

Biovac - Operational ESMP



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Environmental and Social Management Plan (ESMP) for the Operational Phase

**Proposed Vaccine Production Facility and Associated
Infrastructure, located in Pinelands, Western Cape
Province**

**The Biologicals and Vaccines Institute of Southern Africa (Pty)
Ltd**

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Making Sustainability Happen

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Basis of Report

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Executive Summary

The Biologicals and Vaccines Institute of Southern Africa (Pty) Ltd (Biovac) proposes to operate a new vaccine production facility and associated infrastructure located in Pinelands, Western Cape Province. The facility will support vaccine manufacturing activities in accordance with Good Manufacturing Practice (GMP) and Biosafety Level 2 (BSL-2) requirements.

This Environmental and Social Management Plan (ESMP) has been prepared by SLR Consulting (South Africa) (Pty) Ltd to address the Operational Phase of the project only, in response to requirements of international lenders, including the African Development Bank (AfDB), the International Finance Corporation (IFC) and the European Investment Bank (EIB).

The ESMP sets out the mitigation, monitoring, management and reporting measures required to manage environmental, social, health, safety, labour, community health and biosafety risks associated with operation of the facility. The ESMP is aligned with applicable South African legislation, AfDB Operational Safeguards (OS), IFC Performance Standards, EIB Environmental and Social Standards, and World Bank Group Environmental, Health and Safety Guidelines. It is integrated into Biovac's existing Environmental and Social Management System (ESMS).

Key elements of the ESMP include clearly defined roles and responsibilities, operational mitigation measures, rehabilitation and reinstatement of areas disturbed during operations, grievance redress mechanisms for workers and communities, emergency preparedness and response, environmental and occupational health monitoring, and internal and external auditing.

Implementation of the ESMP will be supported by adequate organisational capacity and financial resources, with indicative operational ESMP costs informed by Biovac's existing operations and conservative provision included in the project's financial model.

This ESMP provides a robust framework to ensure that the facility is operated in a safe, environmentally responsible and socially acceptable manner, while meeting lender requirements and supporting the sustainable operation of the project.



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Acronyms and Abbreviations

BSL	Biosafety Level
CIP	Central In Place
CLO	Community Liaison Officer
DEA&DP	Department Of Environmental Affairs and Development Planning
E&S	Environment And Social
EHS	Environmental, Health and Safety
EIB	European Investment Bank
EPRP	Emergency Preparedness and Response Plan
ESIA	Environmental and Social Impact Assessment
ESMP	Environmental And Social Management Plan
ESMS	Environmental and Social Management System
GA	General Authorisation
GBV	Gender Based Violence
GHG	Greenhouse Gases
GMP	Good Manufacturing Practice
GRM	Grievance Redress Mechanism
GWP	Global Warming Potential
HDx	Human Development Accelerator
HEPA	High-Efficiency Particulate Arrestance
HR	Human Resources
HVAC	Heating, Ventilation and Air Conditioning
IFC	International Finance Corporation.
ILO	International Labour Organisation
ISS	Integrated Safeguard System
KPI	Key Performance Indicator
LED	Light-Emitting Diode
LEV	Local Exhaust Ventilation
MSDS	Material Safety Data Sheets
NCR	Non-Conformance Report
NEMA	National Environmental Management Act
OEM	Original Equipment Manufacturer
O-ESMP	Operational Environmental and Social Management Plan
OHS	Occupational Health & Safety
OS	Operational Safeguards (AfDB)
pH	Potential of Hydrogen
PPE	Personal Protective Equipment



PS	Performance Standard
QA	Quality Assurance
SANS	South African National Standards
SAPS	South African Police Services
SARTSM	South African Road Traffic Signs Manual
SDC	Safe Disposal Certificate
SEA	Sexual Exploitation and Abuse
SEP	Stakeholder Engagement Plan
SIP	Sterilise in Place
SOP	Standard Operating Procedure
TIA	Transport Impact Assessment
VOC	Volatile Organic Compound
VSD	Variable Speed Drives
WBG	World Bank Group
WFI	Water for Injection
WWTP	Wastewater Treatment Plant



1.0 Introduction

1.1 Project Description

The Biological and Vaccines Institute of Southern Africa (Pty) Ltd, trading as the Biovac Institute (hereafter referred to as Biovac) ("The Proponent"), proposes the development of a new vaccine production facility and associated infrastructure on unregistered Erf 183467. This site comprises a portion of the remainder of Erven 118296, 103659, and 24176, as well as Erf 1056, located in Pinelands, Western Cape.

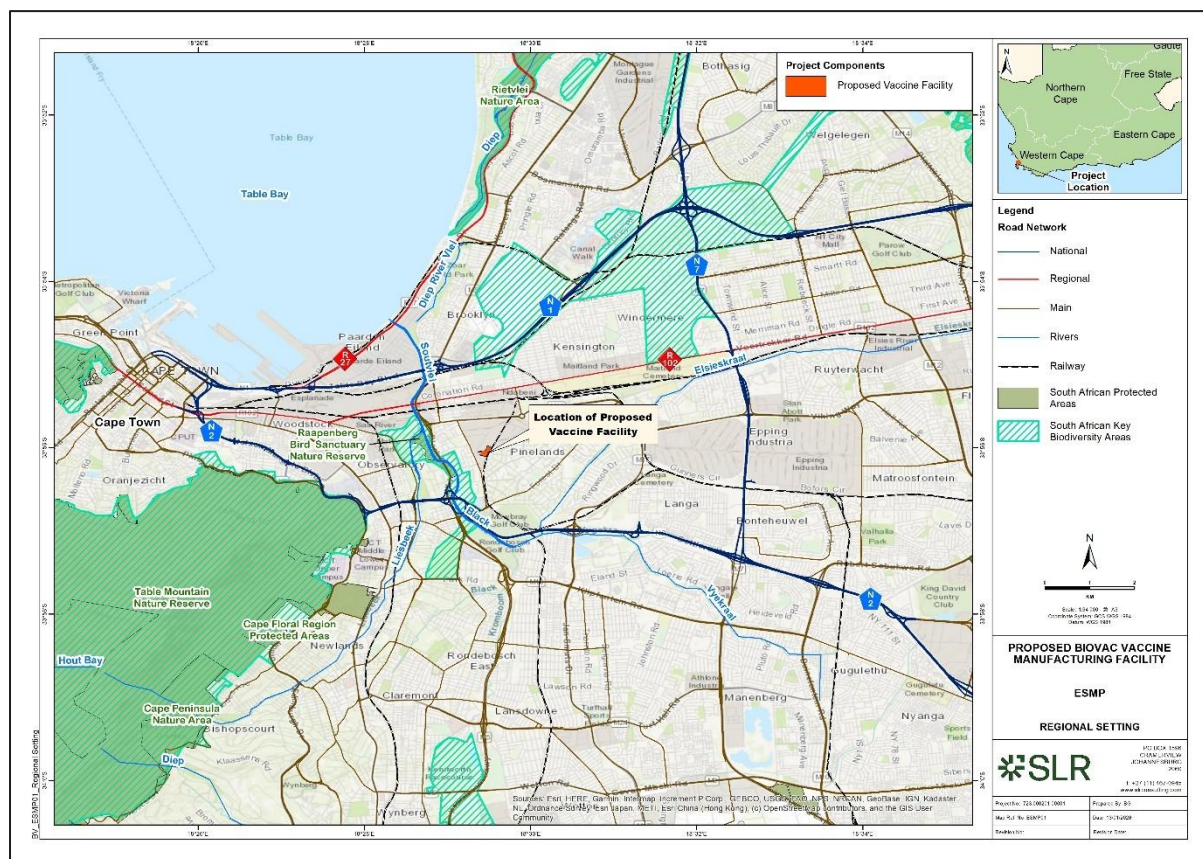


Figure 1-1: Locality Map of Proposed Site

The proposed project will include the following key components:

- A manufacturing building for vaccine production, filling, and packaging.
- A utility building; and
- Associated municipal service infrastructure.

The total footprint of the development is approximately 14,854 m².

The Western Cape Department of Environmental Affairs and Development Planning (DEA&DP) has confirmed that the proposed project does not trigger any listed activities as defined under the National Environmental Management Act (NEMA) (Act No. 107 of 1998) and the associated Environmental Impact Assessment (EIA) Regulations, 2014 (GN No. R. 982 of 2014). Consequently, an EIA process in terms of South African legislation is not required.



Biovac has approached the International Finance Corporation (IFC), the European Investment Bank (EIB), Human Development Accelerator (HDX) and the African Development Bank (AfDB) to secure funding for the development. In response to lender requirements, SLR Consulting has prepared this Environmental and Social Management Plan (ESMP) for the Operational Phase (only).

1.2 Operational Scope

The Operational Phase of the proposed vaccine manufacturing facility will commence once construction, commissioning, and cleanroom qualification activities have been completed. During this phase, Biovac will assume full responsibility for operating and maintaining the facility, including all production suites, cleanrooms, utilities, and supporting infrastructure.

Operational activities will include routine GMP-compliant vaccine manufacturing processes, facility and equipment maintenance, utilities management, waste handling, biosafety controls, environmental monitoring, worker health and safety measures, and community/stakeholder engagement. These activities will be implemented in line with all applicable national legislation, international lender standards, and internal Biovac quality and biosafety requirements.

All operational functions must be carried out in accordance with the Operational Environmental and Social Management Plan (O-ESMP), which sets out the required mitigation, monitoring, reporting, and compliance obligations to ensure that environmental, social, health, safety and biosafety risks are effectively managed throughout the lifecycle of the facility.

1.3 Aim of the ESMP

This ESMP has been developed for use by the Proponent, its contractors, sub-contractors and service providers during the Operational Phase. It is based on the findings of the Environmental and Social Impact Assessment (ESIA), and its outcomes have been used to inform the measures contained in this ESMP. The ESMP is designed to ensure compliance with the relevant national legislation and relevant international standards.

The ESMP demonstrates Biovac's commitment to E&S sustainability, which extends to all contractors, sub-contractors, and the broader project supply chain. It is essential that contractors, subcontractors and service providers fully understand and adhere to the ESMP requirements, including the mitigation, monitoring, and reporting obligations it imposes. The existing ESMS will be updated to incorporate the requirements of this ESMP.

Note: The effectiveness of the ESMP is limited by the level of adherence to the conditions set forth in the ESMP by the Proponent, the contractor, sub-contractors and service providers. It is assumed that compliance with the ESMP will be monitored and audited as set out in this ESMP. It is also assumed that the ESMP will be included in contracts to ensure the requirements detailed herein are legally binding.

1.4 Objectives of the ESMP

This ESMP has the following objectives:

- Ensure compliance with all applicable statutory and regulatory requirements including local, provincial, and national environmental legislation, occupational health and safety laws, public health regulations, and internationally accepted lender standards (IFC, EIB, WBG, and relevant ILO conventions).



- Establish the environmental, social, health, safety, Good Manufacturing Practice (GMP), and biosafety standards that must be achieved and maintained throughout the operational phase in accordance with South African law and international good practice.
- Specify operational mitigation measures and performance requirements to effectively avoid, minimise, or manage environmental and social impacts associated with routine operations, utilities management, waste handling, wastewater discharge, air emissions, biosafety controls, and traffic movements.
- Identify measures to enhance positive socio-economic benefits including local employment, capacity building, supplier development, and skills transfer.
- Prevent long-term or irreversible environmental degradation by ensuring robust control of emissions, discharges, hazardous materials, biological waste, and energy and resource use.
- Establish a monitoring, reporting, and auditing system for tracking environmental and social performance, ensuring operational compliance, and enabling continuous improvement of management practices.
- Define corrective and preventative actions necessary to address non-compliance, incidents, deviations, and near misses.
- Ensure implementation of health, safety, emergency response, and biosafety requirements to safeguard employees, contractors, visitors, neighbouring communities, and the environment.
- Provide mechanisms for ongoing engagement and transparent communication with workers, contractors, neighbouring communities, and authorities, including the operation of accessible grievance mechanisms.
- Specify the timeframes within which ESMP measures must be implemented and sustained throughout the operational life of the facility.
- Promote continuous environmental and social awareness and training through induction programmes, refresher courses, toolbox talks, and competency development for all operational personnel.

This ESMP is a “living document” and must be updated periodically to reflect changes in operations, regulatory requirements, monitoring results, audit findings, or improvements in environmental, social, health, safety, GMP, and biosafety performance.

1.5 Relationship between the ESMP and Biovac’s ESMS

This Operational Environmental and Social Management Plan (ESMP) is embedded within and subordinate to Biovac’s existing Environmental and Social Management System (ESMS). The ESMP does not constitute a parallel management system, but rather sets out project-specific operational controls, mitigation measures and monitoring requirements that shall be implemented through Biovac’s established ESMS frameworks, procedures and governance structures.

Biovac’s ESMS for existing operations shall be reviewed and updated, where necessary, to incorporate the requirements of this ESMP and to reflect the risks, scale and operational profile of the new vaccine manufacturing facility. Implementation, monitoring, reporting and corrective actions associated with this ESMP shall be managed through the ESMS.



2.0 Legal and Regulatory Framework

The Operational ESMP has been prepared in alignment with applicable international, national, and local environmental, social, and health and safety standards and relevant local legislation. These include:

2.1 National Legal Requirements

The main national legislation applicable to environmental, social, and occupational health and safety aspects includes:

- National Environmental Management Act (NEMA, Act 107 of 1998)
- National Environmental Management: Waste Act (Act 59 of 2008)
- National Environmental Management: Air Quality Act (Act 39 of 2004)
- Occupational Health and Safety Act (Act 85 of 1993)
- Labour Relations Act (Act 66 of 1995)
- Basic Conditions of Employment Act (Act 75 of 1997)
- Municipal by-laws (such as *inter alia* the Air Quality Management By-law, Noise Control Regulations, Traffic Management and Road Safety By-law, Community Fire Safety By-law Waste Water Management By-Law and Waste Management By-law)

2.2 International Requirements

To ensure that all environmental, social, health and safety requirements are met during the Operational Phase, this ESMP has been developed with reference to the following standards and guidelines:

- IFC Performance Standards on Environmental and Social Sustainability (2012).
- EIB Environmental and Social Standards (2022);
- African Development Bank Group's Integrated Safeguards System (2023);
- WBG General Environmental, Health & Safety Guidelines (2007);
- WBG Environmental, Health and Safety Guidelines for Construction (2007); and
- Relevant International Labour Organization (ILO) Conventions, including core labour standards on forced and child labour, non-discrimination, freedom of association, and occupational health and safety

3.0 Roles and Responsibilities

The roles and responsibilities associated with the implementation, oversight, and monitoring of this ESMP during the Operational Phase are presented in All human resources appointed to E&S functions must be suitably qualified with demonstrated competence and experience specific to the role and responsibilities outlined hereunder. Biovac, as the Proponent, retains ultimate accountability for Environmental and Social (E&S) performance throughout the construction phase, including ensuring that all appointed contractors, subcontractors, and personnel adhere to the requirements of this ESMP.



Table 3-1 below¹. All human resources appointed to E&S functions must be suitably qualified with demonstrated competence and experience specific to the role and responsibilities outlined hereunder. Biovac, as the Proponent, retains ultimate accountability for Environmental and Social (E&S) performance throughout the construction phase, including ensuring that all appointed contractors, subcontractors, and personnel adhere to the requirements of this ESMP.

Table 3-1: Roles and Responsibilities

Role	Responsibility
Proponent Resources	
Proponent²	• Appoint a Project Manager to assume ultimate project responsibility. • Approve the ESMP and allocate resources for implementation. • Ensure ESMP requirements are embedded in contracts and procurement. • Maintain overall accountability for E&S performance. • Enforce the E&S specification on site. • Report E&S performance to lenders (IFC/EIB/HDX, and the AfDB) as per financing agreements. • Notify lenders (IFC, EIB, HDX and the AfDB) immediately in the event of any significant incident, including fatalities, life-threatening injuries, major spills, pollution events, injuries to members of the public, or Gender Based Violence (GBV) incidents. • Oversee audits and corrective actions. • Maintain a register of complaints and queries by members of the public at the site office. • Ensure the ESMP is implemented as well as revised and updated, as and when required.
Environment, Health and Safety (EHS) Manager	• Oversee implementation of the ESMP throughout the Operational Phase. • Monitor compliance with the requirements of the E&S specification.

¹ Overall accountability for environmental and social performance, including implementation of the ESMS and this Operational ESMP, rests with Biovac's Executive Management. The Executive Management team provides strategic oversight, ensures adequate resourcing, and endorses ESMS policies, performance reviews and material changes. Day-to-day coordination and implementation are delegated to the EHS Manager, who reports into Biovac's management structures in accordance with internal governance arrangements.

² The Proponent (Biovac) may delegate responsibilities to members of its senior management, as deemed appropriate.



Role	Responsibility
	• Ensure continuous improvement and adaptive management of environmental, social, and health & safety performance on site. • Liaise with the Community Liaison Officer (CLO) on stakeholder engagement and grievances. • Prepare monthly ESMP compliance reports based on engagement with CLO. • Request for, review and approve the SOPs. • Undertake regular site inspections and ensure E&S and OHS specifications are implemented. • Review audit reports and take cognisance of the information/ recommendations contained therein. • Update ESMS risk register following internal and external audits (when necessary). • Comply with all applicable legislation. • Coordinate and oversee EHS, GMP and biosafety training programmes. • Ensure investigation, root-cause analysis and close-out of incidents, near misses and non-conformances. • Coordinate internal and external ESMP, EHS and OHS audits and track corrective actions to close-out.
CLO	• Implement the Stakeholder Engagement Plan (SEP). • Operate and maintain the grievance mechanism (acknowledgement within 48 hours; resolution within 14 days). • Issue advance notifications to affected communities regarding disruptive activities (e.g. noise, dust, traffic). • Document stakeholder engagement activities, grievances, and feedback loops and report to the Proponent Project Manager and EHS Manager. • Report social performance, incidents, and corrective actions to the Proponent and Contractor's EHS Managers.
Independent Resources³	
E&S Auditor	• To be appointed by the Proponent to undertake E&S audits according to the requirements of the ESMP.

³ Note: Each role listed refers to an individual position.



Role	Responsibility
	• Be fully conversant with the ESMP. • Monitor the implementation of the ESMP during the Operational phase. • Ensure site protection measures are implemented on site. • Monitor that the Proponent, Contractor, sub-contractors and service providers follow the ESMP. • Conduct annual audits of the site according to the ESMP, and report findings to the Proponent and Lenders. • Recommend corrective action for any E&S non-compliance at the site. • Liaise with the Safety Agent regarding any OHS findings that may be relevant to IFC Performance Standards 2 and 4 respectively.
Safety Agent	• To be appointed by the Proponent to undertake OHS audits according to the requirements of the OHS Plan and local legislative requirements. • Be fully conversant with the OHS Plan. • Monitor the implementation of the OHS Plan during the Operational phase. • Ensure OHS measures are implemented on site. • Monitor that the Proponent, Contractor, sub-contractors and service providers are in compliance with the OHS Plan. • Conduct audits of the site according to the OHS Plan and report findings to the Proponent. • Recommend corrective action for any E&S non-compliance at the site. • Liaise with the E&S Auditor regarding any OHS findings that may be relevant to IFC Performance Standards 2 and 4 respectively.

4.0 Training and Environmental Awareness

Effective implementation of the Operational ESMP depends on ensuring that all personnel involved in running the facility including Biovac staff, contractors, sub-contractors and service providers possess the appropriate level of environmental, social, health, safety, GMP and biosafety competence. Ongoing training is essential to maintain due diligence, minimise environmental harm, and ensure safe, compliant operations.

Training needs must be determined based on the roles and existing capabilities of operational personnel, ensuring that each individual has the knowledge and skills required to fulfil their ESMP responsibilities, implement mitigation measures, and perform monitoring



tasks correctly. All employees must be trained to a standard that ensures consistent, safe and environmentally responsible performance of their duties.

The operational-phase training programme aims to:

- Promote environmental, health, safety and biosafety awareness across the entire workforce.
- Ensure employees and contractors understand all operational environmental procedures, emergency response requirements, biosafety protocols, and GMP-related controls.
- Provide general training on ESMP implementation, pollution prevention measures, safe handling of chemicals, resource efficiency, waste segregation, and incident reporting.
- Provide role-specific, task-specific and department-specific training, including:
 - biosafety Level 2 (BSL-2) entry/exit procedures
 - hazardous materials management
 - wastewater system operation
 - spill response
 - emergency preparedness
 - air quality, noise and stormwater controls
 - waste management and segregation
 - contractor control and stakeholder engagement
- Reinforce good environmental and safety practices through regular refresher training and communication.

Training during the operational phase will consist of:

- Weekly toolbox talks addressing E&S, OHS, GMP and biosafety topics.
- Monthly refresher sessions on key compliance risks, monitoring requirements and emergency response procedures.
- Targeted training sessions following corrective actions, audits, incidents or changes in procedures.
- Induction training for all newly appointed employees, contractors, and visiting personnel prior to accessing operational areas.

In addition to formal training, Biovac will maintain ongoing environmental and safety awareness among the workforce through signage, periodic briefings, internal communications, and visible reporting on performance indicators. This ensures that all personnel understand the importance of their roles in maintaining a safe, compliant and environmentally responsible facility, while minimising the potential for E&S incidents and non-compliance throughout the life of the project.

5.0 Grievance Redress Mechanism

A Grievance Redress Mechanism (GRM) shall be implemented and maintained throughout the Operational Phase of the Project to enable workers, contractors, visitors, and affected communities to raise concerns, complaints or grievances related to environmental, social, labour, health, safety, security, GMP, or biosafety matters arising from operational activities at the Biovac Facility.



The Operational GRM forms an integral component of Biovac's Environmental and Social Management System (ESMS) and provides a structured, transparent and culturally appropriate process for receiving, assessing, resolving and documenting grievances. The GRM is aligned with the requirements of IFC Performance Standards, in particular IFC PS1 (Assessment and Management of Environmental and Social Risks and Impacts), IFC PS2 (Labour and Working Conditions) and IFC PS4 (Community Health and Safety).

The GRM shall be operational prior to the commencement of routine operations and shall remain active for the duration of the facility's operational life.

5.1 Worker Grievance Redress Mechanism

Biovac shall implement and maintain a Worker Grievance Redress Mechanism applicable to all operational-phase workers, including permanent employees, contract workers, service providers and on-site contractors.

The Worker GRM shall:

- Be consistent with the requirements of IFC Performance Standard 2, AfDB's Integrated Safeguard Systems (ISS) Operational Safeguards (OS) 2 and applicable to South African labour legislation;
- Be clearly communicated to all workers during induction and reinforced through ongoing awareness activities;
- Provide accessible, confidential and, where appropriate, anonymous channels for submitting grievances;
- Include safeguards to protect workers from retaliation or discrimination for raising grievances in good faith;
- Define clear roles, responsibilities and timeframes for grievance receipt, acknowledgement, investigation and resolution;
- Provide for escalation of unresolved or serious grievances (including occupational health and safety risks, labour rights violations, or GBV/Sexual Exploitation and Abuse (SEA) allegations) to senior management; and
- Maintain accurate records of grievances received, actions taken, timelines and outcomes.

The EHS Manager, in coordination with Human Resources where applicable, shall oversee the implementation of the Worker GRM, ensure investigations are conducted appropriately, and track corrective and preventive actions to close-out.

5.2 Community Grievance Redress Mechanism (Operational Phase)

A Community Grievance Redress Mechanism shall be implemented and managed by the CLO to receive, document and resolve grievances raised by neighbouring communities, affected stakeholders and members of the public related to operational activities at the facility.

The Community GRM shall:

- Be consistent with AfDB's ISS OS 10



- Be accessible, culturally appropriate and free of charge;
- Allow for confidential and anonymous submissions where requested;
- Provide multiple grievance submission channels (e.g. phone, email, in-person, written submissions);
- Acknowledge receipt of grievances within 48 hours;
- Aim to resolve grievances within 14 calendar days, unless the issue is complex and requires extended investigation;
- Include clear escalation procedures for unresolved, sensitive or high-risk grievances; and
- Maintain a grievance register capturing grievance type, date received, actions taken, resolution timeframe and outcome.

The CLO shall report grievance trends, unresolved cases and corrective actions to the EHS Manager and Proponent management as part of routine E&S reporting and lender reporting requirements.

6.0 Reporting Procedures

6.1 Environmental and Social Documentation

To demonstrate ongoing compliance with the Operational ESMP and to support regulatory, lender and internal audit requirements, Biovac must maintain a comprehensive Environmental and Social Operational File. This file may be held electronically, provided that all records are accessible, traceable, version-controlled, and verifiably communicated to relevant personnel for implementation and close-out.

The Operational E&S File must contain, at a minimum, the following documentation:

- Approved Operational ESMP (O-ESMP)
- Biovac EHS Policy
- BSL-2 Procedures and associated approvals
- Emergency Preparedness and Response Plan, including fire, spill, medical and biosafety-related procedures
- Pollution Prevention Plan, including spill containment requirements
- Stakeholder Engagement and Grievance Procedure
- Labour and Working Conditions Policy (including GBV/Sexual Exploitation and Abuse (SEA) Code of Conduct)
- Standard Operating Procedures relating to:
 - Air emissions and Heating, Ventilation and Air Conditioning (HVAC)/ High-Efficiency Particulate Arrestance (HEPA) maintenance
 - Chemical storage and hazardous substance management
 - Biological waste handling
 - Waste segregation and disposal
 - Wastewater treatment and discharge protocols



- Stormwater and climate resilience controls
 - Noise management
 - Incident reporting and investigation
 - Emergency response
 - Contractor and visitor management
- Monitoring records and logs, including:
 - Air quality logs (generator runtime, filter replacement, Volatile Organic Compounds (VOC) controls)
 - Wastewater sampling results (including bio-positive thermal inactivation logs)
 - Stormwater inspections
 - Noise monitoring reports
 - Energy and water consumption records
 - Waste registers with supporting documentation (manifests, Safe Disposal Certificates (SDCs), (weighbridge slips)
 - Chemical inventory updates
 - HEPA filter maintenance logs
 - Internal audit reports and corrective action registers
 - Monthly E&S performance reports submitted to senior management
- Training and competence records, including:
 - Training attendance registers
 - Toolbox talk logs
 - Competency evaluation forms
 - Biosafety training records
 - OHS and emergency response training documentation
- Operational Hazardous Material Documentation, including:
 - Material Safety Data Sheets (MSDS/SDS) for all chemicals
 - Inventory of hazardous substances on site (updated monthly)
 - Hazardous waste manifests & SDCs
 - Internal chemical inspections (bundling, labelling, signage)
- Stakeholder Engagement Documentation, including:
 - Community meeting records (minutes, attendance registers)
 - Notifications of operational events (e.g., generator testing)
 - Communications register
 - Community complaint investigation reports

The File may be maintained as an electronic copy; however, there needs to be evidence that E&S issues identified have been communicated to site staff to effect close-out.



6.2 Operational Procedures

During the operational phase, Standard Operating Procedures (SOPs) replace construction-phase method statements. SOPs are mandatory under GMP, OHS, biosafety and environmental requirements. They describe how each operational activity must be carried out safely, consistently, and in compliance with legislative and lender obligations.

Each SOP must include:

- Purpose and scope of the activity
- Applicable regulatory, biosafety, GMP and ESMP requirements
- Roles and responsibilities
- Step-by-step procedures for undertaking the activity
- Hazard identification and risk controls (engineering, administrative, Personal Protective Equipment (PPE))
- Emergency and abnormal-condition procedures
- Environmental and biosafety controls
- Waste management and hygiene requirements
- Monitoring, inspection and record-keeping requirements
- Version control, approval dates and responsible person

All SOPs must be:

- Approved by the EHS Manager or Quality Assurance (QA) Manager, as applicable
- Version-controlled and stored in the central document management system
- Communicated to all relevant personnel before implementation
- Updated whenever processes, risks or equipment change

The following SOPs (or equivalent procedures) must be in place during operations:

Environmental SOPs

- Air Quality Management & Filter Maintenance
- Hazardous Chemicals Handling & Storage
- Spill Response
- Waste Management
- Wastewater Treatment & Discharge
- Stormwater Management
- Noise Control
- Energy & Resource Efficiency
- Environmental Monitoring Procedures



Biosafety & GMP SOPs

- BSL-2 Laboratory Entry/Exit
- Biological Waste Segregation and Autoclaving
- Cleanroom Gowning & Behaviour
- Central in Place (CIP)/Sterilise in Place (SIP) Procedures
- HVAC/HEPA System Validation
- Material Transfer (bio-negative & bio-positive segregation)
- Incident Reporting (Biosafety)

Emergency Response SOPs

- Fire Response
- Medical Emergency
- Chemical Exposure
- Biosafety Emergencies
- Evacuation Procedures

Operational Safety SOPs

- PPE Management
- Working at Heights (if applicable)
- Hot Work Permitting
- Contractor and Visitor Management

SOPs are binding operational documents. Failure to comply with approved SOPs constitutes non-compliance with the ESMP and may trigger corrective actions, disciplinary measures, or reporting obligations under OHS, environmental, lender, or biosafety requirements.

7.0 Emergency Preparedness and Response Plan

Biovac shall develop, implement and maintain a site-specific Emergency Preparedness and Response Plan (EPRP) for the Operational Phase prior to the commencement of routine operations. The EPRP shall be proportionate to the operational risks associated with vaccine manufacturing, utilities, biosafety level operations, and supporting infrastructure, and shall be reviewed and updated periodically and following incidents, drills or changes in operations.

The Operational EPRP shall, at a minimum, address:

- Fire prevention, detection and response procedures;
- Chemical, biological and hazardous material spill response;
- Medical emergencies, first-aid and occupational exposure response;
- Biosafety incidents, including containment failures and exposure events;
- Utility failures (e.g. HVAC, WFI, power supply, clean utilities);
- Traffic incidents involving operational vehicles and deliveries;



- Severe weather and climate-related events (e.g. flooding, high winds, heatwaves);
- Security-related incidents, where applicable; and
- Incident notification, escalation, communication and reporting procedures, including notification to authorities and lenders where required.

The EPRP shall be integrated with other operational procedures, including GMP, biosafety and environmental SOPs, and shall align with relevant municipal, national emergency response requirements and the AfDB's Integrated Safeguards Systems.

7.1 Roles and Responsibilities

Table 7-1: Roles and Responsibilities for Emergency Preparedness and Response

Role	Responsibility
Proponent Resources	
EHS Manager	• Ensure that effective emergency preparedness and response arrangements are in place for operations. • Provide adequate resources, equipment and staffing for emergency response. • Ensure coordination with relevant authorities and emergency services. • Retain overall responsibility for emergency preparedness and response during operations. • Develop, review, implement and update the Operational EPRP. • Ensure emergency risks affecting worker and community health and safety are appropriately managed. • Coordinate emergency drills, training and competency assessments. • Oversee incident investigation, corrective actions and reporting. • Ensure alignment between emergency response procedures, ESMP requirements and the ESMS.
Engineering/Operations Management	• Ensure operational systems, alarms and emergency shutdowns are functional and maintained. • Support implementation of the EPRP within operational areas. • Participate in emergency drills and incident response where required.
CLO	• Support communication with surrounding communities, where relevant, during emergency events. • Manage external communications and grievance follow-up arising from emergency incidents, as required.



7.2 Coordination and Communication

Clear internal coordination procedures shall be established to ensure effective communication and escalation during emergency events. All significant incidents, including major spills, fires, biosafety incidents, serious injuries or events with potential community impact, shall be reported in accordance with the ESMP incident reporting and escalation procedures.

Biovac shall ensure ongoing coordination with relevant external emergency services, including local fire services, medical services, municipal authorities and other relevant responders, as appropriate. Emergency contact details shall be maintained, readily accessible, and displayed prominently within the facility and included in induction training and operational awareness materials.

7.3 Training, Drills and Review

Emergency response training shall be provided to all operational personnel, contractors and service providers during induction and refreshed periodically thereafter. Training shall be appropriate to the roles, risks and operational areas to which personnel are exposed.

Emergency drills (e.g. fire response, chemical or biological spill response, evacuation, utility failure) shall be conducted at planned intervals to test preparedness, response effectiveness and coordination. Records of drills, outcomes and corrective actions shall be maintained.

Lessons learned from drills, incidents, near-misses or audit findings shall be used to update the EPRP, SOPs and the ESMS risk register through Biovac's Management of Change and continuous improvement processes.

8.0 Environmental and Social Management System – Risk Identification and Risk Register

8.1 Purpose and Alignment with Lender Requirements

This chapter presents the Environmental and Social Management System (ESMS) risk identification and risk register for the Operational Phase of the Project. It has been prepared in accordance with the requirements of IFC Performance Standard 1 (Assessment and Management of Environmental and Social Risks and Impacts), EIB Environmental and Social Standards 1 (Environmental and Social Impacts and Risks) and AfDB Integrated Safeguards Systems.

The purpose of this chapter is to:

- Identify and assess environmental, social, labour, occupational health and safety, and community health and safety risks associated with the Operational Phase;
- Assign inherent and residual risk ratings; and
- Define management and mitigation measures to reduce risks to acceptable levels consistent with international good practice.



8.2 Risk Identification Methodology

Environmental and social risks were identified using a structured, risk-based approach consistent with the IFC ESMS Risk Identification Tool and the ESIA compiled by (SLR Consulting 2026). The assessment considered:

- Planned Operational activities and associated interfaces;
- Contractor and subcontractor activities;
- Applicable IFC Performance Standards, EIB Environmental and Social Standards, AfDB ISS and WBG EHS Guidelines;
- Local environmental and social context, including proximity to surrounding communities and sensitive receptors; and
- Experience from comparable projects.

Each identified risk was assessed qualitatively in terms of likelihood and severity, resulting in an inherent risk rating prior to mitigation and a residual risk rating following implementation of the mitigation measures described in this ESMP.

8.3 ESMS Risk Register – Operational Phase

Table 8-1 below presents the ESMS Risk Register for the Operational Phase. The risk register is a live management tool and shall be reviewed and updated throughout the Operational Phase to reflect audit findings, incidents, grievances, or material changes to project activities.

8.4 Monitoring, Review and Continuous Improvement

This risk register is a live ESMS tool and will be:

- Reviewed periodically throughout the Operational Phase;
- Updated following audits, incidents, or material changes to project activities; and
- Used to inform corrective actions, management reviews, and lender reporting.

The Proponent's EHS Manager is responsible for updating the ESMS risk register following internal and external audits (when necessary), and facilitating its formal review by Biovac, including prior to the commencement of operations to ensure that environmental and social performance and residual risk levels are properly recorded and communicated to lenders in line with financing agreements and international good practice.

8.5 Management Review

Senior management shall undertake formal management reviews of the ESMS, including the operational ESMP and ESMS Risk Register, on at least an annual basis, and following any significant incident, audit finding or material operational change.

The management review shall consider environmental and social performance, audit and monitoring results, incidents and grievances, compliance status, corrective actions, and opportunities for improvement. Outcomes of the management review shall be documented and used to inform strategic and operational decision-making, resource allocation, and continuous improvement of Biovac's ESMS.

8.6 Management of change

The Operational Environmental and Social Management Plan (ESMP) and associated ESMS Risk Register are living documents and shall be reviewed and updated throughout the



Operational Phase through a formal Management of Change (MoC) procedure. This process is intended to ensure ongoing effectiveness, regulatory compliance, lender alignment and consistency with Good International Industry Practice (GIIP).

The Operational MoC process forms part of Biovac's ESMS and is aligned with IFC Performance Standard 1 requirements for adaptive risk management.

8.7 Triggers for Management of Change

Updates to the Operational ESMP and/or ESMS Risk Register shall be initiated where material changes occur, including but not limited to:

- A significant environmental, social, health, safety, GMP or biosafety incident, accident or near miss;
- Regulatory non-compliance, enforcement action, inspections or fines;
- Findings arising from internal or external audits or inspections;
- Recurring grievances or material stakeholder concerns;
- Changes to operational processes, production lines, utilities, equipment, or capacity;
- Introduction of new raw materials, chemicals, biological agents, or waste streams;
- Changes to applicable legal requirements, lender standards, permits or licence conditions; or
- Organisational changes affecting EHS responsibilities or resource allocation.

8.8 Management of Change Procedure

Where a trigger event occurs, the EHS Manager shall ensure that:

- The implications of the change for environmental, social, health, safety, biosafety and community risks are assessed;
- The ESMS Risk Register is reviewed and updated to reflect revised or new risks;
- Existing mitigation measures are reviewed and revised, or additional controls are identified where required;
- Relevant sections of the Operational ESMP, SOPs, emergency procedures and management plans are updated; and
- Changes are formally approved in accordance with Biovac's ESMS and internal change-control procedures.

All changes shall be documented, version-controlled and communicated to affected personnel. Where relevant, changes shall be integrated into training programmes, toolbox talks and operational communications.

This Management of Change process supports continuous improvement and adaptive management throughout the Operational Phase of the facility.



Table 8-1: ESMS Risk Register

No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
1.	ESMS & Governance	Inadequate implementation of ESMP requirements	Regulatory and lender non-compliance; reputational risk	High	• Appointment of EHS Manager and Community Liaison Officer (CLO) • Contractor O-ESMP • Method statements • Internal and external audits	Low	Proponent / Contractor
2.	ESMS & Governance	Inadequate record-keeping and reporting	Audit failure; inability to demonstrate compliance	Medium	• Maintenance of E&S Site File • Standardised reporting • Monthly audits	Low	EHS Manager
3.	Stakeholder Engagement	Ineffective stakeholder engagement or grievance handling	Community grievances; delays	Medium	• SEP implementation • Grievance Redress Mechanism (GRM) with defined timelines • CLO appointment	Low	CLO / Proponent
4.	Labour & Working Conditions	Non-compliance with labour legislation or ILO standards	Worker grievances; legal and reputational risk	Medium	• Human Resource (HR) policies • Compliant contracts • Worker GRM • Audits	Low	Contractor/Proponent/CLO



No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
5.	Labour & Working Conditions	GBV / SEA risks	Social harm; reputational and lender risk	Medium	• Code of Conduct • GBV/SEA training • Confidential reporting mechanisms	Low	Contractor / Proponent CLO
6.	Occupational Health & Safety	Exposure to chemical, biological, mechanical, ergonomic and process hazards during vaccine manufacturing operations	Injury, exposure, non-compliance, work stoppages	High	• GMP-aligned OHS procedures • PPE programme • HVAC filtration & pressure control • Lock-out/tag-out • Chemical handling SOPs • Cleanroom behavioural training • Incident reporting & investigation	Medium	EHS Manager
7.	Traffic	Additional trips: 67 peak-hour trips + 2–3 trucks/day	Congestion, intersection stress, traffic safety	Low	• Implement Transport Impact Assessment (TIA) upgrades (exclusive right-turn lane; stop-controls) • Maintain 33 m queue storage inside the gatehouse	Low	Proponent



No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
					- Schedule deliveries outside peak hours - South African Road Traffic Signs Manual (SARTSM)-compliant signage & lighting		
8.	Climate Change	Stormwater system insufficient under increased rainfall intensity	Local flooding; damage to infrastructure; operational disruption	High	Maintain and periodically update the stormwater management system to accommodate project climate variability	Medium	EHS Manager
9.	Climate Change Adaptation	Facility assets exposed to extreme weather events (floods, high winds, heat waves)	Damage to infrastructure; business interruption; financial losses	Medium	- Ensure insurance coverage includes climate-related extreme weather events - Implement climate-resilient design upgrades where required - Maintain an Emergency Response Plan for weather-related incidents	Low	Proponent
10.	Resource Efficiency	HVAC system under-performing due to higher-than-expected ambient temperatures	Increased electricity consumption; overheating risks; equipment failure	High	Optimise HVAC systems using programmable controls	Medium	Engineering Manager



No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
					- Improve building insulation, sealing, and ducting - Install variable speed drives (VSDs) for load-matching - Conduct routine maintenance and filter changes - Biovac shall establish and monitor key performance indicators (KPIs) for energy consumption and water use during the Operational Phase, consistent with the approach applied at its existing operations.		
11.	Greenhouse Gas (GHG) Emissions	HVAC system consumes excessive energy due to operational inefficiency	Increased GHG emissions; high operational costs	Medium	- Implement HVAC performance optimisation measures - Use energy-efficient appliances and Light-Emitting Diode (LED) lighting to reduce internal heat loads	Low	Engineering Manager



No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
					Select refrigerants with low Global Warming Potential (GWP) where feasible		
12.	GHG Emissions	Backup generators operating under inefficient loads during outages	Excess emissions; fuel wastage; noise impacts	Medium	- Ensure generators run within optimal load range (70–100%) - Maintain equipment as per manufacturer's schedule - Conduct periodic emissions testing	Low	Engineering Manager
13.	Resource Efficiency	Excessive energy and resource use during operations	High operational cost; increased GHG emissions	Medium	- Implement energy-efficiency measures across the facility - Monitor energy consumption trends quarterly - Introduce staff awareness programmes for energy saving	Low	Proponent/EHS Manager
14.	Air Quality	Emissions from HVAC, backup generators, boilers, solvent use	Localised increases in NO ₂ , SO ₂ , CO, PM, VOCs	Low	HEPA filtration & pressure-controlled cleanrooms	Very Low	EHS Manager



No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
					- Local Exhaust Ventilation (LEV) - Sealed process systems & closed solvent transfer - Low-sulphur diesel for generators - Limit generator testing to off-peak times - Maintenance of HVAC, generators & boilers - Proper chemical storage & low-VOC cleaning agents		
15.	Noise	Continuous HVAC, ventilation, chiller and pump noise	Disturbance at nearest receptors (Beck residence ~200 m)	Medium	- Noise Management Plan - Restricted hours - Monitoring per SANS 10103 - Acoustic enclosures & silencers - Vibration isolation & duct attenuation - Use low-noise equipment - Strategic placement of external mechanical plant	Low	EHS Manager



No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
					Regular maintenance		
16.	Hazardous Materials	Improper storage, handling or spillage	Fire, injuries, chemical exposure	High	- Bunding - MSDS availability - Ventilated, labelled chemical storage - Fire suppression equipment	Low	EHS Manager
17.	Waste Management	Medical, laboratory & hazardous waste mishandling	Contamination; regulatory non-compliance	Medium	- Waste Management Plan - Licensed disposal - Segregated waste streams - Licensed hazardous waste contractor - Bunded storage & SANS-compliant labelling - Spill response equipment	Low	EHS Manager
18.	Water Management	Release of untreated wastewater or overflow	Pollution of sewer infrastructure; compliance breaches	Medium	- Onsite thermal decontamination for bio-positive wastewater - Potential of Hydrogen (pH) adjustment in	Low	EHS Manager



No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
					wastewater treatment area • Prevent cross-contamination of wastewater streams • Maintain and inspect effluent tanks (3 m³, 13 m³, 53 m³)		
19.	Water Consumption	High water demand for formulation, cleaning, Water for Injection (WFI) generation, HVAC, clean utilities, and welfare areas may exceed supply or affect operational continuity.	Insufficient water supply affecting GMP production; over-dependence on municipal system; strain on potable water sources; increased operational costs	Medium	• Maintain 300 m³ onsite potable water buffer (≈3 days' usage) • Integrate borehole water as supplementary supply per existing General Authorisation (GA) (48,000 m³/year) • Use greywater reuse from building roof runoff (80 m³ reservoir) for toilet flushing • Monthly monitoring of water consumption trends • Leak detection program (daily walkdowns) • Annual review of water efficiency measures	Low	EHS Manager



No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
20.	Water quality/pollution prevention	Bio-positive wastewater discharge from upstream/downstream processing may contaminate municipal sewer if not properly treated.	Risk of biological contamination in sewer system; violation of municipal effluent standards; GMP non-conformance	High	• Mandatory onsite thermal decontamination of bio-positive wastewater (53 m³ inactivation tank) before discharge • Maintain separate lines for bio-negative and bio-positive wastewater • Post-treatment pH adjustment at central wastewater collection point • Prevent cross-contamination between streams • Routine sampling & sewer compliance checks	Medium	Engineering Manager
21.	Effluent Management	High-strength wastewater from CIP/SIP, formulation, washing, and equipment sterilisation may overload municipal wastewater acceptance criteria.	Sewer blockages or corrosion; exceedance of industrial effluent limits; reputational and regulatory consequences	Medium	• Segregate high-strength wastewater streams • Pre-treatment: pH adjustment, solids separation, chemical neutralisation • Maintain 13 m³/day wastewater collection tanks to balance flows	Low	Utilities Manager



No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
					- Ensure grease traps are functional for canteen wastewater - Maintain emergency bypass prevention controls		
22.	Domestic Wastewater	Incorrect routing of domestic wastewater (handwashing, toilets, cleaning) may lead to sewer non-compliance	Sewage backup; regulatory non-compliance; community health concerns	Low	- Route all domestic wastewater directly to municipal sewer - Maintain grease traps for canteen wastewater	Very low	Maintenance Manager
23.	Biosafety	Exposure to biological agents in BSL-2 manufacturing areas	Worker exposure, product contamination, regulatory non-compliance	High	- Biosafety training - Cleanroom protocols - Access control (biometric, interlocks) - HEPA filtration maintenance - Strict containment boundaries	Medium	EHS Manager
24.	GMP Contamination Control	Cross-contamination of products or clean utilities due to	Product loss, regulatory non-compliance, safety risk	High	- CIP/SIP validation - Closed-system processing - HVAC pressure cascades	Medium	Quality Assurance Manager



No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
		equipment failure or procedural lapses			- Cleanroom qualifications - Environmental monitoring		
25.	Utilities System Failure	Failure of HVAC, WFI, clean steam, compressed air or UPS	GMP deviation; overheating and product loss	Medium	- Preventative maintenance - Alarms & monitoring	Low	Engineering Manager
26.	Stakeholder Relations	Unrealistic community expectations for jobs	Grievances; tension; reputational risk	Medium	- Transparent communication - Clear recruitment criteria - Community briefings - Worker grievance mechanism	Low	CLO
27.	Security ⁴	Unauthorised access or theft	Safety incidents; delays	Medium	24/7 Security - Controlled access - Coordination with South African Police Services (SAPS)	Low	Proponent/ EHS Manager

⁴ Biovac retains overall responsibility for site security throughout the Operational Phase, including oversight of private security contractors. Security services shall be managed in accordance with legal requirements, GIIP and relevant IFC Performance Standards, and shall be implemented in a manner that protects community health and safety, respects worker and community rights, and is consistent with Biovac's ESMS and incident reporting procedures.



No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
28.	Emergency Preparedness and Response	Delayed or inadequate response to fires, spills, generator failures or abnormal emissions	Escalated impacts; injuries	High	• Full Emergency Response Plan (fire, bio-incidents, chemical spills) • Regular drills • Fire suppression systems • Trained personnel • HVAC emergency shut-off • Spill kits and trained responders • Coordination with emergency services	Medium	EHS Manager
29.	Contractor Management	Sub-contractor non-compliance with ESMP	Increased E&S risk exposure	Medium	• ESMP contractual clauses • Supervision	Low	Proponent/ Contractor
30.	Reputational	Recurrent incidents or unresolved grievances	Lender concern and reputational damage	Medium	• Monitoring • Reporting • Corrective Actions • Transparency	Low	Proponent
31.	Training and Capacity Building	Insufficient or inconsistent training for operational personnel on ESMP,	Non-compliance with ESMP, environmental/social incidents, unsafe	High	• Implement a structured Operational Training Programme covering:	Medium	EHS Manager/CLO



No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
		EHS, GMP, emergency response, hazardous materials, and social requirements.	working conditions, community complaints; reduced process reliability, operational inefficiency; reputational and lender related risks		○ ESMP roles & responsibilities ○ GMP compliance ○ EHS requirements (hazardous materials, waste, emissions, noise) ○ Emergency Response procedures ○ Community Health & Safety requirements ○ Grievance Mechanism protocols • Conduct weekly toolbox talks for operations personnel • Provide monthly refresher training sessions on EHS,		



No.	Risk Category	Risk Description	Key Potential Impacts	Inherent Risk	Mitigation	Residual Risk	Responsible Party
					GMP, and emergency response • Deliver issue-specific training for new or emerging risks (e.g., changes in processes, new chemicals, new equipment) • Maintain training records, attendance sheets, competency evaluations Conduct annual competence audits linked to performance reviews		



9.0 Audit

To ensure effective implementation of the ESMP and compliance with environmental, social, and health and safety requirements, compliance audits will be conducted throughout the Operational Phase. These audits will verify that all mitigation measures are applied correctly and that environmental and social risks are managed appropriately.

9.1 Internal Audits

The implementation of mitigation measures set out in this ESMP will be verified through a structured programme of inspections and audits. Routine internal site inspections shall be undertaken on a weekly basis (unless otherwise specified in the ESMP) by the relevant individual verify day-to-day compliance with the ESMP requirements. Findings from these inspections shall be recorded using standardised inspection checklists and protocols, supported by photographic evidence where relevant.

In addition, monthly internal audits shall be conducted by the EHS Manager to verify the effectiveness of mitigation measures and the level of compliance achieved. Records of all inspections and audits shall be retained on file. The EHS manager shall compile and submit an annual ESMP performance report for the lenders, summarising compliance status, trends, and corrective actions implemented. It is recommended that a grading or rating system be applied to assess compliance levels consistently.

9.2 External Audits

The Proponent shall be responsible for the appointment of an independent external E&S auditor and Safety Agent, as required by this ESMP. The appointed auditors shall be suitably qualified and experienced and shall be responsible for undertaking periodic compliance audits to verify adherence to the commitments, mitigation measures, and performance requirements set out in the ESMP, as well as applicable national legislation and international good practice. In addition, both auditors will play a role in the development of corrective actions and preventative actions.

9.3 Audit methodology

An audit methodology, programme, and protocol shall be developed for internal and external audits. Auditing is an integral component of ESMP implementation and provides a basis to measure compliance, assess the effectiveness of mitigation measures, and identify opportunities for improvement.

The audit process shall follow four key steps:

1. Planning the audit
2. Conducting the audit
3. Producing audit findings, including measuring compliance and identifying non-conformances
4. Reporting audit findings for management action

All audit findings shall be subject to a root cause analysis to identify the underlying causes of non-compliance events. Management actions shall be implemented to address these underlying causes, and improvements shall be made prior to subsequent audits. This process supports corrective action, improved compliance, and prevention of recurrence.



Root cause analysis shall identify not only failures requiring correction, but also effective practices that promote compliance. This approach supports continual improvement and progression towards best practice environmental and social management.

Compliance with the conditions of the ESMP must be evaluated using the ratings defined in Table 9-1 below.

Table 9-1: ESMP Compliance Ratings

Rating	Definition
Compliance (C)	Condition or activity has been addressed / complied with.
Partial Compliance (PC)	Condition or activity has been partially addressed / complied with; however not all requirements were met.
Non-compliance (X)	Condition or activity has not been addressed / complied with.
Not Applicable (N/A)	Condition or activity is not applicable (reason to be specified).

9.4 Corrective Actions

The proponent will implement a formal non-compliance and corrective action tracking procedure for investigating cause and identifying corrective actions in response to accidents, environmental and/or social non-compliances.

Where corrective actions are deemed necessary, specific measures will be developed, with designated responsibility and timing and implemented. In this way, continuous improvement in performance would be achieved.

The proponent will be responsible for keeping records of corrective actions and for overseeing the modification of environmental or social protection procedures and/or training programmes to avoid repetition of non-conformances and non-compliances.



10.0 Environmental and Social Management Plan

10.1 Operational Phase

Table 10-1 below outlines the key impacts and corresponding mitigation measures identified for the Project's Operational phase. The objective of is to provide a structured framework for implementing these mitigation measures to address the identified environmental, social, health and safety impacts.

Table 10-1: ESMP for Operational Phase

No.	Aspect	Environmental and Social Impact	Mitigation Measures	Applicable IFC, EIB, WBG/ ILO Standards and or South African Legislation	Responsibility	Timing
1.	Appointment of EHS Manager	Risk of non-compliance with ESMP during operations	Appoint a designated EHS Manager for operational oversight, who will: • Ensure facility-wide compliance with ESMP, GMP, OHS, biosafety and emergency protocols • Maintain operational E&S performance records (KPIs, inspections, incidents, grievances) • Ensure operational SOPs are aligned with ESMP	• IFC Performance Standard (PS) 1, PS2 • EIB Environmental and Social Standard (ESS) 1 and ESS 8 • AfDB OS 1 • OHS Act 85 of 1993	Proponent	Prior to operations; continuous during operations



No.	Aspect	Environmental and Social Impact	Mitigation Measures	Applicable IFC, EIB, WBG/ ILO Standards and or South African Legislation	Responsibility	Timing
			• Ensure adequate resourcing (staffing, budget, monitoring equipment) • Oversee internal audits and lender reporting requirements			
2.	Training and Capacity Building	Non-compliance due to inadequate competency; increased risk of environmental, safety, or biosafety incidents	• Provide operational E&S, GMP, biosafety inductions • Conduct monthly refresher training • Weekly toolbox talks for operations teams • Provide emergency response, spill response, and hazard-specific training • Maintain competence & training register	• IFC PS1 and PS2 • AfDB OS 1,2,4 • WBG EHS Guideline Section 2.2 • ILO Convention 155 • OHS Act 85 of 1993 Section 8	EHS Manager	Prior to operations; continuous
3.	E&S Operational Records Management	Risk of poor record-keeping leading to audit failures, lender non-compliance,	• Establish and maintain a comprehensive E&S site file, including:	• IFC PS1 • EIB ESS 1 • AfDB OS 1	EHS Manager	Continuous



No.	Aspect	Environmental and Social Impact	Mitigation Measures	Applicable IFC, EIB, WBG/ ILO Standards and or South African Legislation	Responsibility	Timing
		and inability to demonstrate ESMP implementation	- Monitoring data (air, noise, wastewater) - Waste manifests, permits, SDS files - Training records - Incident and corrective action logs - Audit findings and reports - Monthly E&S reports to senior management	SA OHS Act 85 of 1993		
4.	Grievance Logbook (Community and Workers)	Unresolved grievances leading to reputational harm or conflict	- Maintain an accessible, confidential, multi-channel GRM - Acknowledge grievances within 48 hours - Target ≥95% closure within 14 days.	- IFC PS1, PS2, PS4 - EIB ESS 8 - AfDB OS 1,2,4,10	CLO	Continuous
5.	Hazardous Materials and Chemical Handling	Spills; exposure; contamination; fire risk	Maintain bunded hazardous storage (110% capacity)	- IFC PS 4 - EIB ESS 9 - AfDB OS 4	EHS Manager	Continuous



No.	Aspect	Environmental and Social Impact	Mitigation Measures	Applicable IFC, EIB, WBG/ ILO Standards and or South African Legislation	Responsibility	Timing
			• Store solvents/disinfectants per SDS • Maintain spill kits; conduct regular spill drills • Maintain chemical inventory & SDS file • Train staff on safe handling & segregation • Ensure emergency shower/eyewash functionality	• WBG EHS General Guidelines, Sections 1.3, and 4 • SA OHS Act 85 of 1993 (Regulations for Hazardous Chemical Substance) • City of Cape Town Community Fire Safety By-law, 2002 (as amended) • SANS 10087 (South African National Standard)		
6.	Waste Management (General and Hazardous)	Pollution; contamination; regulatory non-compliance	• Implement operational WMP • Segregate waste (hazardous, general, recyclable, infectious)	• IFC PS3 • EIB ESS 3 • AfDB ISS 3 • WBG EHS General Section 1.6	EHS Manager	Continuous



No.	Aspect	Environmental and Social Impact	Mitigation Measures	Applicable IFC, EIB, WBG/ ILO Standards and or South African Legislation	Responsibility	Timing
			• Use licensed transporters & disposal facilities • Maintain manifests and disposal certificates • Prohibit uncontrolled dumping/burning	• NEM: Waste Act 59 of 2008 • City Integrated Waste Management By-law		
7.	Water Use (Potable and Process Water)	High water demand may affect operational continuity	• Maintain 300 m³ onsite buffer storage • Use borehole water per GA (where applicable) • Monitor monthly water consumption • Implement leak detection program • Maintain plumbing, water tanks & pumps	• IFC PS3 • EIB ESS 3 • AfDB OS 3 • National Water Act	EHS Manager	Continuous
8.	Industrial Wastewater Management (Bio-positive & Bio-negative)	Contamination of municipal sewer; regulatory breaches	• Treat bio-positive wastewater via thermal decontamination • Maintain segregation of wastewater streams	• IFC PS3 • EIB ESS 3 • AfDB OS 3 • WBG EHS Pharmaceuticals	Engineering Manager	Continuous



No.	Aspect	Environmental and Social Impact	Mitigation Measures	Applicable IFC, EIB, WBG/ ILO Standards and or South African Legislation	Responsibility	Timing
			- Conduct routine pH/quality testing - Maintain wastewater tanks & pumps - Keep emergency containment protocols	National Water Act		
9.	Stormwater and Climate Resilience	Flooding; contaminated runoff	- Maintain permeable paving - Inspect stormwater drains monthly - Clear debris after rainfall events - Prevent chemicals from contacting stormwater - Maintain 80 m³ reuse reservoir	- IFC PS3 - EIB ESS 3 and 5 - AfDB OS 3 - City of Cape Town Stormwater By-Law	Engineering Manager	Continuous
10.	Energy and GHG Emissions	Increased carbon footprint; inefficiency	- Maintain HVAC at optimal efficiency - Install VSDs & low-GWP refrigerants where possible - Maintain generators per Original	- IFC PS3 - EIB ESS 3 and 5 - AfDB OS 3 - WBG EHS General Guidelines Section 1.2	EHS Manager/ Engineering Manager	Continuous



No.	Aspect	Environmental and Social Impact	Mitigation Measures	Applicable IFC, EIB, WBG/ ILO Standards and or South African Legislation	Responsibility	Timing
			Equipment Manufacturer (OEM) - Track energy consumption monthly - Enforce no-idling			
11.	Air Quality (Operational Emissions)	Low-level emissions from generators, solvents, HVAC	- Maintain HEPA filters and ventilation systems - Use low-sulphur diesel - Implement solvent controls - Monitor generator runtime logs	- IFC PS3 and 4 - EIB ESS 3,5 and 9 - AfDB OS 3 and 4 - NEM: Air Quality Act	Engineering Manager/ EHS Manager	Continuous
12.	Noise	Mechanical plant noise affecting nearby receptors	- Maintain HVAC chillers and compressors - Ensure silencers and acoustic housing - Investigate any complaints - Keep operations within noise limits	- IFC PS3 and 4 - EIB ESS 3 and 9 - AfDB OS 3 and 4 - SANS 10103 - City Noise Regulations	EHS Manager/CLO/Engineering Manager	Continuous



No.	Aspect	Environmental and Social Impact	Mitigation Measures	Applicable IFC, EIB, WBG/ ILO Standards and or South African Legislation	Responsibility	Timing
13.	Biosafety (BSL-2 Operations)	Exposure to biological agents; contamination	• Maintain access control to BSL-2 areas • Follow biosafety SOPs • HEPA-filtered ventilation • Maintain biological waste segregation • Conduct biosafety training	• IFC PS4 • EIB ESS 9 • AfDB OS 4 • WHO Biosafety Guidelines • South African OHS Act	EHS Manager/Engineering Manager	Continuous
14.	Emergency preparedness	Fire, spill, or abnormal event may affect workers or public	• Maintain Emergency Response Plan • Conduct quarterly drills • Maintain fire alarms, extinguishers, hydrants • Maintain spill containment systems • Coordinate emergency notifications with adjacent neighbours	• IFC PS4 • EIB ESS 2 and 9 • AfDB OS 4 and 10 • WBG EHS 3 • City of Cape Town Fire Safety By-Law	EHS Manager	Continuous



No.	Aspect	Environmental and Social Impact	Mitigation Measures	Applicable IFC, EIB, WBG/ ILO Standards and or South African Legislation	Responsibility	Timing
15.	Labour and Working Conditions	Worker grievances; right violations	• Ensure that a Human Resources Policy and relevant procedures will be prepared • Prepare a Social Management Plan • Require compliant employment contracts • Prohibit child and forced labour • Enforce equal remuneration and non-discrimination • Adopt and enforce a Code of Conduct addressing GBV/SEA • Provide confidential and anonymous grievance channels and worker protections • Maintain ongoing training on labour	• IFC PS2 • EIB ESS 8 • AfDB OS 2 • ILO Core Conventions 87, 98, 29, 105, 138, 182, 100, 111) • ILO Convention 190 (harassment) • Basic Conditions of Employment Act 75 of 1997 • Labour Relations Act 66 of 1995	HR Manager/CLO/EHS Manager	Continuous



No.	Aspect	Environmental and Social Impact	Mitigation Measures	Applicable IFC, EIB, WBG/ ILO Standards and or South African Legislation	Responsibility	Timing
			rights and grievance procedures • Prioritise hiring of local workers where qualified • Track local employment and provide basic skills training if required • Ensure that the Contractor provides and monitors anonymous grievance channels (e.g., hotline, suggestion boxes) • Assign GBV oversight roles to Biovac • Establish clear escalation procedures for GBV related grievances to Proponent's senior management			



No.	Aspect	Environmental and Social Impact	Mitigation Measures	Applicable IFC, EIB, WBG/ ILO Standards and or South African Legislation	Responsibility	Timing
16.	Rehabilitation and reinstatement of disturbed areas	Degradation of landscaped areas, stormwater features, or disturbed surfaces due to operational activities, maintenance works, or emergency repairs.	- Rehabilitate and reinstate any areas disturbed during operational activities (e.g. maintenance works, repairs, utility trenching, emergency interventions) as soon as practicable after disturbance. - Maintain landscaped areas, stormwater infrastructure and drainage features in a stable and functional condition. - Prevent erosion, dust generation and visual degradation through appropriate surface stabilisation and vegetation management. - Ensure that temporary operational disturbances do not	- IFC PS 3 and 6 - AfDB OS 3	EHS Manager/Engineering Manager	As required during operations; ongoing.



No.	Aspect	Environmental and Social Impact	Mitigation Measures	Applicable IFC, EIB, WBG/ ILO Standards and or South African Legislation	Responsibility	Timing
			result in long-term land degradation. Final site rehabilitation and closure-related measures will be addressed as part of a future decommissioning or closure plan, where applicable.			



10.2 Monitoring plan

Table 10-2 below presents the Environmental and Social Monitoring Plan to be implemented during the Operational phase. The monitoring, auditing, and reporting framework has been developed to ensure effective implementation and verification of all mitigation measures.

Table 10-2: Operational Environmental and Social Monitoring Plan

No.	Aspect	Target	Key Performance Indicator	Measure/Monitoring Method	Frequency	Reporting	Responsibility
1.	Appointment of EHS Manager	Full compliance with ESMP; effective operational E&S management; timely reporting; adequate resourcing; continuous GMP, OHS, biosafety and emergency compliance	- Number of non-compliance - Number of incidents (EHS, GMP, biosafety) - Number of grievances logged & resolved - Number of internal audits completed - Number of operational SOPs aligned with ESMP - Number of training sessions delivered (E&S, OHS, biosafety)	- Review incident logs - Review monthly E&S reports - Audit findings - Training registers - SOP revision logs	Monthly; quarterly audits	- Monthly E&S Report - Quarterly Audit Report	Proponent / EHS Manager



No.	Aspect	Target	Key Performance Indicator	Measure/Monitoring Method	Frequency	Reporting	Responsibility
			- Evidence of adequate EHS resourcing - Timely corrective actions closed				
2.	Training and Capacity Building	Competent personnel; no training-related non-compliances	- Number of: - Refresher sessions - Toolbox talks - Emergency/biosafety trainings	- Training attendance registers - Toolbox talk logs - Competency assessments	Daily / Weekly / As required	Monthly Internal E&S Audit Report	EHS Manager
3.	E&S Operational Records Management	Full and accurate document control; ≥95% completeness	≥95% completeness of all required documents (logs, audits, permits, training records)	- File review - Compliance documentation audit	Monthly	Monthly Internal E&S Audit Report	EHS Manager
4.	Grievance Logbook (Community and Workers)	Timely and transparent resolution	- All grievances acknowledged within 48 hours ≥95% of grievances closed within 14 days	- Review of grievance log entries and closure timelines - Audit of acknowledgement and	Continuous; formal review monthly	Monthly Internal E&S Audit Report	CLO/ EHS Manager



No.	Aspect	Target	Key Performance Indicator	Measure/Monitoring Method	Frequency	Reporting	Responsibility
			Complex cases escalated as required	- resolution records - Verification of published summaries and escalations			
5.	Hazardous Materials	Zero spills; full compliance with SDS; safe storage	- Number of spills 100% bundled integrity 100% trained staff - Emergency showers functional	- Inspections - Chemical storage audits - Training records	Weekly/Monthly	Monthly Internal E&S Audit Report	EHS Manager
6.	Waste management	100% compliant waste handling & disposal	100% waste removed by licensed transporters 100% manifests complete - Correct segregation	- Site Inspection - Waste Logs - Disposal receipts	Weekly/Monthly	Monthly Internal E&S Audit Report	EHS Manager
7.	Water Use	Efficient consumption and	Monthly consumption volumes	- Meter readings - Inspections	Monthly	Monthly Internal E&S Audit Report	EHS Manager



No.	Aspect	Target	Key Performance Indicator	Measure/Monitoring Method	Frequency	Reporting	Responsibility
		uninterrupted supply	- Number of leaks detected & repaired - Tank level thresholds met				
8.	Industrial wastewater	Compliant discharge; zero untreated bio-positive release	- pH results - Thermal decontamination logs - No exceedances	- Sampling results - Wastewater Treatment Plan (WWTP) logs	Monthly	Monthly Internal E&S Audit Report	Engineering Manager/ EHS Manager
9.	Stormwater	No flooding, clean runoff	% of drains cleared - Number of blockages - Stormwater quality logs	- Inspections - After rain checks	Post-rainfall	Monthly Internal E&S Audit Report	EHS Manager/Engineering Manager
10.	Energy and GHG Emissions	Efficient energy use; reduced carbon footprint	- Energy consumption trends - Generator runtime hours - Number of idling cases	- Meters - Logs - Spot checks	Monthly	Monthly Internal E&S Audit Report	EHS Manager



No.	Aspect	Target	Key Performance Indicator	Measure/Monitoring Method	Frequency	Reporting	Responsibility
11.	Air Quality	Clean emissions; no exceedances	- Filter change logs - Generator emissions logs - Number of complaints resolved	- Air quality logs - Filter maintenance logs	Monthly	Monthly Internal E&S Audit Report	EHS Manager/ Engineering Manager
12.	Noise	Compliance with SANS 10103	- Maintain ambient Noise Levels - Number of complaints	- Noise monitoring - Complaint register	Monthly	Monthly Internal E&S Audit Report	CLO/ EHS Manager
13.	Biosafety	Zero exposure and compliant containment	% biosafety trained staff - Number of biosafety incidents - HEPA maintenance records	- Incident logs - HEPA validation	Monthly	Monthly Internal E&S and OHS Audit Report	EHS Manager/ Engineering Manager
14.	Emergency Preparedness	Effective readiness for fires and spills	- Number of drills conducted - Fire equipment functioning - Spill kits stocked	- Drill reports - Equipment inspection logs	Quarterly/Monthly	Monthly Internal E&S and OHS Audit Report	EHS Manager



No.	Aspect	Target	Key Performance Indicator	Measure/Monitoring Method	Frequency	Reporting	Responsibility
15.	Labour & Working Conditions	Ensure fair labour practices, prevent GBV/SEA, and address worker grievances promptly, maximise local employment	100% of workers have compliant employment contracts - No reports of child or forced labour - All reported GBV/SEA cases are investigated and addressed - Worker grievances resolved within defined timelines 40% of workforce hired from local communities; number of local workers trained; retention of local workers for the duration of Operational phase	- Review of employment contracts and HR records - Grievance log review and corrective action tracking - Training attendance records for labour rights and Code of Conduct	Continuous; monthly audits	Monthly Internal E&S and OHS Audit Report	EHS Manager, CLO,
16.	Emergency Preparedness and Response	Effective emergency preparedness and timely,	Approved Operational Emergency Preparedness and	Review of approved Operational EPRP	Prior to commencement of operations	Monthly Internal E&S and OHS Audit Report	EHS Manager, CLO (Where emergencies have external or



No.	Aspect	Target	Key Performance Indicator	Measure/Monitoring Method	Frequency	Reporting	Responsibility
		coordinated response to incidents to protect workers, neighbouring communities, assets and the environment during the Operational Phase.	Response Plan (EPRP) in place • Number of emergency drills conducted (e.g. fire, chemical spill, biosafety incident, evacuation) • Percentage of workers and on-site service providers trained in emergency response • Number and severity of emergency incidents • Percentage of emergency incidents responded to in accordance with the EPRP • Timeliness of incident notification and	documentation and revision history • Review of emergency drill schedules, records and drill reports • Review of training matrices, attendance registers and competency records • Review of incident, near-miss and emergency response reports • Review of corrective and preventive action tracking logs	(EPRP approval) • Emergency drills: quarterly (or as defined in the EPRP) • Training: during induction and refreshed periodically • Incident-based review: as required • Monthly Formal review: monthly		community impacts)



No.	Aspect	Target	Key Performance Indicator	Measure/Monitoring Method	Frequency	Reporting	Responsibility
			corrective action close-out				
17.	Resource Efficiency (Energy and Water Use)	Efficient and optimised use of energy and water resources during operations, with continuous improvement and alignment with Biovac's existing operational performance standards.	- Total electricity consumption (kWh/month and kWh/year) - Energy intensity indicators (e.g. kWh per unit of production or kWh/m², where applicable) - Total potable water consumption (m³/month and m³/year) - Water intensity indicators (e.g. m³ per unit of production) - Percentage variance from established internal energy and water KPIs	- Review of electricity and water meter readings and utility bills - Review of energy and water consumption tracking reports - Comparison of performance against internal Biovac KPIs and historical trends - Inspection records and leak detection walk-downs - Review of maintenance records for major	- Monthly Meter readings and consumption tracking: - Quarterly KPI performance review and trend analysis - Annual performance review	Annual ESMS / ESMP Management Review Report	EHS Manager (overall monitoring, KPI tracking and reporting); Engineering / Utilities Manager (data provision, system performance and corrective actions); Biovac Management (review and endorsement through ESMS governance processes)



No.	Aspect	Target	Key Performance Indicator	Measure/Monitoring Method	Frequency	Reporting	Responsibility
			- Number of identified efficiency improvements or corrective actions implemented - Number of leaks or abnormal consumption events detected and addressed	- energy- and water-using systems (e.g. HVAC, WFI, utilities) - Review of corrective and preventive action records linked to resource efficiency			
18.	Rehabilitation and Reinstatement of Disturbed Areas	All areas disturbed during operational activities are reinstated promptly and maintained in a stable, safe and visually acceptable condition.	- Number of operational disturbances requiring rehabilitation - Time taken to reinstate disturbed areas - Evidence of erosion, dust generation or surface instability - Condition of landscaped and stormwater areas	- Visual inspections of disturbed areas following maintenance, repairs or emergency works - Review of maintenance and reinstatement records - Photographic records before	As required following disturbance; formal inspection monthly	Monthly Internal E&S Audit Report	EHS Manager/Engineering Manager



No.	Aspect	Target	Key Performance Indicator	Measure/Monitoring Method	Frequency	Reporting	Responsibility
				and after reinstatement			



11.0 Budget and Resources for ESMP Implementation

This section outlines the budgetary provision and resources allocated for implementation of the ESMP during the Operational Phase of the Project.

A financial model has been prepared for the operational phase covering the period 2032 to 2036, which includes provision for the implementation of environmental and social management measures required under this ESMP. The operational ESMP budget presented in this section reflects indicative annual costs, based on the current operating costs of Biovac's existing facility. As the proposed vaccine manufacturing facility will operate at a similar scale and level of complexity, these costs are considered representative of the anticipated operational requirements.

Table 11-1 below presents an indicative breakdown of the annual operational ESMP costs, which are primarily embedded within routine operational expenditure. These costs include maintenance of infrastructure and utilities, health and safety management, security services, waste management, and associated environmental and social compliance activities.

Table 11-1: Indicative Annual Operational ESMP Cost Breakdown⁵

Cost category	Description	Indicative annual cost (ZAR/annum)
Cleaning Services (Waste Management)	Cleaning services and routine handling of operational waste streams	R 870 000
Consumables	Environmental, health and safety consumables used during operations	R 350 000
Repairs & Maintenance: General	General maintenance of operational areas and infrastructure	R 5 000 000
Repairs & Maintenance: Laboratories	Maintenance of laboratory facilities and equipment	R 1 000 000
Repairs & Maintenance: Production	Maintenance of vaccine production areas and equipment	R 1 000 000

⁵ Indicative operational ESMP costs are based on the operating costs of Biovac's existing facility and are considered representative, given the similar scale of operations..

Repairs & Maintenance: Utilities	Maintenance of utilities including HVAC, clean steam and purified water systems	R 1 500 000
Repairs & Maintenance: Spares	Provision of critical spare parts to ensure operational continuity	R 3 400 000
Security	Access control, guarding services and surveillance	R 2 700 000
Staff Health & Safety	Occupational health and safety management and monitoring	R 1 500 000
Total Indicative Annual Operational ESMP Cost		~R 17.3 million per annum

Applying a conservative 5% annual escalation, the indicative operational ESMP costs of approximately R 17.3 million per annum are expected to increase to approximately R 22 million per annum by 2032.

The project financial model includes a higher consolidated environmental and social cost provision of approximately R 31 million per annum in 2032, increasing over the period 2032–2036. This higher provision provides additional contingency and flexibility to accommodate operational growth, enhanced monitoring requirements, inflationary pressures, and potential changes in regulatory or lender requirements. The financial model therefore represents a conservative allocation, ensuring that sufficient budget is available to fully implement the Operational ESMP throughout the operational life of the facility.

Implementation of the Operational ESMP will be funded through routine operational expenditure, and responsibility for allocation and management of these resources' rests with the Proponent. A more detailed breakdown of operational ESMP costs will be refined and confirmed prior to the commencement of operations, once detailed operational programmes, staffing arrangements and monitoring frequencies have been finalised.

12.0 Conclusion

This Environmental and Social Management Plan (ESMP) has been prepared to ensure that all environmental, social, health and safety risks associated with the Operational Phase of the Project are appropriately managed and mitigated. The ESMP provides a clear framework of roles, responsibilities, mitigation measures, monitoring and auditing requirements to ensure compliance with applicable national legislation, IFC Performance Standards, EIB Environmental and Social Standards, World Bank Group Environmental, Health and Safety Guidelines, and relevant ILO Conventions.

Implementation of the ESMP will be supported by adequate organisational capacity and financial resources, with budgetary provision for environmental and social management measures included within the project's operational expenditure. Indicative operational ESMP costs have been defined based on the operating experience of Biovac's existing facility, and

the project financial model includes a conservative allocation to ensure sufficient resources are available to implement all ESMP requirements throughout the operational life of the facility.

Through the implementation of the mitigation, monitoring, auditing and reporting measures outlined in this ESMP, the Proponent, contractors, and the Environmental, Social, Health and Safety (E&S and OHS) teams are committed to minimising potential impacts, safeguarding workers and surrounding communities, and promoting continuous improvement during operations. Regular inspections, internal and external audits, and transparent reporting will ensure accountability to regulators, lenders and other stakeholders, and support the safe, compliant and responsible operation of the facility.

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