product integrity and safety.
- The standard helps organizations maintain compliance with regulatory requirements and ensures that cleanroom environments meet the necessary cleanliness levels for their specific applications.

3.9. World Bank Environmental and Social Standards and Guidelines

3.10.1. World Bank Environmental and Social Standards

According to the World Bank Environmental and Social standards, projects supported by the Bank through Investment Project Financing are required to meet the Environmental and Social Standards (ESS). The ESSs are designed to help developers manage the risks and

impacts of a project, and improve their environmental and social performance, through a risk and outcomes-based approach. Developers are required to manage environmental and social risks and impacts of the project throughout the project life cycle in a systematic manner, proportionate to the nature and scale of the project and the potential risks and impacts.

The following table provides a description of the Environmental and Social Standards (ESSs) applicable to the current project.

Table 2: World Bank Applicable ESS

World Bank ESS	Applicable	Explanation
ESS1: Assessment and Management of Environmental and Social Risks and Impacts	Yes	This foundational standard requires a comprehensive Environmental and Social Impact Assessment (ESIA) to identify, evaluate, and manage potential risks and impacts. For a vaccine facility, this entails rigorous analysis of potential impacts related to biohazardous waste management, chemical handling and disposal, air and water emissions, community health and safety, labor and working conditions and emergency preparedness and response. It also mandates the development of an Environmental and Social Management Plan (ESMP) to implement mitigation measures and monitor performance.
ESS2: Labor and Working Conditions	Yes	Given the occupational risks of construction process and specialized nature of vaccine production, this standard is vital for ensuring fair labor practices, safe working conditions, and the protection of worker rights. It addresses issues such as occupational health and safety, including exposure to potentially hazardous materials as well as labor conditions such as fair wages and working hours, prevention of child labor and forced labor and freedom of association and collective bargaining.
ESS 3: Resource Efficiency and Pollution Prevention and Management	Yes	This standard is highly relevant for a vaccine manufacturing facility due to the potential for significant resource consumption and pollution generation. It requires efficient use of water and energy, management of wastewater and air emissions to meet international standards, proper handling and disposal of hazardous and non-hazardous waste.

World Bank ESS	Applicable	Explanation
ESS 4: Community Health and Safety	Yes	Given the sensitive nature of vaccine production, this standard is paramount for addressing potential community concerns and ensuring public safety. It requires assessment of potential risks to community health from facility operations and development of emergency response plans. It also requires assessing the quality, efficacy, and safety of vaccine proposed to be manufacturing with WHO accredited laboratory prior to distributing the produce vaccine to the public use. Additionally, the safe storage and transportation of vaccines need to be evaluated. The overall drug manufacturing process should be controlled by the national regulatory authority (EFDA).
ESS 5: Land Acquisition, Restrictions on Land Use and Involuntary Resettlement	No	The VMF is to be constructed in the Kilinto Industry Park, which is a government owned entity and it is a dedicated park for bio-pharmaceutical manufacturing with enough spaces even for future expansions. There is no encroachment on the land designated for the development.
ESS 6: Biodiversity Conservation and Sustainable Management of Living Natural Resources	No	Since the project is constructed in a secured government owned area which has no potential biodiversity natural resources that are affected by the project. Hence, ESS6 is not relevant for this project.
ESS 7: Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities	No	ESS-7 is not relevant for the VMF project.
ESS 8: Cultural Heritage	No	The project is not expected to have impacts on tangible or intangible cultural heritage that have archaeological, paleontological, historical, architectural, religious, aesthetic, or other cultural significance in and around the project area. But, chance finds procedure will be included as part of this ESIA, and a chance finds clause will be added to the contracts, requiring contractors to stop construction as per procedures in the event that cultural heritage is encountered.

World Bank ESS	Applicable	Explanation
ESS 9: Financial Intermediaries	No	Financial Intermediaries (FIs) are not involved in this project.
ESS10: Stakeholder Engagement and Information Disclosure	Yes	This standard is essential for ensuring transparency and building trust with affected communities and other stakeholders. It requires meaningful consultation throughout the project lifecycle, disclosure of relevant information in a timely and accessible manner and establishment of a grievance mechanism to address community concerns.

3.10.2. World Bank Group (WBG) Guidelines: Environmental, Health and Safety Guidelines

The World Bank's EHS Guidelines provide essential frameworks for managing environmental, occupational health, and community safety aspects of development projects, particularly relevant for a vaccine manufacturing facility.

a. EHS Guidelines-General (Section 1 - 4)

These general guidelines provide a foundational approach to prevention and control across various project phases, directly applicable to vaccine facility construction and operation.

Section 1: Environmental Aspects:

- Addresses air emissions, wastewater quality, water and energy conservation, and hazardous material management. For a vaccine facility, this translates to stringent controls on bio-burdened air emissions, proper treatment of processed wastewater, efficient resource use, and safe handling of chemicals and biohazards.

Section 2: Occupational Health and Safety:

- Provides strategies for minimizing risks associated with construction and decommissioning activities, including manual labor, working at heights, and confined spaces. This is crucial during the facility's construction phase and for ongoing maintenance.

Section 3: Community Health and Safety:

- Covers fire safety, traffic safety, transport of hazardous materials, and disease prevention. For a vaccine facility, this demands robust emergency response plans,

safe transport of biological and chemical materials, and community awareness programs.

b. EHS Guidelines-Health Care Facilities (2007)

While focusing on general healthcare, these guidelines offer relevant insights into waste management, emissions, and occupational safety.

- Waste management is highly relevant, focusing on minimization, segregation, handling, and disposal of medical waste, which is a key concern for vaccine production.
- The guidelines also address air emissions and wastewater discharges, which are relevant to the vaccine facilities byproducts.
- Occupational health and safety for health workers applies to the lab workers and other employees of the vaccine manufacturing facility.

c. EHS Guidelines for Pharmaceutical and Biotechnology Manufacturing (2007):

The EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing provide information relevant to pharmaceuticals and biotechnology manufacturing facilities. They 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. The guideline provides industry-specific impacts and management recommendations. Potential environmental issues associated with pharmaceutical and biotechnology manufacturing projects covered include air emission, wastewater, solid and hazardous wastes, hazardous materials, threats to biodiversity, and bioethics. Also, the guideline provides facility-specific occupational health and safety hazards during construction and operation periods. Hazards covered during operation period include heat hazards, chemical hazards including fire and explosion, radiological hazards, noise, and process safety. Further, the guideline covers community health and safety issues in pharmaceutical and biotechnology industry. The guideline provides performance indicators and monitoring recommendations. These industry-specific guidelines are particularly crucial for a vaccine manufacturing facility.

- They cover the production of active pharmaceutical ingredients, formulation, and related research activities, directly aligning with vaccine production processes.
- Potential environmental issues, including air emissions, wastewater, solid and hazardous wastes, hazardous materials, biodiversity threats, and bioethics, are

included in this guideline. This helps to ensure that the facility manages its environmental footprint responsibly.

- Facility-specific occupational health and safety hazards, such as heat, chemical, radiological, noise, and process safety hazards, are covered, ensuring a safe working environment.
- Community health and safety issues are also included, emphasizing the importance of transparent communication and risk management.
- Performance indicators and monitoring recommendations are provided, which will help to ensure the facility is operating within acceptable limits.

3.10. Comparison between Ethiopian and World Bank Environmental and Social Safeguards Requirements

Table 3: Comparison between Ethiopian and World Bank Environmental and Social Safeguards Requirements

Sr.No.	Thematic Area	Ethiopian Framework	World Bank ESS / EHS Framework	Comparison Summary
1.	Legal Foundation for ESIA	Anchored in the FDRE Constitution (Art. 92) and Proclamation No. 299/2002 (EIA Proclamation). Requires environmental and social impact assessments for projects with potential adverse effects.	ESS1: Assessment and Management of Environmental and Social Risks and Impacts. Requires a comprehensive ESIA with risk-based management and an Environmental and Social Management Plan (ESMP).	Both frameworks require full ESIAs and ESMPs. WB ESS1 is more performance- and outcome-based, while Ethiopia's approach is procedural and compliance-based.
2.	Labor and Working Conditions	Governed by Labour Proclamation No. 1156/2019 and Public Health Proclamation No. 200/2000 emphasizing OHS, fair treatment, and no child/forced labor.	ESS2: Labor and Working Conditions mandates safe working conditions, grievance mechanisms, and protection of vulnerable groups.	Largely consistent; WB ESS2 adds formal grievance mechanisms and labor management plans, not explicitly required in Ethiopian law.
3.	Pollution Prevention & Resource Efficiency	Proclamations No. 300/2002 (Pollution Control), No. 1090/2018 (Hazardous Waste), and Water Management Policy (1999) regulate emissions, effluents, and hazardous waste.	ESS3: Resource Efficiency and Pollution Prevention and Management; EHS Guidelines (General + Pharmaceutical Manufacturing) set quantitative limits and best practices.	Ethiopia provides general regulatory standards, while WB provides specific emission and discharge limits, encouraging international best practice and energy/water efficiency.
4.	Community	Covered under Public	ESS4: Community	Ethiopian law covers

	Health and Safety	Health Proclamation No. 200/2000 and EPA EIA Guidelines (2003, 2020); requires assessment of risks to communities.	Health and Safety mandates risk assessment, emergency preparedness, and management of hazardous materials and transport safety.	basic requirements; WB adds structured emergency planning, traffic safety, and specific risk communication protocols.
5.	Land Acquisition and Resettlement	Addressed under Expropriation Proclamation No. 1161/2019 (not mentioned but relevant).	ESS5: Land Acquisition, Restrictions on Land Use, and Involuntary Resettlement.	For this project, both are non-applicable; but WB ESS5 is more detailed on livelihood restoration and compensation principles.
6.	Biodiversity and Natural Resources	Biodiversity Policy (1998) and Proclamation No. 120/1998 safeguard ecosystems.	ESS6: Biodiversity Conservation applies if ecosystems are affected.	Ethiopia's laws align conceptually but lack WB's ecosystem service and critical habitat definitions.
7.	Indigenous Peoples / Vulnerable Groups	No direct equivalent; social inclusion handled under general social protection frameworks.	ESS7: Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities.	Ethiopia lacks a distinct policy; WB provides specific requirements for inclusion, participation, and FPIC (Free, Prior and Informed Consent).
8.	Cultural Heritage	Covered under FDRE Criminal Code (Art. 522–525) and EIA Guidelines (2003).	ESS8: Cultural Heritage.	Both frameworks require chance-find procedures; WB provides broader coverage of intangible heritage.
9.	Stakeholder Engagement & Disclosure	Ethiopian ESIA Guidelines require public consultation and documentation.	ESS10: Stakeholder Engagement and Information Disclosure.	WB is more structured, requiring formal engagement plans, ongoing dialogue, and grievance redress mechanisms.
10.	Health & Safety in Manufacturing	Regulated by EFDA through GMP, Pharmacovigilance, Waste Disposal, and Medicine Registration directives.	Addressed under WB EHS Guidelines: Pharmaceutical & Biotech Manufacturing (2007) standards.	Ethiopian GMP and EFDA procedures align closely with WB principles.

4. ENVIRONMENTAL AND SOCIO-ECONOMIC BASELINE

The various methods employed in collecting and documenting environmental and social baseline conditions of the project area are highlighted below. The baseline condition of the

proposed location was established through literature research, and a field data gathering conducted by a multi-disciplinary team of environmentalists, sociologists, and engineers. Both literature review and field assessment were conducted within the framework of national environmental guidelines and World Bank Environmental and Social Standards and best practices.

4.1. Location of the Project Area

The proposed VMF project will be located within plot 22 (which is 22.139 square meters wide) of the Kilinto Industry Park (KIP), situated in the south-eastern part of Addis Ababa, specifically within the Akaki-Kality sub-city (Woreda 9 and 10). The Park is located between 80 55” and 90 05” North latitude and 38 40” and 38 50” East longitude. It is in an area close to Bole International Airport (6 km), Debre Zeit Road (3.5 km) and 777 km from Djibouti. KIP is solely targeted at the pharmaceutical industry. The park started operation in the year 2019 with 279 hectare land, of which 137.97 ha is serviced land ready for rent in the park. KIP has a well-developed road network. There are three different asphalt roads with a width of 30m, 20m and 15m which serves as the main access for each block in the industrial park. Each road is built with slope protection and drainage ditches. The park also has parking areas for light and heavy trucks. While geographically within Addis Ababa, the KIP area has transitioned rapidly from a predominantly rural setting to an urbanizing zone in the last ten years. This rapid urbanization is a crucial factor to consider in the environmental and social impact assessment.

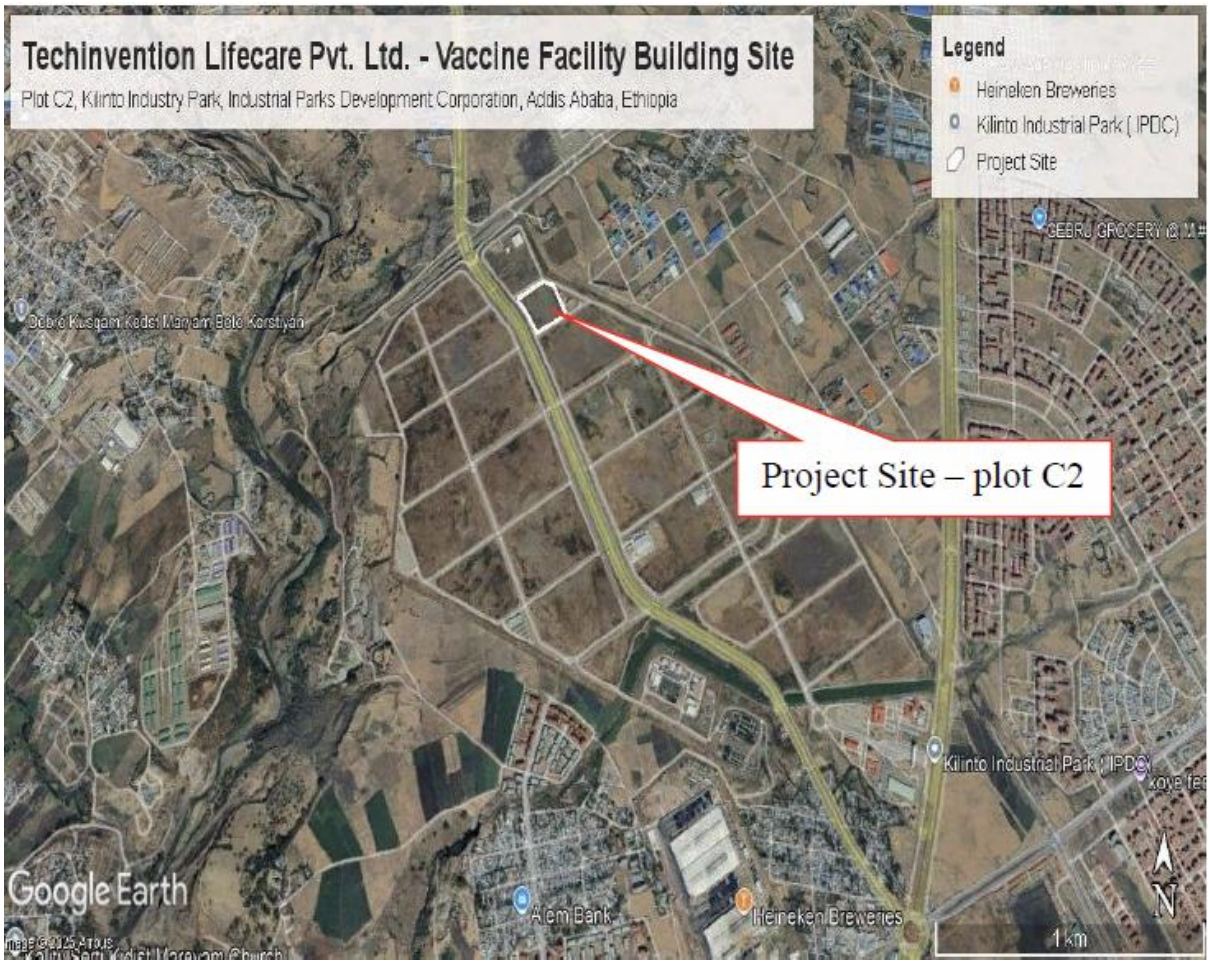


Figure 9: Satellite Image of the Project Area and Vicinity

4.1.1. Area of Influence

The project's Area of Influence (AoI) encompasses the geographical extent and the population (human and ecological receptors) likely to be affected by the VMF throughout its lifecycle (pre-construction, construction, operation, and decommissioning). The AoI is defined to capture both direct and indirect impacts, as well as potential cumulative effects.

- **Direct Area of Influence:** This includes the immediate footprint of the VMF within the KIP. This zone is directly impacted by construction activities (site preparation, building erection) and operational activities (e.g., waste generation, emissions from stacks, internal transport, and utilities consumption). Key elements within this direct AoI include the VMF plot itself, internal KIP roads used for project access and KIP's central utility infrastructure (e.g., wastewater treatment plant, solid waste sorting area, power substation) that directly serve the VMF.
- **Indirect Area of Influence:** This extends beyond the immediate project site to areas where project-related activities may cause secondary or induced impacts. This includes:
    - **Kilinto Industrial Park as a whole:** Due to shared infrastructure and services (e.g., KIP's central wastewater treatment plant, fire brigade, security services, internal traffic flow).

- **Surrounding residential communities:** While the VMF is within KIP, nearby communities (within Akaki Sub-City Woredas 9 and 10) could experience indirect effects such as increased traffic on access roads, changes in air quality from construction dust or operational emissions (even if mitigated), noise disturbances during construction, and potential demand on local services or labor.
- **Transportation routes:** Roads leading to and from KIP used for material delivery, waste transport, and employee commuting.
- **Downstream environments:** Water bodies that could potentially be affected by treated effluent discharge from KIP's central wastewater treatment plant, even though the KIP system aims for Zero Liquid Discharge.

- **Cumulative Area of Influence:** This broader area considers the combined effects of the VMF project with other existing and planned developments within KIP and the wider Addis Ababa region. This includes other industries within KIP, urban expansion, and regional infrastructure projects. The cumulative AoI helps assess the combined stress on shared resources (e.g., water, electricity), infrastructure (e.g., roads, municipal waste management facilities), and environmental receptors (e.g., regional air quality, water quality) from multiple sources.

Figure 10: Estimated distance and slope of the proposed project site relative to nearby rivers (Based on Google Earth Image Analysis)

4.2. The Bio-geophysical Environment

4.2.1. Relief and Topography

Addis Ababa sits at an average elevation of 2,400m above sea level, at the foot of mountains exceeding 3,000m. The elevation decreases towards the south and southeast, where KIP is

located. The topography of the VMF site within KIP is predominantly flat to gently rolling, with elevations ranging from 2119m to 2202m a.s.l. This falls within the Weyna-dega (mid-highlands, 98%) and Dega (highlands, 2%) agro-ecological zones. 76% of the land has a slope below 3 degrees, and 23.4% has a slope between 3 and 6 degrees. Higher ground exists to the south and southeast, including Yerer Mountain and the Yudoro and Fetch Koye hills. The generally flat terrain of KIP facilitated its development as an industrial park.

4.2.2. Geological structure

4.2.2.1. Regional Geology

Addis Ababa is situated on the western margin of the Main Ethiopian Rift Valley, a tectonically active zone characterized by fracturing due to tension forces. The geology of the area comprises primarily volcanic rocks, often covered by recent Quaternary superficial deposits. The rift valley is dominated by acidic Quaternary rocks, while the plateau areas consist of older Tertiary basic formations. Addis Ababa lies on the boundary of these blocks, resulting in a mix of acidic and basic rocks. This geological diversity influences base flow of rivers and runoff coefficients.

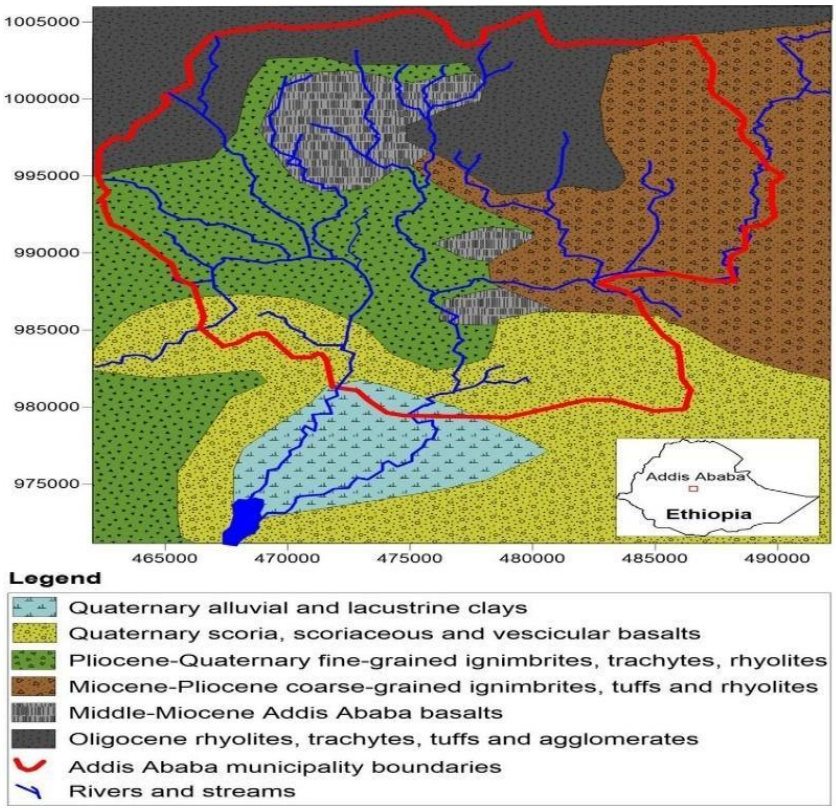


Figure 11: Regional Geological Map of Addis Ababa (Colombani et al., 2018)

4.2.2.2. Site Geology

According to the current study by Techinvention Lifecare Ltd. (Feb, 2025) which drilled six boreholes, site-specific geology is generally represented by soil and rock formations. Coordinates of drilled boreholes are shown in Table 3.

Table 4: Coordinates of drilled boreholes

Borehole Coordinates			
Borehole ID	**Easting**	**Northing**	**Elevation (m)**
BH-1	478071	985510	2189.8
BH-2	478017	985479	2187.9
BH-3	478084	985447	2189.9
BH-4	478049	985437	2188.6
BH-5	478153	985450	2192.5
BH-6	478072	985393	2189.3

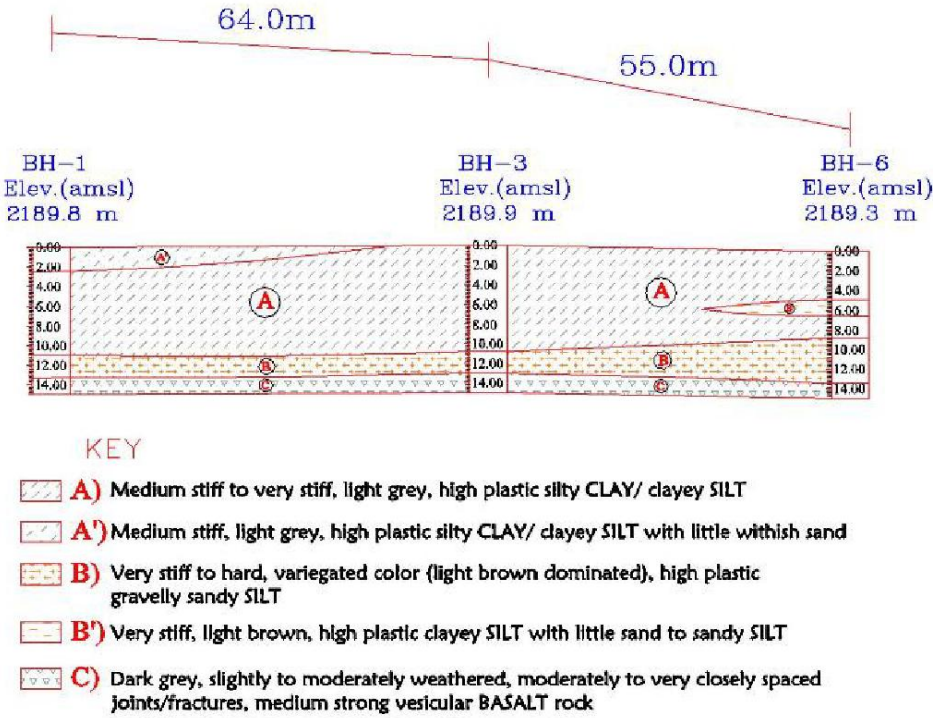
Accordingly, the subsurface profile of the site is divided into major geological/geotechnical units which make up the entire formation down to the maximum investigated depth of 15m which are relevant to foundation design. Generalized Sub Surface Profiles are shown in Figure 11.

- The uppermost layer (Layer A) is light grey, high plastic silty CLAY/clayey SILT formation (expansive soil) that extend to a maximum depth of 15.0m below existing ground level; Characteristically similar soil layer but mixed with little whitish sand layer (Layer A') encountered in BH-1
- Following the upper expansive soil formation is very stiff to hard, variegated color (light brown dominated), high plastic gravelly sandy SILT (Layer B);
- Very stiff, light brown, high plastic clayey SILT with little sand to sandy SILT (Layer B') found intercalated in the expansive soil layer in BH-6;
- The bottom layers (Layer D) described as grey, closely to moderately spaced joints/ fracture medium strong vesicular BASALT layer.

Laboratory tests from the geotechnical investigation (conducted by Tech Invention) revealed that the primary bearing layer (Layer A) exhibits high plasticity and a very high potential for volume change. These expansive soils are prone to volume changes with variations in moisture content, leading to differential settlement (due to non-uniform wetting/drying) and inducing swelling/expansion pressures on foundation structures and floor slabs. Therefore, the foundation and superstructure design must accommodate these movements and stresses, incorporating sufficient flexibility and rigidity to prevent cracking and other structural damage.

For this site, spread footing foundations for the proposed structures should be placed at a depth of 3.00m below the lowest ground level within each building's footprint, to extend beyond the active moisture fluctuation zone of the expansive soil formation.

Geotechnical Cross Section throught BH-1, BH-3 and BH-6



Geotechnical Cross Section throught BH-4, BH-3 and BH-5

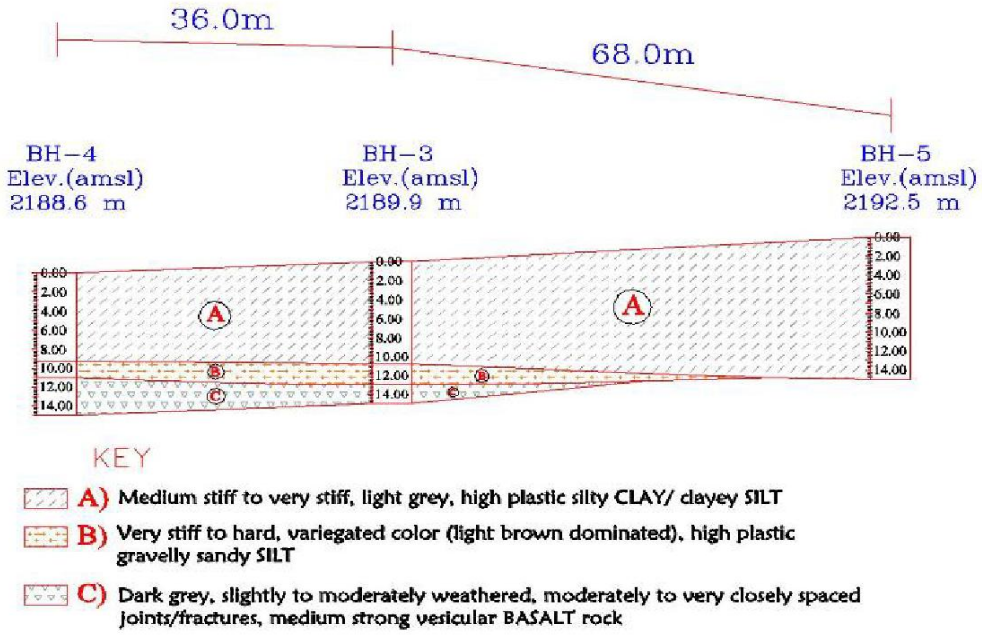


Figure 12: Generalized Sub Surface Profiles

4.2.2.3. Climate

Addis Ababa experiences a bimodal rainfall pattern typical of the Central Highlands of Ethiopia. The main wet season (Kiremt) extends from June to September, contributing approximately 70% of the annual rainfall. A shorter rainy season (Belg) occurs from mid-February to mid-April. The remaining months are dry. The average annual temperature range is 15-20°C (maximum) and 10-15°C (minimum). Average annual rainfall ranges from 800-1200 mm. Data from the Bole Airport meteorological station, located 6 km north-northeast of KIP, indicates a mean maximum annual temperature of 23.5°C, a mean minimum of 10.5°C, and a mean annual temperature of approximately 17°C.

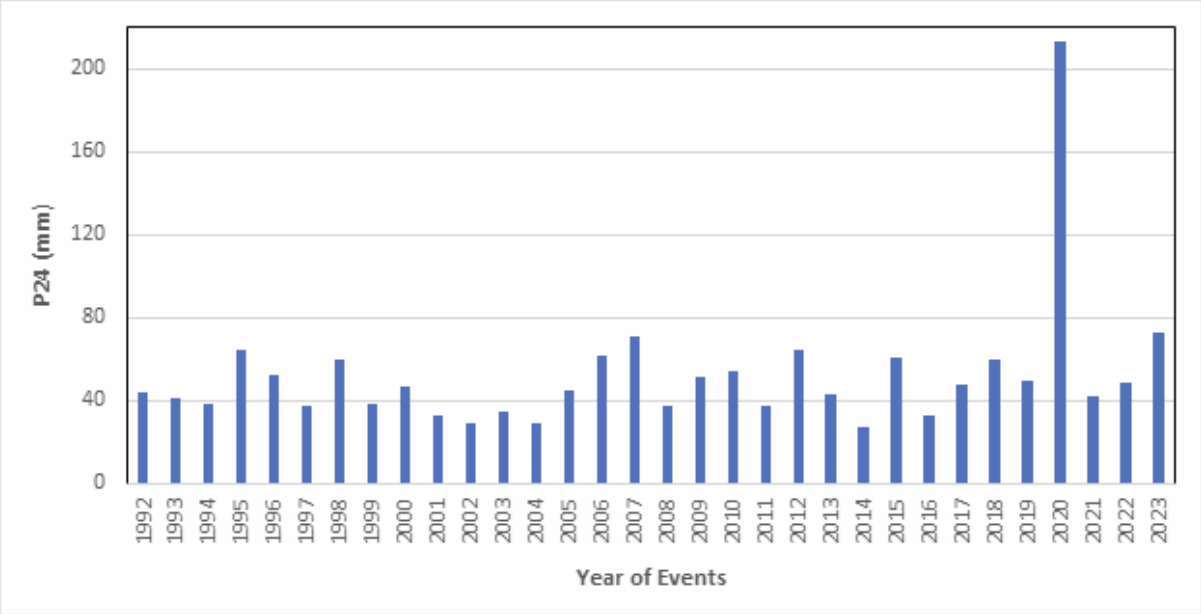


Figure 13: Historical peak daily rainfall events of Addis Ababa (Data from Ethiopian Meteorological Institute)

The daily temperature variation is more pronounced than the annual variation. Temperatures in KIP are expected to be slightly warmer than the city center due to the lower elevation. The Akaki-Kaliti sub-city falls within the Weyna-dega (98%) and Dega (2%) agro-ecological zones. Annual rainfall in the KIP area is estimated at 1080 mm, and wind speed at 0.55 km/hr, with a predominantly westerly direction. Prevalent wind in the three seasons of Addis Ababa Bole station based on long term data (1981-2010) was presented using a wind rose diagram from Figure 14.

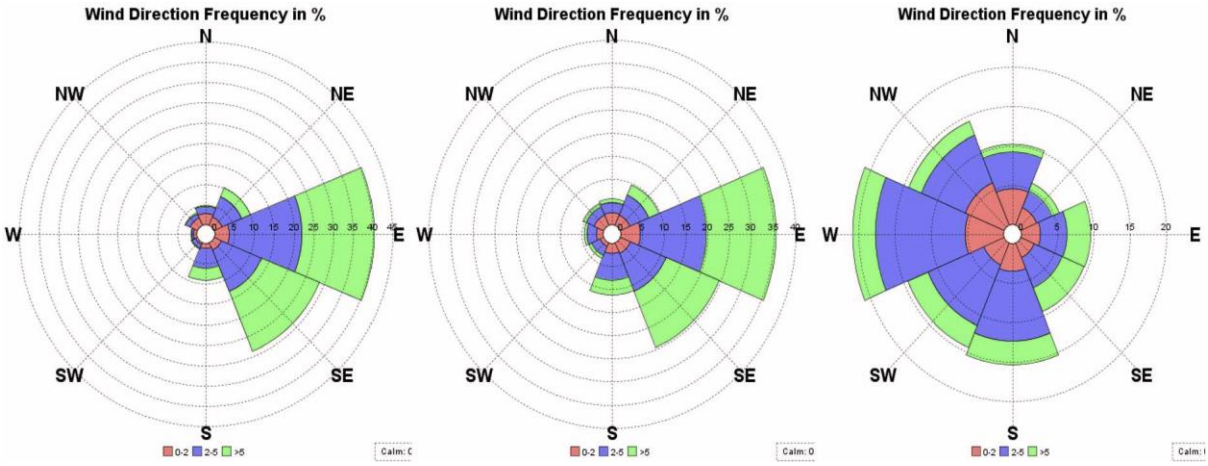


Figure 14: Prevalent wind in the three seasons of Addis Ababa Bole station (Bega, Belg & Kiremt)

4.2.2.4. Soils

The climate and topography of KIP favor the development of thick soil profiles. Field observations indicate that the site is predominantly covered by black cotton soil, deposited over weathered rock. This soil is characterized by high plasticity and waterlogging during heavy precipitation. Despite these characteristics, it is considered fertile by local communities.

Tech Invention Lifecare Pvt. Ltd conducted field-level soil formation tests at six boreholes using dry drilling methods. Standard Penetration Tests (SPT) were used to assess the relative density of expansive soils and the consistency of cohesive soils. The field records of representative SPT N-values with corresponding depth along with the layer's description are summarized under Table 4.

Table 5: Field records of representative SPT N-values with corresponding depth along with the soil layers

BH ID	Depth (m)	SPT N Recorded-Value/450mm	Layer Description
BH-1	2.00 – 2.45	2/3/3	Medium stiff, light grey, high plastic silty CLAY/ clayey SILT with little whitish sand
	4.00 – 4.45	3/4/5	Medium stiff to stiff, light grey, high plastic silty CLAY/ clayey SILT with little sand (expansive soil)
	6.00 – 6.45	5/7/10	
	8.00 – 8.45	4/5/6	
	10.00 – 10.45	5/6/8	
	11.70 – 12.45	6/9/12	Very stiff, variegated color (light brown dominated) high plastic sandy SILT
	13.00 – 15.00	Rock layer	Dark grey, slightly to moderately weathered,

			moderately to closely spaced joints/fractures, medium strong vesicular BASALT rock
BH-2	2.00 – 2.45	3/3/4	Medium stiff to very stiff, light grey, high plastic silty CLAY/ clayey SILT
	4.00 – 4.45	4/6/8	
	6.00 – 6.45	5/8/11	
	8.00 – 8.45	4/8/9	
	10.40 – 15.00	Rock layer	Dark grey, slightly to moderately weathered, moderately to closely spaced joints/fractures, medium strong vesicular BASALT rock
BH-4	2.00 – 2.45	3/4/6	Stiff to very stiff, light grey, high plastic silty CLAY/ clayey SILT
	4.00 – 4.45	6/8/8	
	6.00 – 6.45	7/9/10	
	8.00 – 8.45	5/7/8	
	10.40 – 10.95	6/8/12	Very stiff, variegated color (light brown dominated), high plastic sandy SILT
	11.00 – 15.00	Rock layer	Dark grey, slightly to moderately weathered, closely to very closely spaced joints/fractures, medium strong vesicular BASALT rock
BH-5	2.00 – 2.45	2/2/3	Medium stiff to very stiff, light grey, high plastic silty CLAY/ clayey SILT
	4.00 – 4.50	4/5/6	
	6.00 – 6.45	4/7/8	
	8.00 – 8.45	5/7/9	
	10.00 – 10.45	5/8/9	
	12.00 – 12.45	5/8/10	
	14.00 – 14.45	6/8/12	
BH-6	1.50 – 1.95	2/3/3	Medium stiff to very stiff, light grey, high plastic silty CLAY (expansive soil)
	3.00 – 3.45	2/4/4	
	4.50 – 4.95	2/4/5	
	6.00 – 6.45	4/8/9	
	7.50 – 7.95	4/7/7	
	9.00 – 9.45	6/8/11	Very stiff, variegated color (light brown dominated), high plastic gravelly sandy SILT
	10.50 – 10.95	7/10/7	
	13.50 – 15.00	Rock layer	Dark grey, slightly to moderately weathered, closely to very closely spaced joints/fractures, medium strong vesicular BASALT rock

4.2.2.5. Surface and Groundwater (Drainage)

The project site lies within the Akaki River catchment, which comprises the Big and Little Akaki Rivers that drain a wide area of Addis Ababa. The river system is notably affected by domestic and industrial waste discharges, resulting in considerable pollution. Within the Kilinto Industrial Park (KIP), the Idoro and Kilinto Rivers pass through the area, necessitating the delineation of buffer zones to mitigate potential flood risks. Groundwater resources, accessed through six boreholes within the KIP, serve as a major water supply source.

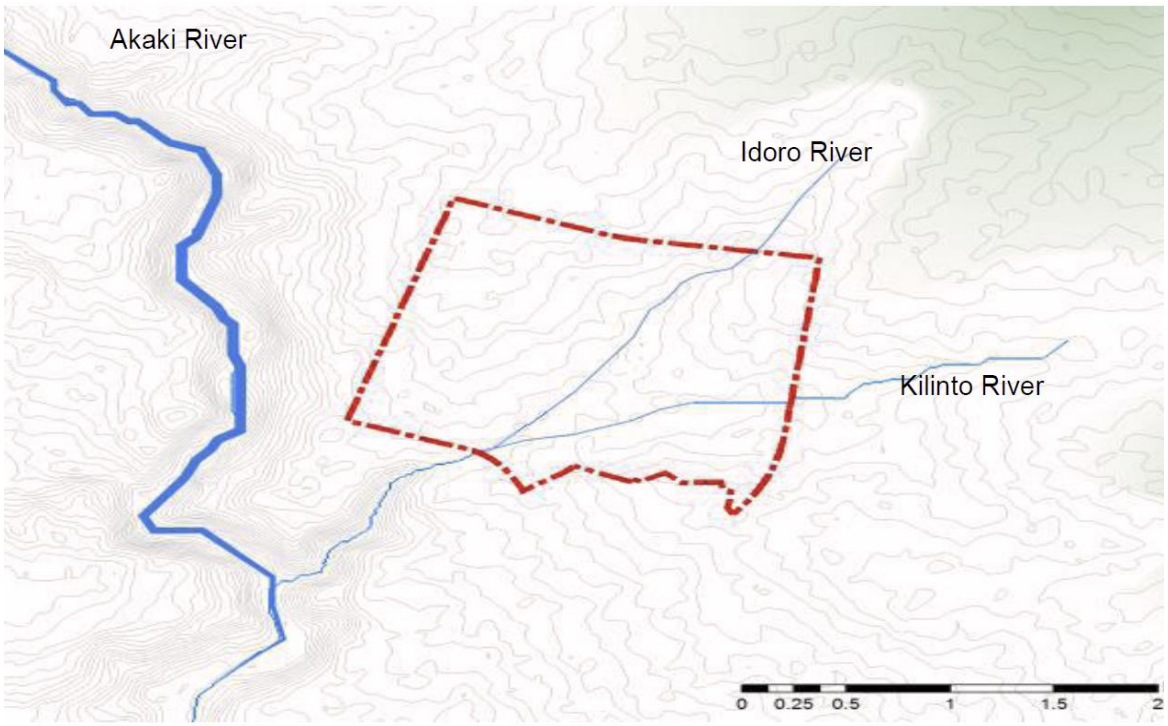


Figure 15: Surface Water Crossing the KIP, Addis Ababa

4.2.2.6. Ground Water Condition

During the course of the drilling by Techinvention Lifecare Ltd; water was not found in all boreholes and variation in location of the long-term water table may occur as a result of changes in precipitation, evaporation, seepage and other factors not immediately apparent at the time of this exploration. Moreover, no corrosion attack is expected on the foundation structure.

4.2.2.7. Flora and Fauna

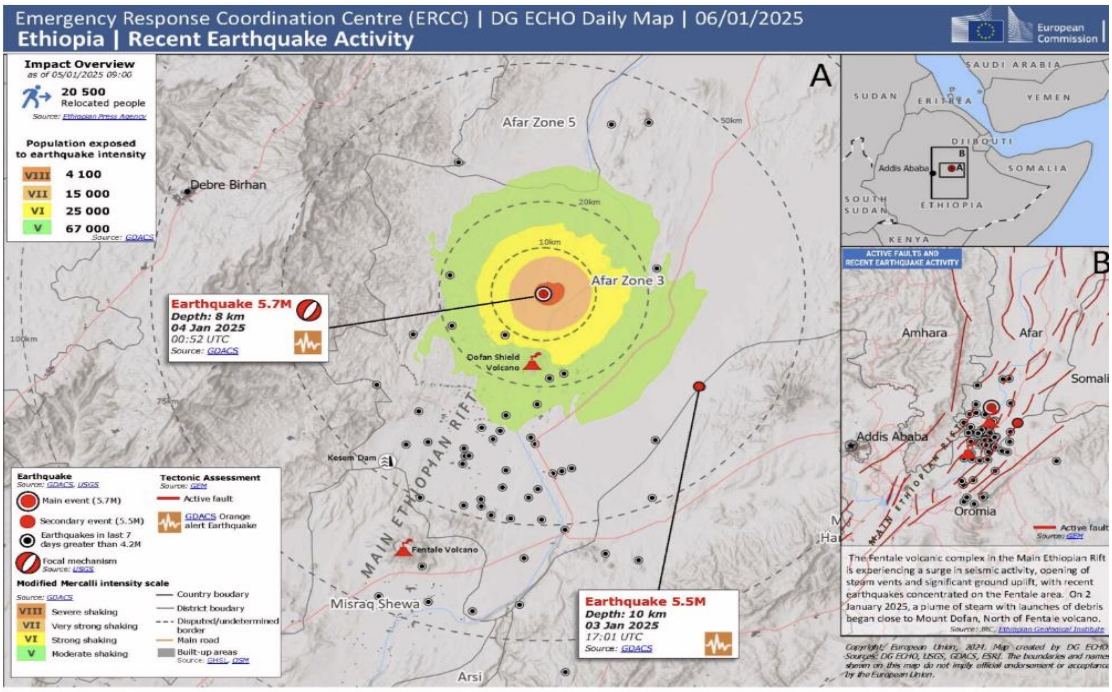
Site observations and information from the KIP community indicate that the area is largely devoid of significant vegetation cover and wildlife due to prolonged farming activities and human interference.

4.3. Natural Calamity Risks of the Project Site

Assessing the potential risks posed by natural calamities to a proposed vaccine manufacturing facility is important to ensure operational continuity, safety, and minimize environmental and social impacts. Addis Ababa's location within the East African Rift System and its specific geographical and climatic conditions necessitate a thorough assessment of seismic, volcanic, and flood risks.

4.3.1. Seismic Zone and Earthquake Risks

Addis Ababa is situated within the seismically active East African Rift System, making it susceptible to earthquakes. The city's proximity to the Ethiopian Rift Valley, which hosts active and dormant volcanoes (e.g., Mount Fentale), further complicates the risk profile. Recent seismic activity near Mount Fentale, including a series of magnitude 5+ earthquakes in late 2024 and early 2025, with tremors felt in Addis Ababa, underscores this vulnerability. This ongoing activity, accompanied by steam vents and evacuations in affected areas, indicates a heightened seismic risk.



ERCC – Emergency Response Coordination Centre map of earthquake activity in Ethiopia dated 06-01-2025 (Map: European Union)

Figure 16: Recent earthquake activity in Ethiopia

4.3.2. Volcanic Eruption Risks

Although Addis Ababa is not directly adjacent to active volcanoes, the city faces indirect risks from volcanic eruptions in the region, primarily through ashfall. While the likelihood of a major eruption directly impacting Addis Ababa is considered low, prevailing wind patterns could carry volcanic ash clouds towards the city.

Volcanic ashfall can disrupt air travel, impacting transportation and logistics. It can also contaminate water sources, potentially affecting public health. Furthermore, ash accumulation can damage infrastructure, including power lines and communication networks. Preparedness measures, such as monitoring volcanic activity and developing ash fall response plans, are essential to mitigate these potential disruptions and protect public safety.

4.3.3. Flood Risks

Addis Ababa, situated within the Akaki watershed, experiences a temperate Afro-Alpine climate with distinct wet seasons. The city's rapid development, coupled with factors like construction near rivers, a weak sewerage system, and inadequate drainage, increases its vulnerability to flooding, particularly during the Kiremt (June-September) rainy season. Some of the greatest flood risk occurs in the southern half of the city where the slope is relatively flatter than in the northern parts of the city (Figure 16). Considering the project site's considerable distance from nearby rivers and its location on an intermediate slope, the likelihood of flooding is minimal. The calculated flood risk for the proposed VMF construction site is 0.15, indicating a very low flood hazard (See Figure 17).

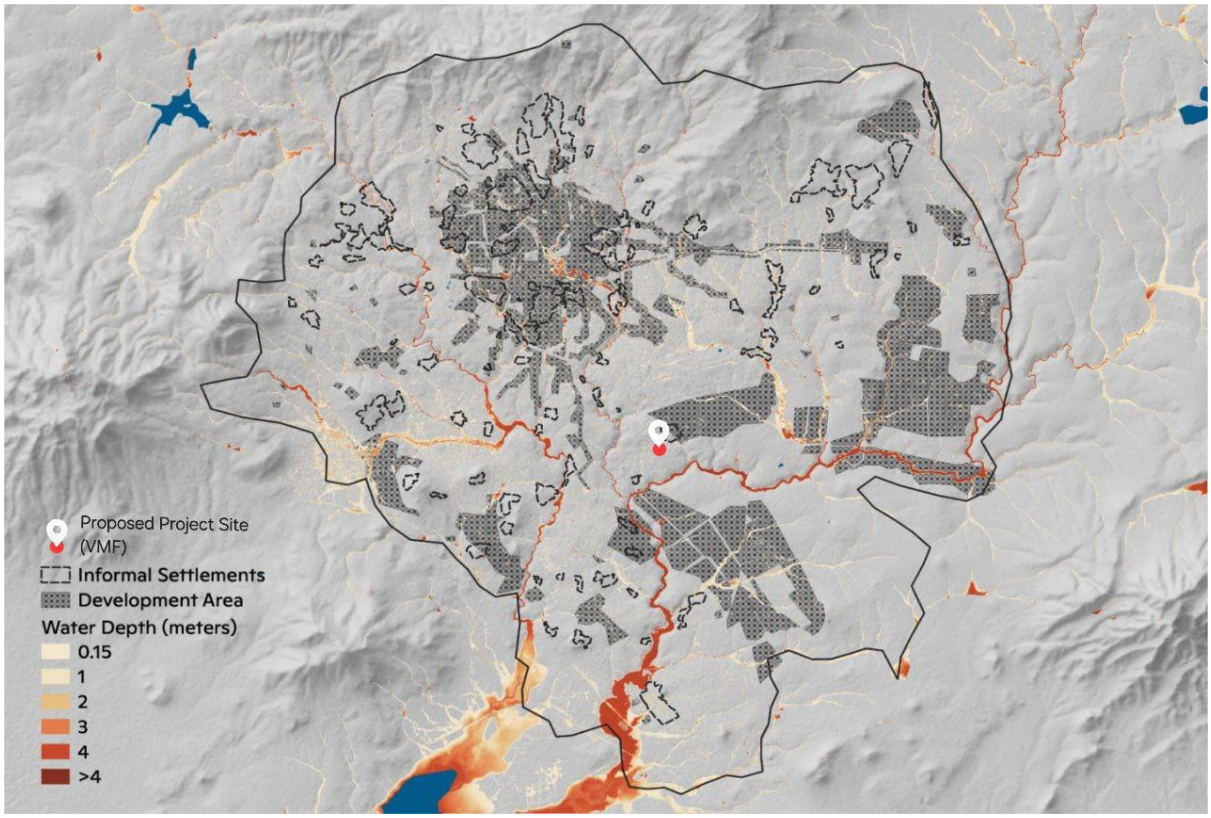


Figure 17: Map illustrating Addis Ababa city prone area to greatest flood risk (Dusseau et al., 2023)

4.4. Land Use of the Project Area (KIP Infrastructure, Service and Practices)

Given the project site's location within the Kilinto Industrial Park (KIP) and its reliance on park-provided facilities and services, an assessment of the park's enabling environment is essential. The KIP encompasses 280 hectares of serviced land from which 166 hectares were specifically designed for pharmaceutical industries, with 22 investors currently occupying plots for investment. Access to the park is facilitated through two gates: a main entrance and

a separate entrance designated for construction vehicles. Each plot benefits from comprehensive utility and infrastructure access, including electricity, manhole connections, telecom lines, domestic and industrial waste sewer lines, a water supply line, and internal roadways. Furthermore, a dedicated health center, complete with a brick-built incinerator for managing its waste, serves the staff of KIP investors. The data collection process illustrated in Figure 18, 19 and 20.

Figure 18: Kilinto Industrial Park Capacity Assessment (Discussion with KIP engineering team experts and Environmental Safeguards Specialists from MOH)

Figure 19: Kilinto Industiral Park Capacity Assessment (Site Visit with KIP engineering team experts and Environmental Safeguards Specialist from MOH)

Figure 20: Waste Water treatment Plant under construction in KIP

4.4.1. Wastewater management

KIP's wastewater treatment plant (WWTP) is under construction (91% physical progress) with state-of-the-art, zero liquid discharge (ZLD) technology. The wastewater collection system consisted of double drainage pipelines for industrial waste and domestic sewer separately. The capacity of the treatment plant is 14 million liters per day (14 MLD) from which 13580 – 13720 m3/day (about 97.0 – 98.0 %) will be recovered. The treated water (reclaimed water) will be re-used for greenery and road cleaning.

The industrial park regulations mandate that all investors install a dedicated septic/holding tank with a minimum retention capacity of 72 hours for wastewater. This 72-hour holding

period is primarily intended to ensure sufficient wastewater volume is accumulated to facilitate the optimal and continuous operation of the Kilinto Industrial Park (KIP) Wastewater Treatment Plant (WWTP).

KIP WWTP plan is designed to meet guidelines like International Finance Corporation (IFC) for wastewater discharge, Ethiopia Environmental standard for industrial pollution, Compulsory Ethiopian Standard 329: for sludge management, ISO 16075-2020: Guidelines for wastewater reuse. The KIP WWTP features several major treatment units, including a screen and grit chamber, air floatation system, biological aeration, membrane bio-filtration, a reverse osmosis system, and a multiple effect evaporator for reject management. The KIP WWTP employs a comprehensive treatment process, including: a receiving chamber, stilling chamber, bar screen chamber, grit removal chamber, equalization tank (with jet mixer), pipe flocculator, high-efficiency air flotation (HAF), membrane bioreactor (MBR), clean-in-place (CIP) system, MBR permeate tank, disinfection, and sludge management. The treatment plant design parameters and expected treated wastewater characteristics are presented in Table 5 and 6, respectively. Detailed process descriptions and design criteria are available in the updated KIP ESIA study report (2017).

The treatment process incorporates sludge thickening and drying beds for managing sludge. Sludge management is a critical environmental consideration within the KIP. Chemical sludge from the HAF system is dewatered using a centrifuge. Biological sludge from the aeration tank is thickened prior to centrifuge dewatering. After Thickening, the sludge feed into the Centrifuge for further dewatering. The resulting dewatered sludge cake is then transported to the sludge storage yard for disposal. Given that the Wastewater Treatment Plant (WWTP) is currently under construction, it is not possible to provide data on treated sludge characteristics. The sludge will be disposed in a landfill upon rigorous testing and confirmation that it meets all applicable permissible limits set by both national and relevant international environmental standards like USEPA's Toxicity Characteristic Regulation, 2024.

Table 6: KIP WWTP Design Parameters

Sr. No.	Parameters	Raw Effluent Pharmaceutical (ppm)	Sewage (ppm)	Blended Effluent & Sewage (ppm)
1	pH	7.0 - 9.0	7.0 - 8.0	7.0 - 9.0
2	Total Suspended Solids **(TSS)**	3000 - 5000	750	3000 - 5000

3	Total Dissolved Solids **(TDS)**	350	300	346.9
4	Biological Oxygen Demand **(BOD)**	500	350	489.3
5	Chemical Oxygen Demand **(COD)**	1500 - 2000	630	1902
6	Oil & Grease	10	-	9.3
7	Color	<100	-	<100
8	Total Nitrogen **(as N)**	76	-	70.6
9	Total Phosphorus **(as P)**	12	-	<12

Table 7: KIP WWTP Expected Treated Wastewater Characteristics

Sr. No.	Parameters	Treated Water Quality (ppm)
1	pH	6.5-8.0
2	Total Suspended Solids **(TSS)**	<400
3	Total Dissolved Solids **(TDS)**	BDL
4	Biological Oxygen Demand **(BOD)**	<5
5	Chemical Oxygen Demand **(COD)**	<15
6	Oil & Grease	BDL
7	Color	BDL
8	Total Nitrogen **(as N)**	<1
9	Total Phosphorus **(as P)**	<5

4.4.2. Solid Waste Management

The waste generated within the KIP can be classified into hazardous and non-hazardous waste (combustible, incombustible, domestic and recyclable wastes). Each investor within the KIP is responsible for segregating their waste at the source, separating materials based on their type.

A designated area within the Kilinto Industrial Park (KIP) facilitates non-hazardous waste sorting activities, demonstrating a commitment to responsible waste management. The KIP administration intends to collaborate with small-scale enterprises specializing in waste management to enhance efficiency and promote local economic development. To support proper waste management practices, adequate waste containers have been strategically positioned throughout the park. A sufficient space for storing waste for three days shall be secured for transfer station and facilities. This segregated waste (non-hazardous waste) is then collected and appropriately disposed of by licensed waste disposal firms, ensuring adherence to environmental regulations and proper handling of various waste streams.

Figure 21: KIP Waste Sorting Site and Containers

4.4.3. Security Services

Security within the Kilinto Industrial Park (KIP) is maintained through a multi-layered approach. Twenty-two elevated security houses strategically positioned across the grounds to provide enhanced visibility. Security personnel operate in three shifts to ensure continuous monitoring. Furthermore, federal police units patrol the area, supplementing the park's security measures. Individual industries within the KIP are required to establish their own perimeter fences and implement 24-hour surveillance camera systems for added security. Regular weekly meetings facilitate case evaluation within and surrounding the park, promoting collaboration between KIP security, local police, and security officers from Akaki Kality Woreda 9 and 10. This collaborative approach fosters a secure environment for both investors and the surrounding community. The emphasis on individual industry responsibility, combined with coordinated security patrols and regular inter-agency meetings, contributes to KIP's overall security framework.

4.4.4. Fire Fighting Services

The Kilinto Industrial Park (KIP) collaborates with the Addis Ababa City Administration (AACA) Fire and Emergency Response Office to ensure adequate fire safety measures. Currently, the park's firefighting capacity includes one firetruck and nine strategically located

fire hydrant spots. While there is currently one fire safety expert on staff, plans are underway to increase the number of experts through a Memorandum of Understanding (MoU) with the AACA, further bolstering the park's capabilities. A 24/7 firefighting service is in place, providing continuous readiness to respond to any fire-related emergencies within the KIP. The collaboration with the city administration, combined with dedicated resources and ongoing efforts to expand expertise, demonstrates a commitment to proactive fire prevention and rapid response capabilities, ensuring the safety of park occupants and assets. The KIP is prepared to respond to any emergencies and will enhance its safety through a partnership with the city. Figure 21 shows the firetruck of the KIP.

Figure 22: Fire truck of KIP

4.4.5. Water supply

The KIP is equipped with state-of-the-art water supply technology, which includes automatic SCADA control system and switchboards for both the submersible and surface pumps. The water supply is obtained from six boreholes, which have been drilled within the compound. The six boreholes have a total discharge capacity of 289.47 liters/s. The park have four reservoirs, of which two are elevated reservoirs each having a capacity of 250 m3, and two ground reservoirs with a capacity of 5,000 m3 and 1,000 m3 respectively, with booster pump station installed at the 1,000 m3 reservoir and 18,000 m reclaimed water line of about 18,000m for greenery and road cleaning. However, KIP does not have a water treatment plant, except for the treatment of the pumped water with chlorine. The tenants of the park are expected to treat the water as per their requirement.

4.4.6. Existing GRM in the KIP

The KIP grievance redress mechanism is designed to provide a supportive and efficient process for individuals to voice their concerns through the established Grievance Redress Committee. Any person with a grievance is encouraged to report their issue directly to the committee, ensuring that every concern is heard and addressed. Should the grievance remain unresolved, individuals have the option to escalate their concerns to the IPDC, either in person or via their user-friendly website at https://www.ipdc.gov.et/organization/contact/ (as indicated in Figure 22). These report channel has been utilized to receive grievance related to project implementation within the KIP as well as comments on service improvement. This structured approach allows the IPDC-level Grievance Redress Committee to thoroughly investigate and resolve cases, fostering a transparent and responsive environment for all stakeholders involved.

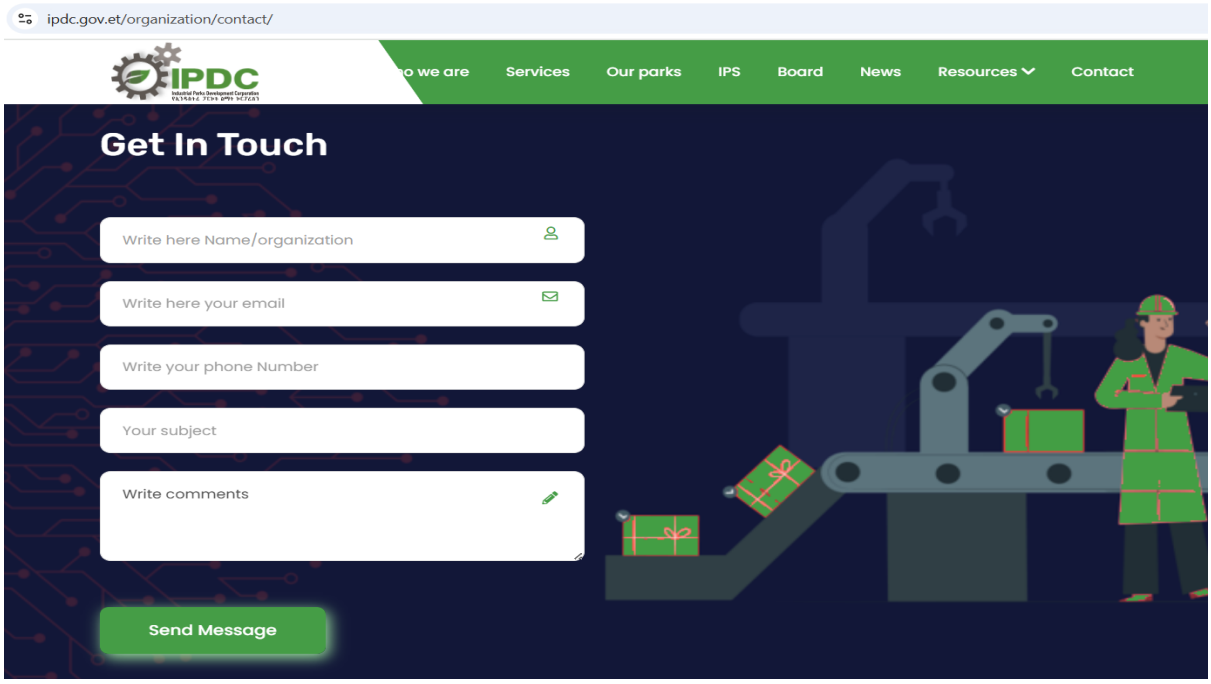


Figure 23: IPDC Website Based Grievance Redress Mechanism

4.5. The Socioeconomic Environment

4.5.1. Population and Settlement, Demographic Condition

The projected population of Addis Ababa, which is currently exceeding 5 million (http://www.macrotrends.net/cities/20921/addis-ababa/population), lives in 11 sub-cities and is divided for administrative purposes. The ten sub-cities are: Addis Ketema, Lideta, Cherkos, Yeka, Bole, Akaki Kaliti, Nefas silk, Kolfe Keranio, Gullele and Lemi kura each with an

average of 300,000 people. However, Akaki-Kaliti still has the lowest number of people from among the 11 sub-cities. The population comprises factory workers, civil servants, daily laborers, merchants, farmers and others. According to the ESIA report prepared for KIP, the inhabitants of the area are settled in villages locally known as 'menders' and zones within each village locally known as 'Ketana', most of the houses have compounds of about 1000m2 in area. The settlements were established during the villagization program that was implemented in the 1977 Ethiopian Calendar by the then military government in the pursuit of avoiding scattered settlements and making potential agricultural land free from settlements as reported in the ESIA of KIP (2017).

4.5.2. Economic and Industrial Activities

The Akaki Kality Sub-City, in which the KIP is located, is an industrial zone where about 60% of the metal, paints, garment and food processing industries of Addis Ababa are found. Currently, there are more than 300 industries in the subcity with an estimated labour force of 80,000. The residents of the Akaki Kality Sub-City woreda 10 are factory workers, daily labourers, people working in urban agriculture, civil servants, military personnel, commercial sex workers, unemployed youth and women, etc. From this factory workers and civil servants constitute the majority population segment.

There is a beer factory and Addis Ababa Science and Technology University near to the KIP that are changing the area fast from cereal based mixed farming to other types of economies where only a practice of urban agriculture in small land holding can have the possibility of being included.

4.6. Municipal Infrastructure

4.6.1. Water Supply in Addis Ababa

Addis Ababa faces significant water supply challenges, with coverage and reliability still falling short of demand despite ongoing efforts. While access to improved water sources has increased, reliable, consistent piped water remains a concern. Recent estimates indicate that access to improved water sources varies considerably depending on the definition used, and while much higher than the 44% previously cited, consistent piped access is still a challenge. Sewerage coverage remains limited, with a significant portion of the population relying on vacuum truck services.

The city's water supply relies on both surface and groundwater sources. Surface water is sourced from the Geffersa, Legedadi, and Dire dams, with treatment occurring at two primary plants. These dams, located to the east and northwest of the city, utilize gravity-fed distribution. Groundwater is extracted from several well fields in the southeastern part of the city, treated, and then pumped into the distribution network.

4.6.2. Electricity

Ethiopia has made substantial progress towards its goal of achieving universal electricity access by 2025, with Addis Ababa demonstrating relatively high electrification rates. While figures vary, it's generally accepted that a significant majority of Addis Ababa residents have electricity access, primarily for household lighting and industrial use. The national grid, heavily reliant on hydropower, provides the primary source of electricity.

However, despite high electrification rates, a considerable portion of the population still relies on biomass fuels for cooking and heating, indicating a need for broader access to clean energy alternatives. The KIP and the proposed VMF rely on the national grid for their primary power supply. To ensure operational continuity during power interruptions, the VMF should incorporate backup power systems, such as diesel generators. This is especially important for critical facilities like VMF, where consistent power is essential. Recent infrastructure improvement projects and investments have aimed to improve power reliability and distribution throughout the city.

4.6.3. Transport and Roads Infrastructure

Addis Ababa City has both international and local transport links which include the Bole International AirPort, the Ethio-Djibouti Railway and the road network. The Airport is within the city in a south-easterly direction outside the ring road. It is easily accessible by car or taxi and buses run nearby. Addis Ababa has adequate roadway connections with most of the regional states and different parts of the country. The national network is being improved under the Road Sector development program according to the city development Plan report. Because of inadequate planning, there is a critical lack of a hierarchical system in the road network. Kilinto Industry Park, a key industrial hub near Addis Ababa, relies heavily on the surrounding transport and road infrastructure for its operational efficiency. The park's primary access is facilitated by major arterial roads extending from Addis Ababa, crucial for the movement of goods, materials, and personnel. However, the pervasive traffic congestion

within Addis Ababa significantly impacts transportation efficiency, causing delays, particularly during peak hours. The quality and maintenance of roads leading to and within the park are vital for smooth logistical operations, given the prevalence of heavy-duty transportation. As Addis Ababa's industrial sector expands, ongoing infrastructure development, including road expansion, traffic management systems, and potential alternative transport modes, is essential to address existing challenges and support the park's growth. The future expansion of public transit systems, such as the Addis Ababa light rail, will also play a critical role in improving access to Kilinto Industry Park.

4.6.4. Municipal Solid Waste Management Facilities

The Repi landfill, covering 19.2 hectares and spanning parts of Nifas Silk and Kolfe Keranyo sub-cities, is integrated with the Repi Waste-to-Energy Power Plant. This plant processes approximately 1,200 tons of solid waste daily, generating 25 MW of net energy. Non-incinerable waste is deposited in the landfill, which accommodates non-hazardous materials like packaging, glass, plastics, paper, cardboard, office supplies, kitchen waste, and non-contaminated containers. Hazardous and contaminated waste, including medical waste, is incinerated on-site to reduce volume and minimize groundwater and surface water pollution.

The Repi landfill has experienced landslides, damaging leachate ponds. The Addis Ababa City Government is actively rehabilitating the site to prevent further incidents and protect the surrounding community, while also extending the landfill’s lifespan. Rehabilitation efforts include terracing for landslide management, landfill emission reduction, gas venting, and leachate collection, supported by both financial and in-kind contributions from the city government. The "Fukuoka Method," a sustainable landfill and solid waste management system developed in Japan, is being implemented to improve decomposition rates and reduce methane emissions. This semi-aerobic landfill concept accelerates decomposition by increasing oxygen intake.

A gas venting pipe system is used to reduce internal heat and enhance aerobic decomposition, significantly decreasing methane production. "Phytocapping" around the landfill provides an additional, cost-effective method for methane emission reduction. Fly and bottom ash from the power plant are utilized for access road construction and daily waste cell cover. Leachate collection and treatment via evapo-transpiration ponds are in place, and plans are underway to construct a central composting facility and increase the waste-to-energy plant's capacity.

Figure 24: Waste to Energy Power plant (left) and Repi landfill (right).

4.6.5. Municipal Wastewater Management Facility

The Kilinto Industrial Park (KIP) will not rely on the Addis Ababa Water and Sewerage Service Authority (AAWSSA) wastewater treatment plants at Kality or Kotebe. The KIP is designed to manage and treat its own industrial effluents through a dedicated on-site wastewater treatment system in compliance with applicable environmental standards. However, it is important to show the available alternative Sewage disposal infrastructure in the city. of the. The Addis Ababa Water Supply and Sewerage Authority (AAWSSA) operate with seventeen wastewater treatment plants. The main ones are Kality and Kotebe and twelve condominium areas. The Kality Wastewater Treatment Plant in Addis Ababa, upgraded in 2018 with World Bank support to a 100,000 m^3/day capacity, currently processes approximately 74,600 m^3/day of municipal wastewater from most of the city. Utilizing Up-flow Anaerobic Sludge Blanket (UASB) and Trickling Filter (TF) technology, the plant achieves high removal efficiencies (97.47% BOD5, 89.39% COD, 94.18% TSS, 95.64% VSS), meeting national and international effluent standards. The treated effluent is suitable for unrestricted irrigation, and the sludge is used in urban agriculture. Additionally, a solar sludge drying plant processes 1,500 m^3/day of liquid waste from vacuum trucks, with dewatered sludge stored on-site.

The Kality wastewater treatment plant, which operates below its design capacity, can accept an additional 25,400 m3/day of domestic wastewater. As it was constructed with the support of the World Bank Group, the plant adheres to national and World Bank EHS standards, including treated effluent quality (Kality Wastewater Treatment Plant Effluent Quality trend is shown in Table 7), occupational health and safety, stormwater management, and monitoring. It

also implements an Environmental and Social Management Plan (ESMP), overseen by the World Bank Group biannually.

The plant is managed by CGGC, a contractor required to comply with standard effluent quality for service payment. Influent and effluent, as well as sludge, are monitored daily by the operating company. The plant uses only two chemicals: sodium hypochlorite and sodium metabisulfite for chlorination and de-chlorination, respectively. As it has adopted a more natural approach, the plant has minimized its environmental impact. Furthermore, the wastewater treatment plant administration has established a grievance redress mechanism (GRM), providing an effective system for handling complaints and grievances.

Table 8: The Kality Wastewater Treatment Plant Effluent Quality
(Source: Kality Wastewater Treatment Plant Administration Unit, June/2023)

Parameters		Year					
		2021			2022		
		Influent	Effluent	Plant Efficiency	Influent	Effluent	Plant Efficiency
BOD	Y-Average	368.33	9.51	97.38	379.15	8.99	97.56
	Y-Min	208.67	5.75	96.85	245.58	5.00	97.73
	Y-Max	541.67	13.83	97.45	580.00	14.83	97.39
COD	Y-Average	621.05	63.77	89.37	641.85	62.25	89.40
	Y-Min	355.55	47.58	85.63	416.25	45.08	86.92
	Y-Max	900.08	70.81	91.88	1005.92	80.83	91.06
TSS	Y-Average	285.32	18.37	93.55	312.59	15.14	94.81
	Y-Min	146.36	9.17	93.06	174.67	9.92	93.31
	Y-Max	480.75	53.33	88.96	565.17	23.33	95.57
VSS	Y-Average	227.87	8.99	95.73	230.24	9.52	95.55
	Y-Min	96.06	5.25	93.89	117.42	6.33	93.04
	Y-Max	394.14	14.33	95.96	441.33	14.42	96.37
pH	Y-Average	7.51	7.60		7.27	7.41	
	Y-Min	7.11	7.17		6.95	7.07	
	Y-Max	7.89	7.96		7.64	7.78	

4.6.6. Storm Water Drainage

There is an onsite stormwater system for the existing infrastructure. During the construction of the new building, the contractor should apply prevention and mitigation measures for flooding. These include the construction of elevated structures to limit the stormwater within

the project site, the highway road to the south, construction of floodwalls, floodgates, levees, and evacuation routes. In addition, there will be the construction of a drainage system by carrying out preliminary calculations to determine the quantity of runoff from the site. For the preliminary calculations, it has been assumed that the entire development site will be impermeable, whether through building development or hard landscape areas and roads.

5. DESCRIPTION OF THE PROJECT

5.1. The Nature of the Project

The ShieldVax's vaccines manufacturing facility is being set up in the Kilinto Industrial Park, on the outskirts of Addis Ababa City. The proposed VMF is expected to produce/fill-finish approximately 80 million doses of vaccine/s annually and expandable to 240+ million doses, including vaccines such as,

Pneumococcal Conjugate Vaccine (PCV), Inactivated Polio Vaccine (IPV), Inactivated Diphtheria, Pertussis (Whooping Cough), Tetanus, conjugate Haemophilus influenzae type b, and recombinant Hepatitis B vaccine (DPT-Hib-HepB), Tetanus Toxoid / Tetanus-Diphtheria (TT/Td), Human Papillomavirus Vaccine (HPV) and Inactivated Rotavirus Vaccine.

The facility is planned to be set up in a staged manner. Stage 1 – Fill-finish (2028-30); Stage 2 (2031-2033) – Formulation & Fill-finish; Stage 3 (2034-2036) – Drug substance manufacturing for recombinant and conjugate vaccines & based on the requirement fill-finish of live attenuated vaccines may be considered. The current and immediate focus of the project is on Stage 1. Essentially, the facility would begin with fill-finish operations which would take around 3 to 5 years. For this, the ready-to-fill (RTF) bulk material will be sourced from WHO prequalified manufacturers. This will ensure quality, safety, efficacy and compliance with the WHO guidelines. The product portfolio would consist of the liquid inactivated vaccines. This shall ensure that the minimum biosafety level would be required. Nevertheless, the provision has been made for biosafety level 2 compliance. In accordance with the above, the facility shall have seven (7) blocks. Of these, the current priority is to operationalize the fill-finish operations in block-1, utilities block-3, central warehouse block-4 and the administrative block 2. The facility is designed to have provision for three filling lines; stage 1 and 2 product portfolios are shown in Table 8.

Table 9: Product Portfolio Prioritization (Stage 1 - Fill-finish) and Filling-line Allocation Stage 2 (Formulation and fill-finsih)

Project Stages	Filling Line 1 – Priority 1	Filling Line 2 - Priority 2	Filling Line 3 - Priority 3	Remark
	Inactivated/Recombinant/Conjugate Injectable	**Inactivated Oral Liquid**	**Live Attenuated Injectable**	
Stage 1	• DTP-Hib-HepB • Tetanus reduced diphtheria (Td) • PCV-13 • Hepatitis B Vaccine	• Oral Cholera Vaccine (OCV)		Planned to start by 2028-2030
Stage 2	• Anti-rabies Vaccine • Inactivated Polio Vaccine • Hexavalent Vaccine • Human Papilloma Virus (HPV)	• Rotavirus Vaccine (RVV)	• Measles	Planned to start by 2031-33

5.2. Site Layout

Vaccine manufacturing facilities will be used for the manufacture, processing, re-packaging, packaging and storage of products shall be appropriately designed, sized and located for ease of use, cleaning and maintenance. The facility is designed to lie on 58,608.23 square meters area. In conformity with the KIP master plan, the proposed VMF will be a multistory building that fulfills the minimum requirements of KIP in the designated area. Accordingly, depending on the intended purpose of each building the numbers of floors proposed for the various buildings required by the envisaged project are listed below.

Table 10: VMF Building Blocks and Their Purpose

Building Name	Floors	Area in sqm
Block 1: Fill finish block	B+G+5	18,919.34
Block 2: Admin block	G+3	5,038.32
Block 3: Utility Block	G+1	2,331.63
Block 4: Warehouse	G+2	4310.81
Block 5: Measles/MMRV Block	B+G+3	5745.32
Block 6: Bulk Manufacturing	B+G+5	16437.74
Block 7: Future Expansion	B+G+3	4459.28

Enclosed corridor	NA	480.79
Cabins, Service – G	NA	885.00
Total built-up area		**58,608.23**

B-Basement level/floor; G-Ground level/floor

5.2.1. Block 1 Details

a) Basement: Utility & Support Services

The basement is designed to support essential operational and utility functions. It will include:

- **Parking Area:** Dedicated space for staff and authorized personnel, ensuring efficient vehicular movement and accessibility.
- **Laundry Facility:** Equipped for handling garment washing, drying, and sterilization to ensure cleanroom and personnel hygiene standards are maintained.
- **Kill Tank System:** A controlled containment and neutralization system for handling liquid bio-waste and effluents before disposal, ensuring compliance with environmental and biosafety regulations.

b) Ground Floor: Formulation & Fill-Finish

The Formulation & Fill-Finish block is designed as a modular, GMP-compliant production facility, ensuring adherence to international regulatory standards. The layout is optimized to enhance process flow efficiency, contamination control, unidirectional man and material movement and operational reliability. It consists of two independent filling lines, ensuring dedicated facilities for inactivated oral and inactivated injectable vaccine presentations.

Each filling line facility is provided with adequate number of cold rooms to store liquid filled dropper bottles, or plastic tubes to facilitate oral administration (Line 1) and single dose vials/ and multi-dose vials/ (Line 2). Visual inspection room with adequate numbers of visual inspection tables is provided for 100% visual inspection of products filled in Line 1 and Line 2. Cold rooms are provided for storage of unlabelled vials/, labelled vials/ under release from National Control Authority and National Control Authority released vials/ ready for dispatch. For each line, one visual inspection room, two labelling areas and one packing hall is provided. The vials at various stages of release will be segregated by marking the area and as per the approved procedures.

Line 1: This filling line is dedicated to inactivated oral vaccines, utilizing appropriate packaging formats such as multi-dose vials (MDVs), dropper bottles, or plastic tubes to facilitate oral administration. These vaccines will be filled on a campaign basis, ensuring efficient utilization of production capacity while maintaining validated

changeover protocols to prevent cross-contamination and uphold regulatory requirements/compliance.

Line 2: This filling line is designated for inactivated, conjugate, and recombinant injectable vaccines, supporting multiple dosage formats (single dose and multi dose), including vials, and Pre-Filled Syringes (PFS) to meet diverse clinical and market requirements. These vaccines will be filled on a campaign basis, ensuring efficient utilization of production capacity while maintaining validated changeover protocols to prevent cross-contamination and uphold regulatory requirements/compliance.

Both the filling lines are equipped with dedicated lyophilization capability in case freeze drying vaccines need to be manufactured. The injectable inactivated vaccines requiring lyophilization can be filled on either Line 1 or Line 2.

Following manufacturing plan is proposed for Line 1 and Line 2:

Filling Line 1 – Inactivated Vaccines (Oral):

- **Stage 1:** Oral Cholera Vaccine (OCV)
- **Stage 2:** Rotavirus Vaccine (RV).

Filling Line 2 – Inactivated/Recombinant/Conjugate Vaccines (Injectables):

- **Stage 1:** Pentavalent (DTwP+ Hep B+ Hib), Hexavalent Vaccines (DTwP+ HepB+ Hib+ IPV [Sabin]), Tetanus-Diphtheria (Td) Vaccine, Pneumococcal Conjugate Vaccine (PCV-13), Recombinant Hepatitis B (Hep B) Vaccine.
- **Stage 2:** Anti-Rabies Vaccine, Inactivated Polio Vaccine (IPV), Meningococcal A (Men A), and Human Papillomavirus (HPV) Vaccine.

c) First Floor: Mezzanine 1 – Technical Service Area

The First Floor is designated as a technical service area to support the Ground Floor Fill-Finish operations. This level houses critical process utilities, maintenance access points, and environmental control systems. The area includes Air Handling Units (AHUs) and HVAC systems for maintaining controlled temperature, humidity, and differential pressure within production zones. This area ensures unidirectional workflows for material and personnel to ensure cross-contamination. Utility distribution corridors accommodate Purified Water (PW), Water for Injection (WFI) and Pure Steam generation systems. The compressed air and nitrogen gas pipelines, supplying essential utilities to the Fill-Finish unit are also provided. Electrical service panels are strategically placed for power distribution, ensuring uninterrupted operations. Dedicated service platforms allow access to lyophilization units, filling machines, and other process equipment, facilitating routine maintenance without disrupting cleanroom operations. Environmental monitoring panels and automation control points are also integrated to enable real-time tracking of temperature, pressure, and humidity, ensuring strict compliance with production standards. This structured layout ensures process efficiency, minimizes contamination risks, and maintains facility integrity for continuous vaccine manufacturing.

d) Fourth Floor: QC

Quality Control laboratory: Quality Control laboratory is separate from production areas, a self-independent unit with the required equipment /machinery. In Biological section of Quality Control, a sterilization unit has been provided for carrying out steam sterilization operations. Cold rooms are also provided for storage of in-process samples, reference standards, retained samples, stability samples and other materials.
The Quality Control laboratory have following laboratories/sections to perform various testing.

Raw Material Testing Lab

- Ensures quality of raw materials as per Pharmacopeia and in-house specifications.

Microbial & Sterility Testing Lab

- **Sterility testing:** Ensure all the intermediates produced in the manufacturing area are free from bacterial and fungal contamination. Sterility tests are being performed (membrane filtration or direct inoculation) as required for the intermediate/Drug Substance/ Finished products. Sterility laboratory with Class A in class B background is provided.
- **Culture room:** Standard reference cultures as per the pharmacopoeia and in-house organisms are maintained at appropriate passage levels and temperatures. These cultures are used for performing Growth Promotion Tests (GPT) for various media used in Quality Control laboratory. The Culture room is with class A in class C background.
- **BET room:** Bacterial endotoxin testing is performed on various media and on Purified Water/Water for Injection samples and if required on intermediates/Drug Substance and finished product. The BET room is with class C back ground.
- **EMP room:** Microbial testing of Water samples (PW, WFI and Pure Steam condensate) will be performed in the EMP laboratory. In addition, Microbial Limit Test (MLT) for RM can be performed in this laboratory. The EMP room is with class A in class C back ground. This laboratory will be involved in microbial Environmental Monitoring of Manufacturing and Quality Control controlled areas (settle plates, active air sampling and surface monitoring).
- **Incubation room:** Separate incubation room with various BOD incubators is provided for incubation of EM plates, sterility samples and water testing plates. The incubation room is with class D back ground.
- **Microbiology laboratory:** This laboratory will be used for taking observations (sterility tubes/canisters, EM plates) and other samples under incubation.
- **Sterilization:** Double door sterilization autoclave for sterilizing of material/media and some equipment is provided. The sterilization autoclave is adjacent to preparation room where various media required for microbiological assays/testing will be prepared. The loading and unloading sides of this autoclave are with class C background. The sterilized material from the autoclave will be unloaded in class A cover.

- **Decontamination:** Decontamination area with Double door decontamination autoclave is provided for decontamination of samples which have completed incubation periods. The decontamination area is with class D background.

Sample receipt and stores:

- Sample receipt room is provided at the entrance of the QC facility. The samples from production or Warehouse will be received in the sample receipt room and will be distributed to various QC sections for testing. A store is provided to store consumables and media used by QC laboratory. The area is CNC.

Stability:

- For performing stability studies on intermediates, Drug Substance and Drug Product, stability room housing stability chambers is provided. The stability chambers for real time stability studies, accelerated conditions and stress stability studies have been provided. For conducting the stability studies at low temperatures ($-20^0 \pm 3^0$C and/or $-70^0 \pm 5^0$C), Deep Freezers are also provided. The area is CNC.

Retained Sample room:

- In this room Retained Samples (Retention/Control samples) of Drug Product and Drug Substance will be stored as per the regulatory requirements. The area is CNC.

Molecular Biology:

- In this laboratory, tests such as conventional PCR, Real Time PCR and Next Generation Sequencing will be performed. The area is CNC.

Immunochemistry:

- In this laboratory, immunochemical test such as ELISA (e.g. estimation of Hepatitis B antigen content), in-vitro antibody induction tests and estimation of Limit of flocculation (Lf) will be performed. In addition, various biochemical tests such as estimations of proteins (by Lowry method and Kjeldahl method), lipids, phosphorus and various sugars testing will be performed. In this laboratory, testing for Host Cell DNA and Host Cell proteins will also be performed. The area is CNC.

Electrophoresis:

- In this laboratory, agarose gel, Polyacrylamide gel and SDS gel electrophoresis will be performed for various recombinant vaccines and in future for viral vaccines. Gel documentation system (GEL DOC) will be provided to store/save the electrophoresis results. Test like Western Blot will be performed in this laboratory to confirm identity of some intermediates and cell banks. The area is CNC.

Central Instrument Laboratory and HPLC/GC rooms:

- These laboratories will be equipped with various instruments like, Gas Chromatography (GC), High Performance Liquid Chromatography (HPLC) and Mass Spectrometry for testing of intermediates, Drug Substances and Drug Products. The area is CNC.

Water testing and Physico-chemical testing:

- Testing of Purified Water (PW), Water for Injection (WFI) and Pure Steam (PS) condensate (chemical tests) and other Physico-chemical testing will be performed in these two laboratories. Total Organic carbon estimation apparatus will be installed to estimate TOC in PW, WFI and PS condensate and also cleaning validation/product changeover samples. The area is CNC.

Cold rooms and deep-freeze rooms:

- Two cold rooms have been provided for keeping/storing the reagents/in-process samples at 2^{o} to 8^{o} centigrade.
- One deep-freeze room is provided for keeping -20^{o} and -70^{o} centigrade deep-freezers. These deep-freezers will be used for storing kits and other reagents required in the QC laboratory.

Washing room:

Washing room is provided to clean the used glassware. Hot Air Oven is provided to dry the cleaned glassware.

e) Fifth floor Mezzanine 2 – Technical Service Area

The area includes Air Handling Units (AHUs) and HVAC systems for maintaining controlled temperature, humidity, and differential pressure within production zones. Utility distribution corridors accommodate Purified Water (PW), Water for Injection (WFI) and Pure Steam generation systems. The compressed air and nitrogen gas pipelines, supplying essential utilities to QC laboratories. The compressed air and nitrogen gas pipelines, supplying essential utilities to the QC laboratories. Environmental monitoring panels and automation control points are also integrated to enable real-time tracking of temperature, pressure, and humidity, ensuring strict compliance with production standards. This structured layout ensures process efficiency, minimizes contamination risks, and maintains facility integrity for continuous vaccine manufacturing.

5.2.2. Block 2 (Admin Block) Details

On the first floor 'Quality Assurance' staff will be accommodated in Admin block. This block will have QA offices, conference rooms and training halls. Provision is made to keep the Compactors (to store the documents) in this facility.

First floor will also be occupied by persons working in Corporate Affairs.

Ground floor of the admin block is proposed for a small R&D laboratory.

5.2.3. Block 3 (Utility Block) Details

Utility block will supply general utilities like raw steam, potable water, RO water and compressed air. It will also house Steam Boilers and Diesel Generators.

5.2.4. Block 4 (Warehouse Block) Details

Two warehouses are provided for storing primary and secondary packing materials (Ground floor) and storing Raw Materials (first floor). There are 18 cold rooms, two recalled goods area and three ice-packs storage cold room.

Ground floor warehouse: This PM warehouse of has following rooms.

1. Two PPM stores for keeping vials, rubber caps, carton, special packaging material for vaccines. This area is CNC.
2. Miscellaneous packing material store. This area is CNC.
3. Three Cold Rooms (2-8^{0}C).
4. Two rooms for Rejected Materials. This area is CNC.
5. PM dispensing room (class A in D).
6. PM sampling room (class A in D).
7. Labels store. This area is CNC.
8. Stores office. This area is CNC.
9. Janitor. This area is CNC.
10. Over printing room. This area is CNC.
11. Change parts room. This area is CNC.
12. Two Dispatch Areas. This area is CNC.
13. Secondary packing material store. This area is CNC.

First Floor Store: This RM warehouse has following rooms.

1. RM dispensing room and Sampling room (class A in D)
2. 16 cold rooms (2-8^{0}C)
3. Three icepack cold rooms (-20^{0}C)
4. Four rooms for Recalled Products. This area is CNC.
5. Sterile sampling and dispensing room (with change rooms, class A in class B).
6. Cold store monitoring room. This area is CNC.
7. Storage room for used pallets. This area is CNC.
8. Room for washing of pallets. This area is CNC.
9. Storage room for keeping cleaned pallets. This area is CNC.
10. Room for storage of Rejected Material. This area is CNC.
11. Janitor. This area is CNC.
12. Stores Office. This area is CNC.
13. One spare room. This area is CNC.

5.2.5. Block 5 (Future Expansion – MMRV) Details

In this block it is proposed to manufacture Measles, Mumps and Rubella vaccine in future stage of the project. The facility will operate based on backward integration

model, starting with Fill-finish and progressing further backwards to formulation and then to ‘Drug Substance (DS)’.

5.2.6. Block 6 and 7 (Future Expansion) Details

Block 6: It is proposed to manufacture vaccine Drug Substance (future expansion)
Block 7: It is for future expansion of the project.

Figure 25: VMF Site Layout and Setting out Plan

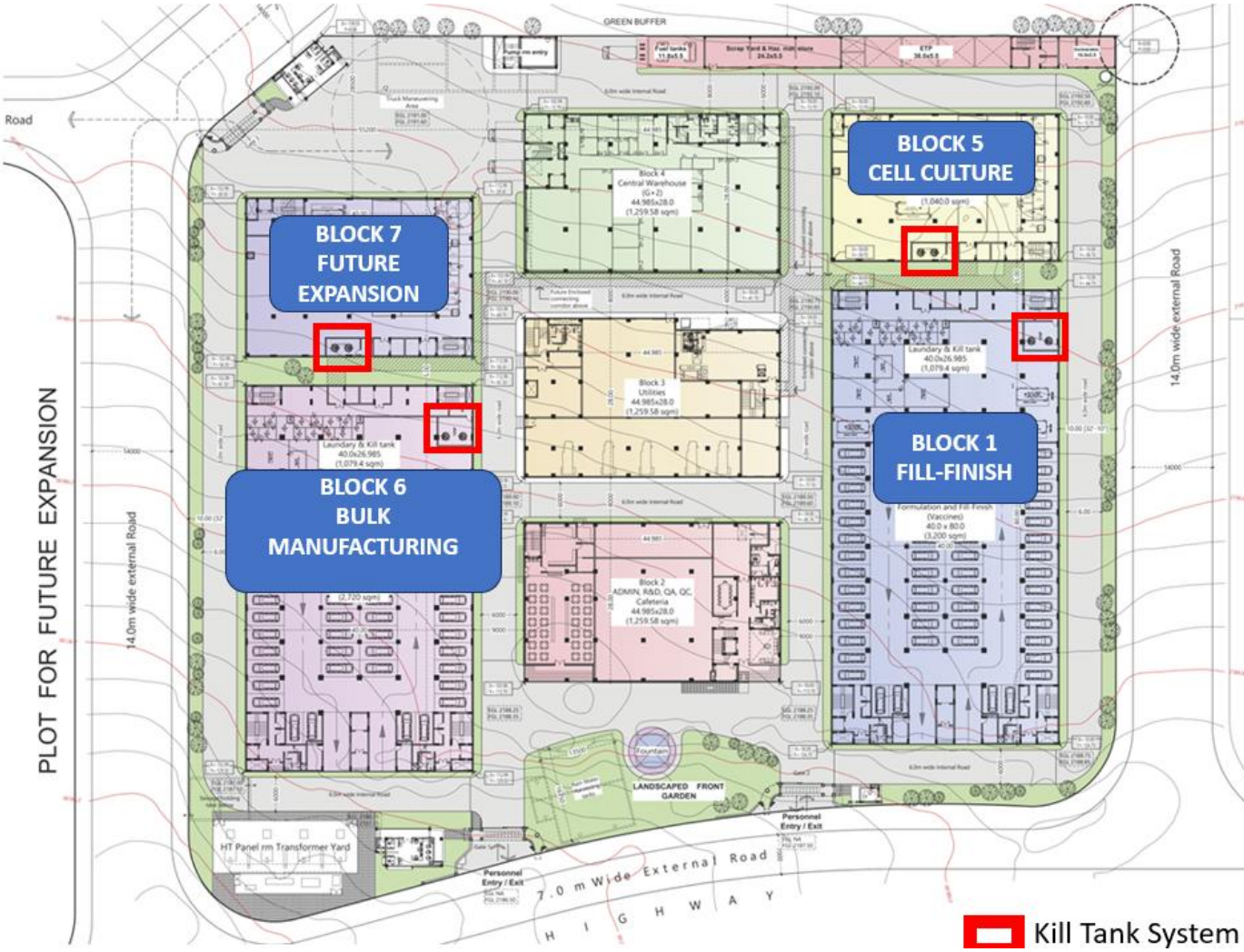


Figure 26: Kill Tanks

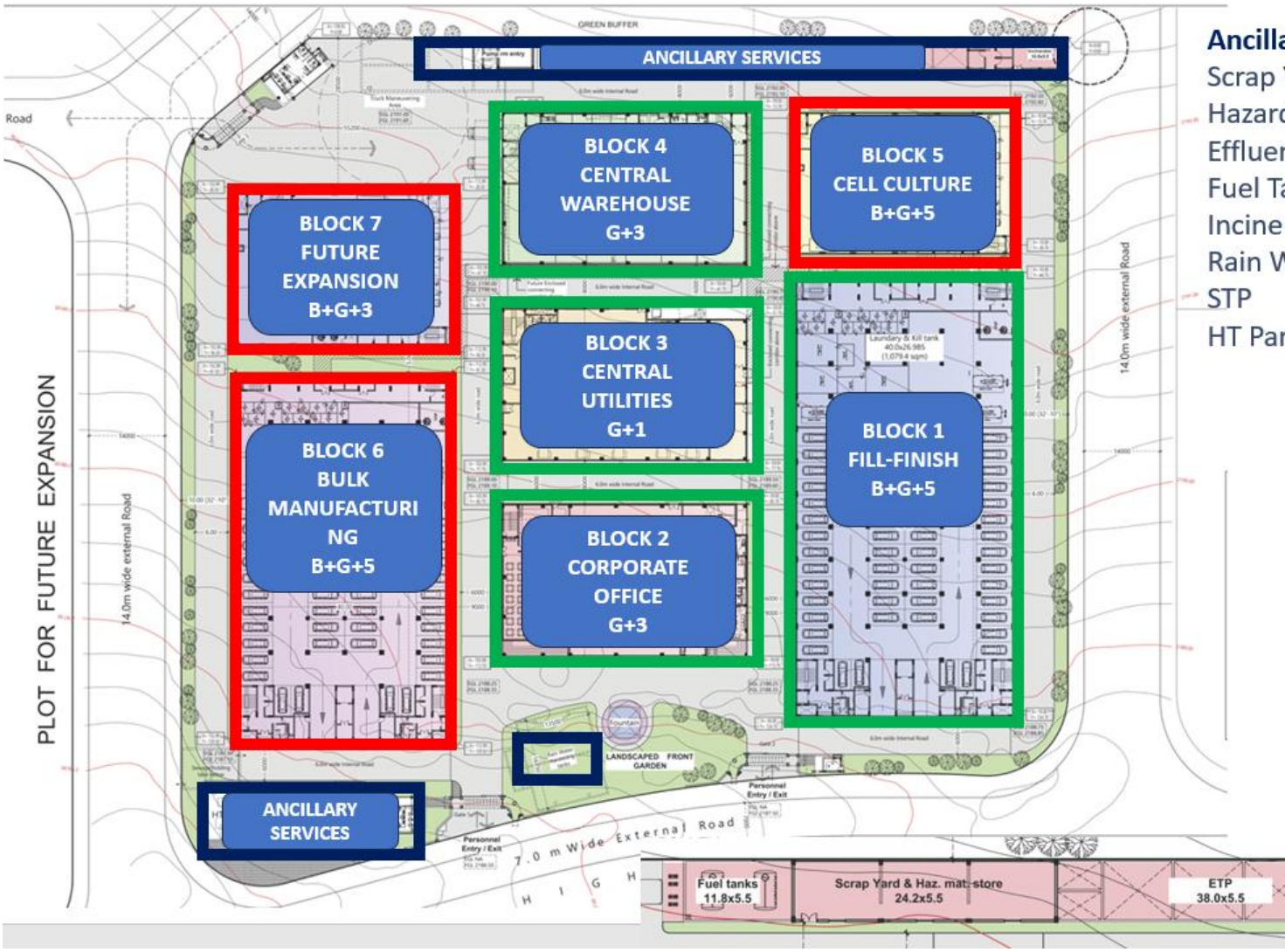


Figure 27: Ancillary Facilities (Liquid and solid waste management facilities)

5.3. Design Requirement of the Proposed VMF

The detailed design of the proposed Vaccine Manufacturing Facility is absolutely critical for establishing a safe, efficient, and compliant operation capable of producing high-quality vaccines. This design must meticulously integrate stringent international and national regulatory guidelines, with a primary focus on biosafety, robust containment strategies, and unwavering product quality. The following elaborates on the high-level design requirements listed below, providing a deeper understanding of the considerations within each area:

- **Process requirements (weighing, sampling, production etc.):** the design must meticulously map out the entire vaccine manufacturing process flow, from the initial weighing of raw materials and components, through various production stages (e.g., cell culture, viral propagation, purification, inactivation, formulation), to final filling, labeling, and packaging.

Each step requires dedicated spaces or defined zones with specific environmental controls and equipment.

- **Weighing and Dispensing:** Dedicated, controlled environments (often cleanrooms or contained weighing booths) with accurate weighing equipment, dust extraction systems, and measures to prevent cross-contamination. Material flow and personnel access must be carefully planned to minimize risks.
- **Sampling:** Designated sampling areas within production zones or separate sampling booths with appropriate containment and environmental controls to obtain representative samples for in-process and final quality control testing without compromising product sterility or worker safety.
- **Production Areas:** These are the core manufacturing zones, requiring specific classifications based on GMP and biosafety levels. The design must accommodate the necessary bioreactors, purification skids, inactivation equipment, and other process-specific machinery. Layout should optimize workflow, minimize material movement, and facilitate cleaning and maintenance.
- **Formulation and Filling:** Highly controlled cleanroom environments with aseptic filling lines, ensuring product sterility. Design must consider equipment for mixing, adjusting concentration, and filling vials or syringes with accuracy and minimal risk of contamination.
- **Labeling and Packaging:** Designated areas with equipment for applying labels, assembling final packaging, and preparing vaccines for storage and distribution. While typically lower GMP classification, these areas must still maintain cleanliness and prevent mix-ups.

The layout must ensure a unidirectional flow of materials and personnel to prevent cross-contamination. Dedicated equipment and cleaning regimes for each process step are essential. Integration of process analytical technology (PAT) and automation shall be considered for enhanced efficiency and quality control.

- **Biosafety Levels (BSL) depending on the type of pathogens handled:** The facility design must incorporate specific BSLs as mandated by international (e.g., WHO) and national guidelines, directly corresponding to the risk posed by the pathogens being handled at each stage of the vaccine production. Different production areas within the VMF may require different BSL classifications. The design must clearly delineate these zones, incorporating appropriate barriers, containment equipment (e.g., biosafety cabinets, isolators), ventilation systems with directional airflow and HEPA filtration, controlled access procedures, dedicated

waste streams and decontamination processes (e.g., autoclaving, chemical inactivation), and emergency protocols.

Table 11: Summary of Biosafety Requirement

	BIOSAFETY LEVEL			
	1	2	3	4
Isolation[a] of laboratory	No	No	Yes	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation:				
— inward airflow	No	Desirable	Yes	Yes
— controlled ventilating system	No	Desirable	Yes	Yes
— HEPA-filtered air exhaust	No	No	Yes/No[b]	Yes
Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Anteroom	No	No	Yes	—
Anteroom with shower	No	No	Yes/No[c]	No
Effluent treatment	No	No	Yes/No[c]	Yes
Autoclave:				
— on site	No	Desirable	Yes	Yes
— in laboratory room	No	No	Desirable	Yes
— double-ended	No	No	Desirable	Yes
Biological safety cabinets	No	Desirable	Yes	Yes
Personnel safety monitoring capability[d]	No	No	Desirable	Yes

[a] Environmental and functional isolation from general traffic.
[b] Dependent on location of exhaust (see Chapter 4).
[c] Dependent on agent(s) used in the laboratory.
[d] For example, window, closed-circuit television, two-way communication.

Source - Laboratory Biosafety Manual, Third edition, WHO

- **GMP requirements for vaccine cleanroom:** All areas involved in vaccine manufacturing that directly impact product quality and sterility must be designed and constructed as cleanrooms adhering to Good Manufacturing Practice (GMP) standards, as defined by regulatory authorities (e.g., WHO GMP, PIC/S). GMP cleanroom design focuses on minimizing particulate and microbial contamination. Key aspects include:
  - **Room Classification:** Different production areas will require specific ISO cleanroom classifications (e.g., ISO 5, ISO 7, ISO 8) based on the criticality of the process step and the required level of environmental control.
  - **Materials of Construction:** Smooth, non-shedding, cleanable, and dis-infectable materials for walls, floors, ceilings, and fixtures.
  - **Surface Finishes:** Seamless and coved junctions to facilitate cleaning and prevent microbial harborage.
  - **Air Handling Systems (HVAC):** Controlled airflow patterns (unidirectional or turbulent with sufficient air changes), HEPA filtration of supply air, pressure differentials between rooms to prevent contamination ingress, and monitoring of temperature and humidity.

- **Cleaning and Disinfection:** Design must facilitate effective cleaning and disinfection procedures.
- **Personnel and Material Airlocks:** Controlled entry and exit points for personnel and materials to minimize the introduction of contaminants into clean areas.
- **Monitoring Systems:** Integration of systems for continuous monitoring of particulate counts, microbial contamination, temperature, and humidity.

The design must specify cleanroom classifications for each area, material specifications, HVAC system design, layout of equipment to minimize turbulence and facilitate cleaning, and the design of personnel and material flow pathways through airlocks.

- **Vaccine production capacity/number of doses expected to output**: The design must be based on the projected annual production capacity (around 80 to 100 million doses annually) and the expected number of doses for each type of vaccine to be manufactured. This will dictate the scale of the production equipment, the size of the manufacturing areas, storage requirements, and overall facility footprint.
  - **Market Demand:** Projected market demand and public health needs will determine the required output.
  - **Production Scale:** The capacity will influence the size and number of bioreactors, purification systems, filling lines, and other critical equipment.
  - **Batch Sizes:** Expected batch sizes will impact the dimensions of processing vessels and holding tanks.
  - **Storage Requirements:** The volume of raw materials, in-process intermediates, and finished products will determine the size and environmental controls of storage areas (e.g., cold rooms, freezers).

Design Implications: The design must accommodate the physical footprint and utility requirements of the specified production equipment. Sufficient space for future expansion shall be considered. Storage areas must be appropriately sized and equipped with validated temperature and humidity control systems.

- **Personnel flows:** The design must carefully plan the movement of personnel within the facility to minimize the risk of contamination, maintain security, and ensure efficient workflow.
  - **Cleanliness Zones:** Personnel flow shall be designed to move from less clean to cleaner areas, utilizing gowning and degowning procedures at each transition point.

- **Dedicated Routes:** Separate pathways for personnel working in different BSL or GMP areas may be required.
- **Airlocks and Change Rooms:** Strategically located airlocks and change rooms with step-over benches and defined gowning sequences are crucial for maintaining cleanroom integrity.
- **Access Control:** Security measures and access control systems must be integrated into personnel flow pathways.
- **Emergency Exits:** Clearly marked and unobstructed emergency exits must be incorporated throughout the facility.

The layout must minimize unnecessary movement of personnel between different zones. The design of change rooms, airlocks, and corridors must accommodate the required number of personnel and the gowning/degowning process.

- **Material flows (product, component and raw material movements:** similar to personnel flow, the movement of raw materials, components (vials, syringes, stoppers), in-process materials, and finished products must be meticulously planned to prevent contamination, mix-ups, and ensure efficient logistics.
  - **Receiving and Quarantine:** Dedicated areas for receiving and quarantining incoming materials before release.
  - **Storage:** Appropriately controlled storage areas for different types of materials based on their requirements (temperature, humidity, light sensitivity).
  - **Transfer Routes:** Defined pathways and transfer hatches or airlocks for moving materials between different processing areas.
  - **Waste Streams:** Segregated and controlled flow of different waste streams (biological, chemical, general) to designated collection and treatment areas.

The layout should minimize material handling and potential for cross-contamination. Dedicated material airlocks and transfer hatches with appropriate cleaning and disinfection protocols are essential.

- **Dimensions, equipment inside the room, number of people working inside:** The design must accurately determine the dimensions of each room and area based on the size and layout of the required equipment and the number of personnel expected to work within that space.

- **Equipment Footprint and Clearance:** Sufficient space must be allocated for the installation, operation, maintenance, and cleaning of all process equipment, analytical instruments, and support systems.

- **Working Space:** Adequate space must be provided for personnel to perform their tasks safely and efficiently, including movement around equipment and access to workstations.
- **Ergonomics:** Design should consider ergonomic principles to ensure comfortable and safe working conditions.
- **Airflow Requirements:** Room dimensions and equipment layout will influence airflow patterns and the effectiveness of the HVAC system.

Detailed equipment layouts, including service connections (utilities), must be developed. Room dimensions must comply with safety regulations and allow for efficient workflow and maintenance.

- **Equipment layout requirements:** The layout of equipment within each room and throughout the facility must be optimized for process flow, cleaning, maintenance, safety, and regulatory compliance.
  - **Process Flow Optimization:** Equipment shall be arranged in a logical sequence that follows the manufacturing process.
  - **Cleaning and Maintenance Access:** Sufficient space around equipment must be provided for thorough cleaning and routine maintenance.
  - **Safety Distances:** Adequate distances between equipment and personnel walkways must be maintained for safety.
  - **Containment Integration:** Biosafety cabinets, isolators, and other containment equipment must be strategically located and properly connected to ventilation and waste disposal systems.

- **Utility Connections:** Efficient and safe connections for water, electricity, gases, and other utilities must be planned.
- **Operational and maintenance access requirements:** The design must consider the accessibility of equipment and systems for routine operation, calibration, preventative maintenance, and repairs.
  - **Maintenance Clearance:** Sufficient space and access points must be provided for maintenance personnel to reach all parts of the equipment.
  - **Service Corridors and Access Panels:** Dedicated service corridors or access panels may be required for utilities and equipment components.
  - **Lifting and Handling:** Provisions for lifting and handling heavy equipment components during maintenance shall be incorporated.
- **Calibration Points:** Easy access to calibration points on critical equipment is necessary.

- **Waste management:** The design must incorporate a comprehensive waste management system that addresses all types of waste generated by the VMF, including biological, chemical, and general waste, ensuring safe collection, segregation, treatment, and disposal in compliance with environmental and safety regulations.
  - **Waste Segregation:** Designated areas and color-coded containers for the segregation of different waste streams at the point of generation.
  - **Containment and Storage:** Secure and appropriately controlled storage areas for different waste types before treatment or disposal.
  - **On-Site Treatment:** Integration of on-site treatment of specific waste streams (including autoclaves for biohazardous waste, neutralization systems for chemical waste).
  - **Holding tank:** A dedicated wastewater holding tank to handle liquid waste generated from production and laboratory areas before transferred to KIP treatment plant.
  - **Air Emission Control:** Systems to treat air emissions from processes and waste treatment (e.g., HEPA filtration for exhaust air from Biosafety Cabinets, scrubbers for chemical fumes).

The layout must include dedicated waste handling areas, access routes for waste collection, and space for on-site treatment equipment. Utility connections for waste treatment systems must be planned.

- **Infrastructure and utilities (Water and HVAC):** The design must provide for reliable and compliant infrastructure and utilities essential for vaccine manufacturing, with a particular focus on water systems and Heating, Ventilation, and Air Conditioning (HVAC) systems.
  - **Water Systems:**
    - **Potable Water:** Supply for general use and sanitation.
    - **Purified Water (PW):** Used in some cleaning and non-critical process steps.
    - **Water for Injection (WFI):** High-quality water meeting stringent purity standards, used as an excipient in vaccine formulations and for critical cleaning. The design must include generation, storage, and distribution systems with validated sanitization procedures.
  - **HVAC Systems:**
    - **Temperature and Humidity Control:** Precise control of temperature and humidity in different manufacturing and storage areas based on GMP and product requirements.

- **Air Filtration:** Multi-stage filtration, including pre-filters and HEPA filters, to achieve the required cleanroom classifications.
- **Airflow Patterns and Pressure Differentials:** Controlled directional airflow and pressure cascades to prevent contamination movement between rooms.
- **Exhaust Systems:** Safe and controlled exhaust of air from BSL areas and processes that generate hazardous fumes, with appropriate treatment (e.g., HEPA filtration, chemical scrubbing).

Detailed piping and ductwork layouts, equipment specifications (water purification units, chillers, air handling units), and control systems are required. Validation of water and HVAC systems is critical. Redundancy in critical utility systems shall be considered.

- **Facility expansion**: The initial design should consider potential future expansion of the VMF to accommodate increased production capacity or the manufacturing of new vaccines.
  - **Modular Design:** Employing modular design principles can facilitate future expansion with minimal disruption to existing operations.
  - **Space Allocation:** Reserving space for future production lines, storage areas, and utility expansions.
  - **Utility Capacity:** Designing initial utility systems with some built-in capacity for future growth.
  - **Phased Development:** Planning for phased construction to align with future needs.

The VMF plan for the facility should outline potential expansion areas and strategies. Utility infrastructure shall be designed to allow for future connections.

5.4. Waste Generation in Fill-Finish Activities

Essentially, the facility would begin with fill-finish operations which would take around 3 to 5 years from now (2025). For this, the ready-to-fill (RTF) bulk material will be sourced from WHO prequalified manufacturers. The product portfolio would consist of the liquid inactivated/recombinant/conjugate vaccine.

There will be no biohazardous or infectious waste generated out of this facility during this phase. Fill-finish operations deal with fully inactivated/recombinant/polysaccharide conjugates which are absolutely non-infectious. Such fill-finish operation/s generate liquid waste, solid waste and in small quantities, chemical waste:

a. Liquid Waste

- Residual vaccine solution from line flushing and in very rare cases of batch rejection
- Spillage or overfills during aseptic operations
- Cleaning and sanitization solutions (CIP/SIP waste)

b. Solid Waste

- Discarded primary packaging (vials, stoppers, aluminum seals)
- Used filters, tubing, and single-use systems
- Gowns, gloves, wipes, and other consumables

c. Chemical Waste

- Disinfectants (e.g., H_2O_2, peracetic acid)
- Detergents and sterilant from cleanroom cleaning protocols

These materials, are non-infectious, may retain **residual adjuvants, preservatives (e.g., thiomersal)**, or biological materials that undergo controlled deactivation and disposal.

5.5. Utility and Services

Utility Requirements: In order for the project to achieve its objectives, varying quantities of utilities will be necessary as ancillary and primary inputs. These utilities and facilities, whose sources are described in this subsection, include Water, Electricity, Sewerage, and Storm Water Drainage.

Water: The VMF requires water for processing and general services. Hence, the location of the VMF has to have a reliable water supply source. The water supply can be obtained from six boreholes constructed to serve all investors in the KIP, which have been drilled within the compound. The six boreholes have a total discharge capacity of 289.47 liter/s. The Park have four reservoirs, of which two are elevated reservoirs each having a capacity of 250 m3, and two ground reservoirs with a capacity of 5,000 m^3 and 1,000 m3 respectively, with booster pump station installed at the 1,000 m3 reservoir and 18,000 m reclaimed water line of about 18,000m for greenery and road cleaning.

Electricity: The VMF requires electricity for its smooth operation. The availability of electric power to run basic pharmaceutical equipment such as sterilization autoclave, fluidized bed dryer, the air handling unit (Heating Ventilations and Air Conditioning) as well as the water treatment plant are critical for both GMP compliance and production capability. More than 40% of energy consumption is due to HVAC systems. Much of the desired area cleanness and air ventilation system to avoid contamination and cross contamination is dependent on the HVAC capacity and it is also assumed

that about 20% of total project cost is due to AHU and HVAC system. The KIP has a total electric power supply capacity of 200 MW.

5.6. Capacity and Experience of the Implementing Organization (MoH)

A nation's prior experience in vaccine manufacturing and the safe management of highly infectious samples and waste acts as a crucial catalyst for establishing a proposed Vaccine Manufacturing Facility. Ethiopia has an experience in vaccine manufacturing and highly infectious sample and waste handling. Previous involvement in vaccine production fosters a trained workforce already familiar with the intricate processes, stringent quality control measures, and complex equipment involved. This prior experience also facilitates smoother regulatory approvals and faster adoption of best practices.

5.6.1. Production of Vaccines and Diagnostics by EPHI

EPHI has previous experience in producing bacterial and viral vaccines. For instance, during cholera epidemics in the 1960s, the Institute used to produce a parenterally administered killed whole cell vaccine. The Institute also produced smallpox and typhoid fever vaccines in early 1950. Furthermore, Fermi type rabies vaccine has been produced by the Institute for over four decades both for human and animal use and it is still in use in the country. To replace this outdated vaccine with cell culture-based rabies vaccine, EPHI adapted this new technology and has transferred the cell culture-based rabies vaccine production to NVI destined for mass vaccination of source animals.

5.6.2. Regulatory Body: Ethiopian Food and Drug Authority (EFDA)

As indicated in section 5.5.1, historically, Ethiopia produced smallpox, cholera, typhoid, and rabies vaccines at the Ethiopian Public Health Institute (EPHI). This emphasizes the long relationship and experience of EFDA to provide regulatory oversight for vaccines manufacturing. Today the local capabilities are limited to small-scale packaging and labelling, primarily for select medicines.

5.6.2.1. EFDA Regulatory and Policy Framework

The Ethiopian FDA has a comprehensive regulatory framework designed to oversee the pharmaceutical and vaccine manufacturing sector. The regulatory authority is one of the agencies reporting to MoH and is a semi-autonomus entity and is responsible for enforcing national laws and regulations relating to medicines, medical devices and vaccines. To keep pace with the evolving global vaccine landscape, the EFDA has updated and strengthened its policies to accommodate the

manufacturing and distribution of vaccines. The regulatory framework ensures that vaccines manufactured within the country or imported into Ethiopia meet international standards.

i. **Updated Regulatory Framework**: EFDA has modernized its regulatory guidelines to align with international standards, such as the **World Health Organization (WHO) guidelines** and **Good Manufacturing Practices (GMP)**. These reforms are designed to streamline the vaccine approval and manufacturing processes, ensuring that vaccines produced in the country meet the required safety, efficacy, and quality standards.

ii. **Fast-Tracking Vaccine Approvals**: EFDA has a fast-track processing of applications for essential and vital medical products including vaccines, even before the era of COVID 19 pandemic era.

iii. **Building Laboratory Capacity**: Establish Vaccine Quality Control Laboratory and Equip with necessary testing facilities to ensure vaccine lot release by Ethiopian Food and Drug Authority.

iv. **Building Regulatory Expertise**: EFDA has been investing in strengthening its regulatory capacity by providing training for its staff and collaborating with international regulatory bodies like the **WHO Prequalification Programme**. This ensures that EFDA's regulatory staff are equipped to handle the complexities of overseeing vaccine manufacturing and approval.

5.6.2.2. EFDA Maturity Level:

The maturity level of a national Food and Drug Authority, as defined by the World Health Organization (WHO) Global Benchmarking Tool (GBT), is a key indicator of the strength and reliability of the country's regulatory system for medical products, including vaccines. A regulator that has achieved WHO Maturity Level 3 (ML3) or above is considered to have a well-functioning and integrated regulatory system capable of performing all core regulatory functions - such as product evaluation and registration, inspection, market surveillance, and laboratory testing - in line with international standards.

For vaccine manufacturing, this is highly relevant because:

- It ensures that locally produced vaccines meet global quality, safety, and efficacy standards.
- It facilitates World Bank and WHO compliance, enabling products to be prequalified for global procurement (e.g., by UNICEF, GAVI).

- It strengthens regulatory oversight, ensuring proper licensing, monitoring, and post-market surveillance of vaccine products.
- It builds international confidence in the country's vaccine industry, promoting technology transfer and investment.

The Ethiopian Food and Drug Authority (EFDA) currently achieved advanced Maturity Level 3 (ML3). ML3 status for vaccines manufacturing would ensure the capability of EFDA to practice and implement WHO global benchmarking tools.

5.6.2.3. Collaboration With International Partners

EFDA has forged important collaborations with global health organizations to support vaccine manufacturing in Ethiopia. The EFDA has participated in capacity-building initiatives through the **African Medicines Agency (AMA)**, which aims to harmonize regulatory standards across African countries. By being part of this broader regional initiative, Ethiopia can streamline regulatory approval processes for vaccines and ensure quicker access to essential vaccines.

i. **WHO Collaboration**: EFDA has worked closely with the **World Health Organization (WHO)** to improve regulatory capacity and ensure that vaccines produced in Ethiopia meet international quality standards.

ii. EFDA has also partnered with **WHO for the 'Collaborative Registration Procedure (CRP)'** which focuses on issuing the **'Marketing Authorization'** for pharmaceutical and vaccine products.

iii. **African Union's Pharmaceutical Initiative**: EFDA is also actively involved in the **African Union's Pharmaceutical Manufacturing Plan for Africa (PMPA)**. This initiative focuses on fostering local vaccine and medicine production across the continent. Ethiopia's participation in this regional program strengthens its position as a hub for vaccine production in East Africa.

iv. **Support from GAVI**: GAVI, the Vaccine Alliance, has been instrumental in supporting EFDA's efforts by providing technical and financial assistance. One of the key impacts of GAVI's support to EFDA is in strengthening safety monitoring of vaccines and our PV function attaining ML3

v. EFDA has collaborated with the **African Vaccine Manufacturing Initiative (AVMI) to** enhance the efforts and collaboration for vaccines manufacturing in Africa.

5.6.2.4. Human Resources and Technical Capacity

The EFDA has prioritized building a skilled workforce with expertise in vaccine development, manufacturing, regulatory compliance, quality control, and distribution. Efforts are being made to train local professionals, including scientists, regulatory experts, and technicians, to meet the demands of vaccine production and quality assurance.

i. **Capacity Building**: EFDA has been investing in training programs to ensure that Ethiopia's vaccine manufacturing sector has the necessary technical expertise. This includes training regulatory staff, production technicians, and quality control personnel to handle vaccine production processes effectively.

ii. **Collaborations with Academic Institutions**: The EFDA has strengthened collaborations with universities and research institutions, such as **Addis Ababa University**, **Haramaya University and Jimma University**, to build a pipeline of skilled professionals in the fields of pharmacology, biotechnology, and vaccine development. These collaborations foster a culture of research and development (R&D), which is critical for the long-term success of vaccine manufacturing in Ethiopia.

iii. EFDA has a dedicated manufacturing Inspection and Enforcement team to oversee the regulatory procedures for pharmaceutical and vaccines, including the auditing and inspection of vaccines manufacturing sites for GMP compliances as per the WHO requirements.

iv. The human resources shall be further strengthened and met maturity level 3-ML3.

v. The National quality Control Laboratory infrastructure is also being enhanced along with the qualified human resource to perform testing of medicines and vaccines and subsequently the lot release.

5.6.2.5. Quality Control and Assurance Systems

The EFDA has a strong focus on ensuring that vaccines produced locally meet international standards of quality. The authority enforces strict Good Manufacturing Practice (GMP) guidelines, which are essential for ensuring the safety and efficacy of vaccines. Ethiopia has invested in establishing high-standard laboratories and quality assurance systems to monitor and regulate the production of vaccines.

i. The **'Centre of Excellence' facility – National quality Control Laboratory**, has multiple quality testing laboratories which will mark a significant advancement in tackling the diverse health challenges through a robust medicines & vaccines testing infrastructure.
ii. The laboratory, recognized for its commitment to ensuring the safety, quality, and efficacy of medicines, **holds an ISO 17025 accreditation** certificate
iii. The Medicine Manufacturing Inspection activity also acquires an ISO 17020 accreditation certificate for its performance of inspection activities in alignment with ISO requirements.
iv. The EFDA also works closely with international regulatory agencies, such as the WHO Prequalification Programme.
v. For the current project, for the stage 1, only fill-finish operations are proposed. The ready-to-fill (RTF) bulk material shall be sourced from the country having maturity level 3 and above. Besides this, the RTF proposed to be sourced shall mandatorily be from the WHO prequalified manufacturer. This will ensure that all the quality, safety and efficacy parameters are in accordance with the requirement of WHO.
vi. Besides the filling operations will be in aseptic conditions which will be monitored and inspected by the EFDA. The filling process proposed shall be automated, ensuring aseptic conditions by use of isolators for the filling operations of vaccines.
vii. The vaccine/s proposed to be filled will be liquid inactivated (killed or recombinant or polysaccharide conjugate vaccine/s) which as such will require preliminary biosafety compliance i.e BSL2.

6. PROJECT ALTERNATIVES

In evaluating the proposed project, the "no action" alternative was considered as a baseline scenario to provide a benchmark against which the potential benefits and drawbacks of the proposed project could be compared. This evaluation helped to understand the consequences of not proceeding with the project, including potential lost opportunities for economic development, improved healthcare access, or environmental remediation. Once the 'No alternative" has failed, a comprehensive alternatives analysis was conducted, exploring various options to minimize potential environmental and social impacts while maximizing benefits. This analysis encompassed several key areas, including project location, design approaches, project schedule, process technologies, material selection, waste management options, source of energy and water.

6.1. No project alternative

The "No action" option is not advisable for several reasons. Ethiopia's public health system is frequently challenged by disease outbreaks and disasters, compounded by its proximity to fragile states, increasing the risk of epidemic spread across Africa. Establishing a vaccine manufacturing facility in Ethiopia is crucial for enhancing public health security and self-sufficiency, enabling quicker responses to outbreaks and reducing import dependence. This initiative will promote cost-effectiveness, create jobs, and position Ethiopia as a regional leader in vaccine production, while also improving immunization rates and fostering local research. As the project is located in the Kilinto Industrial Park which is designed for pharmaceutical industries and established with the support of World Bank i.e. passed through rigorous environmental and social due diligence review, the project will have minimal adverse environmental impact due to existing safeguards. The "No-action" alternative would lead to underutilization of valuable land resources in the industrial park. Ultimately, rejecting the project would hinder the significant socio-economic and political benefits that Ethiopia and its neighbors could gain from the establishment of a cGMP Compliant Vaccine Manufacturing Facility.

6.2. Alternative Site

Site selection is crucial for sustainable vaccine manufacturing as it directly impacts the facility's operational efficiency and environmental footprint. Choosing a less fragile location with robust infrastructure, such as waste management systems and access to clean water, ensures that manufacturing processes can adhere to environmental regulations and minimize resource consumption. The site selection process for the proposed Vaccine Manufacturing Facility was exclusively focused on the Kilinto Industrial Park due several reasons. This industrial park already hosts several pharmaceutical and related facilities and is specifically designed for the production of pharmaceuticals and high-tech products. Covering nearly 280 hectares of serviced land, it boasts a zero-discharge wastewater treatment plant capable of processing 14 million liters per day (14 MLD), ensuring that the manufacturing operations have minimal environmental impact. Furthermore, the park is equipped with a fire brigade featuring two fire trucks, a dedicated waste sorting area, six boreholes for water supply, well-maintained internal roads, and access control measures. Considering the favorable conditions and dedicated land available within the park, the option of selecting alternative locations outside of it for the Vaccine Manufacturing Facility was deemed irrelevant. The park's infrastructure and shared facilities make it an ideal choice for this type of project.

6.3. Alternative Schedule

Postponing the project is not advisable given the current favorable conditions that support immediate action. While delaying the proposal might offer the potential for improved baseline conditions and advancements in technology, these benefits are not guaranteed and could lead to unnecessary uncertainties and complications. By proceeding with the project now, we can take advantage of the existing infrastructure, such as robust waste management systems and access to clean water, which are essential for sustainable vaccine manufacturing. These conditions will enable us to implement the project efficiently while adhering to environmental regulations and minimizing resource consumption.

Moreover, delaying the project could result in increased operational and logistical costs due to inflation and rising living standards. The urgency of the project is underscored by the need to enhance vaccine production capabilities promptly, ensuring we meet public health demands effectively. Therefore, moving forward with the proposed project, coupled with appropriate mitigation measures, is the preferred option. This approach allows us to capitalize on current enabling conditions while avoiding potential future challenges associated with delays.

6.4. Waste Management Technology Alternative

6.4.1. Solid Waste Management Technology Alternative

The KIP has implemented a dedicated waste sorting system for non-hazardous waste. Move-in factories within the KIP are required to source-sort their solid waste on-site. This sorted waste is then transported to a centralized transfer station for temporary storage. At the transfer station, further sorting occurs to separate recyclable materials for diversion. The transfer station is designed with a minimum three-day storage capacity. Waste generated within the KIP is categorized as combustible, incombustible, and recyclable. This system aligns with municipal waste management standards, which mandate initial source separation prior to final disposal at the landfill. Assessment of the solid waste management facility in Addis Ababa revealed that there is only one functional landfill called the Repi landfill. It has a total area is 19.2 hectares and is believed to have a capacity of 3600 tons per day. It receives mainly household waste and non-hazardous wastes, office and commercial waste. Therefore, there is no available space for hazardous waste disposal in Addis Ababa. The VMF project will not generate any hazardous/infectious waste. During Pahse I, the operations will involve the fill-finish of inactivated and recombinant vaccines. However, a provision is made to ensure that whatever waste is generated from VMF, it will be treated primarily by two technologies: high-

temperature incineration with advanced air pollution control systems and/or the Ecosteryl waste management system, which are described below.

The Waste Incineration Technology Alternative: When incinerators are managed effectively, they effectively destroy pathogens present in waste and convert it into ash. However, specific categories of waste—such as biological, pharmaceutical, and chemical waste-demand elevated temperatures to ensure thorough incineration. Operating at these higher temperatures, along with the treatment of exhaust gases, helps minimize both atmospheric pollution and unpleasant odors associated with the incineration process. There is no existing incinerator in the KIP. Therefore, the VMF must construct an incinerator within its own premises that fulfills the national standard considering the waste characteristics generated from VMF. The incinerator will be a pyrolytic technology with a minimum capacity of 50Kg/hr and operating temperature of 50 kg/hr. It will have a pneumatic/hydraulic waste loading system and automatic and manual removal of ash.

Disposal of incinerated hazardous ash: Fly ash and bottom ash from incineration is generally considered to be hazardous, because the waste would have heavy metal content and dioxins and furans may cause potential impacts on water, soil and the biological environment. The VMF use waste bags for waste collection. Sharp items are collected in safety boxes and special hard plastic bottles that are designed for sharp materials. It will also use color coding (red or yellow bags for infectious waste) according to its type and use a labeling system for the containers. After the decontamination of wastes generated from the facility, and carried to the incinerators by personnel dedicated to waste handling using a cart. The personnel must use appropriate PPE during collection and transportation according to the safety manual and waste management procedures. Hazardous wastes from the facility will be incinerated in Pyrolytic Technology incinerators that are designed for medical and pharmaceutical hazardous waste management and fulfill the emission standard (Table 11).

Table 12: Air Emission Levels for Hospital Waste Incineration Facilities

Pollutants	**Units**	**EHS Guidance value**
Total Particulate Matter (PM)	mg/Nm^3	10
Total organic carbon (TOC)	mg/Nm^3	10
Hydrogen chloride (HCl)	mg/Nm^3	10
Hydrogen fluoride (HF)	mg/Nm^3	1

Sulfur dioxide (SO_2)	mg/Nm^3	50
Carbon monoxide (CO)	mg/Nm^3	50
Nox	mg/Nm^3	200-400 (a)
Mercury (Hg)	mg/Nm^3	0.05
Cadmium + Thallium (Cd + Tl)	mg/Nm^3	0.05
Sb, As, Pb, Cr, Co, Cu, Mn, Ni and V	mg/Nm^3	0.5
Polychlorinated dibenzodioxin and dibenzofuran (PCDD/F)	Ng/Nm^3 TEQ	0.1

Notes:

a. 200 mg/m^3 for new plants or for existing incinerators with a normal capacity exceeding 6 tones per hour, 400 mg/m^3 for existing incinerators with a nominal capacity of 6 tones per hour or less
b. Oxygen level for incinerators is 7 percent

Fly ash and bottom ash from incineration require a secured landfill for storage. The appropriate site within the VMF site needs to be selected, near the incinerator. Ideally, the pit shall be lined with low permeability material such as clay and plastic or concrete-based materials at the bottom to prevent the pollution of shallow groundwater and shall be fenced in to prevent scavenger access.

Ecosteryl Technology Options: Ecosteryl employs a technology that integrates thermal treatment with mechanical processes to effectively manage medical waste. Ecosteryl's method utilizes lower temperatures, resulting in decreased energy consumption and lower emissions. The technology is designed to minimize harmful emissions compared to traditional incineration, thereby improving air quality and ensuring compliance with environmental regulations. Additionally, Ecosteryl's process facilitates the recovery of materials from waste, promoting recycling and decreasing reliance on new raw materials. The equipment is typically more compact than traditional incinerators, making it suitable for a range of healthcare environments, including smaller facilities. By decreasing waste volume and recovering valuable materials, this technology can lead to long-term cost savings.

However, the initial investment for Ecosteryl technology may be higher than that of traditional methods. Given that this technology is relatively uncommon in Ethiopia, successful implementation will require staff training and increased awareness of the new processes and technologies. Additionally, operational and maintenance challenges remain a concern.

Waste Stabilization and Solidification Options: This process involves mixing hazardous ash with binding agents (like cement) to immobilize contaminants before disposal. It can enhance the safety

of landfill disposal. However, it requires additional processing and materials; may not eliminate all risks.

Recycling and Recovery: Certain components of hazardous ash may be recoverable for reuse, such as refillable containers, packaging materials, and metals. It reduces waste volume and promotes resource recovery. However, not all waste is suitable for recycling; it requires specialized facilities.

Landfill Alternative: The final solid waste disposal alternatives have been analyzed based on their availability, safety, and national and world bank standards. Sanitary landfills, when properly designed and managed, can offer a relatively safe method for disposing of municipal solid waste, including healthcare waste. However, this approach necessitates a larger area for the compaction of daily waste. In Addis Ababa, the Repi Landfill serves as a sanitary landfill, but there is currently no secured landfill for disposing of hazardous wastes, fly ash, or bottom ash from incineration.

Selected Technology

Given the diverse waste streams generated by the proposed VMF, a multi-faceted approach, combining several technologies, is essential for effective and sustainable waste management. For non-hazardous waste, a robust recycling and reuse program within the KIP transfer station is paramount, aiming to significantly reduce the volume requiring final disposal. Following this, residual non-hazardous waste, after rigorous diversion of recyclable materials, shall be directed to the Repi Landfill. This landfill, however, must be subject to a formal agreement ensuring adherence to best practices in landfill operation, including leachate management, gas collection, and environmental monitoring.

Biological waste necessitates specialized treatment, high-temperature incineration with advanced air pollution control systems. Incineration effectively eliminates pathogens and reduces waste volume. The construction of a secured concrete ash pit, designed to contain and neutralize hazardous incinerated ashes, is recommended. This pit must incorporate impermeable liners to prevent environmental contamination. Additionally, considering hazardous waste management following the FMHACA Medicine Waste Management and Disposal Directive, 2011 including waste segregation, labeling, storage, and transportation, is crucial. This consideration should align with the directives and other national and international regulations, and involve licensed hazardous waste handlers.

In summary, the Repi Landfill, subject to stringent controls, is deemed suitable for the disposal of residual non-hazardous waste, following comprehensive recycling and reuse efforts within the KIP.

Conversely, on-site technologies, including incineration for biological waste and a secured concrete ash pit for hazardous ash waste, are essential for the safe and responsible management of the facility's specialized waste streams. This integrated approach ensures environmental protection, regulatory compliance, and minimizes the facility's environmental footprint.

6.4.2. Effluent Waste Management Alternative

Kill tank

Kill tank typically refers to a tank or chamber used to neutralize or eliminate harmful pathogens, chemicals, or contaminants from wastewater before it is released into the environment or subjected to further treatment processes. Kill tanks help significantly reduce the levels of harmful microorganisms, such as bacteria and viruses, ensuring that the treated water is safe for discharge or reuse. They can be used to neutralize hazardous chemicals and toxins, preventing them from entering the environment and causing pollution. Utilizing kill tanks helps facilities meet environmental regulations and standards for wastewater discharge, minimizing legal and financial liabilities.

Onsite Wastewater Treatment Plant: The effluent generated by the facility must comply with national effluent discharge quality standards, specifically those outlined for healthcare facilities as classified by the World Bank Group (WBG), prior to its release into the environment. There are two options VMF ETP and central KIP WWTP.

Onsite Retention using Septic/holding Tank: On-site wastewater retention is achieved using septic/holding tanks, designed to temporarily store both hazardous and non-hazardous wastewater for a maximum of 72 hours before discharge to the central KIP WWTP. Functionally, these tanks act as sedimentation basins and can be constructed in either rectangular or cylindrical configurations. Due to their cost-effectiveness, durability, low maintenance requirements, and simple operation, the implementation of dedicated septic/holding tanks for on-site wastewater retention is strongly recommended.

Selected Technology:

A multi-step approach is recommended for on-site wastewater management. The liquid waste from the production area will be collected in the Kill tank provided at the basement floor and will be further treated either through heat or chemical. After thorough disinfection, the neutral material will be let into the effluent treatment tank where it will be further treated in compliance with the waste management guidelines before the liquid waste is let into the Kilinto Industrial Park’s (KIP) central

effluent collection line for the centralized treatment by the KIP. In addition, 72-hour wastewater holding tanks would be included for the temporary retention of both hazardous and non-hazardous wastes to comply with KIP SOP.

Regarding the sludge management, the ESIA study team recommended the KIP sludge management approach that chemical sludge from the HAF system is dewatered using a centrifuge. Biological sludge from the aeration tank is thickened prior to centrifuge dewatering. The resulting dewatered sludge cake is then transported to the sludge storage yard for disposal.

6.5. Utilities Source Alternatives

6.5.1.1. Electricity

Commonly, Production and laboratory facilities around the globe have relied on a conventional energy supply model that includes access to national grid power, supplemented by on-site fuel-based generators. While fuel costs represent a significant portion of overall healthcare expenses, diesel generators are often recommended as a reliable backup during power interruptions. For the Vaccine Manufacturing Facility, it is advisable to explore the integration of renewable energy sources, such as solar panels which can serve as either primary or supplementary power sources for minor operations like lighting.

6.5.1.2. Water

Water is essential for various functions within the facility, including domestic use, laboratory processes, and production activities. Domestic water needs encompass drinking and cleaning, while the facility also requires water for production, cleaning, solvent use, sanitation, toilet flushing, and landscaping. To mitigate dependence on municipal water supply, two viable options are borehole water and rainwater harvesting. Given that KIP is equipped with six boreholes capable of supplying 14 million liters per day (MLD), utilizing KIP borehole water could be a sustainable alternative for the vaccine manufacturing facility.

6.5.1.3. Transport

To ensure project site accessibility while mitigating potential impacts, transportation infrastructure will be carefully managed. The project will utilize a dedicated gate (separate from KIP's main operational gate) and construction will utilize a second gate to minimize infrastructure damage and prevent congestion at the main entrance.

6.5.1.4. Materials

When selecting materials for the project, there are two primary options: sourcing locally or importing from abroad. The preferred approach is to procure materials locally, as this not only supports the national economy but also fosters business opportunities for local suppliers. Additionally, it is recommended to obtain construction materials from the nearest possible sources to minimize the project's carbon footprint.

7. PROJECT ACTIVITY PHASES AND ENVIRONMENTAL AND SOCIAL IMPACT ASSESSMENT

7.1. Project Activity Phases

7.1.1. Pre-construction and Construction Phase

The pre-construction activity includes soil test, site clearance, shoring and excavation grading. The construction activities include site preparation, infrastructure utilities installation, erection, and filling. The major activities during the construction phase are civil construction work, vehicular movement, loading and unloading civil items and plant machineries, on-site storage of civil items and plant machineries, erection of plant and civil structures, power supply, maintenance of construction machinery and disposal of excavated soil and solid wastes.

7.1.2. Operation and Maintenance Phase

The operational phase of fill-finish vaccine manufacturing involves several key activities, including vial/syringe preparation, aseptic filling, inspection, labeling, packaging, and quality control (See Section 5.2, Facility Block Service Detail Description). These processes generate a variety of waste streams. Common waste includes contaminated vials/syringes (broken or rejected), residual vaccine product, personal protective equipment (PPE) such as gloves and gowns, packaging materials (cardboard, plastic), and cleaning/disinfection solutions. The nature of this waste can be a concern, as it can potentially contain biological components, posing biohazard risks. Efficient segregation and proper handling are crucial to minimize potential exposure and prevent environmental contamination. The amounts of this waste are related to the number of batches and the facility management. Proper waste management technology must be in place for sustainable vaccine production.

7.1.3. Decommissioning Phase

Decommissioning is the last phase in the lifetime of such facilities, following their design, construction, operation and permanent shutdown. Decommissioning activities such as the removal of

inventory to obtain a state of passive safety, dismantling and removal of the components, systems and equipment including decontamination as appropriate with the aim of re-utilization of facilities for production after construction or making the facility suitable for any activity after construction or operation. It is important to identify and screen the likely impacts and prepare mitigation measures.

7.2. Potential Environmental and Social Impact Assessment

7.2.1. Impact Identification

The main environmental and social impacts shall be identified through professional judgment and a matrix system based on the biophysical and socio-economic baseline data and project characteristics. List of impacts identified are included in Table 12.

7.2.2. Impact Analysis

The most important impacts have been identified, their potential size and characteristics were predicted and evaluated systematically by the environmental and social specialists based on physical, biological, socio-economic and cultural data to estimate the likely characteristics and parameters of impacts (e.g. magnitude, spatial occurrence, etc.). For this analysis a weighted matrix was used to assist the total impact estimation (as well as assign values). The result analysis is displayed in Table 12. Only impacts with moderate and above impact significance were further described and appropriate mitigation measures were developed for these impacts.

Table 13: Total impact analysis of the proposed project

Identified Impacts	Character (C)	Significance (S)	Disturbance (D)	Occurrence (O)	Extension (E)	Duration (D*)	Reversibility (R)	Total Impact (TI)	Remark
Construction Phase Impacts									
Employment opportunities	+	3	2	2	2	2	1	(+12)	Moderate
Increase in skilled workforce	+	2	2	2	1	1	2	(+10)	Moderate
Increased Economic Activity	+	3	2	3	1	1	2	(+10)	Moderate
Environmental Risk									
Air pollution	-	2	2	3	1	1	1	(-10)	Moderate
Water pollution	-	2	2	2	2	1	1	(-10)	Moderate
Soil pollution and erosion	-	2	1	2	1	1	2	(-9)	Moderate
Noise and vibration impacts	-	2	1	2	1	1	2	(-9)	Moderate
Hazard solid and liquid waste	-	1	1	1	2	1	2	(-8)	Low

Identified Impacts	Character (C)	Significance (S)	Disturbance (D)	Occurrence (O)	Extension (E)	Duration (D*)	Reversibility (R)	Total Impact (TI)	Remark
impacts									
Non-hazard solid and liquid waste Impacts	-	2	1	3	2	1	2	(-11)	Moderate
Impact on plant, soil and animal biodiversity	-	1	1	2	1	1	2	(-8)	Low
Risk of social conflict and crime	-	2	1	1	1	1	2	(-8)	Low
Gender-based violence	-	2	2	2	1	1	3	(-11)	Moderate
Child right violation impacts	-	2	2	2	2	1	2	(-11)	Moderate
Increase burden on public service	-	2	2	2	1	1	2	(-11)	Moderate
Occupational health and safety Risks									
Risk related to slip, trip, and falls	-	2	2	2	2	2	1	(-11)	Moderate
Risk related fire and explosion	-	2	1	2	1	2	1	(-9)	Moderate
Electrical hazard	-	2	2	2	1	2	2	(-11)	Moderate
Ergonomic hazard	-	2	1	3	1	2	2	(-11)	Moderate
Biological hazard	-	2	2	2	1	2	2	(-11)	Moderate
Risk of traffic accident	-	2	1	2	1	2	2	(-10)	Moderate
Community health and Safety risk									
Traffic and public safety impacts	-	3	3	3	1	1	3	(-14)	Moderate
Public health impacts	-	2	2	1	1	1	1	(-8)	Low
Flooding risk	-	3	2	1	1	1	1	(-9)	Low
Operation Phase Impacts									
Protect and promote the health of the community	+	3	3	3	3	3	2	(+17)	High
Creation of employment opportunities	+	2	2	3	3	3	2	(+15)	Substantial
Research and community services	+	3	3	3	3	3	2	(+17)	High
Increase in skilled workforce in the country	+	3	2	3	3	2	2	(+15)	Substantial
Regional integration	+	3	1	3	3	3	2	(+15)	Substantial
Increased economic activity	+	3	3	3	3	2	3	(+17)	High
Environmental Risk									
Air pollution	-	3	3	1	2	3	2	(-14)	Moderate
Water pollution	-	3	2	1	2	3	3	(-14)	Moderate
Soil pollution	-	2	2	1	2	3	2	(-12)	Moderate

Identified Impacts	Character (C)	Significance (S)	Disturbance (D)	Occurrence (O)	Extension (E)	Duration (D*)	Reversibility (R)	Total Impact (TI)	Remark
Noise and vibration	-	2	1	3	1	3	2	(-12)	Moderate
Solid and liquid waste impacts (Hazardous and infectious)	-	3	3	3	1	3	3	(-16)	Substantial
Solid and Liquid wastes (Non-hazardous and infectious)	-	3	1	3	2	1	2	(-12)	Moderate
Impacts on plant, soil and animal biodiversity	-	1	2	2	2	1	1	(-9)	Moderate
Improper waste management	-	3	3	1	2	3	2	(-14)	Moderate
Risk associated with final waste disposal	-	3	2	2	2	3	2	(-14)	Moderate
Impacts of incineration of solid wastes	-	3	3	1	2	3	2	(-14)	Moderate
Social Risk									
Risk of social conflict and crime	-	2	1	1	1	3	2	(-10)	Low
Gender based violence	-	2	1	2	1	3	2	(-11)	Moderate
Increase burden on public Service	-	2	1	2	1	3	2	(-11)	Moderate
Community Health and Safety Risk									
Impact on traffic and public safety	-	2	1	1	1	2	2	(-8)	Low
Public health impacts	-	3	2	2	2	3	2	-(14)	Moderate
Flooding risk	-	3	2	1	1	2	1	(-10)	Low
Occupational Health and Safety Risks									
Risk of infection	-	3	3	2	2	2	1	(-13)	Moderate
Risk of chemical hazard	-	2	2	2	2	3	2	(-13)	Moderate
Risk of physical hazard	-	2	2	2	2	2	2	(-12)	Moderate
Ergonomic hazard	-	2	2	1	2	2	1	(-10)	Moderate
Risk related to electricity (electric shock)	-	3	2	2	1	2	2	(-12)	Moderate
Risk related to fire and explosion	-	2	2	2	1	2	2	(-11)	Moderate
Decommissioning Phase (Dismantling of buildings and removal of equipment's)									
Impact on soil quality	-	2	1	2	1	1	1	(-8)	Low
Impact on water resource	-	2	1	1	1	1	1	(-7)	Low
Impact on air quality	-	2	1	3	1	1	1	(-9)	Moderate
Impact on noise environment	-	2	1	3	1	1	1	(-9)	Moderate

Identified Impacts	Character (C)	Significance (S)	Disturbance (D)	Occurrence (O)	Extension (E)	Duration (D*)	Reversibility (R)	Total Impact (TI)	Remark
Solid waste generation	-	2	2	2	2	1	1	(-10)	Moderate
Liquid waste generation	-	1	1	1	1	1	1	-(6)	Low
Impact on plant, soil and animal biodiversity	-	1	1	2	1	1	1	(-7)	Low
Impact on traffic and public safety	-	2	1	2	2	1	1	(-8)	Moderate
Occupational Health and safety Risk									
Risk of physical hazard	-	3	2	3	2	2	3	(-15)	Substantial
Risk of electrical hazard	-	2	2	2	1	2	1	(-10)	Moderate
Risk of biological hazard infection)	-	3	3	1	3	2	2	(-14)	Moderate
Risk of chemical hazard	-	2	2	2	2	3	2	(-13)	Moderate
Positive Impacts									
Income generation	+	2	1	1	1	1	1	(+7)	Low
Creation of employment	+	2	1	2	2	1	1	(+9)	Low
Increase economic activities	+	2	1	2	2	1	1	(+9)	Low

Where, C=Characteristics, S=Significance, D=Disturbance, O=Occurrence, E =Extension, D*=Duration, R=Reversibility

7.4. Beneficial Impact (Positive Impact)

7.4.1. Employment Opportunities

The proposed project is expected to provide direct and indirect employment to several workers during the pre-construction, construction and operation phases. The construction phase is expected to create job opportunities. These range from unskilled casual workers, semi-skilled and skilled employees such as designers, supervisors, contractors, local material suppliers, masons, daily laborers, dwellers, merchants, security guards, cleaners, gardeners, drivers, wood-workers, metal workers, plumbers, consultants, etc.

During the operational phase of the proposed project create additional job opportunities for the local people. These include administrative staff, HVAC technicians, electrical technicians, equipment and instrument maintenance technicians (Biomedical engineers), technical staff, production floor operators, quality assurance and quality control staff, regulatory staff, supply chain & warehouse

management, laboratory staff and interns, incinerator operators, supportive staff, cleaners, and security personnel.

Enhancement measures: Hiring local professionals and service providers at all levels where possible enhance the national benefit. There is also a need to recruit locally available labor for positions that do not demand special skills and experts that fulfill the requirements. This enhances the benefits of local communities and project sustainability. Outsourcing some activities such as greenery and cleaning services for local enterprises found in Akaki Kality Sub-City is important for project sustainability.

7.4.2. Increase Skilled Workforce and Center of Excellence

The project will also increase workforce skills during the construction and decommissioning phases.

Enhancement measures: Provide training for researchers, technical and supportive staff on technologies installed in the VMF, waste handling, transport and disposal.

7.4.3. Increased Economic Activity

Implementation of the VMF project will entail civil works requiring materials such as gravel, bricks, lumber and cement. In addition to the construction materials to be procured locally, the development of the VMF project requires supplies from abroad. It is a positive but short-term impact. Moreover, the people who are involved in these businesses supply and value chains will benefit from the employment creation. Additionally, the project will create business opportunities for the people who are involved in quarrying and brick production, furniture and carpentry, glass production, plant and gardening, building contractors, equipment supply and maintenance, electric fittings, plumbing fittings and water infrastructure and food and drinking establishment service.

Enhancement Measures: Where possible the construction contractor will be advised through contractual means to maximize the application and use of locally produced construction material supplies. This will increase the quantity of materials to be procured from the various local suppliers. On the other hand, earth materials needed for construction, for example, aggregate (stones and sand) are obtained from quarry operations. However, conscious or unwitting purchase of these materials from unlicensed operations indirectly promotes environmental degradation at illegal quarry sites and can cause moderate- to long-term negative impacts. Therefore, there will be a contractual obligation for contractors to procure construction materials from quarries legitimately licensed by the Government.

7.4.4. Protect and Promote Community Health

The establishment of a vaccine manufacturing facility in Ethiopia is pivotal for enhancing public health security and self-sufficiency, enabling the country to respond swiftly to infectious disease outbreaks while reducing reliance on imports. Additionally, the facility can improve immunization rates, foster research and development tailored to local health challenges, and facilitate international collaborations, ultimately building a more resilient healthcare system capable of addressing future public health needs.

Enhancement Measures: The facility shall be constructed as per WHO standards and hiring the right construction agency for the construction of the VMF are the key steps for the success of the project. The VMF shall be operated according to all guidelines and requirements established by the CDC and NIH (CDC 1999), WHO, 2004, and BMBL (2005).

7.4.5. Regional Integration

A regional approach to developing the VMF project can have several benefits, including promoting peer learning among countries and institutions and sharing good policies and practices, and targeting employment toward regional economic corridors. The regional integration facilitates the flow of human capital and ideas and promotes medical tourism in the region.

Enhancement measures: The VMF should identify skills gaps and develop cross-border skills enhancement programs.

7.4.6. Research and Community Services

The implementation of the project will enable Ethiopia to provide a fillip to the research and development sector with respect to healthcare and biopharmaceutical manufacturing across various functions. It will provide evidence-based information and to develop vaccines that addresses community health problems effectively and efficiently in terms of quality, cost, and time and customer satisfaction.

Enhancement measures: VMF is expected to use new and innovative methodologies that are responsive to today's complex and evolving public health challenges.

7.5. Potential Negative Impact

7.5.1 Construction Phase

7.5.1.1. Physical Impacts and its Mitigation Measures

Impact on Air Quality

The site preparation and construction phases of the proposed VMF project will introduce temporary and localized air quality impacts. The operation of heavy construction equipment, including dump trucks, cranes, and material transport vehicles, will generate combustion engine exhaust emissions. These emissions will include particulate matter (PM), sulfur dioxide (SO_2), carbon dioxide (CO_2), carbon monoxide (CO), and nitrogen oxides (NOx).

While the use of heavy equipment and construction vehicles will result in a temporary increase in particulate and gaseous emissions, the limited number of equipment pieces and the short duration of their operation will minimize the overall impact on ambient air quality. The effects will primarily be localized to the immediate construction area and for a short time.

Mitigation Measures for Air Quality Impacts:

To mitigate potential air quality impacts during construction, the following measures will be implemented:

- Construction work shall be performed by a reputable and registered contractor with demonstrated environmental awareness and responsibility.
- Contractors shall use dust screens or nets in windows, doorways and ventilators of rooms where demolition or other dusty construction activities are occurring,
- Dusty roads and work areas will be regularly watered, at least twice daily or more frequently as needed, to minimize fugitive dust emissions.
- Construction structures shall be enclosed with dust-proof netting to prevent the dispersion of particulate matter.
- Rigorous housekeeping practices need to be enforced, including prompt sweeping of dust and debris from surfaces and proper disposal of construction waste in covered containers.
- Construction machinery must undergo regular maintenance according to manufacturer specifications to ensure optimal performance and minimize emissions.
- Only clean fuels, such as unleaded and low-sulfur diesel, will be used. Fuel sourced from unregulated or potentially contaminated sources is prohibited.
- Provide regular training for construction workers on emission reduction techniques and best practices for minimizing air pollution.
- Appropriate PPE shall be provided for workers, including respirators, and the mandatory use of PPE will be strictly enforced.

Water Pollution Impacts

Construction activities at the VMF project site pose a risk of water pollution through increased runoff and drainage containing suspended solids and contaminants. Potential sources of pollution include:

- Runoff from exposed soil surfaces, earth working areas, and soil stockpiles will carry increased loads of suspended solids, leading to sedimentation in nearby water bodies.
- Rainwater runoff may leach contaminants from grouting and cement materials, as well as fuel and lubricants used in construction vehicle and equipment maintenance.
- Inadequate management of domestic sewage generated by the construction workforce can lead to contamination of surface and groundwater.
- Improper disposal of excavated soil can result in the deposition of sediment into rivers and watercourses, altering the physicochemical characteristics of the water and negatively impacting aquatic ecosystems. This can damage individual species, species populations, and natural biological communities.

Water Pollution Impact Mitigation Measures:

To minimize the potential for water pollution during construction, the following mitigation measures will be implemented:

- The contractor should establish designated maintenance areas for trucks and construction machinery, equipped with impermeable surfaces and containment systems to prevent oil and lubricant spills.
- Used oils and other liquid waste shall be stored in secure, labeled containers and disposed of as hazardous waste in accordance with local regulations.
- Dispose of excavated soil only at designated sites with permits from local authorities and environmental clearance from the city administration's EPA office.
- Erosion and sediment control measures, such as silt fences, sediment basins, and temporary drainage ditches, must be implemented.
- Surface water drains and watercourses shall be protected with cut-off ditches, earth bunds, or other appropriate measures to divert runoff and prevent contamination.
- Proper portable toilets need to be installed and maintained for the workers, and sewage must be disposed of by a licensed sewage hauler or follow the KIP sewage management system.

Soil Pollution

Site preparation and construction activities associated with the VMF project present some risks of soil contamination. While the direct impacts on geology and seismicity are expected to be negligible, the following sources of contamination pose a risk:

- Liquid wastes from concrete batching plants, plastic bottles, PVC, rubber wastes, empty oil and grease containers, used oils from machinery and trucks, and thermal insulation wastes can contaminate soil. These wastes can alter soil physicochemical properties, such as pH, and negatively impact plant biodiversity within the park. Non-biodegradable plastic wastes can impede nutrient uptake by plants.
- Accidental leaks of fuel, oil, or chemicals from vehicles and equipment stored on-site can directly contaminate the soil. But this impact will be highly localized and negligible.

Soil Pollution Impact Mitigation Measures:

To minimize the potential for soil contamination during construction, the following mitigation measures will be implemented:

- Minimize soil disturbance and control erosion by avoiding steep slopes and reducing the footprint of construction activities, including roads, staging areas, and crane pads.
- Collected and recycle all plastic tubes and other recyclable materials generated during construction
- Develop and implement a spill response plan in the event of an accidental oil or chemical spill.
- Collect and recycle used oils, including engine lubrication oil, hydraulic fluids, and gear oils, or disposed of as hazardous waste according to local regulations.
- Prepare a designated maintenance area with an impermeable surface and containment systems for construction vehicles and machinery to prevent soil contamination from leaks and spills.

Noise and Vibration Impacts

The construction phase of the VMF project will generate temporary noise and vibration impacts. Site clearance activities, including vegetation removal and land leveling, will involve the use of heavy machinery, resulting in localized noise generation for a limited duration.

Significant noise and vibration levels are expected from the operation of construction equipment, including earthmoving and excavation machinery, concrete mixers, cranes, and

transportation vehicles. These activities, along with heavy construction traffic and regular vehicle movement, will contribute to elevated noise levels during the construction period.

While construction workers will be directly exposed to these noise levels, the impact on the surrounding community is expected to be minimal due to the residential area being located more than 1 kilometer from the construction site.

Mitigation Measures for Noise and Vibration Impact:

To mitigate potential noise and vibration impacts during construction, the following measures will be implemented:

- The contractor should prioritize the use of well-maintained and modern equipment with low noise emission ratings. Older or damaged machinery with excessive noise levels will be avoided.
- Construction activities exceeding normal working hours should require prior approval from the consultant and client and, when necessary, advanced notification to nearby companies.
- Noise levels exceeding 75 dB(A) during daytime hours and 65 dB(A) during nighttime hours will only be permitted with prior approval and a minimum of two days' advance notification to nearby companies.
- Restrict activities generating significant noise disturbances during daylight hours and will be subject to the notification procedures outlined above.
- Diesel generator sets and other noise-generating machinery must be equipped with acoustic enclosures to minimize noise emissions at the construction site.
- All construction equipment and machinery must undergo regular maintenance according to manufacturer specifications to ensure optimal performance and minimize noise generation.
- Provide training and awareness creation sessions for construction workers on noise reduction techniques and best practices for minimizing noise generation.
- Provide appropriate PPE for workers exposed to high noise levels such as earplugs or earmuffs, and the mandatory use of PPE will be strictly enforced.

Solid Waste Generation

Building foundation construction will necessitate the excavation of existing material from the building footprint area, with an additional 0.8 meters beyond the footprint. The majority of this

excavated material will be transported off-site for disposal (as the project site geology study shows it is expansive soil, cut and fill cannot be maximized), and engineered backfill using imported material will be implemented. This process, if not managed appropriately, will generate sediment-laden storm-water runoff.

The construction phase will also produce a diverse range of solid wastes from civil works and materials handling. These wastes include, but are not limited to:

- Plastics, metals, wood, and food waste
- Plant matter and excavated soil
- Fumes from glues and other hydrocarbons
- Construction debris (stone, ceramics, bricks, glass, cardboard, cement, asphalt, sand, concrete, paper, paints, sealants, adhesives, and fasteners)

Improper management of these wastes poses significant environmental and human health risks, including: Soil contamination; Water and air pollution; Respiratory complications and diseases; Potential for carcinogenic effects & Skin disorders and poisoning

Mitigation Measures Solid Waste Generation Impact:

To mitigate the impacts of solid waste generation during construction, the following measures will be implemented:

- Collect solid waste from the project site at least once every 24 hours to minimize nuisance odors and vermin infestations.
- Segregate and recycle usable materials.
- On-Site Reuse of Inert construction and demolition material, including suitable excavated material to the maximum extent possible. Only surplus material will be disposed of off-site.
- Excavated soil must be promptly removed from the site and disposed of at a designated location with an environmental clearance certificate from the Addis Ababa City Administration.
- In place engineering erosion and sediment control measures to minimize sediment laden storm-water runoff.

Impacts of wastewater generation

Liquid waste will be generated from the concrete batching plant during construction. Liquid waste will also be generated from toilet and washing facilities of construction workers. Hazardous materials stored on-site for vehicle and equipment maintenance would include petroleum fluids (lubricating oils, hydraulic fluid, and fuels), coolants, and battery electrolytes. These chemicals can cause environmental damage if they not handled appropriately.

Mitigation Measures Liquid Waste Impact:

- Wastewater from the concrete batching plant shall be stored in a protected pond within the site and used for concrete curing and watering of buildings,
- Construct portable toilets, safety tanks and shower for construction workers,
- Used oils and other liquid wastes shall be stored in a secured area in tanks and disposed of as hazardous wastes

7.5.1.2 Socio-Economic Impacts

Traffic and Public Safety Impacts

Construction activities may result in a significant increase in the number of vehicles during the transport of construction materials and equipment, which will lead to an increased risk of traffic-related accidents or injuries to workers and the KIP community.

Traffic and Public Safety Impacts Mitigation Measures

- Drivers of heavy truck shall be directed by flagmen,
- Limit the speed of the truck to 10 km/hr at the project site,
- Initiation of a safety program and measures by creating awareness and educational campaigns for drivers, workers, including monitoring of speed limits,
- Installation of appropriate road signage, speed signs, and other warning signs at the site and access roads,
- Assuring driver's licenses originality and regular construction site trucks technical performance,
- The contractor's vehicles and equipment must be in proper working condition (roadworthy vehicles) and have registration plates and numbering,
- The contractor ensures proper driving discipline by its employees, and sanctions those in breach,
- Use only permitted gates and access road which is allowed for construction machineries and trucks.

Gender-Based Violence

As the project is located within KIP under operation in Addis Ababa, the workers will have no contact with the community. Hence, the GBV risk will be low.

Mitigation Measures for Gender-Based Violence

- The contractor should provide orientation to its staff to respect the culture of the local people and to limit their relationship with the local people,
- Contractor and implementing agency to prepare and implement a GBV Prevention and Response Action Plan to include at a minimum, in conformance with local laws and customs, equal opportunity for employment,
- All workers and nearby companies and stakeholders will be educated on preventing and responding to sexual harassment and GBV ahead of any project-related works,
- Construction areas shall be separated by a fence and a separate access gate is used for construction workers,
- Ensure that women are given a mentorship orientation before starting their work,
- Provision of gender-disaggregated data, separate bathing, changing, and sanitation facilities for men and women shall be made ready by the contractor,
- Impose zero tolerance on sexual harassment, all forms of gender-based violence and discrimination at all phases of the project,
- MOH must clearly define the SEA/SH requirements and expectations in the bidding documents for contractor,
- MOH environmental and social safeguards team must ensure that the contractors included GBV prevention and response framework like code of conduct in Contractor Environmental and Social Management Plan (C-ESMP) prior to the commencement of the construction project.

Risk of Social Conflict and Crime

The construction phase of the VMF project presents potential risks for social conflict arising from various sources. Disputes may occur between the contractor and workers due to factors such as working conditions, access to resources, and wage disputes. Internal conflicts among workers may also arise, leading to a non-harmonious work environment.

Furthermore, grievances from workers regarding working hours, material access, and wage limitations are likely. The local community may also raise concerns if they perceive exclusion

from temporary employment opportunities, potentially leading to social conflict and strained relationships.

Mitigation Measures for Social Conflict and Crime:

To mitigate the potential for social conflict and crime during the construction phase, the following measures will be implemented:

- The proponent, FMOH HILEO and SHIELDVAX, and the contractor should establish a joint project-specific GRM. This mechanism will include a team comprising a construction supervisor and designated officers from HILEO, responsible for receiving, logging, and addressing all stakeholder disputes, conflicts, and concerns. The GRM will be established according to the guidelines outlined in Section 16 of this report.
- Ensure early and consistent community engagement to address potential issues proactively.
- The contractor expected to provide comprehensive orientation to its staff, emphasizing respect for the cultural, religious, and ethnic diversity of workers, and the KIP community.
- Salaries can be dispersed via electronic bank transfers to workers' bank accounts, minimizing the risks associated with cash payments.
- Local suppliers will be given priority in supplying construction materials, such as sand, bricks, and other locally available resources, whenever feasible.
- Local suppliers will be prioritized for employment opportunities to foster a sense of project ownership and community integration.
- Open and transparent communication channels must be maintained between all stakeholders to facilitate information sharing and address concerns promptly.

Child Right Violation Impacts

While the direct impact of the VMF project on child rights is anticipated to be low, potential risks may arise within the material supply chains used for construction.

Child Rights Violation Impact Mitigation Measures:

To mitigate potential risks to child rights during the construction phase, the following measures will be implemented:

- Enhance the capacity of the Akaki-Kaliti Sub city social service workforce to identify and respond to potential child labor situations through effective case management and social protection services, including early identification, registration, and follow-up.
- Implement a strict zero-tolerance policy for child rights violations. The contractor must conduct mandatory training for all workers on the consequences of child rights and potential violations.
- The contractor should ensure all workers are at least 18 years of age, to comply with the project's commitment to preventing child labor as required under the World Bank Environmental and Social Standard 2 (ESS2), Paragraph 18.
- The contractor will clearly state the minimum age requirement for general work in their hiring policy and job announcements.
- The Ministry of Health (MOH) must conduct regular checks of labor contracts and supervise the deployed construction workforce to ensure compliance.

7.5.1.3 Public Health Impacts

The influx of construction workers to the project place will cause the spread of communicable diseases to the community where the project is hosted. For instance, there are some diseases such as sexually transmitted diseases (STDs), Sexually Transmitted Diseases and other epidemic viruses that would be a threat to the project surrounding dwellers. Besides, there are informal economic sectors directly operated in relation to the enhancement of construction workers like coffee, shops with cigarette and chat and food suppliers that might be exposed to the transmission of disease which in turn would be disseminated to the mass of local people.

Mitigation Measures for Public Health Impacts:

- Implementation of HIV/AIDS, Sexually Transmitted Diseases and MOH declared threat epidemic diseases education programs,
- Information campaigns on STDs among the workers and local community,
- Vaccinating workers against common and locally prevalent diseases including COVID-19,
- Provision of condoms,
- Ensuring construction site has constructed onsite wastewater disposal and septic systems,

7.5.1.4 Occupational Health and Safety (OHS) Impacts

During this phase, several OHS risks may occur due to exposure to occupational hazards such as physical hazards, at the project site. Several OHS risks as a result of the important activities,

processes, materials and equipment carried out during the pre-construction and construction phases of the project are listed as given below:

Physical Hazards: The construction phase of the VMF project will inherently involve numerous physical hazards that can pose significant risks of injury or even fatality to workers on-site. These hazards arise from the dynamic and often high-risk nature of construction activities. Here's a detailed breakdown of common physical hazards anticipated during this phase:

Risk related to slips, trips, and falls: These incidents occur due to hazards on walking and working surfaces, such as uneven ground, spills (water, oil, concrete slurry), loose materials (cables, tools, debris), and inadequate housekeeping are some of the common causes of slips, trips, and falls during construction.

Mitigation Measures for Slips, Trips and fall risks

- Regularly clean the worksite; the worksite shall be neat
- Ensuring employees receive appropriate training and instructions
- Deal with spills straight away as per the spill response plan
- Consider routine monitoring of areas where spills are a high risk
- Use absorbent material to soak up the spill
- Identify areas at high spill risk and locate absorbent materials nearby
- Where possible avoid using wet cleaning as this may spread the potential danger area
- Consider using spill kits
- Placing readable signs alerting people of hazardous such as for slippery floors
- Ensure slip-resistant footwear is provided and worn as needed providing personal protective equipment (e.g. slip-resistant footwear) if required

Eye hazard: Solid particles from a wide variety of industrial operations, and / or a liquid chemical spray may strike a worker in the eye causing an eye injury or permanent blindness. Recommended measures include:

Mitigation Measures for Eye hazard:

- Always to wear personal protective eyewear for workers working on high dust and eye goggles for welders.
- Clean your eyewear several times throughout the day, and always brush yourself off before removing your safety glasses.
- Follow the recommended measures stated in World Bank EHS guideline, 2007

- Use of machine guards or splash shields and/or face and eye protection devices, such as safety glasses with side shields, goggles, and/or a full face shield.
- Specific Safe Operating Procedures (SOPs) may be required for use of sanding and grinding tools and/or when working around liquid chemicals. Frequent checks of these types of equipment prior to use to ensure mechanical integrity is also good practice.
- Machine and equipment guarding should conform to standards published by organizations such as CSA, ANSI and ISO.
- Moving areas where the discharge of solid fragments, liquid, or gaseous emissions can reasonably be predicted (e.g. discharge of sparks from a metal cutting station, pressure relief valve discharge) away from places expected to be occupied or transited by workers or visitors. Where machine or work fragments could present a hazard to transient workers or passers-by, extra area guarding or proximity restricting systems shall be implemented, or PPE required for transients and visitors.
- Provisions shall be made for persons who have to wear prescription glasses either through the use overglasses or prescription hardened glasses.

Welding / Hot Work

Welding creates an extremely bright and intense light that may seriously injure a worker's eyesight. In extreme cases, blindness may result. Additionally, welding may produce noxious fumes to which prolonged exposure can cause serious chronic diseases. Recommended measures include:

- Provision of proper eye protection such as welder goggles and/or a full-face eye shield for all personnel involved in, or assisting, welding operations. Additional methods may include the use of welding barrier screens around the specific work station (a solid piece of light metal, canvas, or plywood designed to block welding light from others). Devices to extract and remove noxious fumes from the source may also be required.
- Special hot work and fire prevention precautions and Standard Operating Procedures (SOPs) shall be implemented if welding or hot cutting is undertaken outside established welding work stations, including 'Hot Work Permits, stand-by fire extinguishers, stand-by fire watch, and maintaining the fire watch for up to one hour after welding or hot cutting has terminated. Special procedures are required for hotwork on tanks or vessels that have contained flammable materials.

Ergonomics, Repetitive Motion, Manual Handling

Injuries due to ergonomic factors, such as repetitive motion, overexertion, and manual handling, take prolonged and repeated exposures to develop, and typically require periods of weeks to months for recovery. These OHS problems should be minimized or eliminated to maintain a productive workplace. Controls may include:

- 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.Adjust the height of working surfaces to reduce long reaches and awkward postures
- Put work supplies and equipment within comfortable reach
- Provide the right tool handle for the worker
- Vary tasks for workers (e.g., employ job rotation)
- Encourage short rest breaks

Working at Heights

Fall prevention and protection measures shall be implemented whenever a worker is exposed to the hazard of falling more than two meters; into operating machinery; into water or other liquid; into hazardous substances; or through an opening in a work surface. Fall prevention / protection measures may also be warranted on a case-specific basis when there are risks of falling from lesser heights. Fall prevention may include:

- Installation of guardrails with mid-rails and toe boards at the edge of any fall hazard area
- Proper use of ladders and scaffolds by trained employees
- Use of fall prevention devices, including safety belt and lanyard travel limiting devices to prevent access to fall hazard area, or fall protection devices such as full body harnesses used in conjunction with shock absorbing lanyards or self-retracting inertial fall arrest devices attached to fixed anchor point or horizontal life-lines

- Appropriate training in use, serviceability, and integrity of the necessary PPE · Inclusion of rescue and/or recovery plans, and equipment to respond to workers after an arrested fall

Chemical Hazards: The construction phase of the VMF project will involve the use, storage, and handling of various chemical substances that can pose significant health and safety risks to workers and potentially the environment if not managed properly. Construction activities like cutting concrete, grinding, sanding wood and excavation can generate significant amounts of dust. Silica dust, generated from concrete, mortar, and stone, is particularly hazardous. Cement dust is alkaline and corrosive. Petroleum-based products used for operating and maintaining construction machinery and equipment. They can be flammable, and prolonged skin contact can cause irritation and dermatitis. Inhalation of vapors can cause respiratory problems. Chemical hazards can most effectively be prevented through a hierarchical approach that includes:

- 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 shall 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

Fire and explosion hazards: portable gasoline containers for generators and other gasoline-powered equipment, fuel transfers for onsite heavy equipment operation, ignition of flammable materials during hot works, welding operations that creative spark, risk of electrocution.

Mitigation Measures for Fire and Explosion Hazards

- Storing flammables away from ignition sources and oxidizing materials.
- 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.

- Implementing hot work permits procedures.
- Ensure the provision of fire extinguishers at all work locations and at all times.
- All flammable gases, liquids and vapors are removed before the start of any hot work.
- Where appropriate, use spark-resistant tools and make sure all equipment is bonded or grounded properly.
- The construction site shall be fenced off to prevent access to members of the public.
- Providing adequate storage for hazardous and flammable substances and controlling access to them.
- Designate separate place and equip them with appropriate medical equipment for first aid treatment.
- Providing specific worker training in handling of flammable materials, and in fire prevention or suppression.

Electrical hazards: Most of the construction equipment uses gasoline so they would be gasoline containers at risk of explosives. All equipment needs electric power, without provisions for electrical safety, there is a risk of an electric hazard in the site. Exposed or faulty electrical devices, such as circuit breakers, panels, cables, cords and hand tools, can pose a serious risk to workers.

Mitigation Measures for Electrical Hazards:

- Inspect portable cord-and-plug connected equipment, extension cords, power bars, and electrical fittings for damage or wear before each use. Repair or replace damaged equipment immediately,
- Always locate all power lines on or near the project sites,
- Perform regular fire risk assessments to identify areas at risk of bad wiring and circuits,
- Maintain proper grounding to eliminate unwanted voltage and reduce the risk of electrocution,
- Verify that all wiring is coming from a properly rated circuit and doesn't exceed the capacity,
- Verify electric cables are not contact with moisture and any liquid.

Biological hazards are rare: (e.g., bacteria, viruses or parasites) and mosquitoes carrying disease-causing agents).

Mitigation Measures for Biological Hazards

- Construction site shall be separated from the main KIP compound by fence and construction workers shall be restricted within the site,

- Remove and reduce debris and rubble piles when possible to help keep insects and rodents away,
- The worker shall be vaccinated based on the type of pathogens they are exposed to.
- In case of any disease outbreak vaccination shall be performed in a construction areas or surroundings to prevent the spread of disease, and
- Workers should cover as much of the body as feasible.

Traffic accident impacts: Construction activities may result in a significant increase in a number of vehicles during the transport of construction materials and equipment, which will lead to an increasing risk of traffic-related accidents or injuries to workers and the community.

Mitigation Measures Traffic Accident Impacts:

- Limit the speed of the truck to 10 km/hr within the site,
- Initiation of a safety program and measures by creating awareness and educational campaigns for drivers, workers.
- Sanctions for reckless driving,
- Installation of appropriate road signage, speed signs, and other warning signs at the site and access roads,
- All construction machineries and cars should have third-parties insurance,
- Use only permitted gates and access roads which are allowed for construction machineries and trucks.

7.5.2 Operation Phase

This ESIA report is dedicated to Stage 1, fill-finish operations, specifically for the production of inactivated, recombinant, and conjugate injectable vaccines, as well as inactivated oral liquid vaccines. It is important to note that during this phase, no pathogens will be handled, significantly minimizing the risk of infectious materials or waste. Consequently, the biosafety and biosecurity risks associated with this phase are very low. When the project progress to Stage 2 (Full-cycle development) and Stage 3 (Drug substance manufacturing for recombinant and conjugate vaccines & live attenuated measles vaccines), this ESIA shall be updated in consideration of associated infectious materials or waste risks; the biosafety and biosecurity risks. Hence, this section only discusses impacts/risks related to the fill-finish vaccine production (Stage I).

7.5.2.1 Physical Impacts

Impact on Air Quality

The operational phase of the VMF project, specifically the use of waste incinerators, presents a minor risk to air quality. Incinerators are known sources of various pollutants including sulfur dioxide (SO_2), carbon dioxide (CO_2), carbon monoxide (CO), nitrogen oxides (NOx), and particulate matter (PM).

Mitigation Measures for Air Quality Impact:

To mitigate the impacts of air pollution during the operational phase, the following measures will be implemented:

- Employ advanced incineration technologies with state-of-the-art emission control systems, including scrubbers, filters, and other pollution control devices, to minimize the release of polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/Fs), heavy metals, and gaseous pollutants.
- Implement rigorous waste segregation and pre-treatment procedures to remove chlorine-containing materials and other hazardous substances before incineration.
- Establish a continuous emission monitoring system to track and record air pollutant levels, ensuring compliance with regulatory standards.
- Conduct regular maintenance and inspections of incinerator and emission control systems to ensure optimal performance.
- Explore and implement alternative waste management strategies, such as recycling, and waste minimization, to reduce reliance on incineration.
- Promote energy-efficient appliances and building designs to reduce overall energy consumption and associated GHG emissions.
- Conduct regular air quality monitoring around the incinerator site to assess the effectiveness of mitigation measures and ensure compliance with ambient air quality standards.
- Ensure all personnel that are operating the incinerators are properly trained.

Water Pollution Impacts

The operational phase of the VMF project presents potential risks of water contamination associated with healthcare waste management. Specifically:

- Improper disposal of untreated healthcare waste in landfills can lead to the generation of leachate, which can contaminate surface and groundwater if landfills are not designed and constructed with adequate containment measures.

- The use of chemical disinfectants, such as perchlorate or chlorine, for facility waste treatment can result in the release of harmful chemical substances into the environment if these substances are not handled, stored, and disposed of according to best environmental practices.
- Incineration of facility waste generates ash residue. Improper disposal of untreated ash in open environments can result in the leaching of contents into soil and water sources, causing significant water pollution.

Mitigation Measures for Water Pollution Impact:

To mitigate the impacts of water pollution during the operational phase, the following measures will be implemented:

- Promoting practices that reduce the volume of wastes generated and ensure proper waste segregation.
- Implement strict protocols for the handling, storage, and disposal of chemical disinfectants, including: Using designated storage areas with secondary containment and providing comprehensive training to personnel on safe handling procedures.
- Implement the following measures for incinerator ash management:
    - Treat ash residue to stabilize the contents before disposal.
    - Dispose of treated ash in secured ash pit designed for hazardous waste.
    - Conduct regular monitoring of leachate from ash disposal site.
- Use the KIP WWTP to treat wastewater generated from the VMF and ensure that wastewater effluent discharged from the KIP WWTP meets regulatory standards.
- Ensure all personnel are properly trained on the proper handling and disposal of all hazardous materials.

Soil Pollution

The operational phase of the VMF project presents a minor potential risks of soil contamination due to the generation and management of certain hazardous wastes. Specifically:

- Incineration of waste material can result in the dispersal of toxic materials into the environment. The resulting ash residue may contain moderate levels of such materials and may pose a risk of soil contamination if improperly managed.

- Liquid waste generated from the VMF is expected to contain a variety of contaminants such as chemicals, traces of residual inactivated and decontaminated biological material, detergents, solvents, and reagents. Discharge of untreated effluent onto soil can lead to:
    - Soil pore clogging, resulting in reduced soil permeability and productivity.
    - Soil hardening, hindering root penetration and plant growth.
    - Disruption of soil microbial communities, negatively impacting soil texture and fertility.

Mitigation Measures for Soil Pollution Impact:

To mitigate the impacts of soil pollution during the operational phase, the following measures will be implemented:

- Implement recommended ash treatment.
- Dispose of treated ash in secured ash pit designed for hazardous waste.
- Implement rigorous waste segregation procedures to recycle the wastes.
- Develop and implement a comprehensive spill prevention and response plan to minimize the risk of accidental releases of hazardous materials.

Noise and Vibration Impacts

Generators and boilers will be installed within the facility and can be sources of sound. Also, there will be occasional noise due to vehicles movement, and maintenance machinery.

Mitigation Measures for noise and vibration impacts:

To mitigate the impacts of noise and vibration during the operational phase, the following measures will be implemented:

- Install acoustic enclosures around generators and boilers to minimize noise emissions.
- Construct noise barriers or utilize existing structures to attenuate noise from vehicle traffic and maintenance activities.
- Select generators and boilers with low noise emission ratings.
- Implement a regular maintenance schedule for all equipment to ensure optimal performance and minimize noise generation.
- Utilize noise dampening materials in building construction and equipment installations to reduce sound transmission.

Impacts of Flooding

The proposed VMF project site, located in the southern part of the city, is less susceptible to flooding due to favorable geographical and hydrological conditions. The site has an overall elevation difference of about five (5) meters (within VMF construction site boundaries), corresponding to a slope ranging between approximately 1.5 % and 9 %, which facilitates efficient surface water runoff. Although the site is situated within 1.2 to 1.4 km of the Idoro and Kerso Deso rivers, its adequate elevation greatly minimizes the potential risk of flooding.

Mitigation Measures for Flooding Impacts:

A comprehensive and multi-layered approach is crucial to mitigate the identified flooding risks at the VMF site. The following mitigation measures shall be implemented:

- Design and construct all critical VMF buildings and infrastructure (production areas, laboratories, storage facilities, power supply) on an elevated platform, including a sufficient freeboard margin to account for uncertainties and potential climate change impacts.
- Utilize permeable paving materials for parking areas and walkways to reduce surface runoff and increase groundwater infiltration. Incorporate green infrastructure elements such as bioswales, rain gardens, and vegetated buffer strips to naturally filter runoff and reduce its volume.
- Design and install a robust underground drainage network with adequately sized pipes and strategically located inlets to efficiently collect and convey surface water runoff from paved areas and building surroundings. Ensure proper maintenance and regular clearing of this network.

Impacts of Solid Waste Generation

The VMF operation will generate contaminated packaging, plastics, expired pharmaceuticals, and incinerator ash containing traces of metals. Improper disposal (burial, uncontrolled dumping) poses risks of soil and water pollution. Without proper management, these wastes can negatively impact air, water, public and occupational health.

Mitigation Measures for solid waste generation impacts:

- Implement strict waste segregation protocols at the source, using color-coded containers and designated storage areas for different waste types.
- Autoclave or other approved treatment methods for infectious waste before disposal, if any.
- Secure and leak-proof containers for sharps waste, followed by incineration.

- Pharmaceutical Waste Disposal:
    - Follow the Medicines Waste Management and Disposal Directive waste, 2011 and the World Bank Environmental, Health, and Safety General Guidelines disposal, 2007 Section 1.5 Hazardous Material Management pharmaceutical waste management services.
- Incinerator Ash Management:
    - ~~o~~ Implement recommended ash treatment. ~~to stabilize heavy metals and reduce their leaching.~~
    - Dispose of treated ash in secured ash pit designed for hazardous waste.
    - Regularly monitor soil and groundwater around disposal sites.
- Plastic Waste Reduction:
    - Promote reusable containers and water dispensers to minimize plastic bottle waste.
    - Implement recycling programs for plastic and other recyclable materials.
- Waste Tracking and Documentation:
    - Maintain detailed records of waste generation, treatment, and disposal.
    - Implement a waste tracking system to ensure proper handling and disposal.
- Training and Awareness:
    - Provide comprehensive training to all staff on proper waste handling and disposal procedures.
    - Raise awareness about the risks associated with improper waste management.

Impacts of Wastewater generation

The VMF operation in Ethiopia will generate hazardous liquid waste posing some risks to personnel, community, and environment. Domestic sewage from offices, labs, kitchens, and bathrooms will also be generated. Improper disposal of both waste streams can contaminate surface water, groundwater, and soil, impacting public health and ecosystems.

Mitigation Measures for wastewater generation impacts:

Hazardous Wastewater Treatment:

- Implement validated sterilization and disinfection methods (e.g., autoclaving, chemical disinfection).
- Ensure treated effluent meets Ethiopian environmental regulations.

- Implement robust containment systems and spill prevention protocols within the VMF laboratories.
- Properly train all VMF personnel on the correct handling and disposal of infectious materials.

Domestic Sewage Management:

- Use a modern, on-site sewage treatment system (as recommended in waste management alternative) to treat domestic wastewater.
- Implement regular maintenance and monitoring of the sewage treatment system.
- If onsite treatment is impossible/failed, have a contract with a reputable company that will properly remove the waste.

Environmental Monitoring:

- Establish a comprehensive environmental monitoring program, including regular testing of surface water, groundwater, and soil around the facility.
- Conduct regular audits of the wastewater treatment systems of the KIP to ensure compliance with Ethiopian environmental standards.

Emergency Response:

- Follow emergency response plan (section) to handle any accidental release of contaminated waste water.
- Ensure all personnel are properly trained on the emergency response plan.

7.5.2.2 Public Health Impacts

a) Contamination by Adventitious Agents, if any:

- **Potential Impacts:** The use of biological raw materials such as cell cultures and animal-derived components introduces a risk of contamination by adventitious agents (unintended microorganisms). This contamination could potentially lead to infections in vaccine recipients if undetected in the final product, or in production staff through occupational exposure. Viruses, bacteria, fungi, mycoplasma, and even prions could be present in source materials and compromise vaccine safety and efficacy. The severity of such infections can range from mild to severe, depending on the nature of the contaminating agent and the susceptibility of the exposed individual. Failure to adequately control this risk could have significant public health consequences, erode trust in vaccination programs, and potentially lead to regulatory action and reputational damage.

- **Mitigation Measures:**
  - **Stringent Raw Material Sourcing and Qualification:**
    - Implement a strict procurement policy prioritizing raw materials, including cell lines, reagents, and animal-derived components, that are sourced from WHO-certified suppliers or facilities adhering to equivalent international standards. Maintain a comprehensive traceability system to track the origin and processing history of all critical raw materials.
    - Obtain documented evidence (e.g., Certificates of Analysis, viral safety testing reports) from suppliers demonstrating the absence of relevant adventitious agents. Implement a rigorous supplier qualification program that includes audits and ongoing monitoring of their quality control systems.
  - **Multi-Barrier Advanced Sterilization and Inactivation:**
    - Employ a multi-layered approach to sterilization and inactivation processes throughout the manufacturing chain. The specific methods (autoclaving, nano-filtration, thermal inactivation, chemical inactivation) shall be selected based on their efficacy against the range of potential adventitious agents relevant to the specific vaccine being produced and the nature of the material being treated.
    - All sterilization and inactivation processes must be rigorously validated to demonstrate their effectiveness in achieving the required levels of sterility or inactivation. Implement continuous monitoring systems (e.g., temperature, pressure, irradiation dose) to ensure processes are consistently performed within validated parameters.
  - **Comprehensive and State-of-the-Art Testing Regimen:**
    - **Broad-Spectrum Detection:** Employ a battery of highly sensitive and specific tests at multiple stages of production, including:
      - Polymerase Chain Reaction (PCR) and Real-Time PCR for the rapid detection of specific viral and bacterial nucleic acid sequences.
      - Next-Generation Sequencing (NGS) for unbiased, broad-range detection of known and novel adventitious agents. Implement robust bioinformatic pipelines for data analysis and interpretation.
      - Sterility Testing following pharmacopoeial standards (e.g., USP, EP) to detect the presence of viable microorganisms.

        - Mycoplasma Testing - employing culture-based and nucleic acid-based methods.
        - Specific Viral and Prion Assays - utilizing validated immunoassays or infectivity assays where relevant based on the raw materials used.
    - Establish an independent Quality Control (QC) laboratory with appropriately trained personnel and validated testing methods to ensure the integrity and reliability of testing results. Implement a robust system for managing out-of-specification results and initiating corrective and preventive actions (CAPA).

b) Environmental Release of Hazardous Materials:

- **Potential Impacts:** Vaccine manufacturing processes can generate various hazardous materials, including wastewater, chemical disinfectants, adjuvants, preservatives (e.g., formaldehyde, thimerosal), and other biological waste. Untreated or inadequately treated discharge of these materials into water sources, soil, or air can lead to significant environmental contamination. This can negatively impact aquatic ecosystems, soil fertility, and air quality, potentially affecting nearby populations through contaminated drinking water, exposure to airborne pollutants, or bioaccumulation in the food chain.
- **Mitigation Measures:**
    - **Comprehensive On-Site Wastewater Treatment System:**
        - Design and implement a comprehensive, multi-stage wastewater treatment system specifically tailored to the types of contaminants generated by the vaccine manufacturing processes.
        - **Validation and Monitoring:** The effectiveness of the wastewater treatment system must be rigorously validated through regular monitoring of key parameters (e.g., pH, temperature, residual disinfectant levels, microbial counts, chemical contaminant concentrations) at various stages of the treatment process and in the final effluent. Establish clear effluent discharge limits for reusing that comply with relevant national and international environmental quality standards (e.g., World Bank Environmental and Social Standards).
    - **Advanced Air Emission Control Systems:**
        - Install High-Efficiency Particulate Air (HEPA) filters in all exhaust systems from production areas, laboratories, and waste handling facilities to effectively remove airborne particulate matter, including bioaerosols and pathogens.

Implement regular testing and maintenance schedules for HEPA filters to ensure their integrity.

- Utilize high-temperature incinerators equipped with appropriate air pollution control devices (e.g., scrubbers, bag filters) for the safe and complete destruction of high-risk biological waste, including contaminated materials and animal carcasses, in accordance with WHO guidelines for the management of healthcare waste.

- **Robust Spill and Leak Prevention and Containment Protocols:**
  - Implement secondary containment measures (e.g., bunds, dikes) around storage tanks and processing areas containing hazardous liquids to prevent spills from reaching the environment.
  - Develop and implement the comprehensive Spill Prevention, Control, and Countermeasure (SPCC) plan, including detailed procedures for immediate containment, cleanup, and reporting of any leaks or spills of hazardous materials. Ensure that personnel are adequately trained in spill response procedures and that necessary equipment is readily available.
  - **Proactive and Transparent Public Awareness Campaigns:** Implement proactive and transparent public awareness campaigns to inform the local community about the facility's operations, potential risks, and the implemented safety measures. This should include:
    - Regular Community Meetings and Information Sessions to address concerns, answer questions, and build trust.
    - Providing clear and understandable information about the ESIA findings, safety protocols, and emergency response plans in local languages.
    - Establishment of a Grievance Mechanism to allow community members to raise concerns and receive timely responses.
    - Clearly outlining how the facility will communicate with the community in the event of an emergency.

c) Occupational Exposure:

- **Potential Impacts:** Workers in the vaccine manufacturing facility may be exposed to various occupational hazards, including certain material/s, toxic chemicals used in production and sterilization (e.g., formaldehyde), adjuvants, and bioaerosols generated during certain

processes. Such exposure can lead to, allergic reactions, respiratory problems, and other adverse health effects depending on the nature and duration of exposure, and the effectiveness of safety precautions.

- **Mitigation Measures:**
    - **Prioritization of Engineering Controls:** Implement engineering controls as the primary means of minimizing occupational exposure. This includes:
        - Utilize closed-system and automated processing equipment wherever feasible to minimize direct worker contact with ~~biological~~ certain materials and chemicals.
        - Install Local Exhaust Ventilation (LEV) systems at points where potential exposure to bioaerosols or chemical vapors may occur (e.g., during sampling, transfer, or cleaning operations). Ensure LEV systems are properly designed, installed, and regularly maintained to ensure their effectiveness.
        - Use biosafety cabinets (BSCs), isolators, and other containment equipment for handling hazardous materials, if any.
    - **Mandatory and Appropriate Personal Protective Equipment (PPE):**
        - Conduct a thorough risk assessment of each job task to determine the appropriate type and level of PPE required. This may include respiratory protection (e.g., N95 respirators, powered air-purifying respirators - PAPRs), gloves (appropriate material for the chemicals being handled), eye protection (e.g., safety goggles, face shields), and full-body protective suits (e.g., Tyvek suits, cleanroom garments).
        - Provide comprehensive training to all employees on the proper use, donning, doffing, maintenance, and limitations of required PPE. Implement strict enforcement of PPE usage policies and conduct regular audits to ensure compliance.
    - **Pre-Employment and Occupational Health Program:**
        - Conduct pre-employment health screenings to assess the baseline health status of new employees and identify any pre-existing conditions that may increase their susceptibility to occupational hazards.
        - Establish a program for regular occupational health surveillance, including periodic medical examinations, biological monitoring (where applicable), and reporting of any work-related illnesses or injuries.

Contamination Risks:

- Contamination of the vaccine product with foreign substances can compromise its safety and efficacy.
- Cross-contamination between different vaccine products can lead to serious errors.

Mitigation Measures for Contamination Control:

- Implement rigorous cleanroom procedures and aseptic techniques.
- Utilize validated cleaning and sterilization methods.
- Conduct regular environmental monitoring and product testing.

7.5.2.3 Socio-Economic Impacts

Traffic and Public Safety Impacts

There will be an increase in traffic flow resulting from the transport for staff and clients and the introduction of new cars from the employees. The area will also experience an increase in traffic, and this will increase the risk of traffic hazards since the probability of occurrence of the hazards will be increased by having more cars on the roads.

Mitigation Measures for Traffic and Public Safety Impacts

To mitigate the impacts of traffic and public safety impacts during the operational phase, the following measures will be implemented:

- Designate entry/exit points and implement one-way traffic patterns.
- Coordinate delivery times to avoid peak traffic hours.
- Establish marked loading/unloading areas away from public roads.
- Employ marshals during peak hours for traffic direction.
- Install clear signage and use variable message signs for real-time updates.
- Ensure compliance with traffic laws and collaborate with local authorities.
- Conduct audits to evaluate and improve traffic management practices.

Gender-Based Violence Risks

The operational activities of the proposed VMF laboratory will have limited interactions with members of the public. The VMF staff will consists of males as well as female members.

Mitigation Measures for Gender-based Violence

To mitigate the impacts of gender-based violence during the operational phase, the following measures will be implemented:

- Establish a gender mainstreaming and monitoring committee,
- Implement a code of conduct for staff to prevent gender-based violence,
- Provide awareness to the newly joined workers about the incidence and impact of domestic violence, sexual assault, and stalking, including reporting requirements and options,
- Conduct continued sensitization and awareness raising to VMF staff on the prevention of GBV,
- Strengthen the Gender and women office of MoH,
- Provision of gender-disaggregated data, separate bathing, changing, sanitation facilities for men and women shall be ready by institution,
- Impose zero tolerance on sexual harassment, all forms of gender-based violence and discrimination at all phases of the project.

Risk of Social Conflict and Crime

Operation Phase: Workers who have different political and religious interns may be employed by this project, which will in turn lead to distrust, suspicion and lack of tolerance among workers.
Mitigation Measures for Risk of Social Conflict and Crime:

To mitigate the risk of social conflict and crime during the operational phase, the following measures will be implemented:

- Transparent local community engagement and participation shall begin during initial project decision-making and continue routinely throughout the life of the project,
- Awareness-raising among the local community, contract workers and staff about the cultures and norms of the local community,
- Provision of cultural sensitization training for all staff regarding engagement with the local community,
- Provide awareness creation program about tolerance of diversity and,
- Develop a code of conduct for staff to prevent discrimination and other ethnocentric behaviors.

Community Health & Safety Concerns:

- There may be fears of exposure to biohazardous materials or accidental leaks.

Mitigation Measures for Community Health and Safety Concerns

- Regular community engagement and communication
- Establishing functional and responsive GRM.

Public Opposition or Mistrust:

- Vaccine scepticism or misinformation could lead to protests or opposition to the facility. Additionally, there is a risk that locally produced vaccines might be prioritized for export or elites, excluding the local population, which could also be a source of public opposition.

Mitigation Measures for Public Opposition or Mistrust

- Regularly communicating the community on the production efficiency, exported vaccines, locally used, and income generated from the sector.
- Undertaking media scanning to early detect and manage public detection.
- Undertaking regular consultation with the community representatives and stakeholders.

7.5.2.4 Occupational Health and Safety (OHS) Impacts

Biological Hazards, if any:

Potential Impacts: Workers involved in vaccine production, quality control, storage, and handling, biological materials, face a risk of exposure to health hazards. This exposure can occur through inhalation, ingestion or skin contact, or accidental inoculation (e.g., needlestick injuries). The consequences can range from mild, self-limiting infections to severe, life-threatening diseases, posing a direct hazard to workers and potentially leading to community spread if containment measures fail. The risks are heightened during activities such handling of raw materials (e.g., cell cultures), processing, storage, internal transport, and waste management.

Mitigation Measures:

- Implement a comprehensive biosafety program based on risk assessment, incorporating administrative controls, engineering controls, safe work practices, and personal protective equipment (PPE), aligned with WHO Biosafety Manual and relevant BSL levels.
- Provide mandatory, job-specific training to all personnel involved in handling biological material. This training must cover the specific hazards associated with the agents they work with, safe handling procedures, emergency response protocols, and the proper use and maintenance of containment equipment and PPE. Competency assessments and regular refresher training are essential. Supervision by experienced and competent staff is mandatory.
- **Primary Containment (Engineering Controls):**
    - All procedures involving the manipulation of infectious materials, including open handling, must be conducted within appropriately certified and maintained Biological Safety Cabinets (BSCs) of the correct class (Class II or III) for the specific agents being handled.

- Implement closed-system processing equipment and automated systems where feasible to minimize direct human contact with infectious materials.
- Design laboratories with appropriate biosafety features, including directional airflow, controlled access, and surfaces that are easily cleanable and decontaminable.

- **Secondary Containment (Facility Design and Procedures):**
  - Adhere to the recommended Biosafety Level (BSL) for the specific pathogens being handled, including facility design requirements and operational procedures.
  - Implement strict access control measures to designated laboratory and production areas.
  - Establish and enforce standard operating procedures (SOPs) for all activities involving infectious materials, including collection, handling, processing, storage, internal transport, and waste management.
  - Ensure readily available handwashing facilities with appropriate disinfectants throughout the facility and enforce strict hand hygiene practices before and after working with potentially hazardous materials and before leaving the facility.
- **Safe Handling and Transport of Biological Materials:**
  - The biological materials must be placed in primary, leak-proof, and shatter-proof containers. These primary containers must then be placed in robust, leak-proof secondary containers with secure closures for collection, handling, processing, storage, or transport within the facility.
  - Implement clear labeling and tracking systems for all materials.
  - Establish designated and controlled routes for the internal transport of materials.
- **Spill Management and Decontamination:**
  - Develop and implement detailed spill response procedures for biological materials, including immediate containment, decontamination using validated disinfectants effective against the specific agents, and safe cleanup by properly trained personnel equipped with appropriate PPE and spill kits.
  - Ensure readily available spill kits in all areas where biological ~~infectious~~ materials are handled or stored.
- **Equipment Decontamination and Maintenance:**
  - Establish and enforce procedures for the routine decontamination of equipment used with biological materials.

- Equipment must be thoroughly decontaminated before any repair, maintenance, or removal from the laboratory or production area. Validation of decontamination procedures is necessary.

- **Personal Protective Equipment (PPE):**
  - Mandatory use of appropriate PPE based on risk assessment, including:
    - Protective clothing with a solid front (e.g., tie-back or wrap-around gowns, scrub suits, coveralls) that is not worn outside of designated laboratory and production areas.
    - Gloves of appropriate material and thickness for the tasks being performed, changed regularly and immediately if contaminated.
    - Eye and face protection (goggles, masks, face shields) for procedures with a risk of splashes or sprays of infectious materials.
    - Respiratory protection (e.g., N95 respirators, PAPRs) when engineering controls are insufficient to control airborne hazards, based on risk assessment and fit testing.
    - Dedicated footwear that remains within the laboratory/production areas.
  - Provide adequate facilities for the safe storage and disposal of contaminated PPE.
  - Ensure reusable clothing is decontaminated (e.g., autoclaved or chemically disinfected) before being laundered. Contaminated clothing must be changed immediately.
- **Medical Surveillance and Immunization:**
  - Implement a medical surveillance program for all personnel working with bio-material agents, including pre-employment health assessments and regular follow-up.
  - Offer relevant vaccinations (e.g., hepatitis B) to at-risk personnel in accordance with WHO recommendations and national guidelines.
  - Establish procedures for the prompt reporting and management of any suspected occupational ~~infections or~~ exposures.

Chemical Hazards:

Potential Impacts: Workers may be exposed to various chemicals during vaccine fill-finish, storage, quality control, and facility maintenance. These include disinfectants (e.g., sodium hypochlorite, potassium hypochlorite), sterilants (e.g., paraformaldehyde), preservatives (e.g., phenol), cleaning agents, and reagents. Exposure can occur through inhalation of vapors, skin or eye contact, or

ingestion. The health effects can range from acute irritation and burns to chronic systemic toxicity, including respiratory problems, organ damage, and may rarely result in carcinogenic / effects.

Mitigation Measures

- Conduct thorough risk assessments for all chemicals used in the facility and implement a hierarchy of controls: elimination, substitution, engineering controls, administrative controls, and PPE.
- **Safe Storage and Handling:**
    - Implement strict procedures for the safe storage and handling of all chemicals, in accordance with their Material Safety Data Sheets (MSDS) or Safety Data Sheets (SDS).
    - Use secondary containment (e.g., leak-proof trays, bins, shelving with lips) to prevent accidental leakage or spillage, especially for liquid chemicals. Ensure secondary containers are compatible with the stored chemicals.
    - Store chemicals in designated, well-ventilated areas, segregated by compatibility (e.g., acids and bases stored separately).
    - Minimize the storage of large quantities of chemicals in laboratory and production areas; store bulk chemicals in dedicated, secure storage rooms.
    - Ensure proper labeling of all chemical containers, including hazard warnings and expiry dates.
    - Use appropriate equipment for dispensing and transferring chemicals to prevent spills and releases.
- **Engineering Controls:**
    - Handle volatile solvents, toxic chemicals, and procedures that may generate hazardous vapors within properly functioning and regularly inspected chemical fume hoods with adequate airflow. Ensure workers are trained in the proper use of fume hoods.
    - Install **Local Exhaust Ventilation** systems at specific workstations or equipment that may release chemical contaminants (e.g., dispensing stations, autoclaves).
    - Utilize closed-loop systems for chemical transfer and processing where feasible.
- **Administrative Controls:**
    - Develop and implement Safe Work Procedures (SWPs) for all tasks involving hazardous chemicals.
    - Provide comprehensive training to all personnel on the hazards of the chemicals they work with, safe handling and storage procedures, spill response, and emergency procedures. Regularly review and update training.

- Maintain an inventory of all chemicals stored in the facility, along with their corresponding SDS. Ensure SDS are readily accessible to all workers.
- Implement strict hygiene practices, including no eating, drinking, or smoking in areas where chemicals are used or stored.
- Limit access to areas where hazardous chemicals are used or stored to authorized personnel.

- **Personal Protective Equipment (PPE):**
  - Mandatory use of appropriate PPE based on the specific chemical and task, including:
    - Fully buttoned laboratory coats, gowns, coveralls, or long-sleeved, back-opening garments made of chemically resistant materials.
    - Aprons (chemically resistant) may be worn over laboratory coats or gowns for additional splash protection.
    - Chemical-resistant gloves with appropriate material and thickness for the chemicals being handled.
    - Eye and face protection (safety goggles, face shields) for anticipated splashes or sprays of hazardous chemicals.
    - Respiratory protection (e.g., respirators with appropriate cartridges

  - **First Aid and Emergency Preparedness:**
    - Ensure readily available and appropriately stocked first-aid stations with specific provisions for chemical exposures (e.g., eyewash stations, safety showers) in areas where hazardous chemicals are used or stored.
    - Provide specific training on first-aid procedures for chemical exposures.
    - Develop and implement emergency response plans for chemical spills, leaks, and other incidents, including evacuation procedures and contact information for emergency services.

Ergonomic Hazards:

Potential Impacts: Vaccine production workers are at risk of musculoskeletal disorders (MSDs) due to repetitive motions, prolonged awkward postures (e.g., working at BSCs or fume hoods), heavy lifting, and prolonged static postures (e.g., computer work). These hazards can lead to pain, discomfort, and long-term disability, affecting worker productivity and well-being.

Mitigation Measures:

- Conduct thorough ergonomic risk assessments of all work tasks and workstations to identify potential hazards.
- **Engineering Controls and Workplace Design:**
    - Select tools and design workstations that reduce force requirements, awkward postures, and holding times.
    - Utilize user-adjustable workstations, chairs, and equipment to accommodate individual worker needs.
    - Design BSC and fume hood workstations to allow for comfortable working postures, potentially using adjustable height chairs and platforms.
    - Provide ergonomic aids such as anti-fatigue mats for standing work, wrist rests for keyboarding, and ergonomic pipettes.
    - Optimize worksite layout to minimize the need for manual transfer of heavy loads.
- **Administrative Controls and Work Practices:**
    - Implement administrative controls such as job rotation and scheduled rest or stretch breaks to reduce exposure to repetitive tasks and prolonged static postures.
    - Provide comprehensive training to workers on proper lifting and materials handling techniques, including weight limits and the use of mechanical aids or team lifts for heavy loads.
    - Encourage workers to report any discomfort or pain related to their work activities.
- Selection of Ergonomic Equipment (equipment and furniture) that is ergonomically designed.

Physical Hazards (Slips, Trips, Falls, Waste Handling):

Potential Impacts: Workers may be at risk of injuries from slips, trips, and falls, especially in wet or cluttered areas. Improper handling of laboratory waste, particularly sharps (needles, broken glass), poses a significant risk of cuts and puncture wounds, potentially leading to infections.

Mitigation Measures:

- **Prevention of Slips, Trips, and Falls:**
    - Maintain clean and uncluttered work areas, including clear walkways and corridors.
    - Implement effective cleaning protocols for spills and leaks.
    - Use non-slip flooring in wet areas.
    - Provide adequate lighting throughout the facility.
    - Clearly mark any potential tripping hazards.
    - Encourage workers to wear appropriate footwear with good traction.

- **Safe Waste Management:**
    - Implement a strict waste management system according to WHO guidelines and national regulations, including proper segregation, labeling, handling, storage, and disposal of different waste streams (e.g., containers, sharps, chemical).
    - Ensure that sharps containers are not overfilled and are securely sealed before disposal.
    - Provide training to all personnel involved in waste handling on the risks and safe handling procedures.
    - Use appropriate PPE (e.g., puncture-resistant gloves, safety shoes) for handling medical waste.
    - Establish designated and secure areas for the temporary storage of medical waste before final disposal.
    - Ensure proper labeling of all waste containers with hazard warnings.
- **Incident Reporting and Investigation:**
    - Establish a clear procedure for reporting all injuries and accidents, no matter how minor.
    - Conduct thorough investigations of all incidents to identify root causes and implement corrective and preventive actions.
    - Provide immediate medical attention to injured workers.

Physical Hazards (Risk Related to Electricity):

Potential Impacts: The use of high-voltage equipment in a laboratory setting, often in proximity to flammable materials and liquids, presents significant risks of electrocution, electrical shocks, and electrically ignited fires. Faulty wiring, inadequate grounding, and the absence of appropriate safety devices can exacerbate these risks.

Mitigation Measures:

- Implement a comprehensive electrical safety program based on national electrical safety codes and standards.
- Conduct regular inspection and testing of all electrical installations and equipment by qualified personnel, including verification of proper earthing/grounding systems. Maintain detailed records of inspections and any corrective actions taken.
- Install appropriate circuit breakers and earth-fault circuit interrupters (EFCIs) in laboratory and production area electrical circuits to prevent electrical shocks and fires.
- Ensure that all VMF electrical equipment is properly earthed/grounded using three-prong plugs and grounded outlets. Verify the integrity of grounding systems during regular inspections.

- All VMF electrical equipment and wiring must conform to relevant national electrical safety standards and codes.
- Implement strict lockout/tagout procedures for disconnecting equipment from high-voltage or high-amperage power sources before any maintenance, repair, or modification work is performed to prevent accidental energization. Train all relevant personnel on these procedures.
- **Safe Use of Electrical Equipment:**
    - Do not use electrical devices near flammable or volatile gases or liquids unless the equipment is specifically designed and certified for use in such hazardous environments (intrinsically safe).
    - Avoid overloading electrical circuits.
    - Regularly inspect electrical cords and plugs for damage and remove damaged equipment from service.
    - Ensure that electrical outlets are properly installed and are not overloaded.
- Strictly adhere to the guidelines for storing flammable liquids in designated, spark-free refrigerators designed for this purpose, never in household refrigerators.
- Provide comprehensive training to all personnel on basic electrical safety principles, the hazards of electricity, and safe work practices when using electrical equipment.

Chemical Hazard (Fire and Corrosive Chemicals):

Potential Impacts: The presence of flammable liquids, combustible solid materials, and potential electrical hazards creates a risk of fire incidents. Additionally, the handling of corrosive chemicals poses a direct risk of chemical burns to the skin and eyes. These incidents can cause serious injuries, potential fatalities, and damage to the facility.

Mitigation Measures:

- **Fire Prevention and Management:**
    - Develop and implement a comprehensive Fire Safety Plan based on relevant national and international fire safety codes and standards, and in coordination with local fire authorities.
    - Clearly delineate fire and emergency assembly points with visible signage and maps throughout the facility (e.g., on elevators, staircases). Conduct regular fire safety awareness training for all personnel.
    - Implement a strict "No Smoking" policy throughout the facility and display appropriate signage.

- Ensure proper grounding/earthing of all laboratory electrical equipment using three-prong plugs and adherence to national electrical safety standards.
- Store combustible materials (flammable liquids, solids) in designated, lockable, fire-resistant cupboards or storage rooms, away from ignition sources. Minimize the quantity of flammable materials stored in work areas.
- Never store flammable liquids in domestic refrigerators; use spark-proof refrigerators specifically designed for flammable materials.
- Install an automatic fire detection and alarm system throughout the facility, with regular testing and maintenance.
- Provide readily accessible and appropriate fire extinguishers in all areas, particularly near fire-risk zones. Ensure regular inspection, maintenance, and servicing of fire extinguishers.
- Conduct regular fire-fighting drills for all staff to ensure they are trained in emergency procedures and the use of fire-fighting equipment.
- Ensure clear and unobstructed emergency exit routes with appropriate signage and emergency lighting.

- **Protection Against Chemical Burns:**
  - Implement the mitigation measures outlined under "Chemical Hazards" to minimize skin and eye contact with corrosive chemicals.
  - Ensure that eyewash stations and safety showers are readily accessible in areas where corrosive chemicals are used or stored. Conduct regular checks and maintenance of this equipment.
  - Provide specific training on the safe handling of corrosive chemicals and emergency procedures for chemical burns, including immediate first-aid measures.

Risks Related to Improper Waste Management

The final disposal of hazardous waste, that is incineration, involves health risks to which the operators are exposed to medical waste incinerators emitting toxic gases such as Dioxin which are detrimental to health. Incinerators that operate at temperatures below 800 degrees Celsius may lead to the production of dioxins, furans or other toxic pollutants as emissions and/or in bottom/fly ash. Transport to centralized disposal facilities may also produce hazards to health-care handlers, if not safely managed. Therefore, risks associated with waste management are expected during waste collection, storage, transport, treatment and disposal.

Mitigation measures for risk related to improper waste management:

- Develop and implement a waste management plan for the proposed VMF project in particular in accordance with the waste management plan to guide the daily waste management operations,
- Initial packaging and storage would take place where HCW is generated,
- Storage of waste will then be moved to a temporary on-site storage location,
- Controlled incineration of medical wastes with a pyrolysis incinerator shall be done at an operating temperature of 800 to, 1200^{o}C,
- Electronic wastes should not be incinerated at the site,
- Flue gas treatment system shall be used for the control of acid gases, particulate matter, and other air pollutants,
- Hazardous and chemical liquid wastes shall be stored in separate concrete-based safety tanks as recommended and disposed of after off-site treatment,
- Wastewater treatment plant works must comply with the effluent reusing international guidelines.

Impacts of Improper Wastewater Treatment

Several risk factors can reduce the efficiency of the septic tank and wastewater treatment plant. The risk can be imparted during the designing or operation phase. During the designing phase if risks such as inadequate tank volume, geometry and compartmentalization, inconsideration of tank access space and plan that involves the use of substandard construction materials are not managed properly it can reduce the efficiency of the septic tank treatment system. In addition, a faulty design can result also in cracking of the tank, leakage (ground infiltration), tank flotation and inadequate retention time of effluent. Faults from designing and operation of the treatment plant can last for long-term and have high impact on the quality of ground water table, soil and receiving surface water.

Mitigation Measures for improper wastewater treatment impacts:

- Ensure adequate access space for maintenance and sludge removal.
- Use high-quality, durable construction materials that meet or exceed standards.
- Implement quality control measures during construction to prevent structural defects.
- Design the treatment plant to handle the specific characteristics and volume of wastewater generated by the VMF.
- Implement redundancy in treatment processes to minimize the impact of equipment failures.

- Establish a comprehensive operation and maintenance plan, including regular inspections, cleaning, and repairs.
- Train all plant operators in proper procedures.
- Use impermeable liners and seals in septic tanks and treatment plant components to prevent leakage.
- Conduct regular inspections for cracks and leaks, and promptly repair any damage.

Impact of Air Pollution due to Waste Incineration

The emissions of compounds such as volatile organic compounds (VOCs), sulphur dioxide, hydrogen chloride and particulate matter (PM) from waste incineration are unlikely to contribute significantly to total emissions. However, waste incinerators have been a major source of emissions of SO_2, CO_2, CO, NOx, particulates, polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs, other persistent organic pollutants (POPs) and some heavy metals such as cadmium and mercury.

During the operation of the VMF laboratory, waste is generated and they should be treated using different techniques such as autoclave, chemical disinfectant, and incinerators. However, an incinerator would contribute to air pollution. So that air quality effects during the operation of the incinerator generate emissions of and other toxic substances. Incineration presents a good option for good disposal and destruction of solid and sharps-wastes. However, concerns such as availability of technical knowhow, maintenance, environmental pollution, etc would be considered. Incineration has the potential for toxic emissions, particularly if the waste stream is not regulated, as is usually the case if the equipment is not properly operated and maintained, and if the emissions management system is inadequate. Human health risks due to dioxin and furan exposure have been reported and evidence for dioxin and furan toxicity in humans comes from studies of populations that have been exposed to high concentrations occupationally or in industrial accidents.

Mitigation Measures:

- Waste segregation for wastes with polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs shall be done and these wastes would never be incinerated,
- Materials free of polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs shall be purchased, for minimizing the environmental and health impacts.
- Workers will be provided with all appropriate PPE and the use of PPE shall be enforced.

- Applicable national requirements and internationally recognized standards for incinerator design and operating conditions shall be followed.
- Wastes shall be introduced into the incinerator only after the optimum temperature is reached in the final combustion chamber,
- The waste charging system shall be interlocked with the temperature monitoring and control system to prevent waste additions if the operating temperature falls below the required limit,
- Minimize the uncontrolled ingress of air into the combustion chamber via waste loading.

Risk associated with off-site Transport of Sludge Waste

The off-site transport of sludge waste from KIP ETP poses some risks that can impact public health, safety, and the environment. Key risks include:

- During transport, waste containers can be compromised, leading to spills that may contaminate soil, water sources, and air, posing immediate hazards to surrounding communities and ecosystems.
- The cumulative effect of transporting waste can contribute to air pollution from vehicle emissions and the carbon footprint associated with long-distance transport.

Mitigation Measures:

- Employ transfer equipment that is compatible with the characteristics of the materials being moved, ensuring it is designed for safe transfer. Conduct regular inspections, maintenance, and repairs of fittings, pipes, and hoses.
- Ensure that transportation is thoroughly documented, with all vehicles carrying a consignment note from the collection point to the treatment facility.
- Disinfect vehicles used for transporting waste before repurposing them for any other use.
- Equip vehicles with sufficient supplies of plastic bags, protective clothing, cleaning tools, and disinfectants to manage and clean up any spills effectively.

Risk related with Vaccine Distribution

Vaccine distribution involves several risks that can impact the efficacy, safety, and overall success of vaccination programs. Below are some common risks along with potential mitigation measures:

Cold Chain Breaks

Risk: Vaccines often require strict temperature controls. Any break in the cold chain can compromise vaccine integrity.

Mitigation Measures:

- Use temperature monitoring devices (data loggers) throughout the distribution process.
- Train staff on proper handling and storage protocols.
- Implement contingency plans for equipment failures, including backup power sources.

Supply Chain Disruptions

Risk: Natural disasters, political instability, or logistical challenges can delay vaccine delivery.

Mitigation Measures:

- Diversify suppliers and transportation routes.
- Maintain buffer stock of vaccines to cover potential delays.
- Develop strong relationships with logistics partners.

Storage Issues

Risk: Inadequate storage facilities may lead to improper handling of vaccines.

Mitigation Measures:

- Ensure all storage facilities meet regulatory standards.
- Conduct regular maintenance and checks on storage equipment.
- Provide training for staff on proper storage techniques.

Vaccine Wastage

Risk: Expired or damaged vaccines can lead to wastage and increased costs.

Mitigation Measures:

- Implement an inventory management system to track vaccine expiration dates.
- Establish protocols for redistributing near-expiry vaccines to areas with higher demand.
- Educate healthcare providers on efficient vaccine usage.
- Establish a system in which the expired vaccine come to the manufacturer for proper disposal

Regulatory Compliance

Risk: Non-compliance with local and international regulations can lead to legal issues and product recalls.

Mitigation Measures:

- Stay updated on regulatory requirements and guidelines for vaccine distribution.
- Conduct regular audits and compliance checks.
- Train staff in regulatory standards and best practices.

7.5.3 Decommissioning Phase

Impact on Air Quality

Most air pollution emissions from platform decommissioning will stem from the combustion of fuel by diesel engines, which are used in virtually all phases and activities of the decommissioning process. Dust will be also produced during dismantling the buildings, site clearing and leveling of the campus as per the design.

Mitigation Measures for air quality impacts:

- Use efficient equipment and machines with efficient engines having low emissions,
- Using clean fuels such de-sulphurized diesel and unleaded fuels,
- Water sprinkling on structures and facilities to be demolished if necessary, and
- Removing components with the potential of emitting hazardous gases or particulates separately and under caution to prevent emissions.

Noise and Vibration Impacts

There will be a considerable increase in noise owing to the demolition process. This will be a short-term impact and will be felt throughout the demolition process. The main sources of noise will include: trucks; the civil works of pulling down the project's-built structures and mechanized equipment that will be used in the processes involved in this project phase.

Mitigation Measures for noise and vibration impacts:

Carrying out the decommissioning works only during the specified time from 8:00 hrs to 17: 00 hrs where permissible levels of noise are high and acceptable,

Machineries shall be maintained regularly to reduce noise resulting from friction as per the manual,

Providing workers with Personal Protective Equipment such as earmuffs when operating noisy machinery and when in a noisy environment,

Provision of billboards at the construction site gates notifying people of the activities and timings

Solid Waste Generation

Waste in the form of debris and pieces of metal and wood will arise. The decommissioning phase of the project will create demolition wastes which share similar characteristics with construction wastes and therefore similar risks.

The key environmental impacts are associated with the residual ash remaining in the incinerator unit and ash collector. The decommissioning and disposal of the incinerators will be limited to internal areas, therefore, the potential impacts are considered to be moderate and cause impacts on soil, water and air quality.

Mitigation Measures for solid waste generation impacts:

- Follow regulations on Waste Management in the country,
- Employing a waste management plan, which will involve assessing and creating opportunities for Regulation, Reducing, Reusing, Recycling, Recovering, and Renovation,
- Allocate responsibilities for waste management and identifying all sources of waste, and ensuring wastes are handled by personnel licensed to do so,
- Making available suitable facilities for the collection, segregation and safe disposal of the wastes, and
- Ensuring all wastes are dumped in their designated areas and through legally acceptable methods.

Occupational Health and Safety (OHS) Impacts

The decommissioning phase will have several OSH risks from the dismantling the building and removal of equipment, materials and processes.

- Risk related to slip, trip, and falls: sloppy area and unstable area during decommission may result in an increasing likelihood of slip, trip, or fall occurring which result in serious injuries**.**
- Injuries or injurious substances, materials and equipment from:
- Falling debris
- Moving parts of equipment such as mechanized saws and other cutting equipment
- Risk of Fire: Heat from gas cutters, friction from abrasive processes, fuel, electricity and electrical equipment

Mitigation Measures for occupational health and safety impacts:

- Employing an OSH plan that will outline all OSH risks and provide a strategy for their management,
- Ensuring all hazards such as movable parts are labeled,
- Raising awareness and educating workers on risks from equipment and ensuring they receive adequate training on the use of the equipment,
- Providing the workers with adequate PPEs and monitoring regularly to ensure they are replaced on time when they wear out,
- Placing visible and readable signs around where there are risks and undertaking the riskier demolition activities first and in isolation,
- All wastes shall be removed from the site,
- Ensure there is security in and around the site to control the movement of people,
- Provide safe and secure storage for the waste and materials on the site,
- Place visible and readable signs to control the movement of vehicles and notify motorists and pedestrians around them, and workers in the site,
- Provide firefighting equipment and in easily accessible areas as well as ensuring site personnel are well trained to use them as well as maintaining them regularly,
- Label chemicals and materials according to the risks they possess,
- Create safe and adequate fire and emergency assembly points and making sure they are well-labeled, and
- Follow/establish emergency procedures against hazards and ensure the workers stay aware/educated on following them and commensurate to the magnitude and type of emergency, by conducting regular drills and involving the neighbors.

8 ENVIRONMENTAL AND SOCIAL MANAGEMENT PLAN

This ESMP is developed with the aim to outline actions necessary to prevent, mitigate and control possible negative impacts or disadvantages during construction, operation, and demolition phases of the project on the environment and to analyze steps that could be taken with respect to this. Specific to the operation phase, the ESMP is limited to the stage one of the vaccine manufacturing. In addition, the ESMP assigns responsibilities for actions to various actors and provides a timeframe within which mitigation measures and monitoring can be done. The purpose of this management plan is not only to ensure that the project complies with the relevant legislation and guidelines but also that it avoids (where possible), reduces/ minimizes its risks. The ESMP is proactive and will be upgraded if new facilities or modifications to existing facilities, with environmental concerns, come

up at a later stage. The ESMP outlined below will address the identified potential negative impacts and mitigation measures of the proposed project.

Table 14: Environmental and Social Management Plan

Potential Environmental & Social Impacts	Recommended Mitigation Measures	Responsibility	Timing frame	Estimated cost (Eth. Birr)
PRE-CONSTRUCTION/DESIGN PHASE				
Cross contamination risk	- The design of the facility should consider adequate facility spacing. - The design shall be according to WHO, cGMP standards and Good International Industry Practice (GIIP) to ensure better material flow, personnel flow, natural and artificial ventilations (Unidirectional airflow), entry and exit arrangements.	MOH	During design phase	Part of design cost
Risks related to waste incinerator and generator location on the facility	- As the most prevalent wind direction is to the west direction during Bega and Belg season and to the east direction during Kiremt season, it is recommended to place the waste incinerator and generator on the north and north east part of the site. - The stack height shall be at least 20 meters.	MOH	During design phase	Part of design cost
Emergency risk	Considering the following points in the design of the facility - Emergency Exit - Assembly Point - Emergency Alarm - Fire hydrant hose - Smoke detector - Fire sprinkler system - Including a dedicated detached first aid room.	MOH	During design phase	Part of design cost
Earthquake risk	- Considering the current frequent appearance of earthquake in addition to earthquake zone classification of the project location	MOH	During design phase	Part of design cost

Marginalization of people with disability	- Considering dedicated disabled bathroom and on all floors, standard ramp for access to all blocks, elevation for all blocks, except warehouse.	MOH	During design phase	Part of design cost
GBV/SEH/ risk	- Separate bathroom for male and female - Separate change room for female and male - CCTV installation	MOH	During design phase	Part of design cost
Impact on utility service risk	- Water recycling System - Rain water harvesting - Solar panel on roof	MOH	During design phase	Part of design cost
Waste management risk	- Separate sewer line - Separate septic tank/holding tank - Integration of Kill Tank and Effluent Treatment Plant - On site waste incinerator	MOH	During design phase	Part of design cost
Lightning risk	- Lightning Prevention System Installation	MOH	During design phase	Part of design cost
Security risk	- Including guard tower, access control systems, CCTV installation, - Remote facility lockdown system	MOH	During design phase	Part of design cost
Traffic risk	- Separate gate for personnel entrance and finished vaccine loading/distribution	MOH	During design phase	Part of design cost
Electric surge risk	- Surge Prevention System Installation	MOH	During design phase	Part of design cost
CONSTRUCTION PHASE				

Air Quality Impact	- Construction work shall be performed by a reputable and registered contractor with demonstrated environmental awareness and responsibility. - Contractors should use dust screens or nets in windows, doorways and ventilators of rooms where demolition or other dusty construction activities are occurring, - Dusty roads and work areas will be regularly watered, at least twice daily or more frequently as needed, to minimize fugitive dust emissions. - Construction structures shall be enclosed with dust-proof netting to prevent the dispersion of particulate matter. - Rigorous housekeeping practices need to be enforced, including prompt sweeping of dust and debris from surfaces and proper disposal of construction waste in covered containers. - Construction machinery must undergo regular maintenance according to manufacturer specifications to ensure optimal performance and minimize emissions. - Only clean fuels, such as unleaded and low-sulfur diesel, will be used. Fuel sourced from unregulated or potentially contaminated sources is prohibited. - Provide regular training for construction workers on emission reduction techniques and best practices for minimizing air pollution. - Appropriate PPE shall be provided for workers, including respirators, and the mandatory use of PPE will be strictly enforced. -	Contractor, Consultant, MOH	During construction	40,000

Impact on water resource	- The contractor should establish designated maintenance areas for trucks and construction machinery, equipped with impermeable surfaces and containment systems to prevent oil and lubricant spills. - Used oils and other liquid waste shall be stored in secure, labeled containers and disposed of as hazardous waste in accordance with local regulations. - Dispose of excavated soil only at designated sites with permits from local authorities and environmental clearance from the city administration's EPA office. - Erosion and sediment control measures, such as silt fences, sediment basins, and temporary drainage ditches, must be implemented. - Surface water drains and watercourses shall be protected with cut-off ditches, earth bunds, or other appropriate measures to divert runoff and prevent contamination. - Proper portable toilets need to be installed and maintained for the workers, and sewage must be disposed of by a licensed sewage hauler or follow the KIP sewage management system.	Contractor, Consultant, MOH	During construction	50,000
Soil pollution and erosion impact	- Minimize soil disturbance and control erosion by avoiding steep slopes and reducing the footprint of construction activities, including roads, staging areas, and crane pads. - Collected and recycle all plastic tubes and other recyclable materials generated during construction - Develop and implement a spill response plan for the event of an accidental oil or chemical spill. - Collect and recycle used oils, including engine lubrication oil, hydraulic fluids, and gear oils, or disposed of as hazardous waste according to local regulations. - Prepare a designated maintenance area with an impermeable surface and containment systems for construction vehicles and machinery to prevent soil contamination from leaks and spills.	Contractor, Consultant, MOH	During construction	30,000

Noise and vibration impacts	- The contractor should prioritize the use of well-maintained and modern equipment with low noise emission ratings. Older or damaged machinery with excessive noise levels will be avoided. - Construction activities exceeding normal working hours should require prior approval from the consultant and client and, when necessary, advanced notification to nearby companies. - Noise levels exceeding 55 dB(A) during daytime hours and 45 dB(A) during nighttime hours will only be permitted with prior approval and a minimum of two days' advance notification to to nearby companies. - Restrict activities generating significant noise disturbances to daylight hours and will be subject to the notification procedures outlined above. - Diesel generator sets and other noise-generating machinery must be equipped with acoustic enclosures to minimize noise emissions at the construction site. - All construction equipment and machinery must undergo regular maintenance according to manufacturer specifications to ensure optimal performance and minimize noise generation. - Provide training and awareness creation sessions for construction workers on noise reduction techniques and best practices for minimizing noise generation. - Provide appropriate PPE for workers exposed to high noise levels such as earplugs or earmuffs, and the mandatory use of PPE will be strictly enforced.	Contractor, Consultant, MOH	During construction	40,000
Solid waste generation impacts	- Collect solid waste from the project site at least once every 24 hours to minimize nuisance odors and vermin infestations. - Segregate and recycle of usable materials. - On-site reuse of inert construction and demolition material, including suitable excavated material to the maximum extent possible. Only surplus material will be disposed of off-site. - Excavated soil must be promptly removed from the site and disposed of at a designated location with an environmental clearance certificate from the Addis Ababa City Administration.	Contractor, Consultant, MOH	During construction	20,000
Liquid waste impacts	- Wastewater from the concrete batching plant shall be stored in a protected pond within the site and used for concrete curing and watering of buildings, - Construct portable toilets, safety tanks and shower for construction workers, and remove once	Contractor, Consultant,	During construction	30,000

	the construction is over. - Used oils and other liquid wastes shall be stored in a secured area in tanks and disposed of as hazardous wastes	MOH		
Traffic and public safety impacts	- Drivers of heavy truck shall be directed by flagmen, - Limit the speed of the truck to 10 km/hr at the project site - Initiation of a safety program and measures by creating awareness and educational campaigns for drivers, workers, including monitoring of speed limits, - Installation of appropriate road signage, speed signs, and other warning signs at the site and access roads, - Assuring driver's licenses originality and regular construction site trucks technical performance. - The contractor's vehicles and equipment must be in proper working condition (roadworthy vehicles) and have registration plates and numbering. - The contractor ensures proper driving discipline by its employees, and sanctions those in breach, - Use only permitted gates and access road which is allowed for construction machineries and trucks	Contractor, Consultant, MOH	During construction	40,000
Public health impacts	- Implementation of HIV/AIDS, Sexually Transmitted Diseases and MOH declared threat epidemic diseases education programs, - Information campaigns on STDs among the workers and local community, - Vaccinating workers against common and locally prevalent diseases. - Provision of condoms, - Ensuring construction site has constructed onsite wastewater disposal and septic systems,	Contractor, Consultant, MOH	During construction	40,000
Impact on cultural, religious & archaeological sites	- No known archaeological sites are expected on-site, however, if encountered the Contractor/ Supervising Consultant is to inform the local authority for further action. - Apply the chance finds procedure. - Orientation for excavation sub-constructors on chance find procedure	Contractor, Consultant, MOH	During construction	40,000
Risk of social conflict and crime	- The proponent (MOH HILEO/SHIELDVAX) and the contractor should establish a joint project-specific GRM. This mechanism will include a team comprising a construction supervisor and designated officers from HILEO, responsible for receiving, logging, and addressing all stakeholder disputes, conflicts, and concerns.	Contractor, Consultant,	During construction	15,000

	The GRM will be established according to the guidelines outlined in Section 16 of this report. - Ensure early and consistent community engagement to address potential issues proactively. - The contractor expected to provide comprehensive orientation to its staff, emphasizing respect for the cultural, religious, and ethnic diversity of workers, and the KIP community. - Salaries can be dispersed via electronic bank transfers to workers' bank accounts, minimizing the risks associated with cash payments. - Local suppliers will be given priority in supplying construction materials, such as sand, bricks, and other locally available resources, whenever feasible. - Local suppliers will be prioritized for employment opportunities to foster a sense of project ownership and community integration. - Open and transparent communication channels must be maintained between all stakeholders to facilitate information sharing and address concerns promptly.	MOH		
Gender equity, GBV/SEA and sexual harassment	- The contractor should provide orientation to its staff to respect the culture of the local people and to limit their relationship with the local people, - Contractor and implementing agency to prepare and implement a GBV Prevention and Response Action Plan to include at a minimum, in conformance with local laws and customs, equal opportunity for employment, - All workers and nearby communities and stakeholders will be educated on preventing and responding to sexual harassment and GBV ahead of any project-related works, - Construction areas shall be separated by a fence and a separate access gate is used for construction workers, - Ensure that women are given a mentorship orientation before starting their work. - Provision of gender-disaggregated data, separate bathing, changing, and sanitation facilities for men and women shall be made ready by the contractor, and - Impose zero tolerance on sexual harassment, all forms of gender-based violence and discrimination at all phases of the project. - MOH must clearly define the SEA/SH requirements and expectations in the bidding documents for contractor - MOH environmental and social safeguards team must ensure that the contractors included GBV prevention and response framework like code of conduct in Contractor Environmental	Contractor, Consultant, MOH	During construction	40,000

	and Social Management Plan (C-ESMP) prior to the commencement of the construction project. - Take appropriate actions on workers violating the CoC.			
Child right violation impacts	- Enhance the capacity of the social service workforce to identify and respond to potential child labor situations through effective case management and social protection services, including early identification, registration, and follow-up. - Implement a strict zero-tolerance policy for child rights violations. The contractor must conduct mandatory training for all workers on the consequences of child rights violations. - The contractor should ensure all workers are at least 18 years of age, to comply with the project's commitment to preventing child labor as required under the World Bank Environmental and Social Standard 2 (ESS2), Paragraph 18.The contractor and subcontractors will adhere to standard occupational health and safety standards throughout the construction phase. - The contractor also must have a legal agreement with the worker including a signed code of conduct. - The contractor will clearly state the minimum age requirement for general work in their hiring policy and job announcements. - The MOH must conduct regular checks of labor contracts and supervise the deployed construction workforce to ensure compliance.	Contractor, Consultant, MOH	During construction	12,000
Occupational health and Safety Impacts	-			
	i) Slip, Trip and Falls Mitigation Measures - Regularly cleaning the worksite; the worksite shall be neat. - Ensuring employees receive appropriate training and instructions - Deal with spills straight away as per the spill response plan - Consider routine monitoring of areas where spills are a high risk - Use absorbent material to soak up the spill - Identify areas at high spill risk and locate absorbent materials nearby - Where possible avoid using wet cleaning as this may spread the potential danger area - Consider using spill kits - Placing readable signs alerting people of hazardous such as for slippery floors, - Ensure slip-resistant footwear is provided and worn as needed providing personal protective	Contractor, Consultant, MOH	During construction	15,000

	equipment (e.g. slip-resistant footwear) if required			
	ii) Eye hazard Mitigation Measures Always wear personal protective eyewear for workers working on high dust and eye goggles for welders, Clean your eyewear several times throughout the day, and always brush yourself off before removing your safety glasses. Follow the recommended measures stated in World Bank EHS guideline, 2007	Contractor, Consultant, MOH	During construction	10,000
	iii) Welding / Hot Work o Provision of proper eye protection such as welder goggles and/or a full-face eye shield for all personnel involved in, or assisting, welding operations. Additional methods may include the use of welding barrier screens around the specific work station (a solid piece of light metal, canvas, or plywood designed to block welding light from others). Devices to extract and remove noxious fumes at the source may also be required. o Special hot work and fire prevention precautions and Standard Operating Procedures (SOPs) shall be implemented if welding or hot cutting is undertaken outside established welding work stations, including 'Hot Work Permits, stand-by fire extinguishers, stand-by fire watch, and maintaining the fire watch for up to one hour after welding or hot cutting has terminated. Special procedures are required for hot work on tanks or vessels that have contained flammable materials.	Contractor, Consultant, MOH	During construction	10,000
	iv) Ergonomics, Repetitive Motion, Manual Handling i) and workstation design with 5th to 95th percentile operational and maintenance workers in mind ii) 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 iii) Selecting and designing tools that reduce force requirements and holding times, and	Contractor, Consultant, MOH	During construction	10,000

	improve postures iv) 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. v) Adjust the height of working surfaces to reduce long reaches and awkward postures, vi) Put work supplies and equipment within comfortable reach, vii) Provide the right tool handle for the worker, viii) Vary tasks for workers (e.g., employ job rotation), ix) Encourage short rest breaks,			
	v) Working at Heights o Installation of guardrails with mid-rails and toe boards at the edge of any fall hazard area o Proper use of ladders and scaffolds by trained employees o Use of fall prevention devices, including safety belt and lanyard travel limiting devices to prevent access to fall hazard area, or fall protection devices such as full body harnesses used in conjunction with shock absorbing lanyards or self-retracting inertial fall arrest devices attached to fixed anchor point or horizontal life-lines o Appropriate training in use, serviceability, and integrity of the necessary PPE · Inclusion of rescue and/or recovery plans, and equipment to respond to workers after an arrested fall	Contractor, Consultant, MOH	During construction	10,000
	vi) Chemical Hazards o Replacement of the hazardous substance with a less hazardous substitute o 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	Contractor, Consultant, MOH	During construction	10,000

	○ 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 shall 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			
	Mitigation Measures for Fire and Explosion Hazards ● Storing flammables away from ignition sources and oxidizing materials. ● 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 ● Implementing hot work permits procedures ● Ensure the provision of fire extinguishers at all work locations and at all times. ● All flammable gases, liquids and vapors are removed before the start of any hot work. ● Where appropriate, use spark-resistant tools and make sure all equipment is bonded or grounded properly, ● The construction site shall be fenced off to prevent access to members of the public, ● Providing adequate storage for hazardous and flammable substances and controlling access to them. ● Designate separate place and equip them with appropriate medical equipment for first aid treatment,	Contractor, Consultant, MOH	During construction	10,000

	• Providing specific worker training in handling of flammable materials, and in fire prevention or suppression			
	vii) Electrical Hazards Mitigation Measures • Inspect portable cord-and-plug connected equipment, extension cords, power bars, and electrical fittings for damage or wear before each use. Repair or replace damaged equipment immediately, • Always locate all power lines on or near the project sites, • Perform regular fire risk assessments to identify areas at risk of bad wiring and circuits, • Maintain proper grounding to eliminate unwanted voltage and reduce the risk of electrocution, • Verify that all wiring is coming from a properly rated circuit and doesn't exceed the capacity	Contractor, Consultant, MOH	During construction	15,000
	viii) Biological Hazards Mitigation Measures Construction site shall be separated from the main KIP compound by fence and construction workers shall be restricted within the site, **ix)** Remove and reduce debris and rubble piles when possible to help keep insects and rodents away. **x)** The worker shall be vaccinated based on the type of pathogens they are exposed to. **xi)** In case of any disease outbreak vaccination shall be performed in a construction areas or surroundings to prevent the spread of disease, and **xii)** Workers should cover as much of the body as feasible.	Contractor, Consultant, MOH	During construction	20,000
	x) **Traffic Accident Impacts Mitigation Measures** • Limit the speed of the truck to 10 km/hr within the site, • Initiation of a safety program and measures by creating awareness and educational	Contractor, Consultant, MOH	During construction	25,000

	campaigns for drivers, workers and local communities, including observation of speed limits, • Sanctions for reckless driving, • Installation of appropriate road signage, speed signs, and other warning signs at the site and access roads, • Copies of drivers‘ licenses and insurance policies for the Contractor‘s drivers and vehicles respectively shall be provided to the Supervision Consultant, • All construction machineries and cars should have third-parties insurance, • Use only permitted gates and access roads which are allowed for construction machineries and trucks,			
OPERATION PHASE				
Air Quality Impact	• Employ advanced incineration technologies with state-of-the-art emission control systems, including scrubbers, filters, and other pollution control devices, to minimize the release of PCDD/Fs, heavy metals, and gaseous pollutants. • Implement rigorous waste segregation and pre-treatment procedures to remove chlorine-containing materials and other hazardous substances before incineration. • Establish a continuous emission monitoring system to track and record air pollutant levels, ensuring compliance with regulatory standards. • Conduct regular maintenance and inspections of incinerator and emission control systems to ensure optimal performance. • Explore and implement alternative waste management strategies, such as recycling, and waste minimization, to reduce reliance on incineration. • Promote energy-efficient appliances and building designs to reduce overall energy consumption and associated GHG emissions.	ShieldVax, MOH	During operation	80,000

	• Conduct regular air quality monitoring around the incinerator site to assess the effectiveness of mitigation measures and ensure compliance with ambient air quality standards. • Ensure all personnel that are operating the incinerators are properly trained.			
Water Pollution Impacts	• Promoting practices that reduce the volume of wastes generated and ensure proper waste segregation; • Implement strict protocols for the handling, storage, and disposal of chemical disinfectants, including: Using designated storage areas with secondary containment and providing comprehensive training to personnel on safe handling procedures. • Implement the following measures for incinerator ash management: o Treat ash residue to stabilize heavy metals before disposal o Dispose of treated ash in secured ash pit designed for hazardous waste. o Conduct regular monitoring of leachate from ash disposal sites. • Use the KIP WWTP to treat wastewater generated from the VMF and ensure that wastewater effluent discharged from the KIP WWTP meets regulatory standards. • Ensure all personnel are properly trained on the proper handling and disposal of all hazardous materials.	ShieldVax, MOH	During operation	20,000
Soil Pollution impacts	• Implement recommended ash treatment to stabilize heavy metals and reduce their leaching. • Dispose of treated ash in secured ash pit designed for hazardous waste. • Implement rigorous waste segregation procedures to recycle the wastes. • Develop and implement a comprehensive spill prevention and response plan to minimize the risk of accidental releases of hazardous materials.			

Noise and Vibration Impacts	• Install acoustic enclosures around generators and boilers to minimize noise emissions. • Construct noise barriers or utilize existing structures to attenuate noise from vehicle traffic and maintenance activities. • Select generators and boilers with low noise emission ratings. • Implement a regular maintenance schedule for all equipment to ensure optimal performance and minimize noise generation. • Utilize noise dampening materials in building construction and equipment installations to reduce sound transmission. • Provide PPE for staff working in noisy rooms.	ShieldVax, MOH	During operation	10,000
Impacts of Flooding	• Design and construct all critical VMF buildings and infrastructure (production areas, laboratories, storage facilities, power supply) on an elevated platform, including a sufficient freeboard margin to account for uncertainties and potential climate change impacts. • Utilize permeable paving materials for parking areas and walkways to reduce surface runoff and increase groundwater infiltration. Incorporate green infrastructure elements such as bioswales, rain gardens, and vegetated buffer strips to naturally filter runoff and reduce its volume. • Design and install a robust underground drainage network with adequately sized pipes and strategically located inlets to efficiently collect and convey surface water runoff from paved areas and building surroundings. Ensure proper maintenance and regular clearing of this network.	ShieldVax, MOH	During design and operation	100,000
Solid Waste Generation	• Implement strict waste segregation protocols at the source, using color-coded containers and designated storage areas for different waste types. • Autoclave or other approved treatment methods for infectious waste before	ShieldVax, MOH	During operation	30,000

Impacts	disposal. • Secure and leak-proof containers for sharps waste, followed by incineration. ○ Follow the Medicines Waste Management and Disposal Directive waste, 2011 and the World Bank Environmental, Health, and Safety General Guidelines disposal, 2007 Section 1.5 Hazardous Material Management pharmaceutical waste management services. • Treat ash to stabilize heavy metals before disposal in secure, lined hazardous waste landfills. • Promote reusable containers and water dispensers to minimize plastic bottle waste. • Implement recycling programs for plastic and other recyclable materials. • Maintain detailed records of waste generation, treatment, and disposal. • Implement a waste tracking system to ensure proper handling and disposal. • Ensure access to post-exposure prophylaxis • Provide comprehensive training to all staff on proper waste handling and disposal procedures.			
Impacts of Wastewater generation	• Implement validated sterilization and disinfection methods (e.g., autoclaving, chemical disinfection). • Ensure treated effluent meets Ethiopian environmental regulations for discharge. • Implement robust containment systems and spill prevention protocols within the VMF laboratories. • Properly train all VMF personnel in the correct handling and disposal of biohazardous materials. • Use a modern, on-site sewage treatment system (as recommended in waste management alternative) to treat domestic wastewater before discharge. • Implement regular maintenance and monitoring of the sewage treatment system. • Establish a comprehensive environmental monitoring program, including regular testing of surface water, groundwater, and soil around the facility. • Conduct regular audits of the wastewater treatment systems of the KIP to ensure compliance with Ethiopian environmental standards • Follow emergency response plan (section) to handle any accidental release of	ShieldVax, MOH	During operation	120,000

	contaminated waste water.			
Risk of Social Conflict and Crime	• Transparent local community engagement and participation shall begin during initial project decision-making and continue routinely throughout the life of the project, • Awareness-raising among the local community, contract workers and staff about the cultures and norms of the local community, • Provision of cultural sensitization training for all staff regarding engagement with the local community, • Provide awareness creation program about tolerance of diversity and, • Develop a code of conduct for staff to prevent discrimination and other ethnocentric behaviors,	VMF, ShieldVax, MOH	During operation	20,000
Gender Based Violence	• Establish gender sensitive GRM • Establish a gender mainstreaming and monitoring committee, • Provide awareness to the newly joined workers about the incidence and impact of domestic violence, sexual assault, and stalking, including reporting requirements and options, • Conduct continued sensitization and awareness raising to VMF staff on the prevention of GBV, • Strengthen the Gender and women office of MOH to address GBV cases when it occurs, • On-going prevention training for staff; • Provision of gender-disaggregated data, separate bathing, changing, sanitation facilities for men and women. • Impose zero tolerance on sexual harassment, all forms of gender-based violence and discrimination at all phases of the project	VMF, ShieldVax, MOH	During operation	20,000
Community Health & Safety Concerns	• Regular community engagement and communication • Establishing functional and responsive GRM	VMF, ShieldVax, MOH	During operation	20,000
Public Opposition or Mistrust risk	• Regularly communicating the community on the production efficiency, exported vaccines, locally used, and income generated from the sector. • Undertaking media scanning to early detect and manage public detection, • Undertaking regular consultation with the community representatives and stakeholders.	VMF, ShieldVax, MOH	During operation	20,000
Traffic and Public Safety Impacts	• Designate entry/exit points and implement one-way traffic patterns. • Coordinate delivery times to avoid peak traffic hours. • Establish marked loading/unloading areas away from public roads.	VMF, ShieldVax, MOH	During operation	20,000

	• Employ marshals during peak hours for traffic direction. • Install clear signage and use variable message signs for real-time updates. • Ensure compliance with traffic laws and collaborate with local authorities. • Conduct audits to evaluate and improve traffic management practices.			
Public Health Impacts	• **Contamination by Adventitious Agents:** • Contamination by Adventitious Agents: • Stringent Raw Material Sourcing and Qualification • Multi-Barrier Advanced Sterilization and Inactivation • Comprehensive and State-of-the-Art Testing Regimen:	VMF, ShieldVax, MOH	During operation	25,000
	• **Environmental Release of Hazardous Materials** • Comprehensive On-Site Wastewater Treatment System • Establishing Advanced Air Emission Control Systems • Implementing Robust Spill and Leak Prevention and Containment Protocols • Establish a scientifically justified buffer zone of at least 500 meters (or as determined by a detailed risk assessment considering prevailing wind patterns, potential emission pathways, and local population density) around the facility. Implement a comprehensive environmental monitoring program within and around the buffer zone • Proactive and Transparent Public Awareness Campaigns	VMF, ShieldVax, MOH	During operation	20,000
	• **Occupational Exposure:** • Install Local Exhaust Ventilation (LEV) systems at points where potential exposure to bioaerosols or chemical vapors may occur (e.g., during sampling, transfer, or cleaning operations). Ensure LEV systems are properly designed, installed, and regularly maintained to ensure their effectiveness. • Use biosafety cabinets (BSCs), isolators, and other containment equipment for handling infectious agents and hazardous materials. • Ensuring Mandatory and Appropriate Personal Protective Equipment (PPE): • Undertaking Pre-Employment and Occupational Health orientation and training program	VMF, ShieldVax, MOH	During operation	20,000
Occupational Health and Safety Impacts	**I) Risk of Infection Mitigation Measures** • Workers working in vaccine manufacturing should receive specific training in handling biomaterial and potentially lethal agents and shall be supervised by competent staff in handling such agents and associated procedures, • All procedures involving the manipulation of biological materials shall be conducted	VMF, ShieldVax, MOH	During operation	80,000

	within a BSC or other physical containment devices, • Persons would wash- their hands after working with potentially hazardous materials and before leaving the facility, • Spills involving biomaterials shall be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with-such material, • Equipment shall be decontaminated before repair, maintenance, or removal from the laboratory, • Workers in the facility should wear protective clothing with a solid front, such as tie-back or wrap-around gowns, scrub suits, or coveralls. Protective clothing will not be worn outside of the laboratory, • Reusable clothing shall be decontaminated before being laundered. Clothing is changed when contaminated, • Biomaterials shall be placed in a durable, leak-proof container during collection, handling, processing, storage, or transport within a facility,			
	ii) Chemical Hazards Mitigation Measures • To avoid accidental leakage or spillage, secondary containers, such as leak-proof boxes, shall be used, fitted with racks so that the specimen containers remain upright, • Respiratory protection shall be used when carrying out high-hazard procedures. The choice of respirator will depend on the type of hazard(s) and it is available with interchangeable filters for protection against gases, vapors, particulates and microorganisms • Volatile solvents shall be handled in a chemical hood, • Material Safety Data Sheets (MSDS) or equivalent shall be considered while handling, storing, using, and disposing hazardous chemicals. • Only small amounts of chemicals necessary for daily use shall be stored in the laboratory, • Where corrosive, oxidizing, or reactive chemicals are used, handled, or stored, qualified first-aid would always be ensured. • Either fully buttoned laboratory coats, gowns, coveralls, or long-sleeved, back-opening gowns or coveralls shall be used in the facility. Aprons may also be worn over laboratory coats or gowns where necessary to give further protection during the handling of chemicals, hazardous and infectious materials, and • Eye and face protection (goggles, mask, face shield or other splash guards) shall be used for anticipated splashes or sprays of infectious or other hazardous chemical materials.	VMF, ShieldVax, MOH	During operation	80,000
	iii) Risk of Burn or Fire Mitigation Measures • Prepare a fire safety plan and the plan should provide employees or building occupants with the instructions they need to leave the building (or respond as appropriate) in the event of a fire, • Delineating fire and emergency assembly points and creating awareness to ensure all	VMF, ShieldVax, MOH	During operation	80,000

	people at the site are aware of them, e.g. through the use of maps on elevators, staircases etc. • All laboratory electrical equipment shall be earthed/grounded, preferably through three-prong plugs, • Combustible materials such as flammable liquids, and solid materials shall be stored in a lockable cupboard, • Fire hazard signs such as 'No Smoking' signs will be provided. Directions to exit in case of any fire incidence and emergency contact numbers will be provided. The contact/emergency numbers will be displayed within the laboratory • First aid treatment facility shall be also available, • Automatic fire alarm system for the entire laboratory will be installed, • All staff will have training in fire control through regular fire-fighting drills. • Fire extinguishers shall be available in an accessible area near fire-risk areas and ensure that all fire-fighting equipment is regularly maintained and serviced,			
	iv) Ergonomic Hazards Mitigation Measures • Training of workers in lifting and materials handling techniques during operation, including the placement of weight limits above which mechanical assists or two-person lifts are necessary, • Planning worksite 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 workstations, • Implementing administrative controls into work processes, such as job rotations and rest or stretch breaks.	VMF, ShieldVax, MOH	During operation	20,000
	v) Risk related to Sharps Mitigation Measures • Injuries should always be reported to supervisors and victims should get medical attention as soon as possible. Collect broken needles in a secured and safe area and dispose all based on WHO standards, • Sharps waste by disposing of it in a sealable container; self-locking and sealable sharps containers are made of plastic so that the sharps cannot easily penetrate through the sides. Such units are designed so that the whole container can be disposed of with other biohazardous waste with the support of the government	VMF, ShieldVax, MOH	During operation	15,000
	Vi) Risk related to Electricity Mitigation Measures • All electrical installations and equipment must be inspected and tested regularly, including earthing/grounding systems. Circuit breakers and earth-fault-interrupters shall be installed	VMF, ShieldVax, MOH	During operation	25,000

	in appropriate laboratory electrical circuits, • Implementation of a lockout/tagout (LOTO) communication system during maintenance. • All laboratory electrical equipment shall be earthed/grounded, preferably through three-prong plugs, • All laboratory electrical equipment and wiring would conform to national electrical safety standards and codes, • Disconnect equipment attached to high-voltage or high-amperage power sources from the source or provide a lockout device on the breaker box to prevent circuit activation before maintenance is performed, • Electrical devices can generate sparks, do not use them near flammable or volatile gases or liquids,			
	vii) Fire and Explosion Mitigation Measures • All staff will have training in fire control through regular firefighting drills, • Fire extinguishers shall be available in an accessible area near fire risk area and ensure that all fire-fighting equipment is regularly maintained and serviced, • Fire emergency telephone numbers shall be displayed in communal areas, • Automatic fire alarm system for the entire laboratory will be installed, • Fire suppression for the facility shall be provided by a standard wet-pipe fire sprinkler system, • Water flow alarms shall be connected to the facilities fire alarm monitoring station so that, • Designated responders shall be notified • Water hose reels will be installed in the laboratory.	VMF, ShieldVax, MOH	During operation	20,000
Contamination Risks (Cross-contamination between different vaccine products)	• Implement rigorous cleanroom procedures and aseptic techniques. • Utilize validated cleaning and sterilization methods. • Conduct regular environmental monitoring and product testing.	VMF, ShieldVax, MOH	During operation	12,000
Equipment and Facility Risks (Malfunction of critical equipment)	• Implement preventive maintenance programs for critical equipment. • Install redundant power systems and backup generators. • Utilize temperature monitoring systems and alarm systems for cold storage.	VMF, ShieldVax, MOH	During operation	28,000

Risks related to Improper Waste Management	• Develop and implement a waste management plan for the proposed VMF project in particular in accordance with the i~~nfection~~ biomaterial control and waste management plan to guide the daily waste management operations, • Initial packaging and storage would take place where HCW is generated, • Storage of waste will then be moved to a temporary on-site storage location • Controlled incineration of medical wastes with a pyrolysis incinerator shall be done at an operating temperature of 800 to 1200oC. • Electronic wastes should not be incinerated at the site, • Flue gas treatment system shall be used for the control of acid gases, particulate matter, and other air pollutants; • Hazardous and chemical liquid wastes shall be stored in separate concrete-based safety tanks as recommended and disposed of after off-site treatment, • Wastewater treatment plant works must comply with the effluent discharge guidelines of the country	VMF, ShieldVax, MOH	During operation	15,000
Impact of Air Pollution due to Waste Incineration	• Waste segregation for wastes with polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs shall be done and these wastes would never be incinerated, • Materials free of polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs shall be purchased, for minimizing the environmental and health impacts. • Workers will be provided with PPE and the use of PPE shall be enforced. • Improve incinerators and infrastructure for healthcare waste treatment and disposal • New environmentally friendly incinerator shall be purchased. • Applicable national requirements and internationally recognized standards for incinerator design and operating conditions shall be followed, mainly rapid quenching of the flue gas after leaving all combustion chambers and before entering any dry particulate matter air pollution control device but also combustion temperature, residence time, and turbulence, • Wastes shall be introduced into the incinerator only after the optimum temperature is reached in the final combustion chamber, • The waste charging system shall be interlocked with the temperature monitoring and control system to prevent waste additions if the operating temperature falls below the required limit, • Minimize the uncontrolled ingress of air into the combustion chamber via waste loading or other route.	VMF, ShieldVax, MOH	During operation	15,000
Risk associated with off-site Transport of	• Employ transfer equipment that is compatible with the characteristics of the materials being moved, ensuring it is designed for safe transfer. Conduct regular inspections, maintenance, and repairs of fittings, pipes, and hoses. • Ensure that transportation is thoroughly documented, with all vehicles carrying a consignment note from the collection point to the treatment facility.	VMF, ShieldVax, MOH	During operation	

Waste	• Disinfect vehicles used for transporting waste before repurposing them for any other use. • Equip vehicles with sufficient supplies of plastic bags, protective clothing, cleaning tools, and disinfectants to manage and clean up any spills effectively.			
Risk related with Vaccine Distribution	• Train staff on proper handling and storage protocols. • Implement contingency plans for equipment failures, including backup power sources. • Diversify suppliers and transportation routes. • Ensure all storage facilities meet regulatory standards. • Conduct regular maintenance and checks on storage equipment. • Provide training for staff on proper storage techniques. • Establish protocols for redistributing near-expiry vaccines to areas with higher demand. • Establish a system in which the expired vaccine come to the manufacturer for proper disposal • Stay updated on regulatory requirements and guidelines for vaccine distribution.	VMF, ShieldVax, MOH	During operation	100,000
• **DECOMMISSION PHASE**				
Air Quality Impact	• Using efficient equipment and machines with efficient engines having low emissions, • Using clean fuels such de-sulphurized diesel and unleaded fuels, • Water sprinkling on structures and facilities to be demolished if necessary, and • Removing components with the potential of emitting hazardous gases or particulates separately and under caution to prevent emissions.	VMF, ShieldVax, MOH	During decommissioning phase	20,000
Noise and Vibration Impacts	• Carrying out the decommissioning works only during the specified time from 8:00 hrs to 17: 00 hrs where permissible levels of noise are high and acceptable, • Machineries shall be maintained regularly to reduce noise resulting from friction as per the manual, • Providing workers with Personal Protective Equipment such as earmuffs when operating noisy machinery and when in a noisy environment, • Provision of billboards at the construction site gates notifying people of the activities and timings	VMF, ShieldVax, MOH	During decommissioning phase	15,000
Solid Waste Generation Impacts	• Making available suitable facilities for the collection, segregation and safe disposal of the wastes, and • Ensuring all wastes are dumped in their designated areas and through legally acceptable methods. • Following regulations on Waste Management in the country, • Employing a waste management plan, which will involve assessing and creating opportunities for Regulation, Reducing, Reusing, Recycling, Recovering, and Renovation, • Allocating responsibilities for waste management and identifying all sources of waste, and	VMF, ShieldVax, MOH	During decommissioning phase	35,000

	ensuring wastes are handled by personnel licensed to do so			
Occupational Health and Safety Impacts	• Employing an OSH plan that will outline all OSH risks and provide a strategy for their management, • Ensuring all hazards such as movable parts are labeled, • Raising awareness and educating workers on risks from equipment and ensuring they receive adequate training on the use of the equipment, • Providing the workers with adequate PPEs and monitoring regularly to ensure they are replaced on time when they wear out, • Placing visible and readable signs around where there are risks and undertaking the riskier demolition activities first and in isolation, • All wastes shall be removed from the site, • Ensuring there is security in and around the site to control the movement of people, • Providing safe and secure storage for the waste and materials on the site, • Placing visible and readable signs to control the movement of vehicles and notify motorists and pedestrians around them, and workers in the site, • Providing fire-fighting equipment, and in easily accessible areas as well as ensuring site personnel are well trained to use them as well as maintain them regularly, • Labelling chemicals and materials according to the risks they possess, • Creating safe and adequate fire and emergency assembly points and making sure they are well-labeled, and • Establishing emergency procedures against hazards and ensuring the workers stay aware/educated on following them and commensurate to the magnitude and type of emergency, by conducting regular drills and involving the neighbors.	VMF, ShieldVax, MOH	During decommissioning phase	30,000
TOTAL COST				**1,627,000.00**

9 ENVIRONMENTAL AND SOCIAL MONITORING PROGRAM

The primary objective of environmental and social monitoring is to evaluate the implementation and effectiveness of mitigation measures, ensuring alignment with national legislation and World Bank standards. This program will achieve this by:

- Quantitatively and qualitatively measuring the effectiveness of mitigation measures.
- Developing proactive responses to non-compliance with project standards and emerging environmental and social issues.
- Verifying adherence to the commitments and requirements outlined in the Environmental and Social Management Plan (ESMP) through periodic audits and reporting.
- Facilitating timely action in response to unexpected environmental and social incidents.
- Identifying and addressing training needs at all levels of the organizational structure.

The Environmental and Social monitoring program is designed to comprehensively assess the project's environmental and social performance. It will:

- Validate Impact Predictions: Verify whether the predicted environmental and social impacts, as outlined in the ESMP, have materialized.
- Evaluate Mitigation Effectiveness: Confirm the implementation and effectiveness of the mitigation measures recommended in the ESMP.
- Identify Unforeseen Impacts: Detect and address any unanticipated environmental or social consequences arising from project activities.

9.1 Monitoring Methodologies:

The monitoring program will employ a multi-faceted approach, including:

- Site Inspections: Regular physical inspections of project sites to assess the implementation of mitigation measures and identify potential environmental and social issues.
- Grievance Mechanism Review: Systematic review of grievances lodged by stakeholders, including construction workers, companies near the project site, and the KIP community, to identify and address concerns.

- Stakeholder Engagement: Ad hoc discussions and consultations with potentially affected persons to gather feedback and address emerging issues.
- Data Review: analysis of any collected environmental data such as air quality, water quality, and noise levels.
- Conducting water quality test, soil analysis, medical examination for workers engaging in the vaccine manufacturing.

9.2 Frequency for Monitoring

Monitoring will be undertaken monthly over a year's construction period. Audits will be necessary both during construction and project operation. While construction audits will aim to verify compliance to impact mitigation requirements, post-construction audits are a regulatory requirement within 12 months and not more than 36 months after completion of construction. Post-construction audits can be conducted internally by MOH or by a consultant hired by MOH.

9.3 Reporting and Feedback:

Monitoring results will be documented in regular reports and disseminated to relevant stakeholders. These reports will:

- Summarize monitoring findings and identify any areas of non-compliance.
- Recommend corrective actions to address identified issues.
- Provide feedback to project proponents and contractors to improve environmental and social performance.

Construction- and post- construction phase auditing should finish in reports that MOH shall share with interested stakeholders. Note that while MOH is under obligation to disclose construction phase audits, annual post-construction audits must be submitted to Addis Ababa City/Federal EPA as a guideline requirement as per EIA Proclamation, 299/2002.

Table 15: Environmental and Social Monitoring Plan

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
Pre-construction phase					
Cross Contamination risk	• The design of the facility should consider adequate facility spacing. • The design shall be according to WHO, cGMP standards and Good International Industry Practice (GIIP) to ensure better material flow, personnel flow, natural and artificial ventilations (Unidirectional airflow), entry and exit arrangements. • Follow the clean room requirements of GMP, WHO, PIC/S to ensuring the sterility and quality of the produced vaccines	The proposed facility design compliance	MOH; HILEO, Environmental and Social Safeguards Specialist, ShieldVax & EFDA	During facility design review/evaluation	Part of design cost
Risks related to waste incinerator and generator location	• Placing the waste incinerator and generator on the north and north east part of the site. • The stack height shall be at least 20 meters.	Relative location of the incinerator and generator Stack height of incinerator			
Emergency Risk	Considering the following the points in the design of the facility • Emergency Exit • Assembly Point • Emergency Alarm • Fire hydrant hose • Smoke detector • Fire sprinkler system Including a dedicated detached first aid room.	Presence of the recommended facilities in the VMF design			

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
Earthquake risk	Considering the current frequent appearance of earthquake in addition to earthquake zone classification of the project location	The proposed structural design of the facility			
Marginalization of people with disability	Considering dedicated disabled bathroom and on all floors, standard ramp for access to all blocks, elevation for all blocks, except warehouse.	Presence of the recommended facilities in the VMF design			
GBV/SEH/ risk	• Separate bathroom for male and female • Separate change room for female and male • CCTV installation	Presence of the recommended facilities in the VMF design Cases logged in GRM			
Impact on utility service Risk	• Water recycling System • Rainwater harvesting • Solar panel on roof • Wind –power harvesting	Presence of the recommended facilities in the VMF design			
Waste Management risk	• Separate sewer line • Separate septic tank/holding tank • Integration of Kill Tank and Effluent Treatment Plant • On site waste incinerator	Presence of the recommended facilities in the VMF design			
Lightning risk	Lightning Prevention System Installation	Presence of the recommended facilities in the VMF design			
Security risk	• Including guard tower, access control systems, CCTV installation, • Remote facility lockdown system	Presence of the recommended facilities			

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
		in the VMF design			
Traffic risk	Separate gate for personnel entrance and finished vaccine loading/distribution	Presence of the recommended facilities in the VMF design			
Electric surge risk	Surge Prevention System Installation	Presence of the recommended facilities in the VMF design			
Construction phase					
Air Quality Impact	● Construction work shall be performed by a reputable and registered contractor with demonstrated environmental awareness and responsibility. ● Contractors should use dust screens or nets in windows, doorways and ventilators of rooms where demolition or other dusty construction activities are occurring, ● Dusty roads and work areas will be regularly watered, at least twice daily or more frequently as needed, to minimize fugitive dust emissions. ● Construction structures shall be enclosed with dust-proof netting to prevent the dispersion of particulate matter. ● Rigorous housekeeping practices needs to be enforced, including prompt sweeping of dust and debris from surfaces and proper disposal of construction waste in covered containers. ● Construction machinery must undergo regular maintenance according to manufacturer specifications to ensure optimal performance and minimize emissions.	Total Particulate Matter, Total organic carbon, Hydrogen chloride, availability of buffer zone, Hydrogen fluoride (HF), Sulfur dioxide (SO2), Sb, As, Pb, Cr, Co, Cu, Mn, Ni and V	Akaki-Kaliti subcity Environmental protection office, MOH Supervisory engineer and Environmental and social Safeguards Specialist	Every three month	2400

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	● Only clean fuels, such as unleaded and low-sulfur diesel, will be used. Fuel sourced from unregulated or potentially contaminated sources is prohibited. ● Provide regular training for construction workers on emission reduction techniques and best practices for minimizing air pollution. ● Workers will be provided with appropriate PPE, including respirators, and the mandatory use of PPE will be strictly enforced.				
Impact on Water Resource	• The contractor should establish designated maintenance areas for trucks and construction machinery, equipped with impermeable surfaces and containment systems to prevent oil and lubricant spills. • Used oils and other liquid waste shall be stored in secure, labeled containers and disposed of as hazardous waste in accordance with local regulations. • Dispose excavated soil only at designated sites with permits from local authorities and environmental clearance from the city administration's EPA office. • Erosion and sediment control measures, such as silt fences, sediment basins, and temporary drainage ditches, must be implemented. • Surface water drains and watercourses shall be protected with cut-off ditches, earth bunds, or other appropriate measures to divert runoff and prevent contamination.	Availability of garage, Availability of water cut-of ditches. Availability of toilet for workers Availability of excavated soil disposal site permits/ sub-contractor permit	Akaki-Kaliti subcity Environmental protection office, ShieldVax, EFDA KIP, MOH Supervisory engineer and Environmental and social Safeguards Specialist	Every month	8,800

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	• Proper portable toilets need to be installed and maintained for the workers, and sewage must be disposed of by a licensed sewage hauler or follow the KIP sewage management system.				
Soil Pollution and Erosion Impacts	• Minimize soil disturbance and control erosion by avoiding steep slopes and reducing the footprint of construction activities, including roads, staging areas, and crane pads. • Collected and recycle all plastic tubes and other recyclable materials generated during construction • Develop and implement a spill response plan for the event of an accidental oil or chemical spill. • Collect and recycle used oils, including engine lubrication oil, hydraulic fluids, and gear oils, or disposed of as hazardous waste according to local regulations. • Prepare a designated maintenance area with an impermeable surface and containment systems for construction vehicles and machinery to prevent soil contamination from leaks and spills.	Availability of spill response plan. Availability of designated maintenance area with an impermeable surface and containment systems. Availability Incidents recorded.	Akaki-Kaliti subcity Environmental protection office, ShieldVax, EFDA, KIP MOH Supervisory engineer and Environmental and social Safeguards Specialist	Every week	*7000*
Noise and Vibration Impacts	• The contractor should prioritize the use of well-maintained and modern equipment with low noise emission ratings. Older or damaged machinery with excessive noise levels will be avoided. • Construction activities exceeding normal working hours should require prior approval from the consultant and client and, when necessary, advanced notification to nearby companies. • Noise levels exceeding 55 dB(A) during daytime	For construction area daytime 75 dB(A) (Acceptable for temporary operations) and nighttime 65 dB(A) (Restricted to essential/emergency work only)	Akaki-Kaliti Sub city Environmental protection office, MOH Supervisory engineer and Environmental and social Safeguards Specialist	Every three months	*5000*

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	hours and 45 dB(A) during nighttime hours will only be permitted with prior approval and a minimum of two days' advance notification to nearby companies. • Restrict activities generating significant noise disturbances to daylight hours and will be subject to the notification procedures outlined above. • Diesel generator sets and other noise-generating machinery must be equipped with acoustic enclosures to minimize noise emissions at the construction site. • All construction equipment and machinery must undergo regular maintenance according to manufacturer specifications to ensure optimal performance and minimize noise generation. • Provide training and awareness creation sessions for construction workers on noise reduction techniques and best practices for minimizing noise generation. • Provide appropriate PPE for workers exposed to high noise levels such as earplugs or earmuffs, and the mandatory use of PPE will be strictly enforced.	Availability of Vehicles maintenance record Availability of training attendance of noise reduction and prevention. Availability of noise protection PPE distribution list.			
Solid Waste Generation Impact	• Collect solid waste from the project site at least once every 24 hours to minimize nuisance odors and vermin infestations. • Segregate and recycle of usable materials. • On-site reuse of inert construction and demolition material, including suitable excavated material to	Absence of accumulated waste in the construction site. Presence of the waste	AA Akaki-Kaliti Sub-city EPA, MOH Supervisory engineer and Environmental and	Every week	*15,000*

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	the maximum extent possible. Only surplus material will be disposed of off-site. • Excavated soil must be promptly removed from the site and disposed of at a designated location with an environmental clearance certificate from the Addis Ababa City Administration.	segregation practice Records related to appropriate disposal.	social Safeguards Specialist		
Liquid Waste Impact	● Wastewater from the concrete batching plant shall be stored in a protected pond within the site and used for concrete curing and watering of buildings, ● Construct separate safety tanks for Construct portable toilets and sanitation of construction workers, ● Used oils and other liquid wastes shall be stored in a secured area in tanks and disposed as hazardous wastes	Availability of separate toilet for construction workers, availability of garages for construction vehicles and machineries	Akaki-Kaliti subcity Sub city Environmental protection office, MOH Supervisory engineer and Environmental and social Safeguards Specialist	Every month	11,000
Traffic and Public Safety Impacts	● Drivers of heavy truck shall be directed by flagmen, ● Limit the speed of the truck to 10 km/hr at the project site ● Initiation of a safety program and measures by creating awareness and educational campaigns for drivers, workers, including monitoring of speed limits, ● Installation of appropriate road signage, speed signs, and other warning signs at the site and access roads, ● Assuring driver's licenses originality and regular construction site trucks technical performance. ● The contractor's vehicles and equipment must be in proper working condition (roadworthy vehicles) and have registration plates and numbering. ● The contractor ensures proper driving discipline by its	Availability of road signs, availability of maintenance plan for vehicles and machineries, incident recorded, signed code of conduct. Availability of separate dedicated gate for heavy trucks and workers.	Akaki-Kaliti Sub-city Environmental protection office, MOH Supervisory engineer and Environmental and social Safeguards Specialist, A.A Traffic management agency	Every month	5,000

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	employees, and sanctions those in breach, ● Use only permitted gates and access road which is allowed for construction machineries and trucks	Availably of training/orientation attendance for the drivers			
Public Health Impacts	● Implementation of HIV/AIDS , Sexually Transmitted Diseases and MOH declared threat epidemic diseases education programs, ● Information campaigns on STDs among the workers and local community, ● Vaccinating workers against common and locally prevalent diseases including COVID-19. ● Provision of condoms, ● Ensuring construction site has constructed onsite wastewater disposal and septic systems.	Availability of training/education attendance related to HIV/AIDS, Sexually Transmitted Diseases and MOH declared threat epidemic diseases Availability of waste water and septic system	Akaki-Kaliti subcity Environmental protection office, ShieldVax, EFDA, KIP, MOH Supervisory engineer and Environmental and social Safeguards Specialist	Every month	15,000
Impact on Cultural, religious & Archaeological Sites	● Apply the chance finds procedure. ● Orientation for excavation sub-constructors on chance find procedure	Availability of chance finds procedure included in the C-ESMP. Availability of chance find procedure orientation attendance	KIP, MOH Supervisory engineer and Environmental and social Safeguards Specialist	Every three months during excavation	-
Risk of Social Conflict and Crime	● The proponent (MOH HILEO/SHIELDVAX) and the contractor should establish a joint project-specific GRM. This mechanism will include a team comprising a construction supervisor and designated officers from HILEO, responsible for receiving, logging, and addressing all stakeholder disputes, conflicts, and concerns. The GRM will	Numbers of job created for local people, Presence of a gender action plan.	ShieldVax, EFDA, KIP, MOH Supervisory engineer and Environmental and social Safeguards	Every month	15,000

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	be established according to the guidelines outlined in Section 16 of this report. • Ensure early and consistent community engagement to address potential issues proactively. • The contractor expected to provide comprehensive orientation to its staff, emphasizing respect for the cultural, religious, and ethnic diversity of workers, and the KIP community. • Salaries can be dispersed via electronic bank transfers to workers' bank accounts, minimizing the risks associated with cash payments. • Local suppliers will be given priority in supplying construction materials, such as sand, bricks, and other locally available resources, whenever feasible. • Local suppliers will be prioritized for employment opportunities to foster a sense of project ownership and community integration. • Open and transparent communication channels must be maintained between all stakeholders to facilitate information sharing and address concerns promptly.	Availability of construction site fence. Availability of GRM System and GRM Committee Availability of recorded complain/grievance	Specialist		
Gender Based Violence	• The contractor should provide orientation to its staff to respect the culture of the local people and to limit their relationship with the local people, • Contractor and implementing agency to prepare and implement a GBV Prevention and Response Action Plan	Availability of signed workers code of conduct. Availability of	Akaki sub-city Women and Social Affairs office, MOH Supervisory engineer and	Every three months	2500

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	to include at a minimum, in conformance with local laws and customs, equal opportunity for employment, • All workers and nearby communities and stakeholders will be educated on preventing and responding to sexual harassment and GBV ahead of any project-related works, • Construction areas shall be separated by a fence and a separate access gate is used for construction workers, • Ensure that women are given a mentorship orientation before starting their work. • Provision of gender-disaggregated data, separate bathing, changing, and sanitation facilities for men and women shall be made ready by the contractor, and • Impose zero tolerance on sexual harassment, all forms of gender-based violence and discrimination at all phases of the project. • MOH must clearly define the SEA/SH requirements and expectations in the bidding documents for contractor • MOH environmental and social safeguards team must ensure that the contractors included GBV prevention and response framework like code of conduct in Contractor Environmental and Social Management Plan (C-ESMP) prior to the commencement of the construction project. • Take appropriate actions on workers violating the CoC.	construction limit fence. Percentage of women employed. Availability of day worktime limit. Availability of training attendance of the GBV prevention and response Availability of SEA/SH requirements and expectations in the contract and sub-contract agreements. Availability of SEA/SH records.	Environmental and social Safeguards Specialist,		
Child Right Violation Impacts	• Enhance the capacity of the social service workforce to identify and respond to potential child labor situations through effective case management and social protection services, including early identification, registration, and follow-up.	Availability of registration and identification of employees to identify	Akaki sub-city women and children and social affairs office, MOH Supervisory	Every three month during construction	15,000

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	● Implement a strict zero-tolerance policy for child rights violations. The contractor must conduct mandatory training for all workers on the consequences of child rights violations. ● The contractor should ensure all workers are at least 18 years of age, particularly for hazardous work, to comply with the project's commitment to preventing child labor. ● The contractor and subcontractors will adhere to standard occupational health and safety standards throughout the construction phase. ● The contractor also must have a legal agreement with the worker including a signed code of conduct. ● The contractor will clearly state the minimum age requirement for general work in their hiring policy and job announcements. ● The MOH must conduct regular checks of labor contracts and supervise the deployed construction workforce to ensure compliance.	the age. Signed workers agreement review. Availability of child labor declaration in the contract and sub-contract agreements.	engineer and Environmental and social Safeguards Specialist		
Occupational Health and Safety Risks	i) **Slip, Trip and Falls Mitigation Measures** - Regularly cleaning the worksite; the worksite shall be neat. - Ensuring employees receive appropriate training and instructions - Deal with spills straight away as per the spill response plan	Availability of OHS plan and emergency plan, Presence of PPE for all workers. Availability of Insurance in which the contractor is a member Availability of buffer	Akaki-Kaliti Sub-city Environmental protection office, MOH Supervisory engineer and environmental social safeguards specialist Akaki-Kaliti Sub-	Every week	150,000

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	- Consider routine monitoring of areas where spills are a high risk - Use absorbent material to soak up the spill - Identify areas at high spill risk and locate absorbent materials nearby - Where possible avoid using wet cleaning as this may spread the potential danger area - Consider using spill kits - Placing readable signs alerting people of hazardous such as for slippery floors, - Ensure slip-resistant footwear is provided and worn as needed providing personal protective equipment (e.g. slip-resistant footwear) if required ii. Eye hazard Mitigation Measures - Always wear personal protective eyewear for workers working on high dust and eye goggles for welders, - Clean your eyewear several times throughout the day, and always brush yourself off before removing your safety glasses. - Follow the recommended measures stated in World Bank EHS guideline, 2007 Welding / Hot Work o Provision of proper eye protection such as welder goggles and/or a full-face eye shield for all personnel involved in, or assisting, welding operations. Additional methods may include the	zone on cliff of the excavation area. Availability of documented work permit Incidence report. Availability of fire extinguisher and Availability of first aid room with full first aid kit. Availability, fire safety management plan. Availability of safety signages. Availability of risk assessment report, Availability of OHS training attendance. Availability of signed code of conduct on work site safety practices. Availability of road	city Social affair office		

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	use of welding barrier screens around the specific work station (a solid piece of light metal, canvas, or plywood designed to block welding light from others). Devices to extract and remove noxious fumes at the source may also be required. o Special hot work and fire prevention precautions and Standard Operating Procedures (SOPs) shall be implemented if welding or hot cutting is undertaken outside established welding work stations, including 'Hot Work Permits, stand-by fire extinguishers, stand-by fire watch, and maintaining the fire watch for up to one hour after welding or hot cutting has terminated. Special procedures are required for hotwork on tanks or vessels that have contained flammable materials. **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.	signage, speed signs, and other warning signs at construction site Availability of adequate PPE. Availability of PPE distribution records. Availability of work permit records. Availability of guardrails for works above 2m. Availability of Safety Full-Body Harness) Fall Protection). Availability of fire extinguishers. Availability of training attendances and records. Availability of Lockout Tag out (LOTO) signages. Availability of complete			

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	- Adjust the height of working surfaces to reduce long reaches and awkward postures, - Put work supplies and equipment within comfortable reach, - Provide the right tool handle for the worker, - Vary tasks for workers (e.g., employ job rotation), - Encourage short rest breaks, **Working at Heights** o Installation of guardrails with mid-rails and toe boards at the edge of any fall hazard area o Proper use of ladders and scaffolds by trained employees o Use of fall prevention devices, including safety belt and lanyard travel limiting devices to prevent access to fall hazard area, or fall protection devices such as full body harnesses used in conjunction with shock absorbing lanyards or selfretracting inertial fall arrest devices attached to fixed anchor point or horizontal life-lines o Appropriate training in use, serviceability, and integrity of the necessary PPE · Inclusion of rescue and/or recovery plans, and equipment to respond to workers after an arrested fall Chemical Hazards o Replacement of the hazardous substance with a less hazardous substitute o Implementation of engineering and administrative control	first Aid Kit. Availability of dedicated first Aid room. Availability of emergency exit procedure .			

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	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 o Keeping the number of employees exposed, or likely to become exposed, to a minimum o 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 shall be in an easily understood language and be readily available to exposed workers and first-aid personnel o Training workers in the use of the available information (such as MSDSs), safe work practices, and appropriate use of PPE Mitigation Measures for Fire and Explosion Hazards ● Storing flammables away from ignition sources and oxidizing materials. ● 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 ● Implementing hot work permits procedures ● Ensure the provision of fire extinguishers at all work				

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	locations and at all times. ● All flammable gases, liquids and vapors are removed before the start of any hot work. ● Where appropriate, use spark-resistant tools and make sure all equipment is bonded or grounded properly, ● The construction site shall be fenced off to prevent access to members of the public, ● Providing adequate storage for hazardous and flammable substances and controlling access to them. ● Designate separate place and equip them with appropriate medical equipment for first aid treatment, ● Providing specific worker training in handling of flammable materials, and in fire prevention or suppression **ii) Electrical Hazards Mitigation Measures** - Inspect portable cord-and-plug connected equipment, extension cords, power bars, and electrical fittings for damage or wear before each use. Repair or replace damaged equipment immediately, - Always locate all power lines on or near the project sites, - Perform regular fire risk assessments to identify areas at risk of bad wiring and circuits, - Maintain proper grounding to eliminate unwanted voltage and reduce the risk of electrocution, - Verify that all wiring is coming from a properly rated				

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	circuit and doesn't exceed the capacity **ix). Biological Hazards Mitigation Measures** - Construction site shall be separated from the main KIP compound by fence and construction workers shall be restricted within the site, - Remove and reduce debris and rubble piles when possible to help keep insects and rodents away. - The worker shall be vaccinated based on the type of pathogens they are exposed to. - In case of any disease outbreak vaccination shall be performed in a construction areas or surroundings to prevent the spread of disease, and - Workers should cover as much of the body as feasible. **x). Traffic Accident Impacts Mitigation Measures** - Limit the speed of the truck to 10 km/hr within the site, - Initiation of a safety program and measures by creating awareness and educational campaigns for drivers, workers and local communities, including observation of speed limits, - Sanctions for reckless driving, - Installation of appropriate road signage, speed signs, and other warning signs at the site and access roads, - Copies of drivers' licenses and insurance policies for the Contractor's drivers and vehicles respectively shall be provided to the Supervision Consultant,				

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	- All construction machineries and cars should have third-parties insurance, - Use only permitted gates and access roads which are allowed for construction machineries and trucks,				
Operation Phase					
Air Quality Impact	• Employ advanced incineration technologies with state-of-the-art emission control systems, including scrubbers, filters, and other pollution control devices, to minimize the release of PCDD/Fs, heavy metals, and gaseous pollutants. • Implement rigorous waste segregation and pre-treatment procedures to remove chlorine-containing materials and other hazardous substances before incineration. • Establish a continuous emission monitoring system to track and record air pollutant levels, ensuring compliance with regulatory standards. • Conduct regular maintenance and inspections of incinerator and emission control systems to ensure optimal performance. • Explore and implement alternative waste management strategies, such as recycling, and	Presence of standard incinerator with flue filter. Availability of incinerator stack height of at least 20m. Availability of standard operating procedure for waste incineration. Availability of qualified operators Availability of regular stakeholder consultation.	Akaki-Kaliti subcity Environmental protection office, EFDA, ShieldVax, KIP	Every three months	40000

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	waste minimization, to reduce reliance on incineration. • Promote energy-efficient appliances and building designs to reduce overall energy consumption and associated GHG emissions. • Conduct regular air quality monitoring around the incinerator site to assess the effectiveness of mitigation measures and ensure compliance with ambient air quality standards. • Ensure all personnel that are operating the incinerators are properly trained. •				
Water Pollution Impacts	• Promoting practices that reduce the volume of wastes generated and ensure proper waste segregation; • Implement strict protocols for the handling, storage, and disposal of chemical disinfectants, including: Using designated storage areas with secondary containment and providing comprehensive training to personnel on safe handling procedures. • Implement the following measures for incinerator ash management: o Treat ash residue to stabilize heavy metals before disposal. o Dispose of treated ash in secured ash pit	Availability of concrete-based safety tank. Availability of waste management plan. Availability of environmentally friendly incinerator ash disposal site. Availability of training attendance on handling and disposal of all hazardous materials	Akaki-Kaliti Sub-city Environmental protection office, Shieldvax, EFDA, KIP	Every three month	7500

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	designed for hazardous waste. ○ Conduct regular monitoring of leachate from ash disposal sites. • Use the KIP WWTP to treat wastewater generated from the VMF and ensure that wastewater effluent discharged from the KIP WWTP meets regulatory standards. • Ensure all personnel are properly trained on the proper handling and disposal of all hazardous materials.				
Soil Pollution impacts	• Implement recommended ash treatment to stabilize heavy metals and reduce their leaching. • Dispose of treated ash in secured ash pit designed for hazardous waste. • Implement rigorous waste segregation procedures to recycle the wastes. • Develop and implement a comprehensive spill prevention and response plan to minimize the risk of accidental releases of hazardous materials.	-Soil test result if there is significant soil pollution -Availability of ash pit management facility	Akaki-Kaliti subcity Environmental protection office, ShieldVax, EFDA, KIP	Every three months	2500
Noise and Vibration Impacts	• Install acoustic enclosures around generators and boilers to minimize noise emissions. • Construct noise barriers or utilize existing structures to attenuate noise from vehicle traffic and maintenance activities.	Availability of machineries complying with noise standard.	Akaki-Kaliti subcity Environmental	Every three months	2500

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	• Select generators and boilers with low noise emission ratings. • Implement a regular maintenance schedule for all equipment to ensure optimal performance and minimize noise generation. • Utilize noise dampening materials in building construction and equipment installations to reduce sound transmission. • Provide PPE for staff working in noisy rooms.	Availability of PPE distribution list for staff	protection office, ShieldVax, EFDA, KIP		
Impacts of Flooding	• Design and construct all critical VMF buildings and infrastructure (production areas, laboratories, storage facilities, power supply) on an elevated platform, including a sufficient freeboard margin to account for uncertainties and potential climate change impacts. • Utilize permeable paving materials for parking areas and walkways to reduce surface runoff and increase groundwater infiltration. Incorporate green infrastructure elements such as bioswales, rain gardens, and vegetated buffer strips to naturally filter runoff and reduce its volume. • Design and install a robust underground drainage network with adequately sized pipes and strategically located inlets to efficiently collect and convey surface water runoff from paved areas and building surroundings. Ensure proper maintenance and regular clearing of this network.	Structural design of the facility	Akaki-Kaliti subcity Environmental protection office, ShieldVax, EFDA, KIP	Every three months	2500

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
Solid Waste Generation Impacts	• Implement strict waste segregation protocols at the source, using color-coded containers and designated storage areas for different waste types. • Autoclave or other approved treatment methods for infectious waste before disposal. • Secure and leak-proof containers for sharps waste, followed by incineration. • Follow the Medicines Waste Management and Disposal Directive waste, 2011 and the World Bank Environmental, Health, and Safety General Guidelines disposal, 2007 Section 1.5 Hazardous Material Management Pharmaceutical Waste Management services Treat ash to stabilize heavy metals before disposal in secure, lined hazardous waste landfills. • Regularly monitor soil and groundwater around disposal sites. • Promote reusable containers and water dispensers to minimize plastic bottle waste. • Implement recycling programs for plastic and other recyclable materials. • Maintain detailed records of waste generation, treatment, and disposal. • Implement a waste tracking system to ensure proper handling and disposal. • Ensure access to post-exposure prophylaxis • Provide comprehensive training to all staff on proper waste handling and disposal procedures.	Availability of waste disposal site, segregation practices and availability of separate collection waste bin. Availability of waste generation, treatment, and disposal records. Presence of constructed incinerator Availability of solid waste management budget in the annual facility plan	Akaki-Kaliti subcity environmental protection office, ShieldVax, EFDA, KIP, AA city Administration solid waste management agency	• Every three months	15,000

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
Impacts of Wastewater generation	• Implement validated sterilization and disinfection methods (e.g., autoclaving, chemical disinfection). • Ensure treated effluent meets Ethiopian environmental regulations for discharge. • Implement robust containment systems and spill prevention protocols within the VMF laboratories. • Properly train all VMF personnel on the correct handling and disposal of biohazardous materials. • Use a modern, on-site sewage treatment system (as recommended in waste management alternative) to treat domestic wastewater before discharge. • Implement regular maintenance and monitoring of the sewage treatment system. • If onsite treatment is impossible/failed, have a contract with a reputable company that will properly remove the waste. • Establish a comprehensive environmental monitoring program, including regular testing of surface water, groundwater, and soil around the facility. • Conduct regular audits of the wastewater treatment systems of the KIP to ensure compliance with Ethiopian environmental standards. • Follow emergency response plan (section) to handle any accidental release of contaminated waste water.	Presence of separate safety tank for hazardous and non-hazardous wastes On-site sewage treatment system Availability of liquid waste management budget in the annual facility plan. Availability records of effluent waste treatment plant efficiency in compliance with World Bank EHS for health facilities guideline.	• Akaki-Kaliti subcity Sub-city Environmental protection office, ShieldVax, EFDA	• Every three months	12,200
Risk of Social Conflict and Crime	• Transparent local community engagement and participation shall begin during initial project decision-making and continue routinely throughout the life of the project, • Awareness-raising among the local community, contract workers and staff about the cultures and norms of the	Numbers of job created for local people, Presence of a gender	Akaki-Kaliti sub city social affair office, Shield Vax, EFDA	• Every three months	5000

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	local community, ● Provision of cultural sensitization training for all staff regarding engagement with the local community, ● Provide awareness creation program about tolerance of diversity and, ● Develop a code of conduct for staff to prevent discrimination and other ethnocentric behaviors.	action plan. Availability of VMF site fence. Availability of GRM System and GRM Committee			
Gender Based Violence	● Establish a gender mainstreaming and monitoring committee, ● Provide awareness to the newly joined workers about the incidence and impact of domestic violence, sexual assault, and stalking, including reporting requirements and options, ● Conduct continued sensitization and awareness raising to VMF staff on the prevention of GBV, ● Strengthen the Gender and women office of MOH to address GBV cases when it occurs, ● On-going prevention training for staff; and ● Provision of gender-disaggregated data, separate bathing, changing, sanitation facilities for men and women shall be ready by institution ● Impose zero tolerance on sexual harassment, all forms of gender-based violence and discrimination at all phases of the project	Availability of signed workers code of conduct. Availability of VMF fence. Percentage of women employed. Availability of day worktime limit. Availability of training attendance of the GBV prevention and response Availability of GBV sensitive GRM	Akaki-Kaliti subcity social affairs bureau, ShieldVax, EFDA	● Every three month	5000
Community Health & Safety Concerns	• Regular community engagement and communication • Establishing functional and responsive GRM	Meeting minutes Numbers of Grievance resolved	Akaki-Kaliti subcity Environmental protection office,	Every three months	2500

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
			ShieldVax, EFDA, KIP		
Public Opposition or Mistrust risk	• Regularly communicating the community on the production efficiency, exported vaccines, locally used, and income generated from the sector. • Undertaking media scanning to early detect and manage public detection, • Undertaking regular consultation with the community representatives and stakeholders.	Meeting minutes, frequency of the community consultation, diversity of participants	Akaki-Kaliti subcity Environmental protection office, ShieldVax, EFDA, KIP	Every three months	2500
Traffic and Public Safety Impacts	• Designate entry/exit points and implement one-way traffic patterns. • Coordinate delivery times to avoid peak traffic hours. • Establish marked loading/unloading areas away from public roads. • Employ marshals during peak hours for traffic direction. • Install clear signage and use variable message signs for real-time updates. • Ensure compliance with traffic laws and collaborate with local authorities. • Conduct audits to evaluate and improve traffic management practices.	Number of accidents that occurred, availability of speed limit	Akaki-Kaliti subcity Environmental protection office, ShieldVax, EFDA, KIP, AA traffic mngt agency	Every month	5000
Public	**Contamination by Adventitious Agents:**	Availability of	Akaki-Kaliti	• Every	15,000

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
Health Impacts	• Stringent Raw Material Sourcing and Qualification • Multi-Barrier Advanced Sterilization and Inactivation • Comprehensive and State-of-the-Art Testing Regimen: • Reversion of Live Vaccines to Virulent Forms: • Prioritize the use of live-attenuated vaccine strains that have been demonstrated to possess a high degree of genetic stability and a low propensity for reversion based on extensive research and post-market surveillance data. Document the genetic characteristics and stability profiles of the chosen strains. • Implement a robust master and working seed lot system, with thorough characterization and quality control testing at each stage to minimize the risk of introducing mutations. Limit the number of passages during production to reduce the potential for genetic drift. • Conduct all manipulations of live vaccine strains, particularly during upstream processing and quality control testing, within laboratories meeting Biosafety Level standards. This includes specialized ventilation systems with HEPA filtration, controlled access, and strict containment protocols to prevent environmental release and occupational exposure. • Establish and maintain a robust pharmacovigilance system for the active and passive surveillance of adverse events following immunization, with a specific focus on monitoring for any signs of vaccine-derived virulence. This system should include timely investigation of reported adverse events, laboratory confirmation where necessary, and prompt reporting to regulatory authorities.	training/education attendance related to HIV/AIDS, Sexually Transmitted Diseases and MOH declared threat epidemic diseases. Availability of wastewater and septic system. Availability of BSCs HEPA filters maintenance. Periodic medical checkup/examination of workers Availability of training for waste handlers and waste management facility operators	subcity Environmental protection office, ShieldVax, EFDA, KIP	month	

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	• For certain live vaccines (e.g., oral polio vaccine), consider implementing environmental surveillance programs (e.g., wastewater testing) to detect the circulation of vaccine-derived polioviruses in the community, allowing for early detection and targeted public health interventions. • Comprehensive On-Site Wastewater Treatment System • Establishing Advanced Air Emission Control Systems • Implementing Robust Spill and Leak Prevention and Containment Protocols • Proactive and Transparent Public Awareness Campaigns on occupational Exposure: • Utilize closed-system bioreactors and automated processing equipment wherever feasible to minimize direct worker contact with biological materials and chemicals. • Use biosafety cabinets (BSCs), isolators, and other containment equipment for handling infectious agents and hazardous materials, if any. • Ensuring mandatory and appropriate personal protective equipment (PPE) usage. • Undertaking pre-employment and occupational health orientation and training program				
Occupational Health and Safety Impacts	**i. Risk of Infection Mitigation Measures** • Workers working in vaccine manufacturing should receive specific training in handling pathogenic and potentially lethal agents and shall be supervised by competent staff in handling infectious agents and associated procedures,	• Availability of infection control waste mgt plan • Availability and use of PPE	Akaki-Kality subcity Environmental protection office, ShieldVax, EFDA	Every three months	3200

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	• All procedures involving the manipulation of infectious materials shall be conducted within a BSC or other physical containment devices, • Persons would wash- their hands after working with potentially hazardous materials and before leaving the facility, • Spills involving infectious materials shall be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material, • Equipment shall be decontaminated before repair, maintenance, or removal from the laboratory, • Workers in the facility should wear protective clothing with a solid front, such as tie-back or wrap-around gowns, scrub suits, or coveralls. Protective clothing will not be worn outside of the laboratory, • Reusable clothing shall be decontaminated before being laundered. Clothing is changed when contaminated, • Potentially infectious materials shall be placed in a durable, leak-proof container during collection, handling, processing, storage, or transport within a facility.	• Availability of safe work procedures • Availability of accident reporting			
	ii. Chemical Hazards Mitigation Measures • To avoid accidental leakage or spillage, secondary containers, such as leak-proof boxes, shall be used, fitted with racks so that the specimen containers remain upright, • Respiratory protection shall be used when carrying out high-hazard procedures. The choice of respirator will depend on the type of hazard(s) and it is available with interchangeable filters for protection against gases, vapors, particulates and microorganisms • Volatile solvents shall be handled in a chemical hood, • Material Safety Data Sheets (MSDS) or equivalent shall be considered while handling, storing, using, and	• Availability of spill clean-up kit and procedure. • Availability of material data sheet and • Availability of safety signages • Availability of safe work procedures	Akaki-Kaliti subcity Environmental protection office, ShieldVax, EFDA	Every three month	3200

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	disposing hazardous chemicals. • Only small amounts of chemicals necessary for daily use shall be stored in the laboratory, • Where corrosive, oxidizing, or reactive chemicals are used, handled, or stored, qualified first-aid would always be ensured. • Either fully buttoned laboratory coats, gowns, coveralls, or long-sleeved, back-opening gowns or coveralls shall be used in the facility. Aprons may also be worn over laboratory coats or gowns where necessary to give further protection during the handling of chemicals, hazardous and infectious materials, and • Eye and face protection (goggles, mask, face shield or other splash guards) shall be used for anticipated splashes or sprays of infectious or other hazardous chemical materials.	• Availability of hood • Availability of adequate PPE • Availability of functional emergency shower and eyewash facilities			
	iii. Risk of Burn or Fire Mitigation Measures • Prepare a fire safety plan and the plan should provide employees or building occupants with the instructions they need to leave the building (or respond as appropriate) in the event of a fire, • Delineating fire and emergency assembly points and creating awareness to ensure all people at the site are aware of them, e.g. through the use of maps on elevators, staircases etc. • All laboratory electrical equipment shall be earthed/grounded, preferably through three-prong plugs, • Combustible materials such as flammable liquids, and solid materials shall be stored in a lockable cupboard, • Fire hazard signs such as 'No Smoking' signs will be provided. Directions to exit in case of any fire incidence and emergency contact numbers will be provided. The contact/emergency numbers will be displayed within the laboratory	• Availability of calibrated fire extinguisher • Availability of material data sheet and • Availability of safety signages • Availability of safe work procedures • Availability of adequate PPE • availability of functional	Akaki-Kaliti subcity Environmental protection office, ShieldVax, EFDA	Every three months	3200

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	• First aid treatment facility shall be also available, • Automatic fire alarm system for the entire laboratory will be installed, • All staff will have training in fire control through regular fire-fighting drills. • Fire extinguishers shall be available in an accessible area near fire-risk areas and ensure that all fire-fighting equipment is regularly maintained and serviced.	emergency shower and eyewash facilities			
	iv. Ergonomic Hazards Mitigation Measures • Training of workers in lifting and materials handling techniques during operation, including the placement of weight limits above which mechanical assists or two-person lifts are necessary, • Planning worksite 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 workstations. • Implementing administrative controls into work processes, such as job rotations and rest or stretch breaks.	• Availability of training attendance for staff. • availability of work rotation schedule	Akaki-Kaliti sub-city Environmental protection office, ShieldVax, EFDA	every three month	3200
	v. Risks related to sharps Mitigation Measures • Injuries should always be reported to supervisors and victims should get medical attention as soon as possible. Collect broken needles in a secure and safe area and dispose all based on WHO standards, • Sharps waste by disposing of it in a sealable container; self-locking and sealable sharps containers are made of plastic so that the sharps cannot easily penetrate through the sides. Such units are designed so that the whole container can be disposed of with other biohazardous waste, with the support of the government.	• Incidence report • availability of safety box for sharps	Akaki-Kaliti sub-city Environmental protection office, ShieldVax, EFDA	Every three months	3200

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	vi. Risk related to Electricity Mitigation Measures • All electrical installations and equipment must be inspected and tested regularly, including earthing/grounding systems. Circuit breakers and earth-fault-interrupters shall be installed in appropriate laboratory electrical circuits, • Implementing lockout/tagout (LOTO) communication system during maintenance. • All laboratory electrical equipment shall be earthed/grounded, preferably through three-prong plugs, • All laboratory electrical equipment and wiring would conform to national electrical safety standards and codes, • Disconnect equipment attached to high-voltage or high-amperage power sources from the source or provide a lockout device on the breaker box to prevent circuit activation before maintenance is performed, • Electrical devices can generate sparks, do not use them near flammable or volatile gases or liquids,	• Implementation of a lockout/tagout (LOTO) communication system during maintenance. • Provision of secure storage for flammable and volatile substances.	Akaki-Kaliti subcity Environmental protection office, ShieldVax, EFDA	Every three month	3200
	vii. Fire and Explosion Mitigation Measures • All staff will have training in fire control through regular firefighting drills, • Fire extinguishers shall be available in an accessible area near fire risk area and ensure that all fire-fighting equipment is regularly maintained and serviced, • Fire emergency telephone numbers shall be displayed in communal areas, • Automatic fire alarm system for the entire laboratory will be installed, • Fire suppression for the facility shall be provided by a standard wet-pipe fire sprinkler system,	Availability of • Training provided attendance • Fire extinguisher • Emergency contact posted • Emergency exit designated • Emergency drill conducted • Smoke, Fire alarm and water hose	Akaki-Kality subcity Environmental protection office, ShieldVax, EFDA	Every six month	3200

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	• Water flow alarms shall be connected to the facilities fire alarm monitoring station so that, • Designated responders shall be notified • Water hose reels will be installed in the laboratory.	installed			
Contamination Risks (Cross-contamination between different vaccine products)	• Implement rigorous cleanroom procedures and aseptic techniques. • Utilize validated cleaning and sterilization methods. • Conduct regular environmental monitoring and product testing.	Availability of quality management system in place.	Akaki-Kality subcity Environmental protection office, ShieldVax, EFDA	Every six month	3200
Equipment and Facility Risks (Malfunction of critical equipment)	• Implement preventive maintenance programs for critical equipment. • Install redundant power systems and backup generators. • Utilize temperature monitoring systems and alarm systems for cold storage.	Availability of contingency Plan	Akaki-Kality subcity Environmental protection office, ShieldVax	Every six month	3200
Risks related to Improper Waste Management	• Develop and implement a waste management plan for the proposed VMF project in particular in accordance with the infection control and waste management plan to guide the daily waste management operations, • Initial packaging and storage would take place where HCW is generated, • Storage of waste will then be moved to a temporary on-site storage location • Controlled incineration of medical wastes with a pyrolysis incinerator shall be done at an operating	Availability of waste management plan. Availability of flue gas treatment system in place	Akaki-Kaliti Sub-city Environmental protection office, Shieldvax, EFDA	Every three month	2400

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	temperature of 800 to 1200oC. ● Electronic waste should not be incinerated at the site, ● Flue gas treatment system shall be used for the control of acid gases, particulate matter, and other air pollutants; ● Hazardous and chemical liquid waste shall be stored in separate concrete-based safety tanks as recommended and disposed of after off-site treatment, ● Wastewater treatment plant works must comply with the effluent discharge guidelines of the country				
Impact of Air Pollution due to Waste Incineration	● Waste segregation for wastes with polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs shall be done and these wastes would never be incinerated, ● Materials free of polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs shall be purchased, for minimizing the environmental and health impacts. ● Workers will be provided with PPE and the use of PPE shall be enforced. ● Improve incinerators and infrastructure for healthcare waste treatment and disposal ● New environmentally friendly incinerator shall be purchased considering the following features: ● Applicable national requirements and internationally recognized standards for incinerator design and operating conditions shall be followed, mainly rapid quenching of the flue gas after leaving all combustion chambers and before entering any dry particulate matter air pollution control device but also combustion temperature, residence time, and turbulence, ● Wastes shall be introduced into the incinerator only after the optimum temperature is reached in the final combustion chamber, ● The waste charging system shall be interlocked with the	Availability of waste incineration standard operating procedure Availability of complain recorded	Akaki-Kaliti Sub-city Environmental protection office, SHIELDVAX, EFDA	Every three month	2400

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	temperature monitoring and control system to prevent waste additions if the operating temperature falls below the required limit, ● Minimize the uncontrolled ingress of air into the combustion chamber via waste loading or another route.				
Risk associated with off-site Transport of Waste	● Employ transfer equipment that is compatible with the characteristics of the materials being moved, ensuring it is designed for safe transfer. Conduct regular inspections, maintenance, and repairs of fittings, pipes, and hoses. ● \ ● Ensure that transportation is thoroughly documented, with all vehicles carrying a consignment note from the collection point to the treatment facility. ● Disinfect vehicles used for transporting waste before repurposing them for any other use. ● Equip vehicles with sufficient supplies of plastic bags, protective clothing, cleaning tools, and disinfectants to manage and clean up any spills effectively.	Presence of vehicles that is suitable for the characteristics of the materials transferred, Presence of contingency plan. Presence of Spill clean plan and kit. Record of training for personnel participating in loading and unloading. Presence of SOP for off-site waste transportation.	Addis Ababa City Administration EPA, Shield Vax, EFDA	Every three month	4600
Risk related with Vaccine quality	● Conducting registration (licensing) of vaccine products, ● Inspection and licensing of vaccine manufacturers, ● Inspection and licensing of vaccine distributors, ● Regulation of claims that can be made for commercial promotion of products, and ● Authorization of clinical trials will be implemented in the regulatory agency.	Number of vaccines registered annually Number of inspections conducted annually • Percentage compliant	EFDA, MOH, WHO	Biannually	5,000,000

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
		with Good Manufacturing Practices (GMP) Number of clinical trial applications processed annually			
Risk related with Vaccine Distribution	• Use temperature monitoring devices (data loggers) throughout the distribution process. • Train staff on proper handling and storage protocols. • Implement contingency plans for equipment failures, including backup power sources. • Diversify suppliers and transportation routes. • Maintain buffer stock of vaccines to cover potential delays. • Develop strong relationships with logistics partners. • Ensure all storage facilities meet regulatory standards. • Conduct regular maintenance and checks on storage equipment. • Provide training for staff on proper storage techniques. • Implement an inventory management system to track vaccine expiration dates. • Establish protocols for redistributing near-expiry vaccines to areas with higher demand. • Educate healthcare providers on efficient vaccine usage. • Establish a system in which the expired vaccine come to the manufacturer for proper disposal • Develop clear communication strategies to educate the public about vaccine safety and efficacy. • Engage community leaders and trusted figures to promote vaccination campaigns. • Monitor social media and public discourse to address	Number of incidents encountered. Number of rumors received. Number of vaccines expired.	Akaki-Kaliti subsidy Environmental protection office, ShieldVax, EFDA, KIP	Every three months	17500

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	misinformation promptly. • Stay updated on regulatory requirements and guidelines for vaccine distribution.				
Decommission Phase					
Air Quality Impact	● Using efficient equipment and machines with efficient engines having low emissions, ● Using clean fuels such de-sulphurized diesel and unleaded fuels, ● Water sprinkling on structures and facilities to be demolished if necessary, and ● Removing components with a potential of emitting hazardous gases or particulates separately and under caution to prevent emissions.	Availability of risk assessment report and C-ESMP for demolition	Akaki-Kaliti subcity Environmental protection office, ShieldVax, EFDA	During decommissioning phase	5000
Noise and Vibration Impacts	● Carrying out the decommissioning works only during the specified time from 8:00 hrs to 17: 00 hrs where permissible levels of noise are high and acceptable, ● Machineries shall be maintained regularly to reduce noise resulting from friction as per the manual, ● Providing workers with Personal Protective Equipment such as earmuffs when operating noisy machinery and when in a noisy environment, ● Provision of bill boards at the construction site gates notifying people of the activities and timings	Availability of PPE for workers, availability of bill board	Akaki-Kaliti Sub-city Environmental protection office, ShieldVax. EFDA	During decommissioning phase	5000
Solid Waste Generation Impacts	● Making available suitable facilities for the collection, segregation and safe disposal of the wastes, and ● Ensuring all waste is dumped in their designated areas and through legally acceptable methods. ● Following regulations on Waste Management in the country, ● Employing a waste management plan, which will involve assessing and creating opportunities for Regulation, Reducing, Recycling, Recovering, and Renovation,	Presence of risk assessment report. Presence of licensed waste disposal sites.	Akaki-Kaliti Sub-city Environmental protection office, ShieldVax, EFDA, KIP	During decommissioning phase	5000

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	● Allocating responsibilities for waste management and identifying all sources of waste, and ensuring waste is handled by personnel licensed to do so;				
Occupational Health and Safety (OHS) Impacts	● Employing an OSH plan that will outline all OSH risks and provide a strategy for their management, ● Ensuring all hazards such as movable parts are labeled, ● Raising awareness and educating workers on risks from equipment and ensuring they receive adequate training on the use of the equipment, ● Providing the workers with adequate PPEs and monitoring regularly to ensure they are replaced on time when they wear out, ● Placing visible and readable signs around where there are risks and undertaking the riskier demolition activities first and in isolation, ● All wastes shall be removed from the site, ● Ensuring there is security in and around the site to control the movement of people, ● Providing safe and secure storage for the waste and materials on the site, ● Placing visible and readable signs to control the movement of vehicles and notify motorists and pedestrians around them, and workers in the site, ● Providing fire-fighting equipment, and in easily accessible areas as well as ensuring site personnel are well trained to use them as well as maintain them regularly, ● Labelling chemicals and materials according to the risks they possess, ● Creating safe and adequate fire and emergency assembly points and making sure they are well-labeled, and	● Availability OSH plan, ● Availability of PPE. ● Availability of training attendance for the workers	Akaki-Kaliti subsidy Environmental protection office, ShieldVax, EFDA	During decommissioning phase	5000

Impact Description	Proposed Mitigation Measures	Monitoring Indicators	Responsible Parties	Monitoring Frequency	Budget required/yr, monitoring ETB
	● Establishing emergency procedures against hazards and ensuring the workers stay aware/educated on following them and commensurate to the magnitude and type of emergency, by conducting regular drills and involving the neighbors. ● Ensuring there is security in and around the site to control the movement of people, ● Providing firefighting equipment and in easily accessible areas as well as ensuring site personnel are well trained to use them as well as maintaining them regularly, ● Creating safe and adequate fire and emergency assembly points and making sure they are well-labeled, and				
Total					5,443,900.00

10 INSTITUTIONAL ARRANGEMENT FOR MONITORING PLAN IMPLEMENTATION

10.1 Institutional Arrangement

During the construction and operational phase, environmental and social monitoring will be conducted collaboratively by the Ministry of Health, Ethiopian Food and Drug Authority, Federal Environmental Protection Authority (or its city counterpart) and the ShieldVax Project Office.

The VMF management shall establish an Environment, Health, and Safety (EHS) unit to oversee mitigation measure implementation and monitoring. Environment, Health, and Safety (EHS) unit will facility monitor biosafety and biosecurity of VMF to ensure compliance with relevant regulations and guidelines, safeguarding the health and safety of staff, researchers, the community, and the environment.

MOH/SheildVax should recruit professional and highly trained experts for VMF. The VMF will employ both full-time and temporary staff, with personnel numbers determined by workload. Key roles include Facility Director, Quality assurance/quality control officer, GMP experts, Biosafety and Biosecurity Officer, HVAC Technician, Electrical Technician, Equipment and Instrument Maintenance Technician, Security Staff, Incinerator Operator, Cleaners, and Effluent Treatment Plant Operator. These personnel will be responsible for ensuring the effective implementation of the Environmental and Social Management Plan (ESMP), with their specific roles and responsibilities detailed in this ESIA report.

10.2 Institutional role and responsibility of Ministry of Health (MoH)

Health Infrastructure Lead Executive Office

The Health Infrastructure Lead Executive Office (HILEO) within the Ministry of Health (MoH) will be responsible for the comprehensive management and oversight of health infrastructure projects throughout construction phase, from design to construction.

- Collaborate with engineering consultancy organizations to integrate recommended mitigation measures into design specifications and technical reports.
- Manage project construction contracts, ensuring that E&S requirements are clearly stipulated and enforceable.
- Conduct regular site supervision to monitor contractor compliance with E&S standards and mitigation measures.
- Ensure that there are regular E&S audits during construction.

- Ensure Contractors has prepared C-ESMP before starting the work
- Delegated staff from HILEO and the construction supervisor's environmentalist will jointly monitor the proper implementation of mitigation measures throughout the construction phase.
- Conduct regular site inspections and audits to ensure compliance.
- Implement a grievance redress mechanism.

Institutional Change Executive Office

This office is responsible to identify and manage all grievance occurred related with all VMF construction and implementation.

- Ensure establishment and implementation of GRMs system in VMF project
- Maintain databases on the status of grievance handling by project GRMs
- Monitor grievance-handling processes
- Coordinate the functions of GRMs
- Monitor the overall grievance redress processes and reporting
- Assess the progress of public complaints resolving through GRCs
- Coordinate and provide training and capacity building related with GRM and community engagement

Women and Social Issues Inclusive Implementation Executive Office

- Provide training on GBV/SEA/SH prevention and Response in collaboration project sociologist.
- Coordinate project related GBV/SEA/SH cases referral and response
- Ensure that GBV sensitive GRM is established

10.3 Institutional Roles and Responsibilities of ShieldVax

SheildVax is a crucial public enterprise under the Public Enterprises Holding and Administration Agency (PEHAA) of Ethiopia, primarily focused on national public health security through the management and operation of the new Vaccine Manufacturing Facility. Its core enterprise role is to ensure Ethiopia's self-sufficiency in critical vaccines by facilitating technology transfer, upholding global manufacturing quality standards (GMP), and building local scientific capacity in biomanufacturing.

- Establish an Environment, Health, and Safety (EHS) unit to oversee mitigation measure implementation and monitoring.

- The ShieldVax Project Office will establish a dedicated biosafety and biosecurity unit to ensure compliance with relevant regulations and guidelines, safeguarding the health and safety of staff, researchers, the community, and the environment
- Providing comprehensive training to personnel handling biohazardous materials, including recombinant or synthetic nucleic acids.
- Ensuring adherence to international best practices such as the NIH Guidelines, BMBL, WHO Biosafety Manual, and this ESIA.
- Establishing and maintaining a Biosafety Committee.
- Implementing a health surveillance program for personnel.
- Reporting significant incidents, violations, or research-related accidents/illnesses to relevant Ethiopian regulatory bodies.
- Developing and implementing guidelines, policies, and plans for smooth facility operations.
- Undertake annual Environmental and social audit and report to the World Bank, EFDA and EPA.
- Update the ESIA to switch from Stage 1 (Fill-Finish) of the project to Stage 2 (Full cycle development).

10.3.1 Organizational Structure of Vaccine Manufacturing Facility

The following structure is considered for organizing the envisaged vaccine manufacturing plant:

- General Manager;
- Deputy General Manager-Technical, and
- Deputy General Manager-Commercial.

Hence, the General Manager, the Deputy General Managers and the Departments under their supervision, as well as the Services under the General Manager constitute the management team of the envisaged vaccine manufacturing plant.

The major organizational units structured under the General Manager and the other two DGM‘s are indicated below.

- **General Manager**
  - Human Resource Management & Development Department;
  - Finance Department;
  - Quality Assurance Department;
  - Regulatory Affairs; and
  - Planning & Information Technology Service;
- **Deputy General Manager (Technical)**
  - Production Department,

- Research & Development Department,
- Material Planning & Warehouse Department;
- Engineering Department, and
- Quality Control Department.

- **Deputy General Manager (Commercial)**
  - Procurement Department; and
  - Sales & Marketing Department.

10.3.2 Management of VMF Activities and Expert Requirements

According to the feasibility study, based on the proposed organizational structure, total number of employees required at full capacity operation is 181. The following list of experts in Table 15 represents the key positions needed.

Table 16: Management of VMF Activities and Expert Requirements

S.N	Department	List of Experts/staff
1.	Office Of the Deputy General Manager-Technical	Deputy General Manager-Technical
		Secretary
		Production Department Manager
		Production Pharmacist
		Production Supervisor
		Operators
		Assistant Production Operator
		Production Cleaner
2.	Quality Control Department	Quality Control Department Manager
		Physico-Chemical Analysis Division Head
		Physico-Chemical Analyst
		Micro-Biological Analysis Division Head
		Biologist
		Documentation Clerk
		Messenger and Cleaner
3.	Engineering Department	Engineering Department manager
		Maintenance Planning and Safety Officer
		Mechanical Engineer
		Electrical Engineer
		Electronics Technician
		Utility Supervisor
		Utility Mechanic
		Attendant
5.	General Service	Security Head

	Department	Guard Shift Leader
		Guard
		Transport Coordinator
		Driver
		Environmental Health, Safety and Sanitation Service Head
		Cleaner

10.4 Institutional Roles and Responsibilities of EFDA

The Ethiopian Food and Drug Authority is the primary regulatory authority responsible for overseeing the development, production, marketing, and surveillance of medical products, including vaccines, in Ethiopia. The EFDA's powers and duties, as defined by Proclamation No. 1263/2021 and Regulation No. 531/2023, are central to the regulatory oversight of the proposed VMF.

- The EFDA is responsible for implementing and following up on the implementation of policies, strategies, and laws related to the regulation of medical products, including vaccines.
- The EFDA will be responsible for the registration, issuance of market authorization, and potentially special regulatory licenses for the vaccines produced at the VMF, based on applicable criteria.
- The EFDA will issue and enforce regulatory criteria concerning regulated products, including GMP standards relevant to vaccine manufacturing.
- The EFDA has the authority to issue certificates of competency or special regulatory licenses to manufacturers of regulated products, such as the proposed VMF.
- The EFDA is responsible for establishing a response system for emergencies caused by regulated products and for collaborating with concerned bodies in such situations.
- The EFDA evaluates clinical trial requests and authorizes, monitors, and inspects clinical trials for vaccines, ensuring adherence to Good Clinical Trial Practice.
- The EFDA adopts and implements relevant international standards, methods, pharmacopeia, and guidelines from organizations like the WHO and stringent regulatory authorities. This underscores the importance of the VMF adhering to WHO GMP standards.
- The EFDA is mandated to establish and implement a modern regulatory system and serve as a regulatory information center.
- The EFDA organizes laboratories necessary for its regulatory functions, which may include testing of vaccines produced at the VMF.

- The EFDA may accept quality assurance reports, inspection reports, declarations, and laboratory results from accredited national or international organizations as deemed necessary.
- The EFDA issues national regulatory criteria for harmonized regulatory activities at the Federal and Regional levels.

Therefore, the establishment and operation of the proposed Vaccine Manufacturing Facility in Ethiopia will be subject to a comprehensive regulatory framework governed by the EFDA, guided by national legislation and international best practices, particularly those outlined by the WHO. Adherence to the principles of Good Regulatory Practices and the specific guidelines related to manufacturing hazardous substances, environmental aspects for preventing AMR, and the transport of infectious substances will be crucial for the successful and compliant operation of the VMF. The VMF's management must establish robust systems and procedures to ensure ongoing compliance with these regulatory requirements and maintain effective communication with the EFDA.

10.5 Roles and Responsibility of Project Implementing Unit

The institutional capacity for managing the complex VMF project rests primarily with the Ministry of Health, which serves as the Implementing Agency, with the Project Implementation Unit (PIU/GMU) acting as the core implementing body.

This structure is built on several key components:

- The Health Infrastructure Lead Executive Office (HILEO) within the MOH is tasked with the comprehensive management and oversight of all health infrastructure projects throughout the construction phase, critically ensuring that Environmental and Social (E&S) requirements are fully integrated into design specifications and technical reports.
- The future management and operation of the VMF will be handled by ShieldVax, a public enterprise under the Public Enterprises Holding and Administration Agency (PEHAA), whose core mandate is to ensure Ethiopia's self-sufficiency in vaccines, and which will oversee the day-to-day implementation of the project plan.
- Integral to ShieldVax's management structure is the mandate to establish a dedicated Environment, Health, and Safety (EHS) unit to oversee mitigation measure implementation and monitoring, with a specific focus on monitoring the biosafety and biosecurity of the VMF.
- To meet the technical demands of a high-containment, cGMP-compliant facility, the PIU/GMU capacity is planned to be substantially enhanced through the recruitment of highly trained and professional experts, including the Facility Director, Quality Assurance/Control Officer, cGMP

experts, Biosafety and Biosecurity Officer, and specialized technical staff such as the Incinerator Operator and Effluent Treatment Plant Operator.

- Finally, the project benefits from Ethiopia's established regulatory environment, as oversight and compliance will be provided by key bodies, including the Ethiopian Food and Drug Authority (EFDA) and the Environmental Protection Authority (EPA), which together provide a robust legal and technical framework.

The PIU for the VMF project is mandated with the following roles and responsibilities, organized by functional area:

- Provide strategic leadership and day-to-day operational management of the VMF construction and pre-operational phases, ensuring all activities are executed within the approved scope, budget, and timeline.
- Oversee the procurement, negotiation, and management of all major contracts, including those for the Engineering, Procurement, and Construction (EPC) contractor, design consultants, and supervising engineers.
- Manage project financial resources, ensuring prudent fiscal management, accurate financial reporting, and compliance with World Bank and national financial regulations.
- Establish a robust Monitoring & Evaluation (M&E) system to track physical and financial progress, and prepare and submit timely, comprehensive progress reports to the MOH, World Bank, and other relevant government bodies.
- Ensure that Good Manufacturing Practice (cGMP) standards are a core consideration during all design, construction, and equipment selection phases to guarantee the facility's future compliance for vaccine production.
- Ensure that the final design of all facilities incorporates all necessary provisions for effective biosafety, biosecurity, and the proper handling and disposal of infectious and hazardous healthcare waste in line with national and international standards.
- Ensure the timely appointment of key operational staff, including the Laboratory Director, Biosafety and Biosecurity Officer, and other essential technical and support personnel.
- Facilitate the preparation of facility-specific operational guidelines, policies, and plans relevant for the smooth and compliant functioning of the VMF.
- Lead the coordination and oversight (in conjunction with MOH/HILEO) for rigorously evaluating and monitoring the contractor's implementation of all Environmental and Social

issues, related management plans, and the fulfillment of all commitments under the scope of the project and World Bank standards.

- Actively participate in the regular updating and revision of the ESMP when triggered by major engineering/design changes, legislative changes, new environmental/social data, or significant stakeholder influence.
- Facilitate the recruitment and employment of competent EHS (Environmental, Health, and Safety) staff and external safeguard experts to work directly under the project's supervision and EHS framework.
- Ensure the immediate notification and detailed reporting (to MOH and the World Bank) of any incident or accident related to the Project which has a significant adverse effect on the environment, communities, or workers.

10.6 Institutional Roles and Responsibilities of Federal EPA

The Ethiopian Environmental Protection Authority (EEPA) is the primary federal agency responsible for environmental protection and sustainable development in Ethiopia. EEPA's role is critical in integrating environmental considerations into all development activities, minimizing adverse impacts, and promoting sustainable practices. Here's its role and responsibilities in ESMP implementation:

- Oversee ESMP implementation.
- Ensures/monitor environmental and social compliances are effectively implemented
- Oversight to ensure that project have implemented a proper GRM, and that the GRM is functioning properly.

10.7 KIP Roles and Responsibilities

- Providing basic utility services like water supply, telecom, electricity,
- Provide wastewater treatment service,
- Provide fire emergency service,
- Ensuring the project design has included 72 hours wastewater holding tank
- Engaging overall grievance redress process.

10.8 Incident Reporting

According to World Bank ESIRT, the Borrower or contractor must notify the Bank promptly (typically within 24 - 48 hours) of any incident or accident related to the project that has, or is likely to have, a significant adverse effect on the environment, affected communities, public or workers.

Specific to this project, the Contractor shall prepare and submit monthly EHS performance reports to the Supervising Engineer (SE) which further reviewed by project Environmental and Social Safeguards Specialists. These reports must demonstrate compliance with the Environmental and Social Management Plan (ESMP), the Contractor's Environmental, Health and Safety Management Plan (EHS-MP), and the project's general EHS obligations.

Each report shall include, but not be limited to, the following information:

- EHS management actions and measures implemented during the reporting period, including any approvals or permits obtained from relevant authorities.
- Summary of EHS incidents, non-conformances, and challenges encountered, including any delays or cost implications resulting from such events.
- Instances of non-compliance with EHS contract requirements and corrective or preventive actions taken.
- Changes or deviations in assumptions, conditions, work methods, or designs that have EHS implications.
- Key observations, issues raised, and decisions made regarding EHS management during site inspections and coordination meetings.

Significant Incident Notification

All major or significant EHS incidents (including accidents, near misses, environmental spills, or property damage) must be reported to the SE immediately or as soon as practicable after occurrence. Each incident shall be documented through a stand-alone incident notification and a detailed follow-up report using the prescribed reporting templates (ANNEX X).

Record Keeping and Documentation

The Contractor shall maintain a comprehensive register of all EHS-related records, including incident reports, health and safety statistics, accident logs, and property damage records. Summaries of these records, together with copies of incident reports, shall be appended to the Contractor's bi-weekly progress reports**.**

11 CAPACITY DEVELOPMENT AND TRAINING

Effective ESMP implementation and monitoring during the construction and operation phases require trained personnel. Capacity development will be achieved through technical support and training

provided to relevant staff from the Ministry of Health (MOH) and SHIELDVAX. Training will focus on occupational health and safety, worker and community safety, and environmental monitoring. An estimated budget of 4,555,000.00 ETB is required for these activities, with a training plan outlined in Table 16.

Table 17: Trainings plan for VMF Staff and Support Staff

Capacity Needs	Target Participant	Number of participants	Estimated Cost (USD)
Training on Infection control and waste management	• Professionals working in VMF Complex • Waste handlers, incinerator operators, liquid waste treatment facility operators and other staff of the VMF	55	750,000.00
Training on OSHA and environmental safety	• Incinerator Operator, Waste handler, Biosafety and biosecurity Officer and other pertinent staff	55	350,000.00
Training on GBV Prevention and Response	• Cleaners, waste transporters and handlers, incinerator operators, facility operators	40	550,000.00
Training on emergency preparedness and response	• Managers • Occupational health and safety officer • Security department • Overall Staff	55	500,000.00
Training on water and energy conservation	• All Staff	60	150,000.00
Training on environmental and social consideration	• VMF/SheildVaxEnvironmental and social safeguard Specialist • Managers • Procurement Specialist	20	50,000.00
Vaccine Development: Overview of vaccine platforms, preparation of antigens (polysaccharide, recombinant, toxoid, inactivated and attenuated)	• Shield Vax Staff	20	1000,000.00
IP and Technology Transfer: IP (Basics of IP, Freedom to Operate (FTO), Licensing and technology transfer, IP Valuation and commercialization, IP	• ShieldVax Staff • EFDA Staff	60	50,000.00

Capacity Needs	Target Participant	Number of participants	Estimated Cost (USD)
Enforcement) and Technology transfer (Matchmaking between tech provider and tech recipient, Negotiation, Preparing legal agreement of IP between parties and managing agreed IP, Dispute resolution, Defining the tech transfer process and know-how, Assessing the capacity and other needs of the recipient party, Documentation)			
Manufacturing (Upstream manufacturing and Downstream manufacturing): Upstream manufacturing: including cell banking, master and working seeds, media (starting materials), growing pathogens of interest, adherent and suspension cell culture, infection and propagation, at scale production using bioreactor, Downstream manufacturing: including harvesting, purification, conjugation, lyophilization, formulation, filling, labeling, Packaging, storing; ascetic manufacturing and sterilization, Warehouse/cold chain management.	• ShieldVax Staff • EFDA Staff	60	50,000.00
Vaccine analytics/Quality controls/Quality assurance including: physical and chemical tests, microbiological, immunological tests etc to determine identity, potency, purity/integrity, safety (sterility, endotoxins,…), stability, consistency, etc of	• ShieldVax Staff • EFDA Staff • VMF Environmental and social safeguard Specialist	60	50,000.00

Capacity Needs	Target Participant	Number of participants	Estimated Cost (USD)
the vaccines;. unit dose calculations and lot release, etc; Validation (lifecycle approach): analytical method validation, cleaning validation, qualification, process validation and software validation			
Biosafety and Biosecurity: Risk assessment and management, containment practices, handling biohazard materials, decontamination procedures, emergency procedures/incident response protocols and development of emergency plan	• Professionals working in facility • Cleaners, waste transporters and handlers, incinerator operators, facility operators	40	650,000.00
GMP Inspection for Regulatory compliance: Facility Design & Layout Evaluation, Advanced Sterile Manufacturing & Aseptic Processing	• EFDA technical experts monitoring the VMF • SheildVAx experts engaged in vaccine manufacturing	60	400,000.00
Facility, equipment and Utility Management: Installation, calibration and maintenance of HVAC, Water system, compressed gas system, Bioreactor, lyophilizer, Chiller, Filling, packaging, labeling machines, CIP/SIP, Good Engineering Practice	• Management Staff • Biomedical Engineers • Electrical engineers • Electromechanical engineers	20	50,000.00
Total			**4,555,000.00**

12 STAKEHOLDER AND PUBLIC CONSULTATION

12.1 Review of Previous KIP Establishment Stakeholder Consultation

The previous KIP establishment ESIA is relevant to the current ESIA because the VMF is located within the KIP compound, which is dedicated to pharmaceutical industries. The Vaccine Manufacturing Facility Construction Project is set to be established on plot C2 within the Kilinto Industrial Park (KIP).

Earlier consultations addressed the potential impacts associated with pharmaceutical industries, making it important to reference the consultations conducted during the KIP's establishment.

As indicated in ESIA of Kilinto Indistrial Park, a key consultation took place on February 5, 2014 and February 07, 2014 with the leadership of Akaki Kality Subcity Woreda 10 Administration and Akaki-Kaliti sub-city administration, respectively, to discuss the nature and type of the Proposed Kilinto Industrial Park Development Project and gather their opinion and recommendations on the project. A total of 18 participants (16 males and 2 females) participated during the establishment of the KIP.

During the consultations, the participants were presented with an overview of the potential positive and negative impacts associated with the project. This included discussions on how the initiative could create jobs, enhance infrastructure, and stimulate local economic growth while also addressing concerns related to environmental impacts and social implications for the community. The engagement aimed to ensure that stakeholders were informed about the project's scope and its potential effects on their lives.

Finally, the consultations provided a platform for gathering feedback from local leaders regarding the project. The meeting ended with recommendations and actions that need to be taken and follow-ups necessary on the part of all responsible stakeholders in the Woreda.

12.2 Current Project Specific Stakeholder Consultation

The consultations included 24 participants (22 Males and 2 Females) from the Ministry of Health, Shield Vax, Kilinto Industrial Park, surrounding security personnel and Ethiopian Food and Drug Authority (Attendance attached in Annex I). The discussions aimed to gauge support for the project, address concerns, and identify potential benefits and risks associated with the facility.

The key issues raised by the participant were duly incorporated in the project design as well as in the ESIA report.

12.2.1 Consultation with MOH design team and ShieldVax experts

The consultation was held with MOH design team and ShieldVax representative on February 13/2025 and February 19/2025 (in the presence of participants from Africure (Dr. Tadesse) and Epharm (Mr. Melaku Tefera). The meeting commenced with a presentation of the draft designs and strategies aimed at optimizing project benefits while minimizing associated risks.

Key findings of the stakeholder consultation were presented as follows:

Stakeholders highlighted the potential benefits of local vaccine production, including improved access to vaccines, reduced dependency on imports, and enhanced national capacity to respond to public health

emergencies. The establishment of this facility is seen as a pivotal step toward strengthening the healthcare system and ensuring that vaccines are readily available for the population.

During the stakeholder consultation, the following concerns were raised:

- The disposal of expired vaccine vials through incineration, along with the management of vaccine wastage shall be considered.
- The implementation of mitigation measures should occur in phases, corresponding to the different project phases associated with waste.

12.2.2 Consultation with KIP management and experts on January 21/2025, and project site security personnel on January 31/2025.

KIP is a key stakeholder, therefore, individual consultations with KIP management and the engineering team were conducted. The discussion focused on onsite waste treatment options for the VMF, such as an incinerator, as well as considerations related to park policy, building height, and buffer zones from the project boundary. Moreover, KIP security system, access control and emergency response issues were discussed.

During the stakeholder consultation, the following concerns were raised:

- The KIP has its own Standard Operating Procedure (SOP); therefore, the consultant should adhere to it. According to the SOP, the client should have its own effluent retention tank capable of holding the facility's effluent for 72 hours.
- The KIP will undertake a weekly meeting with KIP security personnel and the woreda police station, during which every threat and incident is discussed, and a way forward is set for action. This implies there is strong security surveillance in and around KIP.

12.2.3 Consultation with Ethiopian Food and Drug Authority on February 20/2025

During the recent meeting, several critical aspects of the vaccine production facility design were discussed, focusing on biosafety, compliance with cGMP, and material and personnel flow of the facility during operation, waste management, and sustainability of the facility.

Below are the key points from the discussion:

1. Biosafety Level: The facility is designed to operate at Biosafety Level 2 (BSL2), which is appropriate for the vaccine production processes being undertaken during stage/phase I.
2. Changing Rooms: The design includes dedicated changing rooms with separate entry and exit points for Grade B and Grade C areas to maintain cleanliness and prevent cross-contamination.

3. Material Entry/Exit: A color-coded system will be implemented for the entry and exit of materials in Grade B to ensure proper segregation and minimize contamination risks.
4. LAL Testing: Grade C has been deemed adequate for conducting Limulus Amebocyte Lysate (LAL) tests, in accordance with WHO standards.
5. Material of Construction: The facility will primarily utilize Reinforced Cement Concrete (RCC) for structural integrity, with additional aesthetic elements like glass and tiles that will not interfere with internal processes.
6. Environmental Control: The design will ensure that room pressure is adequately managed to protect the environment and maintain unidirectional airflow to prevent cross-contamination.
7. Laundry and Waste Management: Dedicated laundry facilities will be established under the basement of the building for clothing from critical areas, and a separate septic tank will be considered for holding waste, which is connected to the park's waste treatment facilities.
8. Compliance with cGMP: The overall design will adhere to current Good Manufacturing Practices (cGMP), ensuring that all aspects of production meet regulatory standards.

12.2.4 Public Consultation with KIP surrounding residents on June 4/2024

Time: The meeting commenced at 10:00 AM and concluded at 12:30 PM.

Participants: A total of 29 individuals attended, comprising 13 males and 16 females, along with five facilitators from KIP, MOH, and Techinvention. Participants were residents from Woredas 9 and 10 of Kilinto Subsidy, Addis Ababa.

Opening Remarks

The meeting was initiated by Mr. Misikir and Mr. Deribew from KIP management. The consulting team representative outlined the agenda for discussion, which included:

1. Gathering insights on the impact of the park on local communities.

2. Identifying any unresolved environmental and social management issues related to the establishment of KIP.

3. Communicating information about the proposed Vaccine Manufacturing Facility and incorporating community feedback into the Environmental and Social Impact Assessment (ESIA) process.

Then, Mr. Surafel from ShieldVax presented detailed information regarding the project’s objectives, plans, benefits, and current progress.

Following this, a representative from Techinvention discussed the potential impacts associated with the project and proposed enhancement and mitigation measures.

Issues Raised by Participants (Minutes of Meeting attached in Annex II)

Participants were invited to share their concerns and comments, which included:

Impact of KIP:

Participants acknowledged that KIP was established in 2003 E.C., with appropriate compensation provided to displaced farmers and residents. They noted that KIP has positively influenced the local economy by creating job opportunities.

Proposed Vaccine Manufacturing Facility Related Concerns:

- Questions regarding site alternatives and why other locations were not considered for this project.
- Concerns about the potential escape of pathogens from the facility.
- Worries about attenuated microorganisms potentially becoming virulent.
- Queries regarding Ethiopia's capacity to manage such a facility.
- Questions about emergency plans in case of laboratory escapes.
- Emphasis on the need for the project to create job opportunities for local suppliers.
- Concerns regarding waste management practices and the potential threat posed by smoke emissions from the facility.

Responses from Facilitators

The facilitators addressed the participants' concerns as follows:

The selected site is appropriate as KIP is dedicated to pharmaceutical industries. The government aims to consolidate similar industries in one location to enhance resource efficiency and ensure environmental sustainability. The primary objectives of industrial parks include providing improved facilities such as waste management, electricity, and water supply. The project is envisaged to be completed in three stages i.e., Stage 1 – Fill-finish (2028-30); Stage 2 – Formulation & Fill-finish (2030-2033); Stage 3 – Drug substance manufacturing for recombinant and conjugate vaccines & live attenuated measles vaccines (2034-2036). Stage 1 shall involve the importation of ready-to-fill bulk of inactivated vaccines from WHO pre-qualified manufacturers, which will be filled into small containers/vials for distribution. This phase will not involve handling of pathogens. Stage 2: This stage will involve formulation of the inactivated drug substance and fill-finish operations. Stage 3 will involve full-cycle vaccine development, for recombinant, conjugate, and attenuated vaccines.

This phased approach allows for gradual improvement in regulatory capacity, waste management practices, and skill development, ensuring the facility's sustainability. Each transition between the manufacturing stages will require an updated ESIA, including public consultations.

Strengthening an explanation provided by their team, Mr. Yohannis Fetene (Environmental and Social Safeguards Specialist from MOH) provided detailed responses regarding mitigation measures addressing all concerns raised by participants, including site alternatives, waste management practices, national capacity, emergency management protocols, and more.

Closing

Finally, the participants acknowledged the responses and clarifications provided by the facilitators and emphasized the importance of incorporating their comments into the project documents. They expressed a strong desire for the project to be implemented as soon as possible and requested that the consultation process continue throughout the project's lifespan. As a closing remark, the facilitators noted that a grievance redress mechanism will be established to facilitate ongoing feedback from the surrounding community and stakeholders. This mechanism aims to ensure that concerns are addressed promptly and that community engagement remains a priority throughout the project.

13 GRIEVANCE REDRESS MECHANISM (GRM)

Grievances are anticipated during both the construction and operation phases of the VMF project. This GRM establishes procedures, roles, and responsibilities for addressing and resolving disputes and complaints efficiently and transparently. The GRM aims to ensure that appropriate and mutually acceptable corrective actions are identified and implemented, that complainants are satisfied with the outcomes, and that conflicts are resolved without resorting to judicial proceedings.

The objectives of this GRM are to:

- Provide accessible channels for individuals, workers, communities, and organizations to raise concerns about the project's environmental and social impacts.
- Address grievances related to both the construction and operational phases of the VMF project.
- Ensure timely and fair resolution of complaints.
- Promote transparency and accountability in project implementation.
- Strengthen community relations and prevent escalation of disputes.

This GRM is adopted from the GRM Guide Implementation Manual prepared for the World Bank-financed Africa CDC project.

13.1 Grievance Prevention

While grievances cannot be entirely avoided, proactive measures can minimize their occurrence and impact.

General Prevention Measures:

- **Timely Information Disclosure:** Provide sufficient and timely information about the project, its activities, and implementation schedules to affected communities, using appropriate communication channels and accessible formats and languages.
- **Meaningful Community Consultation:** Maintain ongoing consultation and dialogue with communities throughout the project lifecycle to share information, address concerns, and incorporate feedback.
- **Capacity Building:** Equip project staff, particularly community facilitators and field-level staff, with the necessary information, communication skills, and conflict resolution abilities.
- **Good Project Management:** Implement sound project management practices to minimize potential sources of complaints.

Construction Phase-Specific Prevention:

- Clearly communicate construction schedules, potential disruptions (noise, dust, traffic), and mitigation measures to nearby communities.
- Establish clear protocols for contractor conduct and community interaction.
- Implement measures to minimize construction-related impacts such as noise, dust, traffic congestion, and damage to infrastructure.

Operational Phase-Specific Prevention:

- Maintain open communication channels regarding facility operations, environmental performance, and community engagement initiatives.
- Establish protocols for waste management, emissions control, and handling of hazardous materials, and communicate these protocols to the community.
- Implement occupational health and safety programs to protect workers and prevent accidents.

13.2 GM procedure

The following steps will be used to manage all grievances:

Step 1: Receipt and Registration of complaint

- Complaints can be submitted through various channels:
    - In person to designated personnel of the Contractor and/or MOH.
    - Complaint register form.
    - Telephone to MOH (+251-11 551 7011).
    - Email to moh@moh.gov.et.
    - Online application for the World Bank.
- The GRM focal person will receive the complaint and record it in a complaints log, including the date, action taken, and information provided to the complainant.
- The log will indicate grievances, the date lodged, action taken to address the complaint or reasons the grievance was not acted on; information provided to the complainant and date the grievance was closed.
- The complaint shall be recorded, read back to the complainant to confirm accuracy, and signed by the complainant.
- Contact information for the GRM focal person will be widely disseminated through the project website, public meetings, and project brochures.

Step 2: Eligibility and Assessment

- The focal point will establish the eligibility of the complaint based on the following criteria:
    - The complainant is identifiable and has provided contact details.
    - The complainant is affected by the project.
    - The complaint has a direct relationship to the project.
    - The issues raised fall within the GRM's mandate.
- If the complaint is ineligible, the complainant will be informed with reasons.
- If eligible, the seriousness of the complaint will be assessed (high, medium, or low) based on:
    - Severity of the problem.
    - Potential impact on the well-being of an individual or group.
    - Potential impact on the project.
    - Public profile of the issue.
- Assessment may involve field visits, discussions with complainants and relevant parties, and information verification.

Step 3: Formulation of response and corrective action

- A response will be formulated and communicated to the complainant, including:
    - Acceptance or rejection of the complaint.
    - Reasons for acceptance or rejection.
    - Next steps and where to forward the complaint (if applicable).
    - A timeframe for resolution.
    - Requests for further documents or evidence (if needed).
- If the complaint is resolved at this stage, the corrective action and timeframe will be determined in consultation with the complainant and recorded in the complaint log.
- Grievances will be resolved, and status reported back to complainants within a week. If more time is required, the complainant will be informed.
- Unresolved cases will undergo detailed investigations, with results discussed within one month of lodging the grievance.
- Grievances beyond the capacity of project supervisors or VMF heads will be communicated to a higher level.
- Complainants have the right to seek legal recourse if they believe their grievance was not handled fairly.

Step 3: Meeting with the complainant

- The proposed corrective action and timeframe will be discussed with the complainant within one week of receiving the grievance.
- Consent to proceed with the corrective action will be sought from the complainant.

Step 4: Implementation of corrective action

- Agreed corrective action will be implemented by the project or contractor within the agreed timeframe.
- The date of completion will be recorded in the log.
- Once a response has been determined for a complaint, the Grievance Focal Person should log this in the GRM log sheet, they should mark the complaint resolved, and they should draft a response letter to the complainant based on the standard letters.
- A copy of the letter shall be kept in the records with the original complaint form.
- Response letters shall be delivered back to complainants in a timely fashion.
- Each case shall be dealt with individually, and response provided as per standard number of days for feedback as indicated.

- Response letters can be delivered by the Grievance Focal Person.
- When complaints are referred to other offices, the GRM team to be established by MOH should send a letter back to the complainant explaining that the complaint was referred and including contact information for the person to whom the complaint was referred.
- For complaints where there is a contact phone number, a phone call may be used to deliver the initial response on the complaint (if there is a phone call available).

Step 5: Verification of corrective action

- The aggrieved person will be asked to confirm their satisfaction with the corrective action.
- If the complainant is still dissatisfied, they may pursue formal legal processes.
- Courts shall be the last avenue for addressing grievances.
- The grievance will be closed out in the log.

Step 6: Action by MOH and project contractors

- If the work supervisor cannot resolve the grievance, it will be referred to MOH/SHIELDVAX and the contractor through the supervising engineer.
- Grievance resolution strategies may include:
    - Requesting relevant agencies to address the grievance's cause (e.g., contractors clearing access roads, managing noise/dust).
    - Determining reasonable compensation for damages or losses.
    - Signing agreements between affected parties and the project for mutually agreed solutions.
    - Ensuring contractors address grievances at the end of project work (e.g., paying compensation and issuing assurance letters).
    - Initiating monitoring to assess further impacts after addressing the initial problem.

13.3 Gender-Based Violence (GBV) Related Grievance Redress

- GBV-related grievances will be handled with strict confidentiality.
- Complaints will be reported to the PIU coordinator, and immediate action will be taken consistent with the complainant's wishes, rights, and dignity.
- Complainants will be informed clearly about complaint procedures, possible outcomes, timelines, and available support.
- Access to complaint processes will be easy, confidential, and safe for the complainant/survivor.

- Incident recording will be limited to the nature of the complaint (in the complainant's words), the survivor's age, and, if known, the perpetrator's association with the project.
- The complainant will decide whether to be referred to the grievance committee and will give consent to share basic monitoring data.
- The survivor's safety and well-being will be prioritized throughout the process.
- Confidentiality of complainants, survivors, and other parties will be maintained.
- A survivor-centered approach will be followed, respecting the survivor's choices, needs, safety, and well-being.
- The mechanism will be accessible and non-discriminatory, with information provided on how to access it.
- Reports from third parties (witnesses, etc.) will also be accepted and follow accountability protocols.

13.4 Labor Related GRM

- All project workers, individual contractors, and laborers working with contractors have the right to have their complaints addressed.
- The project will primarily involve Ethiopian workers, many of whom may be government civil servants subject to their existing employment terms.
- Anticipated labor-related risks include OHS issues, community health and safety, GBV, discrimination, and unequal opportunities.
- The project recognizes the vulnerability of target communities, labor influx, beneficiaries, and different types of workers.
- The contractor will establish a GRM for workplace which will handle employment-related conflicts and GBV cases.
- Project workers with complaints have the right to present them and obtain redress.
- The GRM will serve direct and contracted workers, and complaints can be received anonymously through a digital system or physical options like suggestion boxes.
- The redress process will follow similar procedures as other grievances, ensuring transparency, timely feedback in an understandable language, and operation in an independent and objective manner.

13.5 Grievance Management Mechanism During Construction Phase

- During construction, the proponent and contractor will jointly establish a project-specific GRM.
- This team will include the construction supervisor and delegated officers from the MOH, Health Infrastructure Lead Executive Office.

- The team will receive, log, and address disputes, conflicts, or concerns from stakeholders aggrieved by the project.

13.6 World Bank's Corporate Grievance Redress Service (GRS)

- Project-affected communities and individuals can submit complaints to the World Bank's independent Inspection Panel.
- Complaints can be submitted after concerns have been brought to the World Bank's attention and management has had a chance to respond. For information on how to submit complaints to the World Bank's corporate Grievance Redress Service (GRS), please visit Grievance Redress Service.
- Information on submitting complaints to the GRS and Inspection Panel is available at the provided websites.

13.7 Integrating the VMF GRM with KIP/IPDC GRM

- As outlined in the previous section regarding the KIP grievance redress mechanism, grievances are addressed through the established Grievance Redress Management Committee. If issues remain unresolved, individuals have the option to escalate their concerns to the IPDC, either in person or via their website.
- The proposed Grievance Redress Mechanism (GRM) for the VMF to be constructed within KIP will integrate smoothly with these existing processes, ensuring a consistent and effective approach to addressing stakeholder concerns. The VMF grievance redress committee will undertake weekly meetings to discuss and resolve any issues or complaints. This alignment will provide stakeholders with a cohesive framework for raising concerns, fostering trust and transparency, while enhancing communication and accountability throughout the project.

14 EMERGENCY PREPAREDNESS AND RESPONSE PLAN

An emergency is an unforeseen event or situation that poses risks to human health, property, or the environment, affecting either the facility itself or the surrounding community. Emergency response plan for a Vaccine Manufacturing Facility is critical to ensuring safety and minimizing disruptions during various disaster scenarios. By implementing a comprehensive emergency response plan, a Vaccine Manufacturing Facility can ensure that it is prepared to respond effectively to various disaster scenarios while prioritizing the safety of its personnel and the integrity of its operations.

The emergency response plan is designed to ensure the safety of all personnel and visitors, protect facility assets and vaccine products, maintain compliance with regulatory requirements, and facilitate a quick recovery and continuity of operations. To ensure effective emergency preparedness and response, key personnel have been designated along with their specific responsibilities. Various emergency scenarios have been identified, and response actions have been established based on best practices. Additionally, general recommendations have been included.

14.1. Key Personnel and Their Responsibilities

Table 18: Key Personnel and Their Responsibilities for Emergency Preparedness and Response

S.No	Key Personnel	Responsibilities
1.	General Manager	● Overall authority during emergencies. ● Communicate with external authorities (e.g., local emergency services, regulatory bodies). ● Ensure that the emergency response plan is reviewed and updated regularly. ● Lead post-incident reviews and implement improvements.
2.	Safety Officer	● Develop and maintain the emergency response plan. ● Conduct regular safety drills and training for all staff. ● Oversee the safety equipment inventory (e.g., PPE, first aid kits). ● Act as the primary contact for safety-related issues during an emergency. ● Coordinate with local emergency services for support.
3.	Security Department	● Monitor facility security systems (CCTV, alarms). ● Control access to the facility during an emergency. ● Assist in the evacuation process, ensuring all personnel are accounted for. ● Provide crowd control if necessary and support first responders upon arrival. ● Maintain communication with the Safety Officer regarding any security threats.
4.	General Staff	● Attend training sessions on emergency procedures and protocols. ● Participate in drills and exercises. ● Follow instructions from the Safety Officer and General Manager during emergencies. ● Report any hazards or unsafe conditions immediately. ● Assist in evacuating personnel if necessary.

14.2. Emergency Scenarios and Procedures

S.No	Emergency Scenarios	Action to be taken	
		Immediate action	**Post-Emergency action**
1.	Fire Emergency	● Activate fire alarms and notify the fire department. ● Evacuate all personnel according to the evacuation plan. ● Use fire extinguishers on small fires if safe to do so.	● Conduct a headcount to ensure everyone is safe. ● The Safety Officer will assess damage and coordinate with fire officials.
2.	Chemical Spill	● Evacuate affected areas immediately. ● Notify the Safety Officer and initiate spill containment procedures using spill kits. ● Follow Material Safety Data Sheets (MSDS) for specific chemicals involved.	● Conduct a thorough cleanup with trained personnel. ● Review spill response protocols for improvements.
3.	Sample or wastes with infectious agent spill	● Evacuation of personnel from the contaminated area ● Notify the Safety Officer and initiate spill containment procedures using spill kits.	● Conduct a thorough cleanup with trained personnel. ● Decontamination or disinfection of the protective clothing, if necessary.
4.	Potentially Infectious Aerosol Release	● All persons should immediately vacate the affected area and any exposed persons shall be referred for medical advice, ● Notify the biosafety officer immediately.	● If the laboratory does not have a central air exhaust system, the entrance shall be delayed (e.g. for 24 h). ● Signs shall be posted indicating that entry is forbidden. ● After the appropriate time, decontamination should proceed.

5.	Natural Disaster (e.g., earthquake, flood)	● Follow established protocols for securing equipment and materials. ● Evacuate to designated safe areas or shelters as per the disaster plan.	● Assess structural integrity of the facility before re-entry. ● The General Manager will communicate with local authorities for recovery efforts.
6.	Active Shooter or Security Threat	● Lockdown the facility and secure all entry points. ● Notify law enforcement immediately. ● Follow "Run, Hide, Fight" protocol as appropriate.	● Conduct a headcount after the situation is resolved. ● Provide mental health support to affected employees.
7.	Accidental contaminated wastewater release	● Communicating the incident immediately ● Environmental remediation	● Investigating the incident, identifying the root causes, immediate causes and underlying causes ● Developing corrective action plan. ● Establishing regular monitoring of treatment unit functionality and efficiency

14.3.Emergency Procedures for Vaccine Production, Storage and Distribution

A. Vaccine Production

- Implement stringent quality control measures during the production process to ensure vaccine efficacy and safety. This includes Good Manufacturing Practices (GMP) compliance.
- Ensure that all personnel involved in vaccine production are adequately trained in safety protocols and emergency procedures.
- Conduct regular risk assessments to identify potential hazards in the production process, including biological, chemical, and physical risks.

B. Storage

- Vaccines often require specific temperature ranges for storage. Implement continuous monitoring systems to ensure that storage conditions are maintained, with alarms for deviations.
- Use a first-in, first-out (FIFO) system to manage vaccine inventory effectively and minimize waste.

- In case of power outages or equipment failures that could compromise vaccine integrity:
  - Ensure all backup systems and equipment are available and regularly tested and maintained.
  - Activate backup power sources immediately to restore refrigeration.

C. Distribution

- Ensure that vaccines are transported under controlled temperature conditions. This includes using validated shipping containers and monitoring devices.
- Provide training for all personnel involved in transportation on handling procedures and emergency response protocols.
- Implement tracking systems to monitor the movement of vaccines from production to administration, ensuring accountability and quick response in case of issues.

14.4. General Emergency Preparedness and Response Strategy Recommendations

- Conduct regular training sessions for all staff on emergency procedures specific to each scenario.
- Schedule drills at least twice a year to practice evacuation, lockdown, and other emergency protocols.
- After each drill or actual incident, conduct a debriefing session to discuss what went well and what could be improved.
- Establish a clear chain of command for communication during emergencies. Ensure that all staff are aware of communication protocols.
- Ensure that first aid service is prepared to handle casualties, including triage and transportation to medical facilities.
- Identify and communicate designated evacuation routes and assembly areas to ensure safe movement away from danger zones.
- All cases shall be registered and annually reported to the MOH.
- Maintain a written emergency procedure/protocol accessible to staff for each type of emergency scenario.
- Conduct reviews following the response phase to evaluate what worked well and what could be improved.
- Update the emergency response plan based on feedback and lessons learned.

15 CONCLUSIONS AND RECOMMENDATION

15.1 Conclusion

The Environmental and Social Impact Assessment (ESIA) for the proposed VMF in Kilinto Industrial Park, Addis Ababa, Ethiopia, has identified both positive and negative impacts associated with the project. The positive impacts include job creation, income generation, business opportunities, improved community health, and the development of a skilled workforce. These benefits are expected to contribute significantly to local, national, and regional development.

However, the project also poses several negative impacts during its pre-construction, construction, operation, and decommissioning phases. These include a possibility of minor air and soil pollution, erosion, noise and vibration disturbances, landscape and visual impacts, traffic safety concerns, wastewater generation, solid waste production, and increased pressure on public services. Occupational health and safety risks are particularly significant during both the construction and operation phases, with potential for air and water pollution, hazardous and waste generation, diseases, waste handling and transportation challenges, and fire hazards.

Environmental and Social Management Plan (ESMP) and monitoring plan have been prepared to mitigate these negative impacts and ensure compliance with World Bank Environmental and Social Standards and national regulations. Moreover, summary of Selected Waste Treatment and Management Technologies/Approach for Shieldvax (Vaccine Manufacturing Facility) is presented in Table 19.

Table 19: Summary of Selected Waste Treatment and Management Technologies/Approach

S. N	Waste Type / Source	Selected Treatment Technology	Key Processes / Components	Rationale for Selection
1	***Non-Hazardous Solid Waste***	Source segregation, recycling & reuse within KIP transfer station	Source sorting → transfer to KIP centralized transfer station → further sorting → recyclable diversion → residuals to Repi landfill	Reduces landfill burden; aligns with KIP and municipal standards; promotes circular economy; minimal environmental impact.
2	***Biological Waste***	High-temperature Pyrolytic Incineration (≥50 kg/hr) with air pollution control systems	Pneumatic/hydraulic waste loading, dual-chamber combustion, gas scrubbing/filtering, automatic ash removal	Complete pathogen destruction, waste volume reduction, compliance with WHO and EHS emission limits, and biosecurity assurance.
	Hazardous Incinerator Ash	Secured Concrete Ash Pit	Deposit in lined, fenced, impermeable pit	Prevents leachate contamination, ensures groundwater protection, and meets FMHACA waste

4				management directives.
5	***Liquid Waste (Process Effluent)***	Kill Tank + Onsite Effluent Treatment + Discharge to KIP WWTP	Disinfection (heat/chemical) → neutralization → retention (72 hr tanks) → discharge to KIP WWTP	Ensures pathogen/chemical neutralization, compliance with effluent discharge standards, reduces contamination risk.
6	***Sludge from Effluent Treatment (KIP)***	Dewatering (centrifuge) & Secure Disposal	Thickening → centrifuge dewatering → storage yard → disposal to Repi landfill	Minimizes volume, facilitates safe handling and disposal per KIP sludge management SOP.
7	***Domestic Sewage***	Septic / Holding Tanks (72-hour capacity)	Sedimentation → temporary storage → transfer to KIP WWTP	Cost-effective, low-maintenance solution for temporary retention; ensures compliance with KIP wastewater management system.
8	***Recyclable Waste (packaging, containers, metals)***	Reuse and Recovery Programs	Sorting → material recovery (plastic, metal, glass) → local recycling streams	Reduces waste volume, supports resource recovery, cost-effective and environmentally friendly.

15.2 Recommendations

1. Implement and monitor the ESMP during all project phases to ensure compliance and address any emerging issues promptly.
2. Follow maximum safety and health procedures during construction and operation phases to protect workers and the community.
3. Focus on managing the most significant environmental and social impacts identified in the ESIA report.
4. Include the construction of a standard incinerator, secured and ash pit
5. Ensure the integration of onsite effluent holding tank, kill-tank, effluent treatment plant, and separate safety tanks for hazardous and ~~infectious~~ biological liquid waste treatment and storage in the VMF design.
6. Utilize environmentally friendly technologies and establish reliable information systems for handling dangerous substances and maintaining safety equipment.
7. Involve stakeholders and local communities in different stages of the project to ensure sustainability and community support.

8. Ensure contractors prepare site-specific environmental and social management plans and get approval from MOH environmental and social safeguards team before starting construction activities.
9. Closely work with KIP particularly on waste management, grievance resolution security issues.
10. Acquire cGMP approval from concerning body before commencing the manufacturing process.
11. Provide adequate and regular training for staff on biosafety, biosecurity, emergency response and waste management.
12. Since the vaccine manufacturing process is divided into ~~two~~ three stages ~~phase~~, with the first phase scheduled to commence by 2028:

    - ShieldVax/MOH at a later stage must update this ESIA to switch from stage one (Fill-Finish) of the project to stage two and three, and submit to the World Bank for approval.
    - ShieldVax/MOH shall undertake annual environmental and social audit and report to the World Bank, EFDA and EPA.
    - The EFDA and ShieldVax should enhance their capacity in terms of expertise and laboratory facilities to reach maturity level 3.
    - KIP should finalize the construction of the wastewater treatment plant (WWTP).
    - The EPA and MOH should establish central hazardous waste disposal facilities.

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24. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8)
25. WHO good manufacturing practices for sterile pharmaceutical products (Annex 6)
26. TRS 1044 - Annex 2: WHO Good Manufacturing Practices for Sterile Pharmaceutical Products

ANNEX I: ATTENDANCES FOR THE STAKEHOLDER AND PUBLIC CONSULTATIONS

በቂሊንጦ ኢንደስትሪያል ፓርክ ውስጥ cGMP Compliant Vaccine Manufacturing Facility ለማቋቋም ለአካባቢ እና ማህበራዊ ተፅእኖ ግምገማ (ESIA) ከባለድርሻ አካላት ጋር የተደረገ ውይይት ተሳታፊዎች

የካቲት 06/2017 ዓ.ም.

በቂሊንጦ ኢንደስትሪያል ፓርክ፣ አዲስ አበባ

ቁ.	ሙሉ ስም	የመጡበት መ/ት	ጾታ	ዕድሜ	ፊርማ
1.	[illegible]	[illegible]	ወ	[illegible]	
2.	[illegible]	>>	ሴ	[illegible]	
3.	[illegible]	>>	ወ		
4.	[illegible]	[illegible]			
5.	[illegible]	[illegible]	ወ		
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በቂሊንጦ ኢንደስትሪያል ፓርክ ውስጥ cGMP Compliant Vaccine Manufacturing Facility ለማቋቋም ለአካባቢ እና ማህበራዊ ተፅእኖ ግምገማ (ESIA) ከባለድርሻ አካላት ጋር የተደረገ ውይይት ተሳታፊዎች

የካቲት 06/2017 ዓ.ም.

በቂሊንጦ ኢንደስትሪያል ፓርክ፣ አዲስ አበባ

ቁ.	ሙሉ ስም	የመጡበት መ/ት	ጾታ	ዕድሜ	ፊርማ
1.	ጀሌቲ ፊጋዳ	ቢሰና ወረዳ ጽ/ቤት	ወ	[redacted]	
2.	አብዲ ሸመሰንሀ	>>	ወ	[redacted]	
3.	አንዳርጋቸው ታደሰ	>>	ወ		
4.	ሄለር ወርቁ አበበ	ጽ/ቤት/መምሪያ ሀ			
5.	ሀጎስ ፍስሀ	ጽ/ቤት ያማጽ	ወ		
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በቂሊንጦ ኢንደስትሪያል ፓርክ ውስጥ cGMP Compliant Vaccine Manufacturing Facility ለማቋቋም ለአካባቢ እና ማህበራዊ ተፅእኖ ግምገማ (ESIA) ከባለድርሻ አካላት ጋር የተደረገ ውይይት ተሳታፊዎች

ጥር 23/2017 ዓ.ም.

በቂሊንጦ ኢንደስትሪያል ፓርክ፣ አዲስ አበባ

ቁ.	ሙሉ ስም	የመጡበት መ/ት	ጾታ	ዕድሜ	ፊርማ
1.	ተስፋልርቃኖ ኃይሌ	ቂሊንጦ ዲ/ኢ/ዞ	ወ	35	
2.	ገ/ክንድ ተክለ	ጉጭት Healthy	ወ	55	
3.	ይገኔ ሻ ረዲ	የጭሮ ማዘጋጃ ቤት	ወ	29	
4.	ቀነዒ ሰመ	ምሽ ሰፈ	ወ	35	
5.	ኮሎኖ:ሮ ሰ	ቴሌን·ቡቦርሳ	ሴ	40	
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በቂሊንጦኢንደስትሪያልፓርክውስጥለሚቋቋምcGMP Compliant Vaccine Manufacturing Facility Plan and Design'በተሞክሮተከባለድርሻአካላትጋርየተደረገ ወይይት

የካቲት13/2017ዓ.ም.

ቦታ: የኢትዮጲያምግብና መዳሃኒትባለስልጣን አዳሰለበባ

ተ.	የተሳታፊሙሉስም	የሚወክሉትተቋም	ጾታ	ፊርማ
1.	ሳሙኤል ማሬ(SamuelMare)	EFDA	M	
2.	ሸምሰዲን ኢሰአ(shimeID Asfaw	MOH-HILEO	M	
3.	ተፈሪ ማሞጋሳ	EFDA	M	
4.	ማርቆስ ጌጡ	Shieldvax	M	
5.	Sarang Pathak	Techimvention	M	
6.	Ajit Nair	Techinvention	M	
7.	Abdela Kasso	EFDA-GMP	M	
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በቂሊንጦ ኢንደስትሪያል ፓርክ ውስጥ ለሚቋቋመው ክትባት ማምረቻ (Vaccine Manufacturing Facility) የአካባቢና ማህበራዊ ተጽእኖ ግምገማ ፓርኩ ዙሪያ ከሚኖሩ ማህበረሰብ ጋር የተደረገ ውይይት

የስብሰባው ቦታ፡ ቂሊንጦ ኢንደስትሪያል ፓርክ፣ አዲስ አበባ

ቀን፡ ግንቦት 27/2017 ዓ.ም.

ቁ.	የተሳታፊው ስም	የመጡበት አካባቢ/አድራሻ	ጾታ	ስልክ	ፊርማ
1.	[illegible]	[illegible] ቂሊንጦ	ወ	0912021898	
2.	[illegible]	[illegible]	ሴ	0910987300	
3.	[illegible]	[illegible]	ወ	0913741109	
4.	[illegible]	[illegible]	ወ	0921067154	
5.	[illegible]	〃 〃	ወ	0913483060	
6.	[illegible]	[illegible] ወ-9	ሴ	0965690981	
7.	[illegible]	〃 〃	ሴ	0921180080	
8.	[illegible]	〃 〃	ሴ	0938279051	
9.	Gadise Kuma	〃 〃	ሴ	0980552066	
10.	Sukare Dekere	〃 〃	F	0992432817	
11.	[illegible]	〃 〃	ወ	098708[illegible]026	
12.	[illegible]	〃 〃	ሴ	0920533499	
13.	[illegible]	〃 〃	ወ	0965804173	
14.	[illegible]	〃 〃 〃	ሴ	0921738142	
15.	[illegible]	〃 〃 〃	ሴ	0923940082	

በቂሊንጦ ኢንደስትሪያል ፓርክ ውስጥ ለሚቋቋመው ክትባት ማምረቻ (Vaccine Manufacturing Facility) የአካባቢና ማህበራዊ ተጽእኖ ግምገማ ፓርኩ ዙሪያ ከሚኖሩ ማህበረሰብ ጋር የተደረገ ውይይት

የስብሰባው ቦታ፡ ቂሊንጦ ኢንደስትሪያል ፓርክ፣ አዲስ አበባ

ቀን፡ ግንቦት 27/2017 ዓ.ም.

ቁ.	የተሳታፊው ስም	የመጡበት አካባቢ/አድራሻ	ጾታ	ስልክ	ፊርማ
1.	[illegible]	ቂሊንጦ/[illegible] 01	ወ	0934187491	
2.	[illegible]	[illegible] 09	ወ	09046317[illegible]	
3.	Jemila Fentaw	[illegible]	ሴ	0901421338	
4.	[illegible]	〃 09	ሴ	0962363959	
5.	[illegible]	〃 09	ሴ	0921733811	
6.	[illegible]	〃 09	ሴ	0941139558	
7.	[illegible]	〃	ሴ	0954909053	
8.	[illegible]	〃 03	ሴ	0921299455	
9.	[illegible]		ሴ	0943882380	
10.	[illegible]	ወ-9	ሴ	0911565923	
11.	[illegible]	ወ-9	ወ	0913175664	
12.	[illegible]	ወ-10	ወ	0911764362	
13.	[illegible]	ወ-10	ወ	0968236155	
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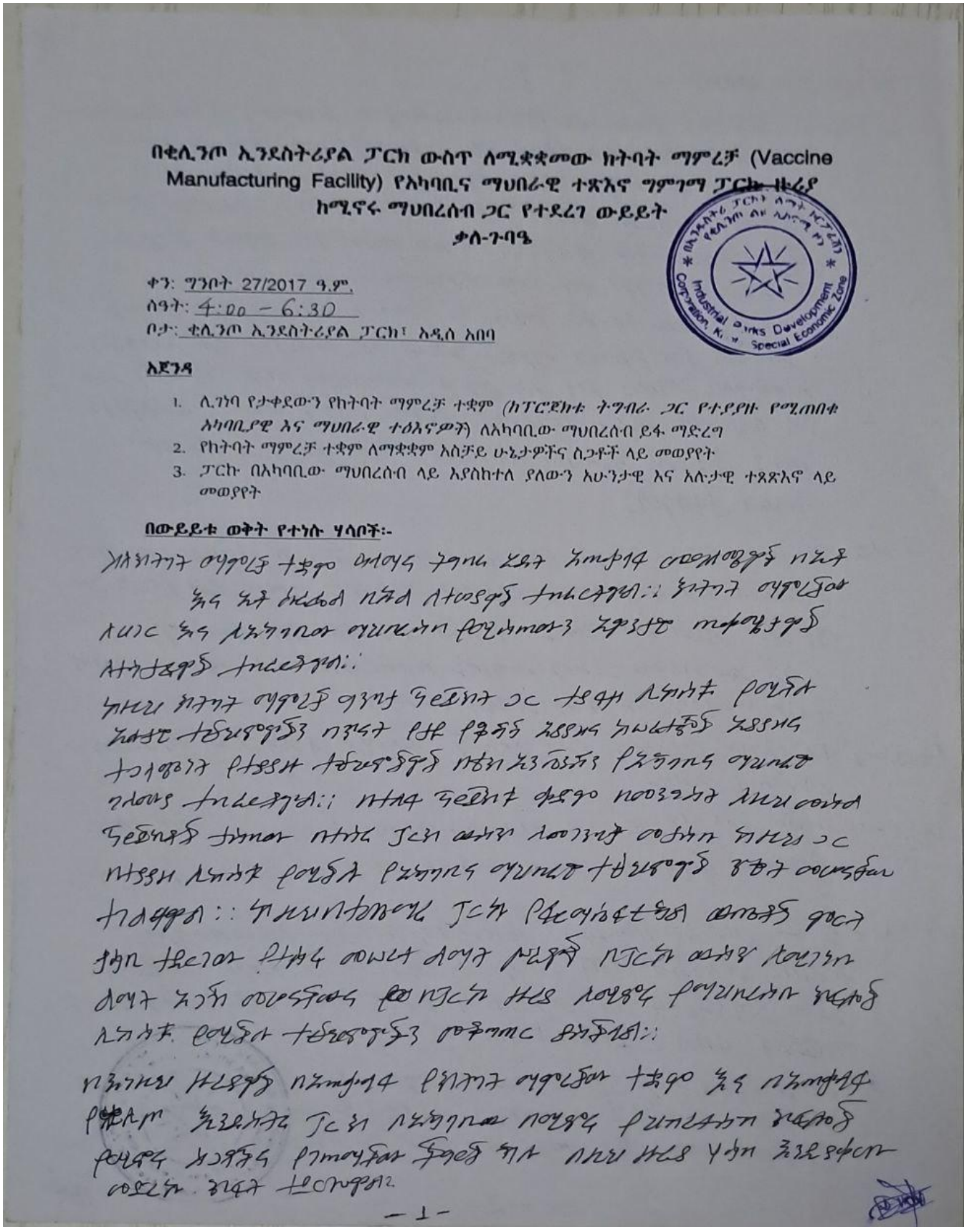
15.					

ANNEX II: MINUTES OF MEETING FOR PUBLIC CONSULTATION



በቂሊንጦ ኢንደስትሪያል ፓርክ ውስጥ ለሚቋቋመው ክትባት ማምረቻ (Vaccine Manufacturing Facility) የአካባቢና ማህበራዊ ተጽእኖ ግምገማ ፓርኩ ዙሪያ ከሚኖሩ ማህበረሰብ ጋር የተደረገ ውይይት
ቃለ-ጉባዔ

ቀን: ግንቦት 27/2017 ዓ.ም.
ሰዓት: 4:00 – 6:30
ቦታ: ቂሊንጦ ኢንደስትሪያል ፓርክ፣ አዲስ አበባ

አጀንዳ

1. ሊገነባ የታቀደውን የክትባት ማምረቻ ተቋም (ስፖርደክቱ ትግብራ ጋር የተያያዙ የሚጠበቁ አካባቢያዊ እና ማህበራዊ ተፅእኖዎች) ለአካባቢው ማህበረሰብ ይፋ ማድረግ
2. የክትባት ማምረቻ ተቋም ለማቋቋም አስቻይ ሁኔታዎችና ስጋቶች ላይ መወያየት
3. ፓርኩ በአካባቢው ማህበረሰብ ላይ እያስከተለ ያለውን አሁንታዊ እና አሉታዊ ተጸጽእኖ ላይ መወያየት

በውይይቱ ወቅት የተነሱ ሃሳቦች፡-

ክለክትባት ማምረቻ ተቋም ወለሳና ትግባሬ ሂደት አጠቃላይ መመለሻዎችን በእኔ እና እኔ ወክዬለ በሽለ ለተወያዮች ተጠቀርቷል:: ክትባት ማምረቻው ለሀገር እና ለአካባቢው ማህበረሰብ የሚሰመጡን እድንታው ጠቀሜታዎች ለተሳታፊዎች ተጠቀርቷል::

ከዚህ ክትባት ማምረቻ ግንባታ ዓቀደክት ጋር ተያይዞ ለክሰቱ የሚኖሩ አለተኛ ተፅእኖዎችን በንሩት የሰዉ የቅሻት እንደሁሩ ከመሬቶቻቸው እንደሁሩ ተጋላጭነት የተደገዙ ተፅእኖዎችን በዚህ እንዲሁም የእንግሪና ማህበረሰቡ ግለሰቡና ተጠቀርቷል:: በተጨማ ዓቀደክቱ ቀደምም ለመንገስት ለዚህ መሰሰል ዓቀደክቶች ትክመው በተሰሩ ፓርክ ውስጥ ለመንገስት መሬትስ ከዚህ ጋር በተያያዘ ለክሰቱ የሚኖሩ የእንግሪና ማህበረሰቡ ተፅእኖዎች ቅድመ መሰሩዳደል ተገልጿል:: ከዚህ በተጨማሪ ፓርኩ የሚሰማሩ ተቋማት ወጣቶች ቅመርገ ታክቢ ተደርገው የተቋቋሙ መሠረተ ልማት ሶሊዎች በፓርኩ ውስጥ ለሚገነቡ ልማት አገኝ መሆናቸውና ከመ በፓርኩ ዙሪያ ለሚኖሩ ማህበረሰቡ ክፍሎች ለክሰቱ የሚኖሩ ተፅእኖዎችን መቅለል ይክላል::

ከገንዘብ ዙሪያዎች በእጠቃላይ የክትባት ማምረቻው ተቋም እና በእጠቃላይ የፋርሊ እንደሁሩ ፓርክ ለእንግሪው ለሚኖሩ ቀጠሮሪታክ ክፍሎች የሚኖሩ አጋጣሚና የገጠሚክው ችግሮች ካሉ ለዚህ ዙሪያ ሃሳብ እንደያቀርቡ መድረኩ ክፍት ተደርጎላቸዋል.

– 1 –

የተሳታፊዎች ሀሳቦች:-

ተሳታፊ-1= ኢንዱስትሪ ፓርኩ የአካባቢው ማህበረሰብ ኑሮውን እንደሚያሻሽል ተስፋ አድርገው ነበር። ነገር ግን በፊት የኢንዱስትሪ ፓርክ ኢንቨስትመንቱ ሲጀመር ለአካባቢው ማህበረሰብ ስራ የስራ ዕድል ፈጥሯል። ነገር ግን ለአርሶአደሩ የነበረ መሬቱ ለፓርክ ልማት ኢንዱስትሪ ቦታ መሆኑ ተወስዶበት የነበረ ወደ አካባቢው ፋብሪካ ነገር ግን ለአርሶአደር ስራ እድል በመፍጠር ረገድ ግን ያለው የሚቀርበው ነው። ለምሳሌ ከግንባታ ጋር ተያይዞ ስራ የሚሰሩ ሰራተኞች ደረጃ ሳይሆን ወደ ፋብሪካ የስራ ዕድል ነገር ግን ይህ ከላይ ተገኝቶ ለሙያዊ ስራ በሚያሳድገው መልኩ አይደለም ወይ? በፋብሪካ ለመስራት ከማህበረሰቡ ብዙ የሚያውቁ ተወዳዳሪ እንዲሆን ይፈለጋል?

ተሳታፊ-2 - ወጣቶች እንደገና የሚያስቡበት ነው! ፓርኩ ተግባራት ለአካባቢው የመኖሪያ አካባቢ አለመኖር መተዳደሪያ እንደ ሁኔታ ለማንም ቢሆን የሚቻል ነው፣ ማህበረሰቡ ብዙ ችሎ ነው? ለምሳሌ ከአካባቢው ያሉ ፋብሪካዎች ብዙዎች አመለካከት ያላቸው ለመስራት ከማህበረሰቡ ጋር ተቀራርቦ ለመሥራት ግንባታ ማህበረሰቡ ሳይገባ እንደሆነ ይሰማኛል።

ተሳታፊ-3 ፋብሪካዎች የሚሰሩት ያለፈ ብዙዎች ችግሮችን ለአካባቢው ማህበረሰብ መስጠት አለበት!

ተሳታፊ-4 /ሴቶች ጉዳይ ተጨማሪ ወደ አካባቢው ቤት ለአካባቢው ሁሉም ለሴቶች የሚሰጠው ፋይዳ ካለ ነገር ከፍተኛ ወደ ቤተሰብ እንደገና እንመለሳለን።

ተሳታፊ-5 — መሬቱ (ወጣቶች) መዝናኛን ከእነሱ እናመቻቻለን፡፡ እንደ ሁኔታው መንግስት የስራ ማህበራት ለመገንባት እንዲያሳድጉ መደራጀት እንደገና የሚያስቡበት ነው ምክንያቱም ከፍተኛ ስራ ላይ ብዙ ሰራተኛ ኢንዱስትሪ ፓርኩ ቋሚ የሚያስፈልግ ነው፡፡

- ፓርኩ ከ2003 ዓ.ም ~~የአካባቢው~~ ከተቋቋመ ጀምሮ ... ኢንቨስተሮች ተሰማርተዋል፡፡ ከመጀመሪያ አርሶአደሩ ... የኢንቨስትመንት መሬቱ ማህበረሰቡ ተጠቃሚ አለመሆኑ ... ነው።

ኢንቨስትመንት ፕሮጀክቶች ላይ ያተኮረ ስልጠና ለመስጠት ታቅዷል።

ስልጠናው የሚሰጠው በኢንዱስትሪ ፓርክ ልማት ኮርፖሬሽን ባለሙያዎች እና ከሌሎች የመንግስት ተቋማት ጋር በመተባበር ነው።

ተሳታፊ - 9 ከክልሉ ዕድገት ጋር ተያይዞ ኢንቨስትመንት ለመሳብ ከፍተኛ ጥረት እየተደረገ ነው።

ተሳታፊ - ፯ ኢንቨስትመንት ለመሳብ ከፍተኛ ጥረት እየተደረገ ነው ? ከዚህ አንፃር ተሞክሮአችሁን ብታካፍሉን ? ከዚህ በፊት ኢንቨስትመንት ለመሳብ ምን ጥረት አድርጋችሁ ነበር ? ውጤቱስ ?

ተሳታፊ - ፰ አብዛኛው Investors የሚፈልጉት ወይም የሚጠይቁት ነገር ከኛ ጋር ያለው ነገር ሊለያይ ይችላል። ስለዚህ ከኛ ጋር ያለው ነገር ከሌሎች ጋር ሲነፃፀር ምን ጥቅም እንዳለው ማስረዳት ያስፈልጋል።

ምላሽ

- ተሳታፊዎች ያነሷቸውን ሃሳቦች ከግምት ውስጥ በማስገባት ስልጠናው ተሻሽሎ እንዲሰጥ ይደረጋል።
- ስልጠናው ወይም ከዚህ በፊት ከኢንዱስትሪ ፓርክ ልማት ኮርፖሬሽን ጋር በመተባበር ስልጠና የወሰዱ ኢንቨስተሮች ልምዳቸውን እንዲያካፍሉ ይደረጋል።
- የኢንዱስትሪ ፓርክ ልማት ኮርፖሬሽን ከክልሉ ወይም ከዞኑ ጋር በመተባበር ለኢንቨስተሮች የሚሰጠውን ድጋፍ በተመለከተ ገለፃ ይደረጋል።

ተጨማሪ - 3 - ተጠቃሚው ገለባ ማዳ ማረጋገጫ እና ኢንዱስትሪ ፓርክ ማኔጅመንት ኮርፖሬሽን JCP ስለሚሰጠው አገልግሎት ክፍያ ይፈጽማል።

ተጨማሪ - 4 = ተጠቃሚው ማሽነሪ ገጠመ ነው. የሽንኩርት ዘንግ ማንሻ መሳሪያ ተጠናቅቆ እና የጠመቀውን ሰማንያኛ ቀመር ፣ ጀምሮ ለተጠቃሚው መሸጋገሪያ እንዲሰጠው ይጠበቃል. ይህንንም ማጣት ወይም ሥራ ላይ ማዋል ይጠበቃል።

ማጠቃለያ - ኅብረተሰብ ኢንዱስትሪ ፓርክ ዘርፉ ላለ ሳይንስ ጋር በቅርበት መሰራት ይኖርበታል ማለታችን ነው። የሀገራችን ሳይንስ ቴክኖሎጂ እና ማህበረሰቡ ላይ ለውጥ የሚያመጣ ሳይንስ ነክ ቴክኖሎጂ ማስፋፋት ይጠበቅብናል። የሽያጭ ገበያን ያገናዘበ ትንበያ ማዘጋጀት ያስፈልጋል። ቴክኖሎጂንም ማስወገድ ተገቢውን ወደ ሥራ ለማስገባት ይጠቅማል። መሰራት ያለበት ይመስለኛል።

ANNEX III: STANDARD GRIEVANCE APPLICATION FORMAT

Date:_____

Woreda _____ Kebele_____ Forest block/zone _____

Name of applicant/s:_____,_____,_____

Issue_____

_____

_____

_____

_____

_____

Evidences

Person:_____,_____,_____

Material or other evidence

_____

_____

_____

_____

_____

___

Applicant Name_____

I, the undersigned applicant, confirm that my application and evidences are true and understand that inclusion of fraudulent issues and evidence result in automatic rejection of my application.

Signature_____

Date_____

ANNEX IV: SPECIFICATION REQUIREMENT FOR WASTE INCINERATOR

Table 20: Specification requirement for waste incinerator

Type	Pyrolytic- Hot Medical Waste Disposing Machine
Technology	Pyrolytic
Operation Condition	8-16 Hr /day
Controls	Built in data recording
Incinerator /Primary Combustion Chamber	**Type:** continuous loading
	Capacity/Burn rate per hour 50 kg/hr
	Temperature: ≥900 ºC
	Material: **External-** 3 layers **Internal lining:** a fire proof material of pre-fired refractory bricks with Aluminium lining, resistant to corrosive waste or gas and to thermal shock
Secondary Combustion Chamber	**Type:** horizontal/vertical
	Temperature: ≥1200 ºC
	Residence time of gases : ≥2 seconds
	Material **External-** Low thermal mass insulation 14-30 ºC **Internal lining**: a fire proof material of pre-fired refractory bricks with Aluminium nettle lining, resistant to corrosive waste or gas and to thermal shock.
Burner system	auxiliary burners (for start-up and close-down operations), High turbulence of exhaust gases and reduction of air excess: e.g. injection of secondary air or recirculated flue gas, preheating of the air streams, regulated air inflow
Ash Handling System	Both Automatic and manual removal of Ash. Must ensure removal/treatment of hazardous remnants of ash.
Flue gas treatment system	Capable of treating the flow of flue gas as the incinerator is operating at its maximum

	Capacity
	Auxiliary device: Water level gauge, pressure sensor, PH sensor..etc
	Auxiliary device: Fuel cutoff device
Waste feeding mechanism	Automatic pneumatic/hydraulic waste loading system or conveyor belt , capacity > 650L at a time
Chimney (Stack)	**Type:** Vertical type
	height:≥12 meter
	Material: Fireproof cast, stainless steel
Wet scrubbing system	Vertical sprat tower with baffles or packing inside
Gas emission	Reduction of Pollutant gas SO2, HCL, HF and line particulate that meet WBG/EU requirement including the other emissions
Emission control device	The emission reduction device control (Fabric filter coated with catalyst) made from PTFE, with parallel dedusting, lower contamination of filter dusts to PCDD/PCDF destruction at the catalytic surface that have high efficiency reduction of dioxin upto<0.1 ng TEQ/m3
OUTPUT	ASH -Max ≤5% of original waste size
	GAS- Smokeless, Odorless
Emission standard (all emission standards will also meet both WB and EU requirements).	WB emission standards as follow: Total Particulate Matter (PM) 10 mg/Nm^3 Total organic carbon (TOC) 10 mg/Nm^3 Hydrogen chloride (HCl) 10 mg/Nm^3 Hydrogen fluoride (HF) 1mg/Nm^3 Sulfur dioxide (SO2) 50 mg/Nm^3 Carbon monoxide (CO) 50 mg/Nm^3 NOx 200 mg/Nm^3 Mercury (Hg) 0.05 mg/Nm^3 Cadmium + Thallium (Cd + Tl) 0.05 mg/Nm^3
	Sb, As, Pb, Cr, Co, Cu, Mn, Ni and V 0.5 mg/Nm^3 Polychlorinated 0.1 Ng/Nm^3 TEQ

	dibenzodioxin and dibenzofuran (PCDD/F) *Notes: Oxygen level for incinerators is 7 percent*
Test report for emission testing	Must be provided
Additional Requirement	• Local agent or branch in Ethiopia • Training for users • Fuel tanker with a minimum capacity of 2500 litre (material type need to be specified) • The bidder should be willing to sign at least a five years' service and maintenance agreement with the client (SHIELDVAX)

Description: Incinerator should be smokeless, odourless combustion and it should be made by high-quality cast, insulation, and steel plate as well as minimum generation of dust. All emission standards will also meet both WB and EU requirements.

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ANNEX V: ENVIRONMENTAL AND SOCIAL CLAUSES

1. General

a) The Contractor shall comply with the specific Environmental and Social Management Plan (ESMP) for the work he is responsible for. The Contractor shall prepare its own ESMP taking into account relevant provisions of that ESMP in the VMF ESMP.

b) The Contractor shall prepare method statements indicating that during construction phase all significant adverse impacts arising from each activity have been appropriately addressed.

c) The Contractor shall adhere to the proposed activity implementation schedule and the monitoring plan / strategy to ensure effective feedback of monitoring information to project management so that impact management can be implemented properly, and if necessary, adapt to changing and unforeseen conditions.

d) Besides the regular inspection of the sites by the Supervising Engineer (SE) for adherence to the contract conditions and specifications, the Owner may appoint an inspector to oversee the compliance with these environmental and social conditions and any proposed mitigation measures. Environmental Protection Authority (EPA), regional environmental authority or other relevant stakeholders may carry out similar inspection duties. In all cases, as directed by the SE, the Contractor shall comply with directives from such inspectors to implement measures required to ensure the adequacy of rehabilitation measures carried out on the bio-physical environment and compensation for socio-economic disruption resulting from implementation of all works.

e) The Contractor shall implement all measures necessary to avoid undesirable adverse environmental and social impacts wherever possible, restore work sites to acceptable standards, and abide by any environmental performance requirements specified in an ESMP.

f) If the Contractor fails to implement the approved ESMP after written instruction by the Supervising Engineer (SE) to fulfill his obligation within the requested time, the Owner reserves the right to arrange through the SE for execution of the missing action by a third party on account of the Contractor.

2. Dust abatement

a) The contractor shall minimize the effect of dust on the surrounding environment resulting from earth moving sites, heavy truck movement, vibrating equipment, temporary access

roads, etc. to ensure safety, health and the protection of workers and communities living in the vicinity dust producing activities.

b) During the performance of the work and any operations appurtenant there to, the contractor shall carry out proper and efficient measures, such as sprinkling with water or other means, whenever necessary to reduce the dust nuisance, and to prevent dust which has originated from his operations from damaging crops, cultivated fields, and dwellings or causing a nuisance to persons. The contractor will be held liable for any damage resulting from dust originating from his operations.

3. Noise due to Construction Activities

The contractor shall ensure the noise levels emanating from machinery, vehicles and noisy construction activities (e.g. excavation, blasting) are kept at a minimum for the safety, health and protection of workers within the vicinity of high noise levels and nearby communities.

4. Protection of Archeological and Historical Sites

a) Upon discovery of ancient heritage, relics or anything that might or believed to be of archeological or historical importance during the execution of works, immediately suspend and report such findings to the SE so that the appropriate authorities may be expeditiously contacted for fulfilment of the measures aimed at protecting such historical or archaeological resources.

b) The contractor shall take the necessary measures for preventing that any person or equipment may damage the article or things and shall provide barricades, fences, and signals and, if necessary, protect against atmospheric agents, as directed by the engineer. Also guard service may be required by the engineer.

c) The supervising engineer shall take the following measures:

- Notify the relevant department of antiquities,
- Request for representative to make site inspection,
- Secession of work in the vicinity of the find until the visit of representative; and
- Decision by the department of antiquities on possible salvage or excavation within 48-72 hours of notification

5. Vegetation and Wildlife

a) The contractor shall care, in planning, constructing, maintaining and operating temporary works such as toilet, change rooms, roads, spoil, stockpile and construction facilities areas,

to avoid unnecessary damage to areas of particular environmental interest, such as patches of valuable trees and erosion sensitive areas, as well as areas in which the presence of wildlife has been noted.

b) In case some part of forest or single trees has to be removed, or where erosion problems that may affect some portion of the permanent or temporary works are expected, and in any case where in the engineer's opinion it is beneficial for the land conservation, landscaping, seeding and planting of trees, as well as executing drainages and water control works may be required to the contractor, who shall carry out the work according to the prescriptions contained in the pertinent sections of these specifications.

c) No valuable trees hall be damaged or removed by the contractor during the execution of the works without the prior consent of the engineer.

6. Use of Material

The contractor, in as much as possible, shall use local materials to avoid importation of foreign material and long-distance transportation.

7. Worksite Site Waste Management

a) All vessels (drums, containers, bags, etc.) containing oil/fuel/surfacing materials and other hazardous chemicals shall be banded in order to contain spillage. Used oil and hydraulic fluid generated on the construction sites must be collected in a closed container and stored temporarily in a safe place and sent to an authorized recycling depot.

b) All drainage and effluent from storage areas, workshops and construction sites shall be captured and treated before being discharged into the drainage system in line with applicable government water pollution control regulations.

c) The contractor shall take all possible steps to prevent pollution of streams, rivers, and other water supplies, at or in the vicinity of the site and shall comply with applicable laws, orders and regulations in force in the country of the works concerning the control and abatement of water pollution.

d) Entry of runoff to the site shall be restricted by constructing diversion channels or holding structures such as banks, drains, dams, etc. to reduce the potential of soil erosion and water pollution.

e) Construction waste shall not be left in stockpiles along the road, but removed and reused or disposed of on a daily basis and should be restricted within the project site.

f) If disposal sites for clean spoil are necessary, they shall be located in areas, approved by the SE, for landfill and where they will not result in material being easily washed into drainage channels. Whenever possible, spoil materials should be placed in low-lying areas and should be compacted and dressed with top soil and then planted with species indigenous to the locality.

g) The contractor shall provide all sanitary facilities (e.g. garbage collection and disposal, safety tank, drinking water facilities, etc.) are provided in construction sites.

8. Rehabilitation and Soil Erosion Prevention

a) To the extent practicable, the Contractor shall rehabilitate the site progressively so that the rate of rehabilitation is similar to the rate of construction.

b) Always remove and retain topsoil for subsequent rehabilitation. Soils shall not be stripped when they are wet as this can lead to soil compaction and loss of structure.

c) Topsoil shall not be stored in large heaps. Low mounds of no more than 1 to 2m high are recommended.

d) Re-vegetate the stockpiles with recommended grass species to protect the soil from erosion, discourage weeds and maintain an active population of beneficial soil microbes.

e) Locate stockpiles where they will not be disturbed by future construction activities.

f) The contractor shall reinstate natural drainage patterns where they have been altered or impaired.

g) The contractor shall collect toxic materials from construction areas and keep protect in designated sites until proper disposal. Backfill excavated areas with soils or overburden that is free of foreign material that could pollute groundwater and soil.

h) Identify potentially toxic overburden and screen with suitable material to prevent mobilization of toxins.

i) Ensure reshaped land is formed so as to be inherently stable, adequately drained and suitable for the desired long-term land use, and allow natural regeneration of vegetation.

j) Minimize the long-term visual impact by creating landforms that are compatible with the adjacent landscape.

k) Minimize erosion by wind and water both during and after the process of reinstatement.

l) Compacted surfaces shall be deep ripped to relieve compaction unless subsurface conditions dictate otherwise.

m) Re-vegetate with plant species that will control erosion, provide vegetative diversity and, through succession, contribute to a resilient ecosystem. The choice of plant species for

rehabilitation shall be done in consultation with local research institutions, forest department and the local people.

9. Water Resources Management

a) The Contractor shall at all costs avoid conflicting with water demands of local communities.
b) Abstraction of both surface and underground water shall only be done with the consultation of the local community and after obtaining a permit from the relevant Water Authority.
c) Abstraction of water from wetlands shall be avoided. Where necessary, permission has to be obtained from relevant authorities.
d) No construction water containing spoils or site effluent, especially cement and oil, shall be allowed to flow into natural water drainage courses.
e) Wash water from washing out of equipment shall not be discharged into water courses without pretreated.
f) Site spoils and temporary stockpiles shall be located away from the drainage system, and surface runoff shall be directed away from stockpiles to prevent erosion.

10. Traffic Management

a) Location of access roads shall be done in consultation with the local community especially in important or sensitive environments. Access roads shall not traverse wetland areas.
b) Upon the completion of civil works, all access roads shall be ripped and rehabilitated
c) Access roads shall be watered regularly to suppress dust emission.

11. Disposal of Unusable Elements

a) Unusable materials and construction elements such as electro-mechanical equipment, pipes, accessories and demolished structures will be disposed of in a manner approved by the SE. The Contractor has to agree with the SE which elements are to be surrendered to the Client's premises, which will be recycled or reused, and which will be disposed of at approved landfill sites.
b) Unsuitable and demolished elements shall be dismantled to a size fitting on ordinary trucks for transport.

12. Repair of Private Property

a) Should the Contractor, deliberately or accidentally, damage private property, he shall repair the property to the owner's satisfaction and at his own cost. For each repair, the Contractor

shall obtain from the owner a certificate that the damage has been made good satisfactorily in order to indemnify the Client from subsequent claims.

b) In cases where compensation for inconveniences, damage of crops etc. are claimed by the owner, the Client has to be informed by the Contractor through the SE. This compensation is in general settled under the responsibility of the Client before signing the Contract. In unforeseeable cases, the respective administrative entities of the Client will take care of compensation.

13. Contractor's Environment and Social Management Plan (ESMP)

Within 6 weeks of signing the Contract, the Contractor shall prepare a C-ESMP to ensure the adequate management of the health, safety, environmental and social aspects of the works, including implementation of the requirements of these general conditions and any specific requirements of an ESMP for the works.

The Contractor's EHS-MP will serve two main purposes: -

a) For the Contractor, for internal purposes, to ensure that all measures are in place for adequate EHS management, and as an operational manual for his staff, and,
b) For the Client, supported where necessary by SE, to ensure that the Contractor is fully prepared for the adequate management of the EHS aspects of the project, and as a basis for monitoring of the Contractor's EHS performance.

The Contractor's EHS-MP shall provide at least: -

- a description of procedures and methods for complying with these general environmental and social management conditions, and any specific conditions specified in an ESMP;
- a description of specific mitigation measures that will be implemented in order to minimize adverse impacts;
- a description of all planned monitoring activities (e.g. sediment discharges from borrow areas) and the reporting thereof; and
- The internal organizational, management and reporting mechanisms put in place for such.

The Contractor's EHS-MP will be reviewed and approved by the Client before start of the works. This review should demonstrate if the Contractor's EHS-MP covers all of the identified impacts, and has defined appropriate measures to counteract any potential impacts.

13.1 Health and Safety

a) The contractor shall ensure that the project adheres to the Environmental, Health and Safety Guidelines in the ESMP.
b) In advance of the construction work, the Contractor shall mount an awareness and hygiene campaign. Workers and local residents shall be sensitized on health risks particularly of HIV/AIDS.
c) Adequate road signs to warn pedestrians and motorists of construction activities, diversions, etc. shall be provided at appropriate points.
d) Construction vehicles shall not exceed maximum speed limit of 40km per hour.

13.2 Traffic Safety

a) Ensure public safety, and meet traffic safety requirements for the operation of work to avoid accidents.
b) The contractor shall be responsible for the safety along the roads related to the site, and he shall take all necessary precautions for the protection of the work and the safety of the public on the roads affected by his activities.
c) Roads subject to interference by the work shall be kept open or suitable detours shall be provided and maintained by the contractor, who shall provide, erect, and maintain all necessary barricades, suitable and sufficient flashlights, flagmen, danger signals, and signs.
d) The contractor shall submit his weekly activities schedule and the locations of his work along the existing public roads to the authorities concerned, and obtain all necessary approvals prior to commencement of the respective work.
e) At the road crossings or in heavy traffic locations, the contractor shall carry out the work within the working hours as directed by the engineer, and after the completion of the work he shall immediately make the necessary backfill and pavement at the crossings.
f) The contractor shall provide temporary passes and bridges to give access to the existing villages, houses, etc., to the satisfaction of the engineer and the authorities concerned whenever he disturbs such existing way during the execution of the works.

14. Workers and Contractors Code of Conduct

- Construction Managers should be guided in all their relationships by the highest standards of integrity and honesty.
- Construction Managers and workers should conduct themselves honorably, responsibly, ethically, and lawfully so as to enhance the honor, reputation and value of the profession.

- Construction Managers and workers should avoid conduct or practices that deceive the public or represent a real or perceived conflict of interest.
- Construction Managers should respect the rights of others and should not discriminate on the basis of race, color, gender, marital status, religion, national origin, age, disability, or sexual orientation nor knowingly violate any law, statute, or regulation in the performance of professional services. Construction managers should strive to create a diverse workforce.
- Construction Managers should have a zero-tolerance policy for any form of harassment including sexual harassment and bullying.
- Contractors must not engage in the exploitation of child labour and contractors must take the necessary steps to prevent the employment of child labour.
- Contractors, their staff, sub-contractors and any other personnel engaged by the contractor, must not exploit the vulnerability of any target group in the context of development, humanitarian and advocacy work, especially women and children, or allow any person/s to be put into compromising situations. Never abuse a position to withhold development or humanitarian assistance, or give preferential treatment; in order to solicit sexual favours, gifts, payments of any kind, or advantage.
- The use of physical abuse, disciplinary punishment, sexual abuse, the threat of sexual and physical abuse, and other forms of intimidation may never be practiced by contractors and workers.

15. Reporting

The Contractor shall prepare monthly progress reports to the SE on compliance with these general conditions, the project ESMP if any, and his own EHS-MP. It is expected that the Contractor's reports will include information on:-

- EHS management actions/measures taken, including approvals sought from local or national authorities;
- Problems encountered in relation to EHS aspects (incidents, including delays, cost consequences, etc., as a result thereof);
- Lack of compliance with contract requirements on the part of the Contractor;
- Changes of assumptions, conditions, measures, designs and actual works in relation to EHS aspects; and
- Observations, concerns raised and/or decisions taken with regard to EHS management during site meetings.

It is advisable that reporting of significant EHS incidents be done “as soon as practicable”. Such incident reporting shall therefore be done individually. Also, it is advisable that the Contractor keeps his own records on health, safety and welfare of persons, and damage to property. It is advisable to include such records, as well as copies of incident reports, as appendixes to the bi-weekly reports. Example formats for an incident notification and detailed report are given below. Details of EHS performance will be reported to the Client through the SE’s reports to the Client.

16. Training of Contractor’s Personnel

The Contractor shall provide sufficient training to his own personnel to ensure that they are all aware of the relevant aspects of these general conditions, any project EMP, and his own EHS-MP, and are able to fulfill their expected roles and functions. Specific training should be provided to those employees that have particular responsibilities associated with the implementation of the EHS-MP. General topics should be:-

- EHS in general (working procedures);
- Emergency procedures; and
- Social and cultural aspects (awareness creation)

17. Cost of Compliance

It is expected that compliance with these conditions is already part of standard good workmanship and state of art as generally required under this Contract. The item “Compliance with Environmental and Social Management Conditions” in the Bill of Quantities covers these costs. No other payments will be made to the Contractor for compliance with any request to avoid and/or mitigate an avoidable EHS impact.

ANNEX VI: CHANCE FIND PROCEDURES

Proclamation No. 209/2000, which focuses on the research and conservation of cultural heritage, establishes clear protocols for handling chance finds, as detailed in Article 41. According to this article, any individual who uncovers cultural heritage artifacts during activities such as mining, construction, or roadwork is required to report the discovery to the relevant Authority. The discoverer must ensure that the artifacts are preserved in their original state until the Authority can take possession of them.

The Authority is responsible for implementing appropriate measures to examine, receive, and register any cultural heritage items that are found. If the Authority does not act within six months of the report, the individual who made the discovery can be relieved of their responsibilities by providing a written notification that includes a comprehensive description of the circumstances to a Regional Government official.

To prevent damage to cultural properties, it is essential to engage in consultations with relevant authorities and local communities during project planning. This proactive approach helps identify known or potential archaeological sites. In the event of a chance find during construction, work must be halted immediately. The significance of the find must be assessed by the appropriate authorities in collaboration with local inhabitants. Only after this evaluation can suitable measures be taken to address the site and ensure its protection.

ANNEX VII: WHO GMP TRS CONSIDERED IN THE VMF DESIGN

A. WHO good practices for pharmaceutical microbiology laboratories (Annex 2)

The document outlines WHO good practices for pharmaceutical microbiology laboratories, focusing on guidelines for personnel, environment, equipment, and testing procedures to ensure quality control and safety in microbiological testing. It emphasizes the importance of personnel training, environmental monitoring, and equipment maintenance to ensure accurate and reliable test results.

Personnel Qualifications and Training Requirements

Personnel involved in microbiological testing must be qualified and trained adequately to perform their duties competently.

- Microbiological testing should be supervised by experienced personnel.
- Job descriptions and records of qualifications, training, and experience must be maintained.
- Personnel must receive training in containment procedures and safe handling of microorganisms.
- Continuous monitoring of competence is essential, with retraining provided as necessary.

Laboratory Premises and Environmental Controls

Microbiology laboratories must be designed to minimize contamination risks and ensure proper environmental conditions for testing.

- Laboratories should be dedicated and separated from production areas.
- Sufficient space is required to avoid contamination and mix-ups.
- Separate air supply and handling units are necessary for microbiological laboratories.
- Access should be restricted to authorized personnel, with clear entry and exit procedures.

Environmental Monitoring and Cleaning Protocols

An effective environmental monitoring program is crucial for maintaining laboratory integrity and cleanliness.

- Environmental monitoring should include active air monitoring and temperature controls.

- A documented cleaning and disinfection program must be in place.
- Adequate hand-washing and disinfection facilities should be available.

Sterility Testing Facility Requirements

Sterility testing facilities must meet specific environmental standards to ensure test integrity.

- Sterility testing should occur under aseptic conditions equivalent to those for sterile product manufacturing.
- Facilities must be classified appropriately, with Grade A zones for testing.
- Environmental microbiological monitoring should be performed during every work session.

Validation and Qualification of Test Methods

Test methods must be validated to ensure their suitability for specific products and conditions.

- Standard test methods are considered validated, but specific laboratory methods require verification.
- Non-compendial methods must undergo validation for accuracy, precision, and robustness.
- Laboratories should demonstrate that performance criteria can be met before routine use.

Equipment Maintenance and Calibration Procedures

Proper maintenance and calibration of laboratory equipment are essential for reliable testing results.

- Equipment should be uniquely identified and maintained at predetermined intervals.
- Calibration dates and servicing schedules must be clearly indicated on instruments.
- Regular checks and verifications should be performed based on documented experience.

Reagents and Culture Media Management

The quality of reagents and culture media is critical for microbiological testing accuracy.

- Laboratories must verify the suitability of each batch of critical reagents.
- Media should be prepared or purchased from qualified vendors, with growth promotion tests conducted on each batch.
- Proper storage conditions for raw materials and media must be maintained to ensure quality.

Reference Materials and Cultures Usage

Reference materials and cultures are vital for validating methods and ensuring consistent testing performance.

- International standards and pharmacopoeial reference substances should be used for method validation.
- Reference cultures must be traceable and stored appropriately to maintain their integrity.
- Working stocks should not be sub-cultured excessively to preserve their properties.

Sampling and Sample Handling Procedures

Sampling procedures must ensure the integrity and representativeness of test items.

- Sampling should be performed aseptically by trained personnel using sterile equipment.
- Samples must be transported and stored under conditions that maintain their integrity.
- Detailed records of sample conditions and characteristics should be maintained.

Disposal of Contaminated Waste Protocols

Disposal procedures for contaminated materials must minimize contamination risks.

- Procedures should conform to national and international regulations for health and safety.

- Contaminated materials should be disposed of in a manner that prevents environmental contamination.

Internal Quality Control Systems

A robust internal quality control system is necessary for consistent testing results.

- Laboratories should implement quality assurance measures, including handling deviations and proficiency testing.
- Consistency of results must be ensured through regular internal quality control checks.

Testing Procedures and Reporting Results

Testing should follow established procedures, with clear reporting of results.

- Tests should be performed according to recognized pharmacopoeial methods or alternatives.
- Results should be reported accurately, with appropriate expressions for negative findings.

Equipment Qualification and Monitoring Procedures

This section outlines the requirements and suggested monitoring frequencies for various types of laboratory equipment to ensure their proper functioning and reliability. The frequency of checks is determined by the equipment's criticality, previous performance, and specific needs.

- Temperature-controlled equipment requires stability checks every 2 years and daily monitoring.
- Sterilizing ovens and autoclaves also need initial checks every 2 years and monitoring with each use.
- Grade A areas and unidirectional cabinets have annual performance checks and microbiological monitoring every 6 months.

- Timers, microscopes, pH meters, and balances require daily checks, while de-ionizers need weekly and monthly checks for conductivity and microbial contamination.
- Environmental monitoring should be based on risk assessments.

General Use of Reference Cultures

This section describes the management and storage of reference cultures, emphasizing the importance of maintaining detailed records and purity checks. Proper handling ensures the reliability of cultures used in laboratory settings.

- Reference strains must come from accredited sources and be stored under specified conditions.
- Each reference stock (G1 to G4) should be freeze-dried or stored in liquid nitrogen, with defined storage times.
- Working cultures must also adhere to specified conditions and storage times for routine use.
- Documentation of all processes, including purity checks and biochemical tests, is essential for maintaining culture integrity.

B. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Annex 8)

The document provides guidelines on good manufacturing practices for heating, ventilation, and air-conditioning (HVAC) systems used in the production of non-sterile pharmaceutical products.

Guidelines for HVAC Systems in Pharmaceuticals

The WHO guidelines provide recommendations for good manufacturing practices (GMP) regarding heating, ventilation, and air-conditioning (HVAC) systems specifically for non-sterile pharmaceutical products. These guidelines emphasize the importance of HVAC systems in maintaining product quality and preventing contamination.

- The guidelines were first published in 2006 and revised in 2011, with further amendments proposed after public consultation in 2017.
- The document is divided into two parts: recommendations for GMP and a second part with examples and clarifications.
- HVAC systems are crucial for ensuring quality in the manufacture of non-sterile dosage forms, including tablets, capsules, and liquids.
- The design of HVAC systems should be integrated with architectural considerations to control contamination and cross-contamination.

Key Changes in the Revised Guidelines

The revised guidelines reflect a comprehensive approach to HVAC system design, management, and qualification throughout their lifecycle. They are intended to complement existing GMP guidelines for pharmaceutical products.

- The guidelines have been rewritten to include recommendations for design, management, control, and qualification of HVAC systems.
- A science- and risk-based approach is emphasized for the lifecycle of HVAC systems.
- The guidelines are applicable to various dosage forms and should be read alongside the parent GMP guidelines.

- Specific requirements for HVAC systems handling hazardous substances and sterile products are addressed in separate WHO guidelines.

Definitions of Key Terms in HVAC Guidelines

The document provides definitions for critical terms related to HVAC systems to ensure clarity and consistency in understanding the guidelines.

- Acceptance criteria refer to numerical limits for test results.
- Air changes per hour measure the airflow supplied to a room relative to its volume.
- Clean areas are defined as spaces with controlled environmental conditions to minimize contamination.
- Critical parameters are those that directly affect product quality, such as temperature and humidity.

Recommendations for HVAC System Design

The guidelines outline essential recommendations for the design of HVAC systems to ensure a controlled environment for pharmaceutical manufacturing.

- Manufacturing environments should be controlled to prevent contamination, with positive pressure maintained relative to the outside.
- Cleanliness levels for different areas should be determined based on the products manufactured and their susceptibility to degradation.
- HVAC systems must achieve specified room conditions, including temperature, humidity, and airflow rates.
- Detailed schematic diagrams should be maintained to reflect air supply, return, and pressure differentials.

Risk Management in HVAC Systems

The guidelines stress the importance of applying risk management principles to HVAC systems to ensure their effectiveness and compliance.

- Risk management should encompass design, operation, monitoring, and contamination prevention.
- HVAC system capacity must account for room and duct leakage, ensuring performance during normal use.
- Components of HVAC systems should not introduce contamination, and clear labeling is recommended for ease of identification.
- Monitoring systems should be capable of indicating out-of-limit conditions and should be validated if classified as GXP systems.

Filtration and Air Quality Control

The guidelines provide specific recommendations regarding air filtration and quality control measures to prevent contamination.

- Fresh air should be adequately filtered, and recirculation systems must not pose contamination risks.
- HEPA filters should meet at least H13 classification to effectively remove contaminants.
- The amount of fresh air intake must compensate for facility leakage and operator occupancy.
- Exhaust air filtration should be based on risk assessments and local regulations.

Pressure Differential and Airflow Management

The guidelines emphasize the importance of maintaining appropriate pressure differentials and airflow management to prevent cross-contamination.

- Measures should be taken to prevent dust movement between different areas in multiproduct facilities.
- Pressure differentials should be assessed based on the products handled and the required level of protection.
- Airflow directions must be designed to ensure containment, with corridors typically maintained at higher pressure than production areas.

- Monitoring devices for pressure differentials should be calibrated and linked to alarm systems.

Qualification and Validation of HVAC Systems

The guidelines outline the processes for qualifying and validating HVAC systems to ensure they meet specified performance criteria.

- HVAC systems should be qualified to ensure continued performance according to specifications.
- A master plan should define the scope and extent of qualification testing based on risk management principles.
- Performance parameters for qualification should be determined through risk assessments.

- Standard operating procedures should be established for actions when alert and action limits are reached.

Operation and Maintenance of HVAC Systems

The guidelines highlight the importance of proper operation and maintenance of HVAC systems to ensure ongoing compliance and performance.

- Operation and maintenance manuals should be kept up to date with system revisions.
- A planned preventive maintenance program should be established, considering the criticality of the system.
- Maintenance activities should be scheduled to avoid negative impacts on product quality.
- Records of maintenance and filter changes should be maintained for a sufficient period.

WHO Guidelines on Good Manufacturing Practices

The World Health Organization (WHO) provides comprehensive guidelines on good manufacturing practices (GMP) for pharmaceutical products, emphasizing the importance of quality assurance in the production process. These guidelines cover various aspects, including non-sterile and sterile products, as well as specific practices for hazardous substances.

- WHO has published multiple reports on GMP, including the fortieth, forty-fifth, and forty-eighth reports.
- Key documents include guidelines for heating, ventilation, and air-conditioning systems for non-sterile dosage forms.
- GMP principles are essential for ensuring the safety and efficacy of pharmaceutical products.

Good Manufacturing Practices for Biological Products

The WHO outlines specific good manufacturing practices for biological products to ensure their quality and safety. These practices are crucial for the production of vaccines, blood products, and other biological therapeutics.

- The guidelines for biological products were detailed in the forty-second and fiftieth reports.
- Emphasis is placed on the validation of manufacturing processes to maintain product integrity.
- Compliance with these practices is vital for regulatory approval and market access.

Quality Risk Management in Pharmaceuticals

Quality risk management is a critical component of pharmaceutical manufacturing, as outlined by the WHO and ICH guidelines. It involves identifying, assessing, and controlling risks to ensure product quality throughout the manufacturing process.

- The ICH Harmonised tripartite guideline on quality risk management (Q9) was published in 2005.
- WHO guidelines on quality risk management were included in the forty-fifth report.
- Effective risk
- management practices contribute to improved product safety and regulatory compliance.

C. WHO good manufacturing practices for sterile pharmaceutical products (Annex 6)

The document provides guidelines on good manufacturing practices for for sterile pharmaceutical products.

General considerations

- The production of sterile preparations should be carried out in clean areas, entry to which should be through airlocks for personnel and/or for equipment and materials. Clean areas should be maintained to an appropriate standard of cleanliness and supplied with air that has passed through filters of the required efficiency.
- The various operations of component preparation (such as those involving containers and closures), product preparation, filling and sterilization should be carried out in separate areas within the clean area.

Quality control

- The sterility test applied to the finished product should only be regarded as the last in a series of control measures by which sterility is assured. The test should be validated for the product(s) concerned.
- Samples taken for sterility testing should be representative of the whole of the batch but should, in particular, include samples taken from parts of the batch considered to be most at risk of contamination.
- The sterility of the finished product is assured by validation of the sterilization cycle in the case of terminally sterilized products, and by “media simulation” or “media fill” runs for aseptically processed products.

Sanitation

- Monitoring should be regularly undertaken to detect contamination or the presence of an organism against which the cleaning procedure is ineffective
- Disinfectants and detergents should be monitored for microbial contamination;

- A disinfectant programme should also include a sporicidal agent since many common disinfectants are ineffective against spores.
- Fumigation of clean areas may be useful for reducing microbial contamination in inaccessible places.

Manufacture of sterile preparations

- Clean areas for the manufacture of sterile products are classified according to the required characteristics of the environment. Each manufacturing operation requires an appropriate level of environmental cleanliness in the operational state to minimize the risks of particulate or microbial contamination of the product or materials being handled.
- For the manufacture of sterile pharmaceutical preparations, four grades of clean areas are distinguished as follows:

    - Grade A: The local zone for high-risk operations, e.g. filling and making aseptic connections. Normally such conditions are achieved by using a unidirectional airflow workstation. Unidirectional airflow systems should provide a homogeneous air speed of 0.36–0.54 m/s (guidance value) at a defined test position 15–30 cm below the terminal filter or air distributor system. The velocity at working level should not be less than 0.36 m/s.
    - The uniformity and effectiveness of the unidirectional airflow should be demonstrated by undertaking airflow visualization tests.
    - Grade B: In aseptic preparation and filling, this is the background environment for the Grade A zone.
    - Grades C and D: Clean areas for carrying out less critical stages in the manufacture of sterile products or carrying out activities during which the product is not directly exposed (i.e. aseptic connection with aseptic connectors and operations in a closed system). A unidirectional airfl ow and lower velocities may be used in closed isolators and glove boxes.

- In order to reach the B, C and D air grades the number of air changes should be appropriate for the size of the room and the equipment and personnel present in it.

Personnel

- Only the minimum number of personnel required should be present in clean areas; this is particularly important during aseptic processes. As far as possible, inspections and controls should be conducted from outside such areas.
- All personnel (including those concerned with cleaning and maintenance) employed in such areas should receive initial and regular training in disciplines relevant to the correct manufacture of sterile products, including hygiene and the basic elements of microbiology. When outside staff who have not received such training (e.g. building or maintenance contractors) need to be brought in, particular care should be taken over their instruction and supervision.
- Changing and washing should follow a written procedure designed to minimize the contamination of clean-area clothing or the carry-through of contaminants to clean areas. The clothing and its quality should be appropriate for the process and the grade of the working area. It should be worn in such a way as to protect the product from contamination.
- Outdoor clothing should not be brought into changing rooms leading to Grade B and C rooms. For every worker in a Grade A/B area, clean sterile (sterilized or adequately sanitized) protective garments should be provided at each work session. Gloves should be regularly disinfected during session. Operators working in Grade A and B areas should wear sanitized goggles.
- Wrist-watches, cosmetics and jewelry should not be worn in clean areas.
- The clothing required for each grade is as follows:

    - Grade D. The hair and, where relevant, beard and moustache should be covered. Protective clothing and appropriate shoes or overshoes should be worn. Appropriate measures should be taken to avoid any contamination from outside the clean area.
    - Grade C. The hair and, where relevant, beard and moustache should be covered. A one-piece jumpsuit, gathered at the wrists and with a high neck, and appropriate shoes or overshoes should be worn. The clothing should shed virtually no fibers or particulate matter.
    - Grades A and B. Entry of personnel into Grade A areas should be minimized. Headgear should totally enclose the hair and, where relevant, beard and moustache. A one-piece jumpsuit, gathered at the wrists and with a high neck, should be worn. The

headgear should be tucked into the neck of the suit. A facemask should be worn to prevent the shedding of droplets. Sterilized, non-powdered gloves of appropriate material and sterilized or disinfected footwear should be worn. Trouser-bottoms should be tucked inside the footwear and garment sleeves into the gloves. The protective clothing should shed virtually no fibres or particulate matter and should retain particles shed by the body.

- Clothing used in clean areas should be laundered or cleaned in such a way that it does not gather additional particulate contaminants that can later be shed. Separate laundry facilities for such clothing are desirable. If fibres are damaged by inappropriate cleaning or sterilization, there may bean increased risk of shedding particles. Washing and sterilization operations should follow standard operating procedures.

D. TRS 1044 - Annex 2: WHO Good Manufacturing Practices for Sterile Pharmaceutical Products

- Annex 2 of TRS 1044 serves as a comprehensive guide for manufacturers of sterile pharmaceutical products, emphasizing stringent controls to ensure product quality and safety. It provides guidelines and principles for the manufacturing of sterile pharmaceutical products. These guidelines are designed to ensure the quality, safety, and efficacy of sterile medicines through adherence to good manufacturing practices (GMP). It includes the following points: -
- Emphasizes the importance of a robust quality management system that encompasses all aspects of production, including documentation, training, and internal audits.
- Stresses the need for adequately trained personnel who are competent in their roles and responsibilities related to sterile manufacturing processes.
- Details requirements for the design and maintenance of facilities and equipment to prevent contamination. This includes controlled environments such as cleanrooms with appropriate air filtration and HVAC systems.
- Outlines strict controls over production processes to minimize risks of contamination. This includes validated cleaning and sterilization procedures, as well as monitoring critical parameters throughout production.
- Highlights the necessity for validation of processes, methods, and equipment to ensure that they consistently produce sterile products that meet predetermined specifications.

- Discusses the role of quality control in testing raw materials, in-process materials, and finished products to ensure they meet quality standards before release.
- Stresses the need for comprehensive documentation practices, including batch records, standard operating procedures (SOPs), and change control processes to maintain traceability and accountability.
- Encourages the implementation of risk management principles to identify potential hazards in the manufacturing process and mitigate them effectively.
- Addresses the requirements for the distribution of sterile products, ensuring that they are stored and transported under conditions that maintain their sterility and integrity.

ANNEX VIII: VMF WASTE MANAGEMENT AND DESIGN LAYOUTS

1. GENERAL WASTE MANAGEMENT APPROACH:

There will no biohazardous or infectious waste generated out of this facility during fill-finish phase. Even though the fill-finish stage of inactivated vaccines is free from infectious material, a system has been put in place to ensure **precautionary biocontainment and decontamination**. Integration of **kill tanks for inactivation** and **ETPs for treatment and safe disposal has been done to** ensures that the facility operates in full compliance with GMP, biosafety, and environmental norms. A structured and validated waste management system shall safeguard personnel, communities, and ecosystems while supporting sustainable biopharmaceutical manufacturing.

Waste Management in Fill-Finish Operations for Inactivated Vaccines consist of three steps**: -**

Step 1: The waste material will be autoclaved/sterilized withing the facility before it is let out.

Step 2: The solid waste will be taken to the designated incineration area for incineration. The liquid waste from the production area will be collected in the Kill tank provided at the basement floor and will be further treated.

Step 3: After thorough disinfection, the neutral material will be let into the effluent treatment tank where it will be further treated in compliance with the waste management guidelines before the liquid waste is let into the Kilinto Industrial Park's (KIP) central effluent collection line for the centralized treatment by the KIP.

2. Integration of Kill Tanks and Effluent Treatment Plant (ETP)

The **fill-finish stage** in inactivated vaccine manufacturing, is devoid of live pathogens.

It involves handling of **sterile inactivated (non-infectious)** drug product, components (vials, stoppers). Effective waste management in this stage is ensured through sterilization and disinfection process that helps in complying with **Good Manufacturing Practices (GMP)**, **biosafety**, and **environmental stewardship**.

2.1. Role of kill tanks in fill-finish waste management

ShieldVax facility shall be a GMP-compliant vaccine facility. **A provision for kill tank has been made for all blocks including the fill-finish stage** to manage waste containing trace biological materials or adjuvants before release into the ETP.

a. Function:

- Thermally or chemically inactivate any residual vaccine formulation
- Neutralize and dilute cleaning fluids and biological residues
- Serve as a potential containment barrier before environmental discharge

b. Design and Operation:

- Constructed using appropriate grade stainless steel (SS); capacity scaled to batch size and clean-in-place volumes
- **Thermal Kill Tanks**: Operated at 100–121°C for validated hold time
- **Chemical Kill Tanks**: Dosed with NaOCl or validated disinfectants for vaccine traces denaturation
- Integrated with **level sensors, agitation systems, and temperature/pH control**

c. Compliance:

- Aligned with GMP and biosafety standards (e.g., WHO TRS, EU GMP Annex 1)
- Subject to validation for deactivation efficiency (≥6 $\log_{10}$ reduction where required)

2.2. Effluent treatment plant (ETP) for fill-finish operations

After kill tank processing, the liquid waste will be routed to the ETP, which ensures environmental safety and regulatory compliance for final discharge.

a. ETP Treatment Flow:

i. Pre-Treatment

- Equalization tank for flow stabilization
- Screening for particulates and vial fragments

ii. Primary Treatment

- Neutralization of pH (from acidic/basic cleaning agents)
- Coagulation/flocculation for suspended solids

iii. Secondary Treatment

- Aerobic biological treatment to reduce BOD/COD
- Suitable for wastewater with organic residuals from adjuvants/preservatives

iv. Tertiary Treatment

- Sand and carbon filtration
- UV or chlorination disinfection
- RO/evaporator integration for Zero Liquid Discharge (ZLD), if applicable

v. Sludge Management

- Dewatering and hazardous waste disposal as per local regulations

3. Integration, monitoring, and control

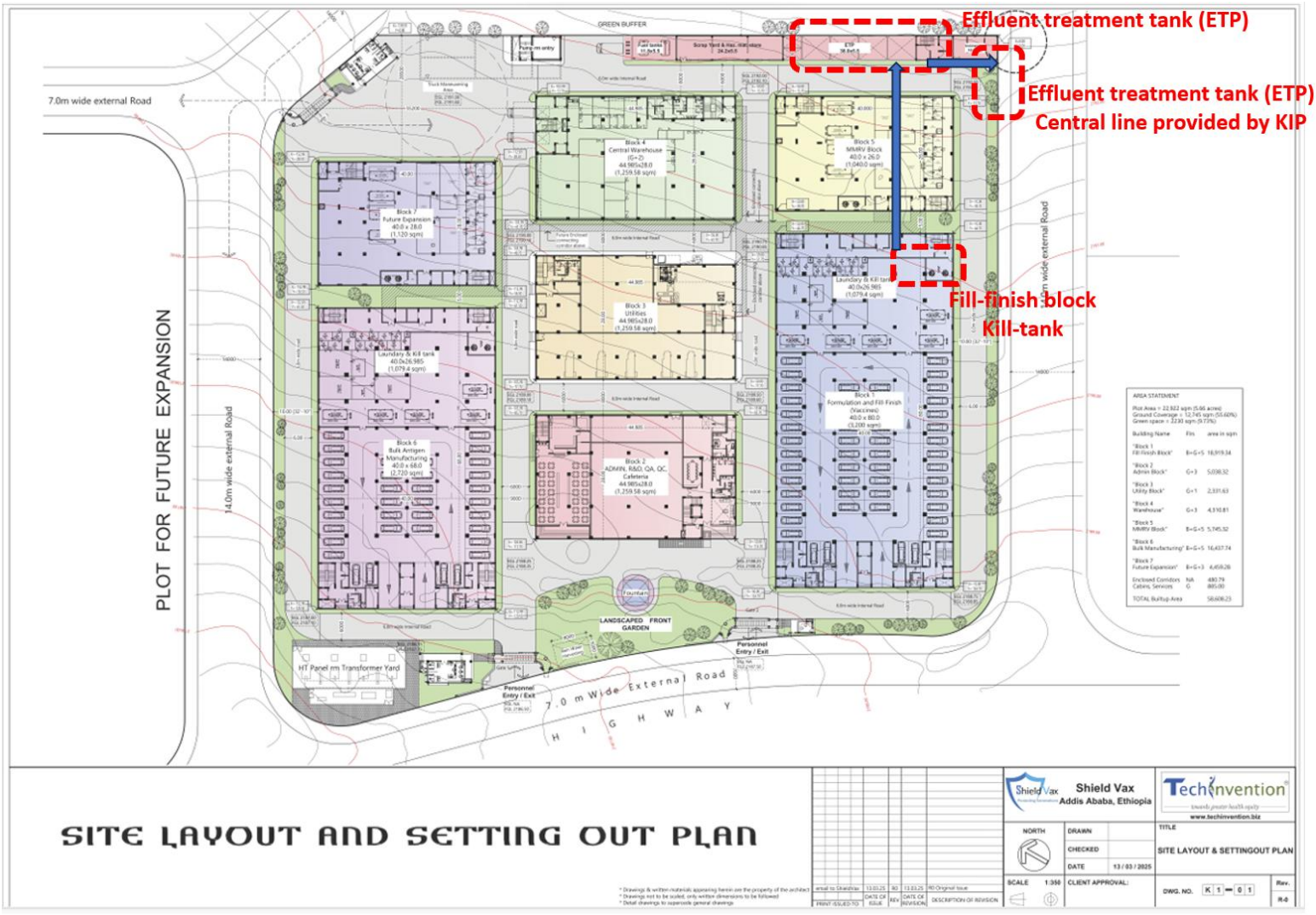
- All effluent pipelines from Grade B/C areas routed to kill tanks
- Batch-wise effluent logbooks maintained for traceability
- SCADA or PLC-based control for kill tank and ETP operation
- Regular monitoring of key parameters: pH, BOD, COD, TSS, disinfectant residuals

4. Regulatory and environmental considerations

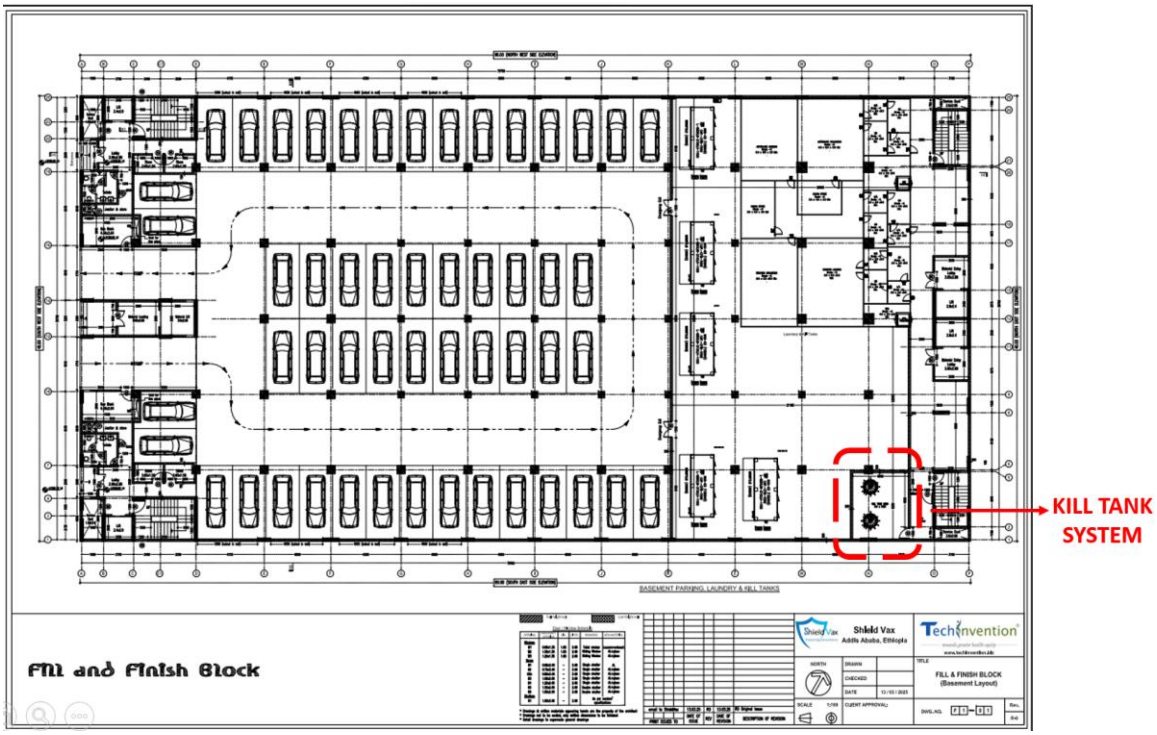
- Compliance with **local and international discharge norms** (e.g., EFDA in Ethiopia)
- Adherence to **Biomedical Waste Management Rules**

- Annual Environmental Audit Reports submitted to regulatory bodies
- Implementation of **SOPs for spill management and waste segregation**

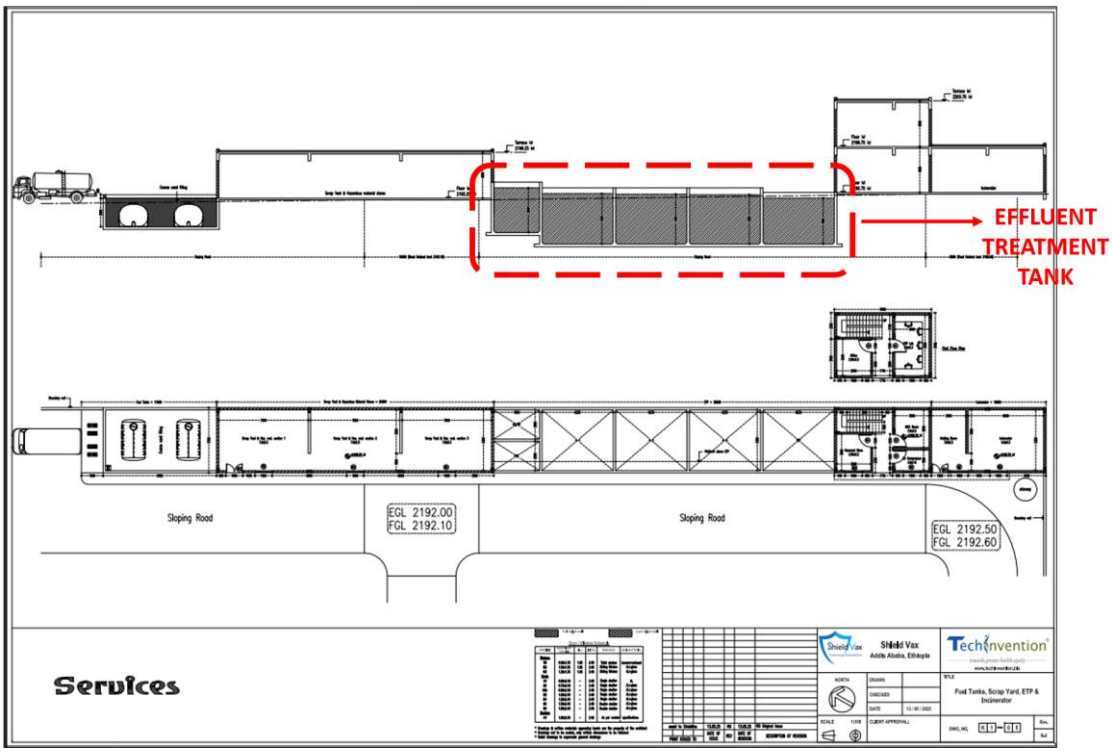
5. Site layout - provision for the kill tank & effluent treatment tank



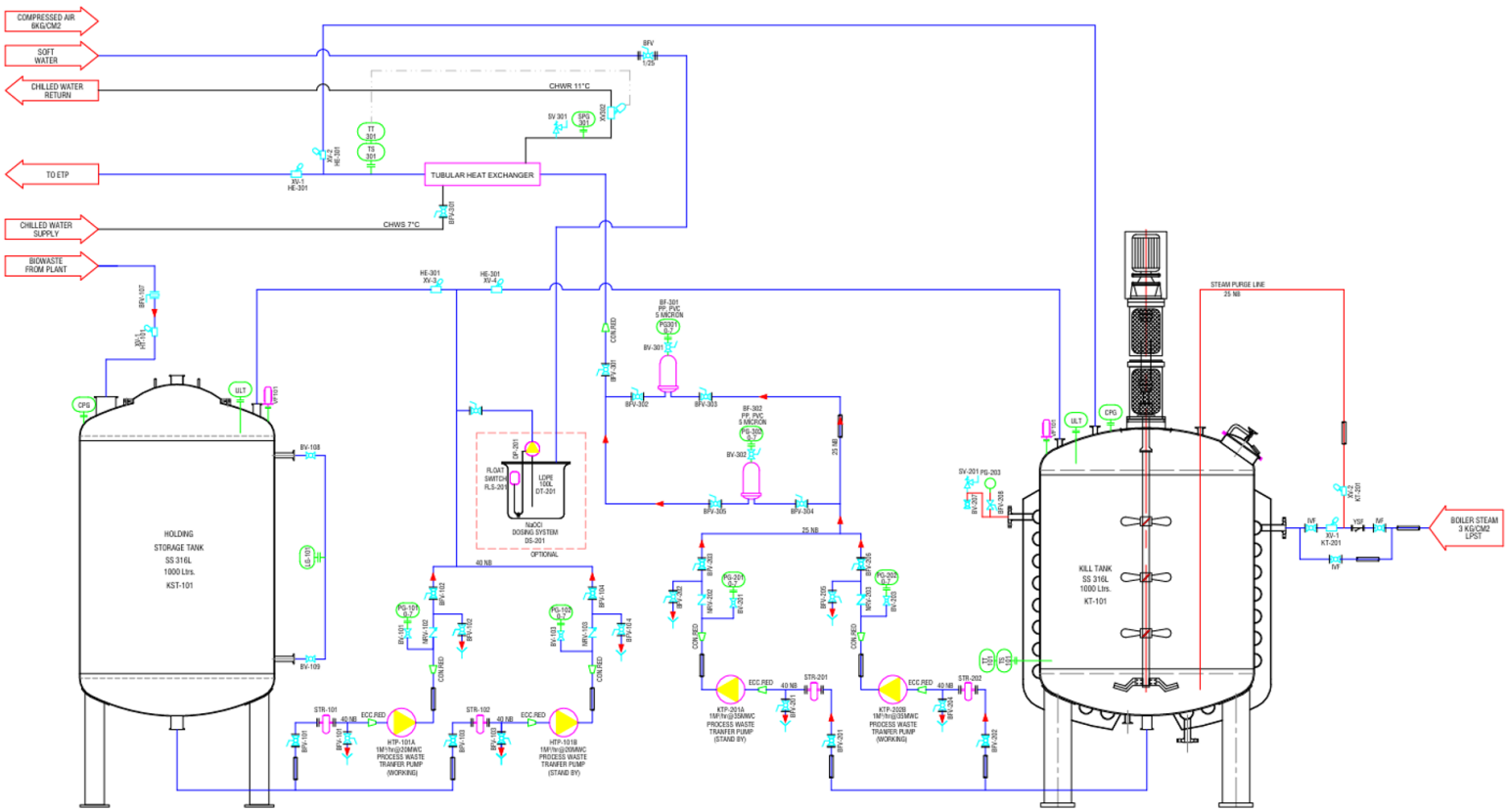
6. LAYOUT PROVISION FOR THE KILL TANK – FILL FINISH BLOCK – BASEMENT FLOOR



7. LAYOUT PROVISION FOR THE EFFLUENT TREATMENT TANK – SITE – SERVICES



8. KILL TANK PIPING &INSTRUMENTATION DIAGRAM (P&ID) – (GENERAL)



LEGEND

BUTTER FLY VALVE MANUAL

BALL VALVE SCREWED MANUAL

BALL VALVE FLANGED MANUAL

PUMP

NON-RETURN VALVE

ANGLE SEAT VALVE ELCTRO-PNEUMATIC

DRAINAGE

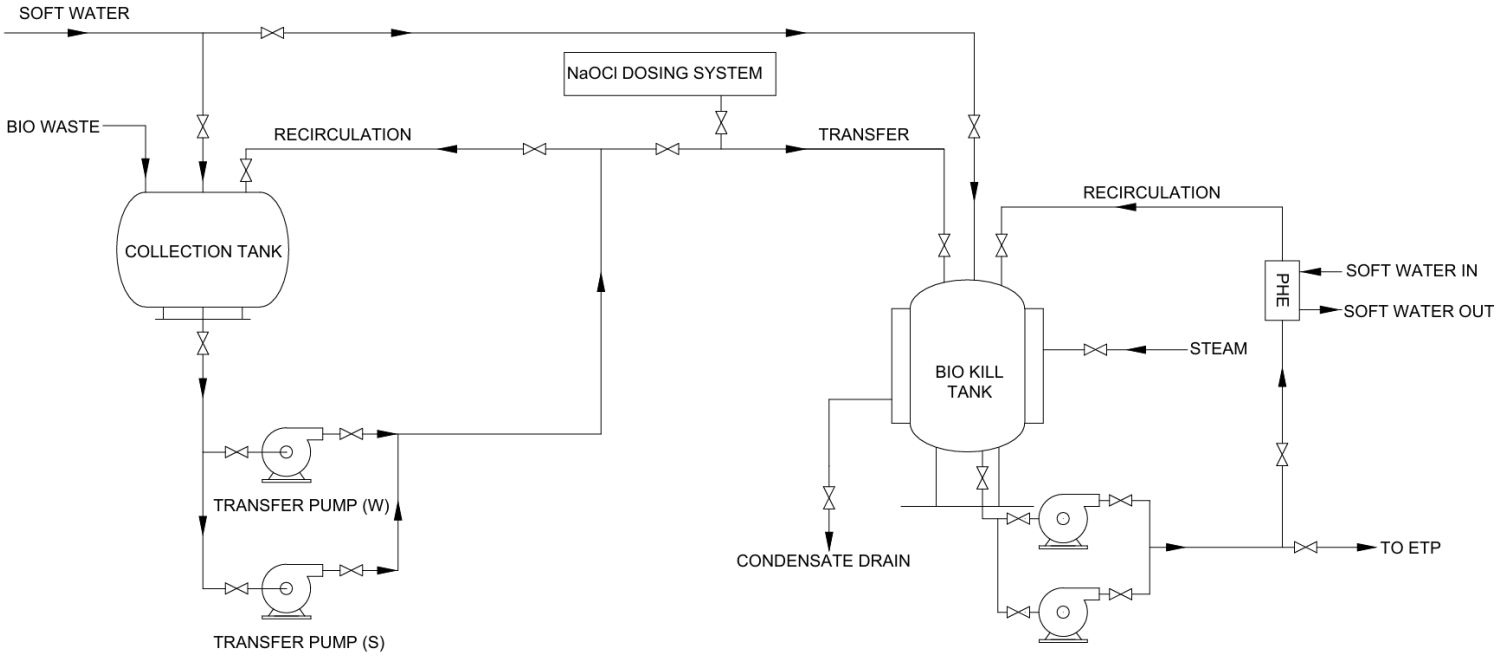
PG - PRESSURE GAUGE

TS/TT - TEMPERATURE SENSOR CUM TRANSMITTER

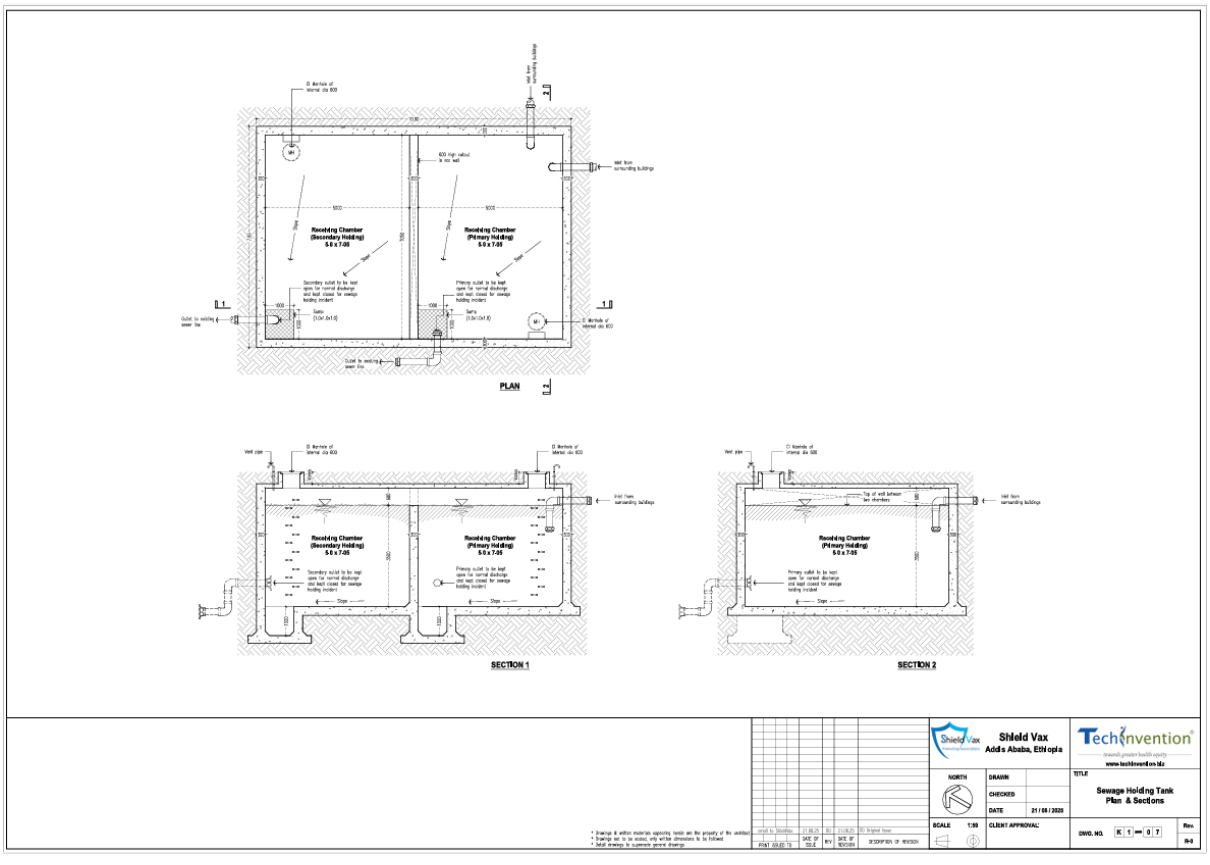
BF - BAG FILTER

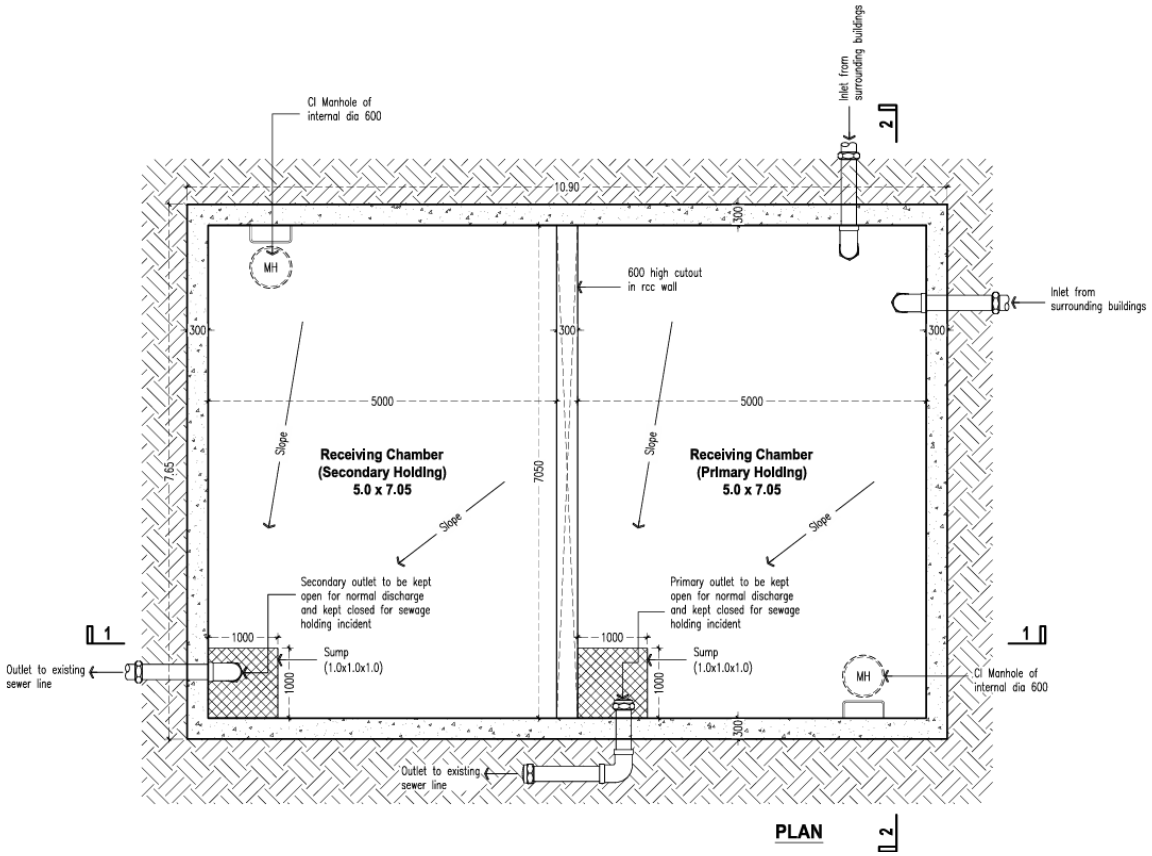
STR - BASKET STAINER

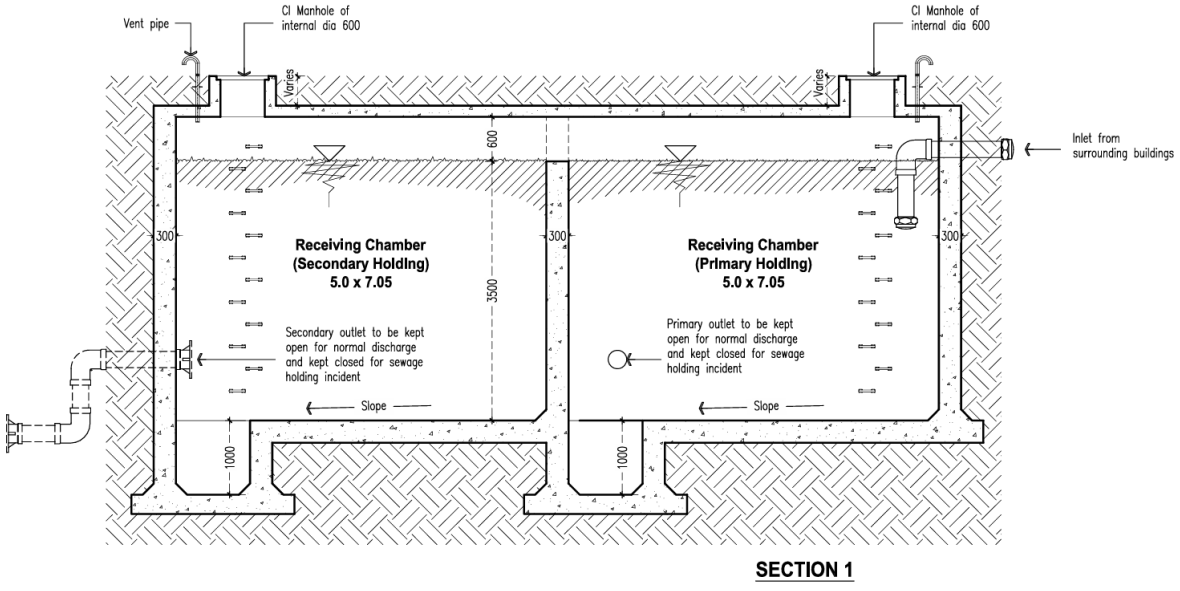
9. KILL TANK – PROCESS FLOW DIAGRAM - PFD (GENERAL)

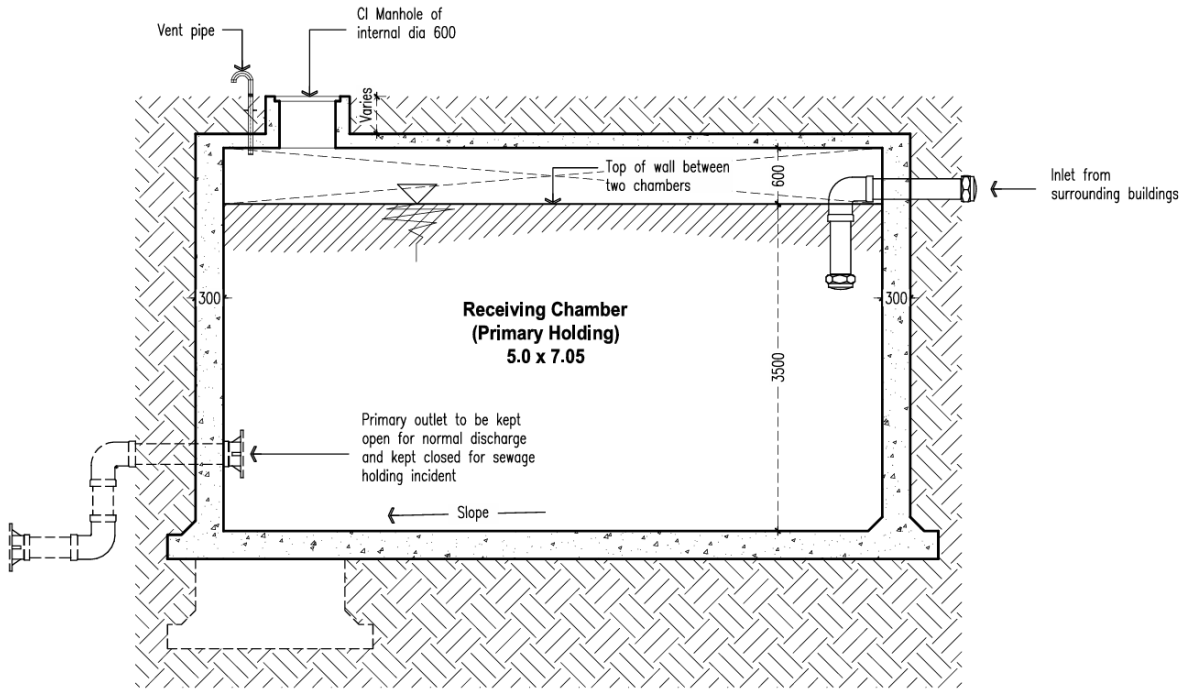


10. SEWAGE/WASTE WATER TRETAMENT TANK DESIGN FOR THE SHIELDVAX'S FACILITY




CI Manhole of internal dia 600
Inlet from surrounding buildings
2
10.90
300
MH
600 high cutout in rcc wall
Inlet from surrounding buildings
300
300
300
5000
5000
Slope
Receiving Chamber (Secondary Holding) 5.0 x 7.05
7050
7.65
Slope
Receiving Chamber (Primary Holding) 5.0 x 7.05
Slope
Slope
Secondary outlet to be kept open for normal discharge and kept closed for sewage holding incident
Primary outlet to be kept open for normal discharge and kept closed for sewage holding incident
1
1000
1000
Sump (1.0x1.0x1.0)
1000
1000
Sump (1.0x1.0x1.0)
1
Outlet to existing sewer line
MH
CI Manhole of internal dia 600
300
Outlet to existing sewer line
PLAN
2


Vent pipe
CI Manhole of internal dia 600
CI Manhole of internal dia 600
Varies
Varies
600
Inlet from surrounding buildings
300
300
300
Receiving Chamber (Secondary Holding) 5.0 x 7.05
3500
Receiving Chamber (Primary Holding) 5.0 x 7.05
Secondary outlet to be kept open for normal discharge and kept closed for sewage holding incident
Primary outlet to be kept open for normal discharge and kept closed for sewage holding incident
Slope
Slope
1000
1000
SECTION 1


Vent pipe
CI Manhole of
internal dia 600
Varies
Top of wall between
two chambers
600
Inlet from
surrounding buildings
300
Receiving Chamber
(Primary Holding)
5.0 x 7.05
300
3500
Primary outlet to be kept
open for normal discharge
and kept closed for sewage
holding incident
Slope

SECTION 2

ANNEX IX: Checklist for Data collection

Baseline date	Parameter	Description
1. Demography of the proposed project implementation area	Population number (male and female)	
	Age group	
	Religion	
	Ethnicity	
	Type of livelihood Agriculture, commercial or both)	
	Livelihoods and employment rate to the city	
	Birth/Death rates	
2. Physical Environment	2.1 Description of the project site including boundary areas	
	2.1 Air resource such as meteorological data (Temperature, wind and wind direction), Ambient air quality (Particulates), Stationary source of emission; mobile source of emission (e.g Cars and truck etc)	
	2.3 Water Resource	
	Surface water: such as location and type (e.g estuaries, streams lakes and their position relative to the site, water quality information (e.g BOD, COD, temperature, nutrients), existing pollutant source (location and amount of discharge), future uses	
	Ground water: description of key factors (e.g., depth to water table, overlying soil, geologic features), water quality information (e.g pH, Solid),	
	2.4 Soil and Geology: topography, soil structure, ground water movement, erosion potential, subsidence, seismic activity (e.g proximity to faults, history of earthquakes and volcanic eruptions), mineral resources (e.g locations of deposit, type and quantities, ownership of mining right)	
	2.5. Natural Calamities Risks: Project Construction Sitev Risk of Earthqauke, flood, volcanic erruption will be assessed)	
	2.6. Wind direction (wind direction and wind speed will be investigated)	
3. Biological Conditions	3.1 Wildlife and vegetation: description and listing of aquatic, wetland, and terrestrial flora and fauna (e.g species list and abundances), description and listing of native species of wildlife and vegetation present, description and listing of particularly invasive exotic species of wildlife and vegetation, description and listing of rare and threatened species,	

	3.2 community and Habitat Characterization: maps and description of the aquatic, wetland, and terrestrial communities found in and around the project site,	
	3.3 Ecologically significant features: support of broader ecosystem by the project site (e.g nutrient source through flooding, storm water retention), important ecological functions of the project site (e.g nutrient source through flooding storm water retention), characterization of relevant disturbance regimes, natural and project-induced (e.g flood, fire, potential impact of logging), description of important biotic interactions (e.g interdependence of plant and animals at the site and with other site)	
4. Waste Management and pollution prevention	Estimation of expected waste disposal or discharge	
	Assessment of available waste disposal sites in Addis Ababa (capacity, current condition and future capacity	
	Description of waste management techniques (E.g treatment, storage, transport, recycling for each type of waste)	
	Project waste characterization (e.g types, quantities, toxicity profile) focus on clinical wastes and municipal solid waste separately	
5. Socioeconomic Environment	5.1 Land use: like description of present and historic land use, map of present and historic land use,	
	5.2 Population and Housing: demographic information (e.g average household size, age, age/sex distribution, Ethnic composition, and community cohesion	
	5.3 Economic Activity: description of present economic activity (e.g number and type of business, annual revenues, ownership patterns), Description of unique features of business community (e.g high seasonality of trade, high outflow of profit, declining of trade, or downtown revitalization)	
	5.4 Community service and public finance: description of existing public facility and services within vicinity of project including existing level of use and remaining capacity to accommodate growth, This include road, health facility (Number of clinics, health centers, health posts, hospitals, Diagnostic centers), school (Kindergarten primary school, secondary school, college, university, Girls and boys enrolment rate), water and sanitation, electricity, Telecommunications; Communal and Recreation Facilities, market, recreational areas, green areas	
	5.5 Transportation: Description of all relevant forms of transportation for facility, current traffic volume, current traffic capacity, provision of public transportation, assessment of the adequacy of the system for meeting peak demands during	

	construction and operation phase;	
	5.6 Health and safety: description of present health and safety issues, description of possible risks of the project, identification of special populations areas more likely to be exposed to adverse impacts, identification of top ten disease of the area,	
	5.7 waste treatment and disposal sites: Assessment of the capacity/due diligence of Solid and wastewater treatment plants related to the proposed facility.	
6. Cultural resource	6.1 Archeological sites relating to the project, paleontological sites related to the project, historic sites in relation to the project, education, religious scientific, or cultural sites in relation to the project,	
7. Project characterization	7.1 Project description: Name, ownership, establishment, vision, mission, objective; type of facility available, project components, location of the project including Google map, Description of the proposed Project.	
	7.2 Design requirements of construction project and: general design and safety requirements	
	7.5 Waste management approaches and practices: Types and quantity of waste generated, waste management practices	
	7.6 Utility requirements: water supply and consumption, source of energy and consumption, amount of fuel required, amount of natural gas required, oil and grease requirements,	
8. Public consultation	8.1 Stakeholder engagement: identification of stakeholders such as Woreda EPA officer, Woreda Socio-economic office, plan commission, health office, education office, Cultural and tourism office, sanitation office (City administration and Woreda level),	
	8.2 Public consultation: selection of participants from youth, elders' business community, residents around the project site, community leaders, religious leaders, affected and interested parties	

ANNEX X: Incident Reporting Template (Adapted from Environment and Social Incident Response Toolkit (ESIRT) of the World Bank)

A. Incident Notification Form

(for prompt submission upon occurrence of a reportable incident)

Project Name: _____
Project ID: _____
Date of Report: ___ / ___ / ____
Time of Report: _____
Reporting Party (Name/Role): _____
Contact Information: _____

1. Incident Basic Information

Date of Incident: ___ / ___ / ____

Time of Incident: _____

Location (facility/area): _____

Type of Incident (tick all applicable):

- ☐ Fatality or serious injury
- ☐ Near-miss with serious potential harm
- ☐ Major environmental release/spill
- ☐ Breach of containment / chemical exposure
- ☐ Fire / explosion
- ☐ Security incident / community grievance / SEA/SH (*)
- ☐ Other (specify): _____

* SEA/SH = Sexual Exploitation/Abuse or Sexual Harassment. (Based on ESIRT Annex 1 for "reportable incidents".)

Immediate Impact / Harm (people/environment/property):

_____

Is the incident likely to have a significant adverse effect on workers, community, environment, or project?

□ Yes □ No □ Unknown

2. Immediate Actions Taken

Describe immediate response (e.g., medical attention, containment, shutdown):

_____

Is the site safe now? □ Yes □ No □ Controlled

Has the incident been reported to regulatory/local authorities? □ Yes □ No
If yes, which authority and on which date: _____

3. Project Relation

Was the incident:

□ Directly caused by the project's works/activities?

□ Indirectly related to project (contractor/supply chain)?

□ Not related to project but occurred on project site?

□ Unknown

Brief description of how the project may have contributed:

_____

4. Proposed Next Steps

Investigation required: □ Yes □ No

Responsible person/unit for investigation: _____

Estimated timeline for investigation/report: ___ days

Interim measures to prevent recurrence (if known):

_____

5. Attachments

Photographs of incident site: □ yes □ no

Witness statements: □ yes □ no

Other documents: _____

Signature of Reporting Party: _____

Date / Time: ___ / ___ / ____ _____

B. Detailed Incident Investigation & Corrective Action Report

(to be completed after investigation, submitted to Supervising Engineer/Client and relevant authorities)

Project Name: _____

Project ID: _____

Incident Notification Form Ref. No.: _____

Date of Incident: ___ / ___ / ____

Date Investigation Report Submitted: ___ / ___ / ____

Investigating Team / Lead Investigator: _____

1. Incident Overview

Description of Incident: (what happened, when, where, who)

_____

_____

_____

Immediate Impacts:

People (injuries, fatalities): _____

Environment (spill, emissions, damage): _____

Property / Equipment: _____

*** Photos / Diagrams:** (attach)

2. Root Cause Analysis

Underlying causes: (technical, organizational, human error, systems failure)

_____

_____

_____

Project-related factors: (design, supervision, contractor performance, maintenance)

_____

_____

External factors: (weather, third-party actions, regulatory lapses)

_____

_____

4. Corrective & Preventive Actions

#	Action Description	Responsible Person/Unit	Timeline	Status
1				□ Not Started □ In Progress □ Completed
2				□ Not Started □ In Progress □ Completed
3				□ Not Started □ In Progress □ Completed

Signature of Lead Investigator: _____
Date: ___ / ___ / ____

Reviewed by (Project Manager / EHS Manager): _____
Date: ___ / ___ / ____

ANNEX XI: Volumes of daily waste to be incinerated

Types of waste material emerging from SHIELDVAX'S vaccines manufacturing facility

Sr.No.	Waste Type		Examples	Treatment Method	Disposal Method
1	Manufacturing activity based	Liquid	reagents, solvants, buffers, waste water (washing & cleaning); rejected - expired inactivated vaccine material; CIP discharge	Autoclaving/Sterilization /Decontamination/Chemical Neutralization/Pre-treatment	Kill tank - ETP - Centralized ETP waste collection by KIP
		Solid	PPE Kits, swabs, packaging material (Poly bags), broken or waste vials, rubber stoppers, alluminium caps	Autoclaving/Sterilization /Decontamination/	**Incineration** / Approved 3rd party disposal / KIP waste disposal
			Warehouse Material - Packaging material - poly bags, cartons - corrugated boxes, paper, labels.	Shredding of packaging material/Shrinkpack	**Incineration** / Approved 3rd party disposal / KIP waste disposal
2	General Waste		Office supplies, food waste	Segregated collection as per organizational SOPs and KIP guidelines	General municipal waste disposal / KIP waste disposal
3	E-Waste		Electronics, sensors, batteries, computers, computer components, laptops etc.	Segregated collection as per organizational SOPs and KIP guidelines	Certified e-waste recycling

Packaging types and daily estimated generation

Sr. No.	Packaging Type	Material	Weight Estimate	Remarks	Waste available for incineration
1	Primary Packaging	Glass vial (10R) Rubber stopper Aluminum crimp cap	15–18 kg	Consumed. Used in the manufacturing process. Negligible waste generated.	None/Negligible
2	Secondary Packaging	Plastic trays or molded pulp trays, Cardboard partitioning, Carton box to hold trays	2–4 kg	Used in the warehouse.Can be returned to the vendor or 3rd party waste collection or the waste collection services provided by the KIP.	None/Negligible
3	Tertiary Packaging	Corrugated cardboard master shipper, Insulation (polystyrene, foam, or phase change materials if cold chain required), Pallet wrap, labels, etc.	3–6 kg	Can be returned to the vendor or 3rd party waste collection or the waste collection services provided by the KIP.	None/Negligible

Approximate quantification of possible ash generation from the SHIELDVAX'S facility

Sr. No.	Year	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040	2041	2042	2043	2044	2045	2046	2047
1	Number of doses (Million) per annum	**8**	**21**	**41**	**50**	**54**	**72**	**72**	**73**	**74**	**75**	**75**	**76**	**77**	**78**	**78**	**79**	**80**	**81**	**82**	**82**
2	Number of Vials-Multidose (million) per annum	1	2	4	5	5	7	7	7	7	7	8	8	8	8	8	8	8	8	8	8
3	Number of Vials-Multidose in 1000s per annum	820	2050	4100	4969	5437	7164	7236	7308	7382	7455	7530	7605	7681	7758	7836	7914	7993	8073	8154	8235
4	Approx Weight (Kg) of Waste generated per 1000 Vials	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
5	Total Weight of the waste generated per Annum	4920	12300	24600	29815	32623	42987	43417	43851	44289	44732	45180	45631	46088	46549	47014	47484	47959	48439	48923	49412
6	Total Weight of the waste generated per Annum per month	410	1025	2050	2485	2719	3582	3618	3654	3691	3728	3765	3803	3841	3879	3918	3957	3997	4037	4077	4118
7	Total Weight of the waste generated per Annum per day	14	34	68	83	91	119	121	122	123	124	125	127	128	129	131	132	133	135	136	137
8	Ratio of the Ash generated to actual weight (100:1)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
9	**Weight (Kg) of the Ash generated per day**	**0.14**	**0.34**	**0.68**	**0.83**	**0.91**	**1.19**	**1.21**	**1.22**	**1.23**	**1.24**	**1.25**	**1.27**	**1.28**	**1.29**	**1.31**	**1.32**	**1.33**	**1.35**	**1.36**	**1.37**